Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number: 001-38520

MEIRAGTX HOLDINGS PLC

(Exact name of registrant as specified in its charter)

Cayman Islands (State or other jurisdiction of incorporation or organization)	**98-1448305** (I.R.S. Employer Identification No.)
450 East 29th Street, 14th Floor **New York, NY** (Address of principal executive offices)	**10016** (Zip Code)

(646) 860-7985
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Ordinary Shares, $0.00003881 par value per share	**MGTX**	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's ordinary shares held by non-affiliates of the registrant was approximately $272,320,427 (based upon the closing sale price of the registrant's ordinary shares on that date on the Nasdaq Global Select Market).

As of March 9, 2025, the registrant had 78,854,936 ordinary shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2025 annual shareholder meeting to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024 are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

CONTENTS

		Page
PART I		4
Item 1.	Business	4
Item 1A.	Risk Factors	52
Item 1B.	Unresolved Staff Comments	114
Item 1C.	Cybersecurity	114
Item 2.	Properties	115
Item 3.	Legal Proceedings	115
Item 4.	Mine Safety Disclosures	115
PART II		116
Item 5.	Market For Registrant's Common Equity, Related Stockholder Matters And Issuer Purchases Of Equity Securities	116
Item 6.	[Reserved]	116
Item 7.	Management's Discussion And Analysis Of Financial Condition And Results Of Operations	116
Item 7A.	Quantitative And Qualitative Disclosures About Market Risk	136
Item 8.	Financial Statements And Supplementary Data	F-1
Item 9.	Changes In And Disagreements With Accountants On Accounting And Financial Disclosure	124
Item 9A.	Controls And Procedures	124
Item 9B.	Other Information	125
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	125
PART III		126
Item 10.	Directors, Executive Officers And Corporate Governance	126
Item 11.	Executive Compensation	126
Item 12.	Security Ownership Of Certain Beneficial Owners And Management And Related Stockholder Matters	126
Item 13.	Certain Relationships And Related Transactions, And Director Independence	127
Item 14.	Principal Accountant Fees And Services	127
PART IV		128
Item 15.	Exhibits and Financial Statement Schedules	128
Item 16.	Form 10-K Summary	133

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Form 10-K") contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Form 10-K, including, but not limited to, statements regarding our future results of operations and financial position, business strategy, financing, licensing and manufacturing arrangements, prospective products, development and timing of product candidates, timing of and expected success and efficacy of our product candidates, plans and objectives for future operations, expected future results of anticipated products and prospects, and plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "would" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Form 10-K entitled "Item 1A. Risk Factors" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

You should read this Form 10-K and the documents that we reference in this Form 10-K and have filed as exhibits to this Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. These statements should not be relied upon as representing our views as of any date subsequent to the date of this Form 10-K.

RISK FACTOR SUMMARY

We are providing the following summary of the principal risk factors contained in this Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review in their entirety the full risk factors set forth in the section of this Form 10-K captioned "Item 1A. Risk Factors" for additional information regarding the material factors that make an investment in our ordinary shares speculative or risky. These risks and uncertainties include, among others, the following:

- We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future, and may never achieve or maintain profitability.
- There is no guarantee that we will receive in a timely fashion or at all the additional milestone payments contemplated under the Asset Purchase Agreement or the revenues associated with our manufacture of the commercial supply of the RPGR Product under the Supply Agreement.
- We will require additional capital to fund our operations, which may not be available on acceptable terms, if at all.
- We may not have sufficient cash flows or cash on hand to satisfy our debt obligations or covenants under our financing arrangements, or we may not be able to effectively manage our business in compliance with such covenants.
- Our review of potential strategic transactions may not result in an executed or consummated transaction or other strategic alternative and may not result in anticipated benefits to us or our shareholders, and the process of reviewing strategic transactions or its conclusion could be disruptive and distracting to our business operations and management.
- We are heavily dependent on the success of our product candidates, which are still in development, and if none of them receive regulatory approval or are successfully commercialized, our business may be harmed.
- It is difficult to predict the time and cost of product candidate development on our novel gene therapy platform. A limited number of gene therapies have been approved in the United States or in Europe.
- Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.
- Clinical trials are expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.
- The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.
- We and our contract manufacturers for plasmid are subject to significant regulation with respect to manufacturing our products. Our manufacturing facilities and the third-party manufacturing facilities which we rely on may not continue to meet regulatory requirements and have limited capacity.
- Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

- We are subject to regulation and other legal obligations relating to data privacy and protection. Compliance with these requirements is complex and costly. The actual or perceived failure to comply with such obligations could materially harm our business.

- We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

- We depend on proprietary technology licensed from others. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.

- If we are unable to obtain and maintain patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

- We may need to increase or decrease the size of our organization, and we may experience difficulties in managing these organizational changes, which could disrupt our operations.

- Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

BASIS OF PRESENTATION

Unless the context otherwise requires, references in this Form 10-K to "Meira," "MeiraGTx," "we," "us", "our" or "the Company" refer to MeiraGTx Holdings plc and its subsidiaries.

We have proprietary rights to trademarks, trade names and service marks appearing in this Form 10-K that are important to our business. Solely for convenience, the trademarks, trade names and service marks may appear in this Form 10-K without the ® and TM symbols, but any such references are not intended to indicate, in any way, that we forgo or will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, trade names and service marks. All trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners.

INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data in this Form 10-K from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research as to such matters is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

PART I

ITEM 1. BUSINESS

Overview

We are a vertically integrated, clinical-stage genetic medicines company with a broad pipeline of late-stage clinical programs, including Parkinson's disease, radiation-induced xerostomia and AIPL1-associated retinal dystrophy. Our clinical programs use targeted local delivery of small doses of genetic medicines to treat both inherited and more common conditions with severe unmet need. The successful development of the clinical pipeline is supported by our internal end-to-end manufacturing capabilities. We have two viral vector production facilities for good manufacturing practices, or GMP, internal plasmid production for GMP, as well as an in-house Quality Control hub for stability and release, all fit for Investigational New Drug application (IND) through commercial supply. In addition, we have developed a proprietary manufacturing platform with leading yield and quality aspects and commercial readiness. Our core capabilities in viral vector and capsid optimization allow increased potency, decreased dose and significantly reduced cost of goods for our genetic medicines. We have developed a potentially transformative gene regulation platform using bespoke synthetic riboswitch technology invented in-house that allows for the precise, dose-responsive expression of any transgene under the control of oral small molecules. We are focusing the riboswitch platform on the *in vivo* delivery of biologic therapeutics such as the metabolic peptides glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic polypeptide (GIP), glucagon, amylin, peptide YY (PYY) and leptin via oral small molecules, as well as cell therapy for oncology and autoimmune diseases, and long term intractable pain. We have developed unique comprehensive technology capabilities to apply genetic medicine to more common diseases, increasing efficacy, addressing novel targets, and expanding access in some of the largest disease areas where the unmet need remains high.

We own and operate manufacturing facilities in London, United Kingdom and Shannon, Ireland that we expect can supply our current clinical and preclinical programs, as well as our third party supply obligations, through regulatory approval and, should they be approved, provide sufficient capacity for commercial production. Completed in early 2018 and designed to meet global regulatory requirements, including GMP, our 29,000 square foot flexible and scalable viral vector manufacturing facility in London, United Kingdom has two cell production suites, three independent viral vector production suites providing multi-product and multi-viral vector manufacturing capabilities and an integrated, flexible fill-and-finish suite. In May 2018, we were granted a license to manufacture gene therapy product candidates in our GMP compliant manufacturing facility by the United Kingdom's Medicines and Healthcare products Regulatory Agency, or MHRA. The MHRA re-certified the facility in the second quarter of 2024.

Our second, large scale GMP viral vector manufacturing facility and our first GMP plasmid and DNA production facility in Shannon, Ireland, both of which are designed to meet GMP requirements, came online in 2022. The campus encompasses 150,000 square feet. It is the first commercial-scale gene therapy manufacturing site in Ireland and is unique in its scale and integrated capabilities. The site contains three facilities, one built to be flexible and scalable for viral vector production for clinical and commercial supply, in addition, a facility to manufacture plasmid DNA – the critical starting material for producing gene therapy products – and thirdly, a Quality Control (QC) hub performing advanced biochemical quality control testing for MeiraGTx clinical and commercial programs. In June 2023, we received a Manufacturer's/Importer's Authorization (MIA) for QC testing of commercial products in our GMP compliant manufacturing facility in Shannon from the Irish Health Products Regulatory Authority ("HRPA"). In September 2023, we received a second MIA from the HRPA for QC testing of investigational medicinal products. We believe that our second viral vector manufacturing facility and bringing GMP plasmid and DNA production in-house will provide greater flexibility and efficiency as we advance our product candidates through development, and should they be approved, commercial production.

We have also established a comprehensive platform designed for the efficient clinical development of the next generation of gene therapies and manufacturing in accordance with GMP requirements. We believe that our deep understanding of disease models informs our development of potency assays for the GMP production of our product

candidates, and our experienced teams in viral vector design and optimization work closely with our process development team to design viral vectors and develop proprietary production cell lines for efficient scaling of manufacturing processes. Our wholly-owned facilities have now produced GMP clinical trial material for eight different indications, using multiple AAV serotypes, including administration into the eye, salivary gland and central nervous system.

We have also developed a potentially transformative technology to precisely and specifically control gene expression levels via dose-response to orally delivered small molecules. This completely novel technology allows us to control the expression of any DNA sequence using a bespoke oral small molecule, circumventing the need for manufacturing of biologics outside the body or stabilization for long term activity. With this riboswitch platform, we can control the precise timing of production of any mRNA from any DNA sequence - and therefore regulate the protein or peptide produced within the body dependent on the dose of the chosen oral small molecule. The need for injection of stabilized drug product is replaced by an oral small molecule that can repeatedly activate mRNA production every time it is dosed. This platform opens a whole array of targets that are not currently druggable, particularly in the area of metabolism where many of the known peptide agonists have proven difficult to address pharmaceutically. We can deliver the sequence that is the most physiologically active without the need for modification to extend the half-life or manufacturing outside the body.

Relationship with Johnson & Johnson Innovative Medicine

On January 30, 2019, we and our wholly-owned subsidiary MeiraGTx UK II Limited entered into a Collaboration, Option and License Agreement with Johnson & Johnson Innovative Medicine (formerly known as Janssen Pharmaceuticals, Inc.), as further amended by that certain First Amendment to Collaboration, Option and License Agreement, dated as of December 16, 2021 (the "Collaboration Agreement"), for, among other things, the research, development and commercialization of gene therapies for the treatment of IRDs, including botaretigene sparoparvovec, or bota-vec (formerly referred to as AAV-RPGR), for the treatment of X-linked retinitis pigmentosa related to mutations in the retinitis pigmentosa GTPase regulator gene, or XLRP-RPGR (the "RPGR Product"), and two genetic forms of achromatopsia. Under the Collaboration Agreement, Johnson & Johnson Innovative Medicine paid us a non-refundable upfront fee of $100.0 million in March 2019 and a milestone payment of $30.0 million in December 2021. We also received funding for certain research, manufacturing, clinical development and commercialization costs, and had the opportunity to obtain potential additional milestone payments upon the achievement of such milestones and royalties on future net sales of products.

On December 20, 2023 (the "Closing Date"), we and MeiraGTx UK II Limited entered into and consummated an Asset Purchase Agreement (the "Asset Purchase Agreement") with Johnson & Johnson Innovative Medicine pursuant to which we sold and assigned to Johnson & Johnson Innovative Medicine, and Johnson & Johnson Innovative Medicine purchased and assumed, that certain License Agreement, dated February 5, 2019, by and between UCL Business Plc (now UCL Business Ltd.) ("UCLB"), on the one hand, and MeiraGTx UK II Limited and our wholly-owned subsidiary MeiraGTx Limited, on the other hand (the "UCLB RPGR License Agreement"), relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the Asset Purchase Agreement. In connection with entering into the Asset Purchase Agreement, we and MeiraGTx UK II Limited entered into a Termination Agreement with Johnson & Johnson Innovative Medicine on the Closing Date terminating the Collaboration Agreement.

MeiraGTx UK II Limited and Johnson & Johnson Innovative Medicine also entered into a Supply Agreement on the Closing Date pursuant to which MeiraGTx UK II Limited agreed to manufacture and supply the RPGR Product for Johnson & Johnson Innovative Medicine (the "Supply Agreement"). Under the Supply Agreement, MeiraGTx UK II Limited, together with its affiliates, will manufacture commercial supply of the RPGR Product for Johnson & Johnson Innovative Medicine for an initial term of four years, with Johnson & Johnson Innovative Medicine having an option to extend the Supply Agreement for a fifth year upon written notification to us.

Under the Asset Purchase Agreement, Johnson & Johnson Innovative Medicine paid us a non-refundable upfront cash purchase price of $65.0 million in December 2023. Additionally, pursuant to and subject to the terms and conditions set forth in the Asset Purchase Agreement, Johnson & Johnson Innovative Medicine agreed to pay us future contingent consideration of up to an aggregate of $350.0 million, as follows: (i) a milestone payment of $50.0 million in connection with the achievement of the initiation of the extension study for the Phase 3 LUMEOS clinical trial for the RPGR Product; (ii) $10.0 million upon completion of certain specified development services for the drug substance for the RPGR Product; (iii) $5.0 million upon completion of certain specified development services for the drug product for the RPGR Product; (iv) $175.0 million upon the first commercial sale of an RPGR Product in the United States; (v) $75.0 million upon the first commercial sale of an RPGR Product in at least one of the United Kingdom, France, Germany, Spain and Italy; (vi) $25.0 million upon completion of the transfer of certain manufacturing technology for drug substance and drug product from us to Johnson & Johnson Innovative Medicine; and (vii) $10.0 million upon regulatory approval of a Johnson & Johnson Innovative Medicine-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. As of December 31, 2024, we have received $60.0 million in milestone payments from Johnson & Johnson Innovative Medicine. Johnson & Johnson Innovative Medicine is also responsible for any royalty or milestone amounts that become payable on the RPGR Product under the UCLB RPGR License Agreement.

Strategic Investment from Sanofi

On October 30, 2023, we entered into an Investment Agreement (the "Investment Agreement") with Sanofi Foreign Participations B.V. (the "Sanofi Foreign Participations"), a wholly-owned subsidiary of Sanofi, and solely for the limited purposes set forth therein, Sanofi, pursuant to which, among other things and subject to the terms and conditions specified therein, we issued an aggregate of 4.0 million of our ordinary shares at a purchase price of $7.50 per share for gross proceeds of $30.0 million. The Investment Agreement also provides Sanofi Foreign Participations and its affiliates with a right of first negotiation for use of our riboswitch gene regulation technology for certain Immunology and Inflammation (I&I), including modulation of IL-4 and IL-13, and Central Nervous System (CNS) targets, as well as for GLP-1 and other gut peptides for metabolic disease, and for our Phase 2 xerostomia program, in each case, on the terms set forth therein.

Our Pipeline

Our focus is on *in vivo* delivery of vectorized biologic therapeutics addressing unmet needs in prevalent disorders, including severe forms of xerostomia, neurodegenerative diseases and ocular diseases, including inherited retinal diseases, or IRDs, as well as large degenerative ocular diseases. Utilizing our product development platform, we have assembled a pipeline of gene therapies to treat these serious diseases. Our criteria for selecting our initial product candidates included:

- unmet medical need;
- high potential for meaningful clinical benefit;
- promising preclinical data using multiple animal models as well as human stem cell derived organoids;
- compartmentalized anatomy of target tissue and the partially immune protected nature of target tissue; and
- understanding of the disease state from natural history studies and detailed long-term characterization of patients prior to entry into gene therapy treatment studies.

We are also focusing the riboswitch platform on delivery of metabolic peptides, as well as cell therapy for oncology and autoimmune diseases, and long term intractable pain.

A summary of our product candidates and the status of such product candidates as of March 1, 2025 is described below.

[1] Remaining interests in program sold to Janssen in December 2023; MeiraGTx to receive up to an aggregate of $350.0 million upon achievement of milestones and will manufacture and supply commercial product for Janssen.

In addition to these clinical and preclinical programs, we have preclinical and research programs in other indications and novel molecular technologies that we aim to advance into clinical development, including:

- riboswitch gene regulation—use of our proprietary RNA shape regulation cassette to precisely control gene expression with novel small molecules, potentially transforming gene therapy technology into a delivery mechanism for a broad array of biologic drugs;
- central nervous systems/peripheral nervous system diseases—brain-derived neurotrophic factor gene therapy for treatment of genetic obesity disorders, as well as the development of gene therapy product candidates for other central nervous system diseases; and
- inflammatory/autoimmune diseases—use of gene therapy technology for the local delivery of immunomodulatory therapeutics, including osteoarthritis, gout and certain rare inflammatory disorders.

Our Salivary Gland Programs

The clinical focus of our salivary gland program is xerostomia, a chronic and debilitating disorder of the salivary glands in which saliva production is impaired. Xerostomia may be caused by a number of different insults to the salivary glands, including radiation therapy for head and neck cancer and certain autoimmune diseases.

AAV-hAQP1 for the Treatment of Radiation-Induced Grade 2/3 Xerostomia

Radiation-induced xerostomia, or RIX, is a severe and debilitating long-term side effect of radiation treatment for head and neck cancer. Chronic RIX results in severe side effects, including difficulty swallowing, or dysphagia, oral discomfort, malnutrition, oral mucositis, changes in taste, increased oral infections and dental cavities, resulting in a significant negative impact on patient quality of life. Current treatment options for RIX are few and are of limited benefit. The sialogogues pilocarpine (approved for RIX) and cevimeline (used off-label) are minimally effective in

patients with grade 2/3 RIX where the gland structure and function have been significantly impaired. No new medications for RIX have been approved in over 20 years.

Worldwide, there are approximately 650,000 new cases of head and neck cancer diagnosed each year, with approximately 54,000 cases in the U.S. alone, making it the fifth most common malignancy. Approximately 85% of patients who receive radiation treatment for head and neck cancer experience reduced saliva production during treatment, and approximately 40% of those patients who remain cancer free for two or more years after treatment continue to suffer from grade 2 or 3 RIX. There are approximately 170,000 such patients in the U.S., with approximately 15,000 new cases of persistent grade 2 or 3 RIX each year in the U.S. In addition to the RIX patient population from treatment for head and neck cancer, new therapies such as prostate specific membrane antigen (PSMA)-targeted radioligand therapy can also lead to xerostomia, providing additional potential patient populations that may benefit from our AAV-hAQP1 treatment.

Salivary glands are an attractive target organ for gene therapy treatments because they are self-contained, partially immune protected and easily accessible, allowing for non-invasive delivery of small vector doses.

We are developing AAV-hAQP1 to treat RIX by introducing a water conducting channel into the remaining epithelial cells of these damaged glands, thereby increasing water flow into the mouth. Adequate water secretion by surviving epithelial cells has the potential to deliver the protective exocrine proteins produced by remaining gland cells into the mouth.

The key to our approach is that, unlike the water conducting acinar cells, the water impermeable duct cells of the glands appear to be resistant to ionizing radiation exposure. As a consequence of this relative resistance to radiation treatment, salivary glands damaged by radiation treatment tend to contain mostly water impermeable ductal epithelial cells. To make these duct cells permeable to water, AAV-hAQP1 introduces the gene for the human aquaporin water channel, or *hAQP1*. We have demonstrated that this has the potential to convey water permeability and cause ductal cells to generate an osmotic gradient, and secrete fluid into the lumen of the duct.

The proof of concept for this mechanism and its ability to increase the volume of fluid secreted by damaged salivary glands was observed in a Phase 1 clinical trial conducted by the NIH in patients with chronic grade 2 or 3 RIX. The trial was designed as a short-term dose escalation trial of a gene therapy using adenovirus as the vector to deliver the *hAQP1* to the remaining epithelial cells in the parotid gland of 11 patients suffering from chronic RIX. There were no reported severe adverse events among the patients treated, two out of three patients in each of the first three cohorts in this clinical trial were observed to have objective increases in saliva volume produced by the treated parotid gland, with increases in parotid flow ranging from 60% to 540%, and all but one of these patients showed a decrease in symptoms of dry mouth as measured by subjective visual analog scales, validated in other forms of xerostomia. The results of this study were published in *Proceedings of the National Academy of Sciences* in 2012.

Clinical Development of AAV-hAQP1 for the Treatment of Radiation-Induced Grade 2/3 Xerostomia

We are currently conducting a Phase 1 dose escalation clinical trial of AAV-hAQP1 at the NIH in patients with grade 2 or 3 RIX who remain cancer free for at least five years after receiving radiation treatment. In this trial we are using AAV2 to deliver the *hAQP1* gene, as we believe AAV2 efficiently transfects the salivary gland cells and does not spread beyond the target cells. The aim of the trial is to determine the safety of inserting *hAQP1* locally into the salivary glands of RIX patients, as well as to measure changes in salivary flow resulting from the introduction of this channel. This clinical trial is being conducted in conjunction with the National Institute of Dental and Craniofacial Research at the United States National Institutes of Health, or the NIH, Dental Clinic.

In the third quarter of 2019, we also initiated an open-label, multi-center Phase 1 dose escalation clinical trial of a single administration of our product candidate AAV-hAQP1 to one or both parotid glands in patients with grade 2 or 3 RIX. In December 2021, we announced preliminary data from this Phase 1 clinical trial. The announcement included

data from seven patients treated in cohorts 1, 2 and 3 of the unilateral dose escalation phase of the clinical trial. Six of the seven patients who reached 90 days following treatment reported their symptoms of dry mouth as better following treatment pursuant to a validated patient reported assessment of xerostomia symptoms, constituting clinically meaningful improvement. One patient who reported the maximum response evaluable at 12-months had reached the 24-month time point and reported the same level of response. In March 2022, we completed enrollment of the study. A total of 24 patients received either unilateral (n=12) or bilateral (n=12) treatment in one of eight escalating dose cohorts of three patients each.

In June 2023, we announced additional positive clinical data from the completed Phase 1 dose escalation clinical trial of AAV-hAQP1. All unilaterally and bilaterally treated participants had undergone their 12-month assessment, with four having completed their 24-month assessment and three having completed their 36-month assessment in the long-term follow-up study. The investigational gene therapy AAV-hAQP1 was observed to be well tolerated in the Phase 1 trial, with no dose limiting toxicity or treatment-related serious adverse events observed, and patient reported assessments of xerostomia symptoms and whole salivary flow rate improved. All subjects are to be followed for one year post-treatment in the present study and for an additional four years in the long-term follow-up study, per U.S. Food and Drug Administration, or FDA, guidelines. The study's primary endpoint is safety. Secondary endpoints include change from baseline in patient reported measures of xerostomia symptoms as well as whole salivary flow rates. Based on the safety and efficacy data observed for AAV-hAQP1 in the Phase 1 clinical trial, we initiated in June 2023 a randomized, double-blind, placebo-controlled Phase 2 AQUAx2 study evaluating two active doses of AAV-hAQP1 for the treatment of grade 2 or 3 RIX with participants currently being enrolled and dosed in the U.S., Canada and UK. During 2024, we gained alignment with the FDA on requirements for the Phase 2 AQUAx2 clinical trial to be considered a pivotal trial in support of a potential Biologics License Application, or BLA, filing.

The FDA granted orphan drug designation to AAV-hAQP1 for the treatment of symptoms of grade 2 and grade 3 late xerostomia from parotid gland hypofunction caused by radiotherapy for cancer of the oral cavity. In December 2024, the FDA granted Regenerative Medicine Advanced Therapy, or RMAT, designation to AAV-hAQP1 for the treatment of grade 2 or 3 RIX.

AAV-hAQP1 for the Treatment of Sjogren's Syndrome

The destruction of salivary tissue resulting in chronic xerostomia may also be caused by chronic autoimmune disease. Sjogren's syndrome is an autoimmune disease in which a patient's immune system may target the salivary glands. Chronic inflammation of the salivary glands results in long term damage and chronic xerostomia in many Sjogren's patients. Data from preclinical studies in animal models of Sjogren's syndrome and data from explants of minor salivary glands of Sjogren's patients suggest that Sjogren's syndrome may also be treatable with our AAV-hAQP1 vector. Supported by data from our preclinical studies and our ongoing RIX clinical trials, we are currently conducting IND-enabling studies of AAV-hAQP1 for xerostomia caused by Sjogren's syndrome.

Our Neurodegenerative Disease Programs

Relying on our expertise in viral vector design, delivery, production and manufacturing, we are aiming to develop and optimize vectors to effectively treat both genetic and sporadic forms of certain neurodegenerative diseases.

AAV-GAD for the Treatment of Parkinson's Disease

Our first target indication is Parkinson's disease, affecting nearly one million Americans and 10 million worldwide. Parkinson's disease is the second-most common neurodegenerative disease after Alzheimer's disease and is the 14th-leading cause of death in the United States. It is associated with a progressive loss of motor control (e.g., shaking or tremor at rest and lack of facial expression), as well as non-motor symptoms (e.g., depression and anxiety). There is no cure for Parkinson's disease and 60,000 new cases are diagnosed each year in the United States alone.

Our product candidate targeting Parkinson's disease, AAV-GAD, is designed to deliver the glutamic acid decarboxylase, or *GAD*, gene via a one-time infusion through a minimally invasive procedure, using our proprietary device that allows infusion of the equivalent of one drop of gene therapy solution to the subthalamic nucleus in order to increase production of GABA, the primary inhibitory neurotransmitter in the human brain. GAD is the rate-limiting enzyme in the synthesis of GABA, therefore we believe that increasing subthalamic nucleus GAD expression through gene therapy has the potential to address the dysregulation of motor circuits and improve symptoms in Parkinson's disease patients without affecting other brain regions, which can be responsible for complications of existing therapies.

Clinical Development of AAV-GAD

In a blinded Phase 2 clinical trial of AAV-GAD in patients with medically refractory Parkinson's disease, 45 patients were randomized 1:1 to receive either AAV-GAD gene therapy delivered by injection into the subthalamic nucleus on both sides of the brain or bilateral sham surgery. Subjects were followed for one year and all results remained blinded until the final treated patient reached the 6-month primary endpoint. The trial met the primary endpoint, of six-month change from baseline in double-blind assessment of off-medication motor scores of the Unified Parkinson's Disease Rating Scale, or UPDRS. At the six-month endpoint, UPDRS score for the AAV-GAD group decreased by 8.1 points (SD 1.7, 23.1%; $p<0.0001$) and by 4.7 points in the sham group (1.5, 12.7%; $p=0.003$). The AAV-GAD group showed a significantly greater improvement from baseline in UPDRS scores compared with the sham group over the six-month course of the study (RMANOVA, $p=0.04$). An improvement in complications of medical therapy as measured by the UPDRS part 4 was observed in the AAV-GAD group at both six and 12 months. A significant decline in duration of disabling dyskinesia was observed only in the AAV-GAD treated patients.

AAV-GAD was reported to be well-tolerated, with no significant adverse events related to the therapy and no speech or cognitive complications observed. The results of the trial were published in the March 2011 issue of *The Lancet Neurology*, the August 2014 issue of the *Journal of Clinical Investigation* and the April 2017 issue of *JCI Insight*, building upon publications of the Phase 1 trial data in *The Lancet* and the *Proceedings of the National Academy of Sciences*. In addition, in research published in the November 28, 2018 issue of *Science Translational Medicine*, fifteen patients treated with AAV-GAD gene therapy were observed to have expressed a treatment-related reorganization of functional brain connectivity that was related to disease symptom improvement. These flurodeoxyglucose positron emission tomography analyses provided objective biological evidence of improvements in abnormal brain networks associated with Parkinson's disease following AAV-GAD gene therapy.

These results were observed in patients treated in both Phase 1 and Phase 2 studies. Blinded analyses showed significant improvements in abnormal thalamic metabolism, a key node in the movement circuitry, in the AAV-GAD treated patients. This pattern of brain network activity was not seen in untreated hemispheres or patients in the sham arm. Furthermore, a specific pattern of brain network activity was identified in those subjects with clinical improvements in the sham arm, which was different from the pattern observed in AAV-GAD responders.

We filed an IND for AAV-GAD in May 2022, and we have completed dosing patients in MGT-GAD-025, an AAV-GAD Phase 1 bridging study. MGT-GAD-025 was a 6-month, three-arm, randomized, double-blind, sham-controlled study using AAV-GAD drug product manufactured at our wholly-owned facilities with our commercial platform process. Participants had idiopathic Parkinson's disease, a history of levodopa responsiveness for at least 12 months, and a UPDRS Part 3 score of ≥25 points in the "off" state. Fourteen subjects were randomized to one of three groups (high dose n=5, low dose n=5, and sham n=4). Subjects received either AAV-GAD infused bilaterally into the subthalamic nucleus or a sham procedure in a blinded fashion. The total dose per treated participant was 7.0×10^{10} vg (low dose group) or 21×10^{10} vg (high dose group). The primary objective of the study was to evaluate the safety and tolerability of AAV-GAD, with exploratory efficacy endpoints including the mean change from baseline to Week 26 in MDS-UPDRS Part 3 (motor examination) scores in the "off" state and the Parkinson's Disease Questionnaire (PDQ-39) score, a key patient-reported quality of life measure in Parkinson's disease. Subjects who completed this trial may enroll in a long-term follow-up study (NCT05894343), where they will be monitored for a total of five years post-treatment.

In October 2024, we announced preliminary data from this Phase 1 bridging study and the investigational gene therapy AAV-GAD was observed to be safe and well tolerated, with no treatment-related serious adverse events observed. At Week 26, a statistically significant 18-point average improvement from baseline in UPDRS Part 3 "off" medication score was demonstrated in the high dose group (p=0.03), with no significant change in the sham or low dose groups. A change of 5 to 10 points is considered clinically meaningful for the UPDRS Part 3 in the "off" state. Significant improvements from baseline in the disease-specific, patient-reported quality of life PDQ-39 score were demonstrated in both the high and low dose groups with no significant change in the sham group at Week 26:

- In the high dose AAV-GAD group, the PDQ-39 score improved by 8 points from baseline (p=0.02), the low dose group improved by 6 points from baseline (p=0.04), while the 0.2 point worsening in the sham surgery group was not statistically significant. For the PDQ-39, a 2 to 4-point change is considered clinically meaningful.

- A dose response in PDQ-39 score was observed, with 100% of participants in the high dose group, 60% of participants in the low dose group, and 25% of participants in the sham surgery group reporting an improvement.

- For the PDQ-39 score, there was a trend to significance between the high dose and sham surgery groups at 6 months (n=4 evaluable per group).

Neurodegenerative Disease Preclinical Development Pipeline

In addition to our clinical stage Parkinson's disease program, we continue to conduct research to develop our preclinical pipeline of gene therapy product candidates for the treatment of other serious diseases of the central nervous system, including AAV-UPF1 to address motor neuron death in amyotrophic lateral sclerosis (ALS), and an Alzheimer's disease program focused on endosomal trafficking dysfunction. Each of these programs is directed towards the underlying cell biology that may be driving neurogeneration in these diseases.

ALS

ALS is a devastating, progressive, neurodegenerative disease leading to the loss of motor neurons, which are the neurons that control the ability to move, speak, swallow and ultimately to breathe. The gradual paralysis in ALS invariably leads to death. While 10% of ALS cases are caused by inherited genetic mutations, most ALS occurs sporadically, with no known genetic cause. Mutations in over 20 genes have been identified that cause the inherited ALS cases. Characterization of these disease-causing genes has implicated several cellular pathways in the disease, with a prominent role emerging for genes involved in the cellular control of RNA. Many new regulatory roles are being discovered for RNA, particularly in neurons.

We have designed a viral vector product candidate, AAV-UPF1, with the aim of increasing *UPF1* expression in the motor neurons of ALS patients. In preclinical studies, we observed that administration of AAV-UPF1 reduced motor neuron death thought to be driven by the toxic effects of several different genetic causes of ALS including, TDP-43, FUS and C9*orf*72. Improvements in ALS-like symptoms related to limb strength and mobility in rodent models of ALS have also been observed following administration of AAV-UPF1.

We believe that gene therapy using AAV-UPF1 may increase *UPF1* levels in cells affected by ALS, and we intend to deliver our viral vector product candidate to the central nervous system via intrathecal injection, or injection into the spinal canal.

Alzheimer's Disease

With the world population aging, Alzheimer's disease has emerged as an extremely common and costly disease. While some treatments that have temporary effects on Alzheimer's disease symptoms are available, there is currently no approved treatment that halts the progression of the disease.

Our Alzheimer's disease program focuses on the endosomal trafficking pathway. In preclinical studies, we observed that increasing levels of key retromer proteins may reverse endosomal trafficking defects. We are identifying suitable retromer targets for gene augmentation in pre-symptomatic Alzheimer's patients.

There are several reasons why gene therapy is, in principle, well suited for Alzheimer's disease and other neurodegenerative diseases. The first relates to the pathophysiology, time course, and anatomical spread of these disorders. Neurodegenerative diseases generally begin locally in selectively vulnerable regions with "cell sickness" years before rampant cell death and wide-spread anatomical distribution. To be most effective, we believe interventions should be administrated early and will benefit from local delivery. Even then, however, an intervention must maintain its efficacy for years because, unlike other cells in the body, neurons do not typically divide over the course of their life. We believe AAV-delivered gene therapy products may have a durable effect. In the best case scenario, one delivery successfully taken up by targeted neurons would be sufficient for years of efficacy.

An important component of our approach is the development and validation of surrogate markers of endosomal dysfunction and predictive markers of Alzheimer's disease. In particular, several well studied biomarkers linked to Alzheimer's disease, such as amyloid-beta and tau, have also been shown to be biomarkers of endosomal trafficking dysfunction in neurons. Such biomarkers could potentially be used to identify patients with Alzheimer's disease, as well as demonstrate potential product efficacy in the absence of Alzheimer's disease symptoms. By targeting endosomal trafficking dysregulation we aim to address the underlying cause of Alzheimer's disease as well as other neurodegenerative diseases, such as certain forms of Parkinson's disease.

Our Ophthalmology Programs

Under our ophthalmology programs, we aim to provide treatments for eye diseases with durable, long-term clinical benefit that will halt vision loss in patients. We have three Phase 1/2 clinical programs targeting IRDs, including AAV-CNGB3 and AAV-CNGA3 for the treatment of achromatopsia, or ACHM, related to mutations in *CNGB3* and *CNGA3* genes, respectively, and AAV-RPE65 for retinal dystrophy related to mutations in the *RPE65* gene, or RPE65 deficiency. We have completed enrollment and dosing in all three of these programs. In addition to these three programs, AAV-AIPL1 has been manufactured and released for compassionate use under an MHRA specials license in the United Kingdom, or UK, to treat patients with Leber congenital amaurosis 4, or LCA4, caused by mutations in the *AIPL1* gene. We also have preclinical programs that apply novel approaches to both wet and dry AMD, glaucoma and uveitis, as well as several other IRDs including retinol dehydrogenase 12, or RDH12, mutation-associated retinal dystrophy, Bardet-Biedl syndrome, or BBS, due to *BBS10* mutations, Leber congenital amaurosis type 1, or LCA1, due to *GUCY2D* mutations and Stargardt disease related to mutations in the *ABCA4* gene.

We chose diseases of the eye as an area of clinical focus because we believe the eye is ideally suited for gene therapy for the following reasons.

- The eye is easily accessible and has highly compartmentalized anatomy, which allows for accurate delivery of vectors to specific tissues using direct visualization and microsurgical techniques.

- The structure of the eye allows for efficient delivery to specific cell subtypes with small volumes of vector, making the dose per patient much lower than is needed for systemic treatment.

- Anatomical barriers and unique structure of the eye make the immune response to the intraocular administration of vectors more attenuated than systemic administration.

- Largely non-dividing cell populations in the eye make good targets for potentially stable, long-term gene delivery and expression.

- The retina, a structure in the back of the eye, is visible and there are many well validated structural and functional readouts allowing the detailed assessment of the therapeutic impact of the gene therapy treatment.

Our strategy for developing gene therapies targeting eye diseases was to begin with a number of monogenic IRDs that are good candidates for gene replacement therapies and expand to more common eye diseases over time. We have taken a portfolio approach to the development of IRDs because, while some of these genetic defects are rare, IRDs as a class are one of the most common causes of blindness in working age adults and there are multiple synergies at the clinical, regulatory and commercial levels between many of these diseases caused by different gene mutations.

We believe that the deep scientific and clinical understanding of IRDs driving our approach to gene therapy development helps us to optimize our product candidates for each specific genetic mutation and phenotype. We develop our viral vectors by selecting and modifying proprietary cell specific promoters, selecting appropriate capsids for transfection of target cells and refining the vector for efficient production and scalable manufacturing. Not only does this allow us to synergistically target a portfolio of inherited eye conditions, we also believe it has potential to be applied to the development of gene therapies for other diseases.

Our longstanding relationships with leading institutions in retinal disease treatment, including the Moorfields Eye Hospital in London, the University of Michigan Kellogg Eye Center, Massachusetts Eye and Ear, the Medical College of Wisconsin & Froedtert Hospital and the Casey Eye Institute at the Oregon Health & Science University, provide us with access to experts whose guidance and insight informs our development strategy, as well potential patients for our clinical trials.

We intend to leverage our platform to take advantage of the many synergies across our ophthalmology programs, including identification, diagnosis and characterization of patients, specialized surgical techniques, clinical and regulatory process, vector production and GMP manufacturing.

AAV-RPE65 for the Treatment of RPE65-Associated Retinal Dystrophy

We are developing AAV-RPE65 for the treatment of retinal dystrophy associated with mutations in the *RPE65* gene. *RPE65*-associated retinal dystrophy causes rod photoreceptor dysfunction and impaired vision from birth. Absence of RPE65 results in severe dysfunction of rods and causes impaired vision in dim lighting conditions. Although cone photoreceptors are generally preserved during childhood in *RPE65*-deficient patients, the lack of function and degeneration of the rods eventually results in the loss of cones and degeneration of the whole retina over time. Consequently, most *RPE65*-associated retinal dystrophy patients experience central vision loss progressing to complete blindness by early adulthood.

Based on an estimated prevalence of approximately one in 500,000 people in the United States (U.S.) suffering from Leber congenital amaurosis, or LCA, related to mutations in the *RPE65* gene, and approximately one in 70,000 people in the United States having retinitis pigmentosa, or RP, due to mutations in the *RPE65* gene, *RPE65*-deficiency occurs in approximately one in 125,000 people in the United States. There are estimated to be approximately 6,000 *RPE65*-deficiency patients in the United States, Japan and Germany, France, Spain, Italy and the UK, with almost 30% of those patients being under the age of 30 and approximately 50 new cases being diagnosed annually. We have developed a gene therapy candidate optimized for safety and potency for the treatment of *RPE65*-associated retinal

dystrophy, AAV-RPE65. AAV-RPE65 is an AAV2/5 viral vector, in which a codon optimized *RPE65* gene is driven by a novel synthetic retinal pigment epithelium cell specific promoter.

The FDA has approved the first gene treatment for *RPE65*-associated retinal dystrophy, Luxturna, a commercially available product developed by Spark Therapeutics, Inc., which was purchased by Roche. While *RPE65*-associated retinal dystrophy primarily causes a loss of rod function initially leading to impaired vision in dim light, these patients ultimately experience complete blindness because of degeneration of the cone rich fovea. To prevent blindness, therefore, we believe it is critical to treat the central retina in order to maintain structural integrity in this region and save central vision. We aim to treat as extensive an area of the central retina as possible, including the cone rich fovea. Thus, in addition to improving rod function, we aim to provide sufficient RPE65 protein to the cells in the central retina to prevent the degeneration of both rods and cones in this region, and thereby prevent the progression to complete blindness.

Clinical Development of AAV-RPE65

We conducted a natural history study in patients with RPE65-associated retinal dystrophy with approximately 30 patients enrolled that has allowed us to collect structural and functional data on prospectively defined endpoints, including functional tests, retinal imaging, and electrophysiological assessments.

Our Phase 1/2 clinical trial enrolled *RPE65*-associated retinal dystrophy patients in the UK and U.S. Dosing in the Phase 1/2 clinical trial was completed in June 2018. The primary endpoint of this open-label, dose-escalation clinical trial is safety. Secondary endpoints include the outcomes of a range of functional tests, detailed structural analysis of the retina and quality of life measures. A total of 15 patients were treated in this clinical trial, including nine adult patients in three dose escalation cohorts and six pediatric patients in the pediatric extension arm of the trial.

In May 2019, we announced positive topline safety and efficacy data from the Phase 1/2 trial of AAV-RPE65. Additional data from this study were presented at the Retina Subspecialty Day of the American Academy of Ophthalmology Annual Meeting in October 2019.

AAV-RPE65 met the study's primary endpoint of safety and tolerability. Additionally, AAV-RPE65 demonstrated statistically significant improvement across several secondary endpoints assessing clinical activity. Significant improvement in vision was demonstrated at six months after AAV-RPE65 treatment, as measured by assessments of vision-guided mobility, retinal sensitivity, visual acuity and contrast sensitivity. Larger improvements from baseline in functional vision were observed between treated and control eyes at lower light levels. We believe these outcomes address the core functional manifestation of *RPE65*-associated retinal dystrophy, which typically causes vision impairment beginning in early childhood that is most pronounced in low-light conditions, and is consistent with the proposed mechanism of action of AAV-RPE65.

We continue to evaluate the initiation of a Phase 3 clinical trial for AAV-RPE65.

The FDA granted orphan drug designation and the European Commission (based on the European Medicines Agency's, or EMA, opinion) granted orphan designation to AAV-RPE65 for the treatment of LCA caused by mutations in the *RPE65* gene. The FDA also granted AAV-RPE65 rare pediatric disease designation for the treatment of inherited retinal dystrophy due to biallelic *RPE65* mutations.

AAV-CNGB3 and AAV-CNGA3 for the Treatment of Achromatopsia

Achromatopsia, or ACHM, is an IRD that specifically prevents cone photoreceptors from functioning. ACHM patients are legally blind from birth and usually suffer from severely reduced visual acuity of 20/200 or worse, a disabling sensitivity to light, or photoaversion, total color blindness and involuntary back and forth eye movements, or nystagmus. ACHM patients suffer significant vision loss due to the complete lack of cone function. ACHM occurs in

approximately one in 30,000 people in the United States. The *CNGB3* and *CNGA3* genes are the two most common genes that have been identified as causing ACHM, together accounting for up to 92% of ACHM cases, with *CNGB3* slightly more common than *CNGA3* in most geographic territories.

There are estimated to be approximately 12,000 patients with ACHM caused by mutations in *CNGB3* in the United States, Japan, Germany, France, Spain, Italy and the UK, with about 25% of those patients being under the age of 18 and approximately 125 new cases being diagnosed annually. We believe the availability of a therapeutic option may increase patient identification and the estimated prevalence of ACHM.

ACHM is predominantly a stationary disease, which means that ACHM patients' retinas contain non-functioning cones that survive intact for many decades. This is in contrast to many IRDs in which the entire retina slowly degenerates over a patient's life. This extended survival of cones with their potential for light sensitivity presents a wide window of opportunity to introduce a normal copy of the mutated gene via a gene therapy product candidate and thereby restore cone function. While the stationary nature of ACHM means that cones remain present for decades, the functional connections between active cones and the visual cortex in the brain are thought to become fixed in teenage years. Therefore, we believe that younger individuals are likely to benefit most from gene therapy treatment for ACHM because of their greater visual plasticity. Another debilitating symptom of ACHM, which lasts throughout life, is photoaversion. A disabling and ubiquitous symptom of ACHM, photoaversion is the avoidance of light due to discomfort in the presence of levels of light equivalent to a normally lit room or daylight. ACHM patients often avoid light and wear dark glasses, which further diminishes their already very poor vision. We believe it is possible that restoration of cone function in adult patients might have an impact on photoaversion even if brain plasticity is limited.

We believe that gene therapy treatment for ACHM in which we aim to restore cone function via a gene replacement strategy may offer benefits across a range of ages, which we aim to define in our clinical development programs.

We have designed specifically optimized gene therapy viral vector candidates to treat ACHM caused by mutations in each of *CNGB3* and *CNGA3*, with which we aim to address the majority of patients suffering from ACHM. Our product candidates are delivered via subretinal injection covering the central macula region of the eye, where most of the cones in the retina are located.

We have also conducted a natural history study in ACHM including over 90 patients that allows us to collect structural and functional data on prospectively defined endpoints, including functional tests, retinal imaging and electrophysiological assessments. We believe access to these ACHM patients enabled us to efficiently enroll the most appropriate patients into our *CNGB3* and *CNGA3* Phase 1/2 clinical trials. In addition to giving us access to patients and potentially accelerated enrollment in our treatment studies, we believe the prospective natural history data on each treated patient allowed us to gather robust data from our Phase 1/2 clinical trials in a condensed timeframe.

Clinical Development of AAV-CNGB3 for the Treatment of ACHM Caused by Mutations in the CNGB3 Gene

We have developed a product candidate, AAV-CNGB3, to treat ACHM caused by mutations in the *CNGB3* gene. Mutations in the *CNGB3* gene prevent cone photoreceptors from functioning because *CNGB3*'s gene product is integral to the formation of a specific membrane channel that enables cones' electrical response to light. *CNGB3* is a gene exclusively expressed in cones and our aim is to replace the absent function of the mutant *CNGB3* gene with a normal copy of the gene in cones of IRD patients and thereby restore cone function. In order to drive expression of the functional *CNGB3* gene specifically in cones and not in other cells of the retina, we use the cone specific human cone arrestin, or CAR, promoter to drive the expression of a codon optimized *CNGB3* cDNA. Codon optimization improves protein expression by increasing translation efficiency. To transfect cone photoreceptors, we use the AAV8 capsid, which enables the efficient delivery of the *CNGB3* gene cargo to those photoreceptors. As the vast majority of the cones in the eye are located centrally and concentrated in the macula, we treat this central region of the retina through subretinal injection to deliver the viral vector product candidate to the photoreceptors in which its activity is required.

We have completed enrollment and dosing of the Phase 1/2 clinical trial of AAV-CNGB3 in both adult and pediatric patients. In this trial, AAV-CNGB3 was delivered via subretinal injection of up to 0.5mL targeting the central region of the retina, including the macula and fovea, where most of the cones are located. One eye is treated in each patient. The primary endpoint of this open-label, dose-escalation clinical trial is safety. Secondary endpoints include the outcomes of a range of functional and structural assessments.

Dosing was completed in this clinical trial in May 2019. In the dose escalation portion of the trial, we treated 11 adults. We also treated 12 children in the pediatric expansion cohorts. Six months following treatment, patients could participate in a long term follow up study in which they were followed for safety and indication of benefit.

Our gene therapy product candidate AAV-CNGB3 was granted orphan drug designation by the FDA and orphan designation by the European Commission for the treatment of achromatopsia caused by mutations in the *CNGB3* gene, rare pediatric disease designation by the FDA for the treatment of achromatopsia caused by mutations in the *CNGB3* gene, and Fast Track designation by the FDA for the treatment of achromatopsia caused by *CNGB3* mutations. We were granted PRIME designation by the EMA in October 2018 based on data from the first adult treatment cohort along with preclinical data.

Clinical Development of AAV-CNGA3 for the Treatment of ACHM Caused by Mutations in the CNGA3 Gene

We are also developing AAV-CNGA3 to treat ACHM caused by mutations in the *CNGA3* gene. We have designed a synthetic promoter to drive high levels of *CNGA3* expression specifically in cones because we believe a larger amount of *CNGA3* protein is required to restore cone function as compared to *CNGB3*. AAV-CNGA3 utilizes this proprietary pan cone promoter to drive a codon optimized *CNGA3* gene sequence. We believe this novel promoter can drive sufficient expression of *CNGA3* in cones to restore light sensitivity to these cones in *CNGA3* deficient patients. We use the AAV8 capsid to transfect cone photoreceptors in the back of the eye and we target the cones concentrated in the central region of the retina via a subretinal injection that covers the macula.

We have completed enrollment and dosing of the open-label, dose-escalation Phase 1/2 clinical trial of AAV-CNGA3 in patients with ACHM due to mutations in the *CNGA3* gene. Six months following treatment, patients could participate in a long term follow up study in which they were followed for safety and indication of benefit.

Our gene therapy product candidate AAV-CNGA3 was granted orphan drug designation by the FDA and orphan designation by the European Commission, rare pediatric disease designation by the FDA, and was granted Fast Track designation by the FDA for the treatment of ACHM caused by *CNGA3* mutations.

AAV-AIPL1 for the Treatment of LCA4

LCA4 is an IRD that causes profound visual impairment from birth, with all children being legally blind (often light perception only) from birth. Despite the severe lack of retinal function, there is a narrow window of relative preservation of central retinal structure until four years of age. Aryl-hydrocarbon-interacting protein-like 1, or AIPL1, is a key protein for the maintenance of photoreceptor structure and function. LCA4 is rare, representing approximately 5% of all LCA cases.

There are currently no approved treatments for LCA4, and we believe an effective intervention will require introducing a normal functional copy of the *AIPL1* gene into rod and cone photoreceptors early in a patient's life while some retinal structure remains in order to activate function and survival of the photoreceptors that are still present. We believe gene therapy has the potential to be the only effective way to address the disease's root cause. In research published in the March 2024 issue of *Molecular Therapy Nucleic Acids*, AAV-AIPL1 was reported to have effectively rescued molecular features of AIPL1-associated LCA4 in a study involving LCA4 patient-derived retinal organoids.

LCA4's extremely rapid progression (e.g., no targetable central retina beyond four years of age), rarity and early age of onset all make the standard process of seeking regulatory approval through clinical development challenging because adult safety trials would not yield meaningful data given the early onset of the disease.

To address LCA4, we developed a viral vector to replace the *AIPL1* gene in all photoreceptors by using the *AIPL1* cDNA driven by the rhodopsin kinase promoter, which is active in both rods and cones.

We have manufactured and released AAV-AIPL1 for compassionate use under an MHRA specials license in the UK to treat 11 children with LCA4. A specials license allows physicians to prescribe a treatment of AAV-AIPL1 for patients with LCA4 that they deem appropriate with local ethics approval. We play no role in the physician's treatment decision. The results from the first-in-human interventional study to treat children with AIPL1-associated retinal dystrophy were published in *The Lancet* in February 2025, which study sought to evaluate whether early intervention by gene supplementation therapy was safe and could improve outcomes in young children with this condition. The findings indicate that children under the age of 4 years old with AIPL1-related retinal dystrophy benefited substantially from subretinal administration of rAAV8.hRKp.AIPL1, with improved visual acuity and functional vision and evidence of protection against progressive retinal degeneration, without serious adverse effects.

The non-randomized, single-arm, clinical study conducted in the UK involved four children aged one year to three years with severe retinal dystrophy associated with biallelic disease-causing sequence variants in AIPL1. The genetic medicine was a recombinant adeno-associated viral vector, comprising the human AIPL1 coding sequence driven by a human rhodopsin kinase promoter region (rAAV8.hRKp.AIPL1). The product candidate was administered to one eye of each child by subretinal injection. Outcome measures included visual acuity (as assessed with standard-of-care testing as well as a novel touchscreen test), functional vision (assessed by observing and recording the children's visual behavior and their ability to perform simple vision-guided tasks), visual evoked potentials (assessed by recording cortical electrophysiological responses to full-screen black-and-white flickering stimuli), and retinal structure (assessed with handheld OCT and widefield fundus imaging).

Prior to intervention, the children's binocular visual acuities, or VA, were limited to perception of light. At a mean of 3.5 years (range 3.0 to 4.1 years), after intervention the VAs of their treated eyes improved to a mean of 0.9 logarithm of the minimal angle of the minimum angle of resolution (LogMAR) (range 0.8 to 1.0); VAs before intervention were equivalent to 2.7 LogMAR. In contrast, the VAs of their untreated eyes became unmeasurable at the final follow-up. In the 2 children able to comply with testing, an objective test of VA confirmed improvements in visual function, and measurement of visual evoked potentials showed enhanced activity of the visual cortex, specific to the treated eyes. In 3 of the children, structural lamination of the outer retina was better preserved in the treated eye than in the untreated eye, and, for all 4 children, retinal thickness appeared better preserved in the treated eye than in the untreated eye.

To date, two cohorts of children have been treated with rAAV8.hRKp.AIPL1. The first cohort of 4 children (data published in *The Lancet*) received treatment in one eye. A second cohort has been treated, with 7 children (ages 1 to 3 years old) receiving sequential bilateral treatment. Meaningful responses have been observed in all 11 out of 11 LCA4 children treated with rAAV8.hRKp.AIPL1 to date, with all gaining visual acuity 4 or more weeks following treatment.

Following recent meetings with the MHRA, we intend to submit a marketing authorization application, or MAA, under exceptional circumstances for AAV-AIPL1 in the UK based on the results from the 11 treated children. We are also currently engaging with the FDA to discuss a path forward for regulatory approval in the U.S.

As the manufacturer of AAV-AIPL1 under a specials license, we have a record retention requirement and a continuing obligation to inform the MHRA of any suspected adverse reaction to our medicinal product which is a serious adverse reaction.

The UK's Human Medicines Regulations 2012 (as amended) allow for the manufacture and supply of medicinal products not authorized for marketing to patients with special needs at the request of the healthcare professional responsible for the patient's care (these products are referred to as "specials"). A special may only be supplied in: (i) response to an unsolicited order from a healthcare professional responsible for the care of the patient, (ii) if the product is manufactured and assembled in accordance with the specifications of that healthcare professional to fulfil the special needs of the individual patient that cannot be met by products already authorized for marketing and (iii) if the product is manufactured under a specials license granted by the MHRA.

Manufacturing a special also imposes a five year record retention requirement subject to review by the MHRA, including details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware, as well as a continuing obligation to notify the MHRA of any suspected adverse reaction to the medicinal product which is a serious adverse reaction.

We were awarded an Innovation Passport Designation by the U.K. Innovative Licensing and Access Pathway Steering Group for AAV8-RK-AIPL1. This designation provides entry into the U.K.'s Innovative Licensing and Access Pathway, or ILAP, designed to accelerate time to market and patient access to innovative medicines. Other benefits of ILAP include access to a range of development tools, such as the potential for accelerated MAA assessment, rolling review, and a continuous benefit-risk assessment, or potential marketing authorization under exceptional circumstances.

Our gene therapy candidate AAV-AIPL1 was granted orphan drug designation by the FDA and orphan designation by the European Commission for treatment of inherited retinal dystrophy due to defects in the *AIPL1* gene, and in November 2024, rare pediatric disease designation by the FDA for treatment of inherited retinal dystrophy due to defects in the *AIPL1* gene.

Ophthalmology Preclinical Development Pipeline

We also have a preclinical IRD development pipeline focused on diseases caused by mutations in additional genes. In order to expand our gene therapy pipeline for retinal diseases, we are also developing treatments for certain multifactorial eye diseases, which are diseases caused by multiple genetic or environmental factors.

AAV-RDH12 for the Treatment of RDH12 Mutation-Associated Retinal Dystrophy

Disease-causing sequence variants in *RDH12* cause severe retinal dystrophy most often resulting in the clinical diagnosis of Leber congenital amaurosis (LCA) and early onset severe retinal dystrophy (EOSRD); although RDH12 variants have also been associated with a clinical diagnosis of RP. Sequence variants in *RDH12* account for 3.4%–10.5% of LCA/EOSRD. Individuals with RDH12 deficiency exhibit widespread retinal degeneration impacting both rods and cones, with early macular involvement. Most people with RDH12–LCA/EOSRD experience marked central visual loss by their late teens to twenties. AAV-RDH12 is an AAV based gene therapy designed to deliver a functional copy of the *RDH12* gene to the retina of patients with genetically defined RDH12 deficiency.

We received orphan drug designation from the FDA and orphan designation from the European Commission, and in November 2024, rare pediatric disease designation from the FDA, for AAV-RDH12 for the treatment of RDH12-associated retinal dystrophy.

AAV-BBS10 for the Treatment of BBS due to BBS10 Mutations

BBS is a rare genetic disease affecting approximately 1 in 250,000 people around the world. One of the primary symptoms of BBS is visual impairment secondary to retinal degeneration. More than 20 different genes are associated with the development of BBS, with BBS10 accounting for approximately 25% of cases. Our investigational genetic medicine AAV-BBS10 is an adeno-associated virus with a serotype 8 capsid with a complementary DNA (cDNA)

encoding the human BBS10 gene for treatment of BBS due to *BBS10* mutations. In November 2024, the FDA granted rare pediatric disease designation to AAV-BBS10 for the treatment of BBS due to *BBS10* mutations.

AAV-RetGC for the Treatment of LCA1

Mutations in the GUCY2D gene coding for guanylate cyclase lead to severe retinal diseases in humans, with 88% of cases causing autosomal recessive LCA1 whilst heterozygous missense mutations cause autosomal dominant cone-rod dystrophy, or CRD. In LCA1, photoreceptor function loss and blindness emerge very early in life. In CRD, degeneration starts in the cones and leads to loss of the central visual field due to the high presence of cones in the macula. CRD can lead to complete blindness when degeneration of rods follows those of cones. In January 2025, the FDA granted rare pediatric disease designation to AAV-RetGC for the treatment of LCA1 due to *GUCY2D* mutations.

Wet and Dry Neovascular Age Related Macular Degeneration (AMD)

We are developing pre-clinical programs relating to neovascular age related macular degeneration, or wet AMD. We use a gene therapy product candidate to deliver an antibody targeting the vascular endothelial growth factor receptor 2, or anti-VEGFR2, with the aim of blocking disease related vascular formation in the eye.

Additionally, we are developing a novel approach designed to treat advanced dry AMD patients who have lost central vision through our innovative "rod-to-cone" technology. By genetically engineering rods with molecules that will improve their speed of response to light, we aim to effectively transform a patch of rod photoreceptors in the outer part of the retina to behave more like cone photoreceptors, thus improving vision. There is no currently approved therapy that impacts disease progression of dry AMD. The best available treatment for patients after they lose central vision and acuity is support and rehabilitation services to help them better utilize the remaining peripheral part of their retina.

Our Strengths

In addition to our three core therapeutic areas of focus, our ongoing clinical development programs, and our broad pipeline of preclinical programs, we have core capabilities in viral vector design and optimization, gene therapy manufacturing and a potentially transformative gene regulation platform using bespoke synthetic riboswitch technology invented in-house that allows for the precise, dose-responsive expression of any transgene under the control of oral small molecules. Utilizing the following key strengths, we aim to develop, commercialize and expand our portfolio of product candidates.

- **Deep Expertise in Gene Therapy Development:** We believe our expertise in viral vector design, optimization and process development allows us to efficiently advance gene therapy products candidates from preclinical development to GMP manufacturing and clinical development through commercialization.

- **Potentially Transformative Gene Regulation Platform Technology:** We have developed a proprietary riboswitch technology platform to enable us to control the expression of any DNA sequence in the body using a bespoke oral small molecule, circumventing the need for manufacturing of biologics outside the body or stabilization for long term activity. We believe the capacity for temporal control of gene expression has the potential to transform the way gene and cell therapy can be used, including opening a whole array of targets that are not currently druggable, particularly in the area of metabolism where many of the known peptide agonists have proven difficult to address pharmaceutically.

- **Manufacturing Capabilities and Capacity:** We have manufacturing facilities in London, United Kingdom and Shannon, Ireland, which we expect can supply our current clinical and preclinical programs, as well as our third party supply obligations, through regulatory approval and, should they be approved, provide sufficient capacity for their commercial production. Our 29,000 square foot flexible and scalable viral vector manufacturing facility in London has two cell production suites, three independent viral vector

production suites providing multi-product and multi-viral vector manufacturing capabilities and an integrated, flexible fill-and-finish suite. Our second, large scale GMP viral vector manufacturing facility and our first GMP plasmid and DNA production facility in Shannon, Ireland came online in 2022 and stretches over 150,000 square feet. It is the first commercial-scale gene therapy manufacturing site in Ireland and is unique in its scale and integrated capabilities. The site contains three facilities, one built to be flexible and scalable for viral vector production for clinical and commercial supply, in addition, a facility to manufacture plasmid DNA – the critical starting material for producing gene therapy products – and thirdly, a QC hub performing advanced biochemical quality control testing for our clinical and commercial programs.

- **Robust and Diverse Clinical and Preclinical Pipeline:** Applying our portfolio approach to gene therapy product development, our focus is on *in vivo* delivery of vectorized biologic therapetuics addressing unmet needs in prevalent disorders, including treatments for ocular disorders, including IRDs and large degenerative ocular diseases, as well as salivary gland disorders and neurodegenerative diseases. We also have a broad preclinical development pipeline.

- **Relationships with Leading Institutions:** Our longstanding relationships with leading institutions and experts provides us with guidance on development strategy and access to potential patients for our clinical trials.

- **Natural History Study Data:** We sponsor ongoing prospective long-term natural history studies in IRDs that facilitate our ability to efficiently enroll our treatment studies, potentially reducing clinical trial timelines and providing insight into the appropriate endpoints for clinical studies to support potential regulatory approval.

Our Strategy

Our goal is to develop and commercialize innovative gene therapy products to treat serious disorders and broaden the scope of indications that may be treatable by our gene therapies. Our strategy to achieve this goal is to:

- successfully complete clinical development, obtain regulatory approval and commercialize our pipeline of gene therapy product candidates;

- continue to advance the development of our preclinical pipeline product candidates;

- utilize our viral vector design and optimization capabilities to identify and develop new gene therapies for serious diseases;

- advance the development of our potentially transformative proprietary technology for regulating the activity of gene therapy products using small molecules and initiate clinical trials of new regulatable product candidates; and

- continue to pursue and evaluate further strategic collaborations with additional biotechnology and pharmaceutical companies to leverage our capabilities, manufacturing capacity and proprietary gene regulation technology.

Gene Therapy Overview

Gene therapy uses a delivery vehicle, referred to as a vector, to insert a functionally active gene into cells in the body. The gene encodes a therapeutic protein that may block disease pathways or may enhance a deficient pathway.

Gene therapy has been studied for over 55 years, with a variety of different viral vectors employed to deliver therapeutic genes. Since the first clinical study of therapeutic gene transfer in humans in 1990, thousands of gene therapy studies covering a broad range of disease targets have been initiated. In recent years, more than 40 gene therapies have received regulatory approval, including approval by the FDA of Luxturna, marketed by Spark Therapeutics, Inc. which was purchased by Roche, for treatment of *RPE65*-associated retinal dystrophy, and Zolgensma, marketed by AveXis, Inc., a Novartis company, for the treatment of spinal muscular atrophy, resulting in a growing acceptance of gene therapy technology as a potentially safe and effective therapeutic approach.

Our current programs use adeno-associated virus, or AAV, as the vector for delivering gene sequences into a patient's cells. The key components of an AAV vector include: (i) the capsid, or the outer viral protein shell that encloses the target DNA, which is responsible for binding to the cell surface and allowing the therapeutic gene that it is carrying to enter the cell; (ii) the therapeutic gene, or transgene, that encodes the therapeutic protein; and (iii) the promoter, or the DNA sequence that drives the expression of the transgene. AAV is a good vector for gene therapy delivery because of its relative safety and broad applicability. AAV is less immunogenic, or less prone to causing an immune reaction, than previous generations of gene therapy vectors, such as adenoviral vectors and AAV does not readily integrate into the genome of the target cell, reducing the potential for oncogenesis, or the induction of cancer. AAV vectors can transfer a therapeutic gene into, or transduce, numerous cell types. Slight differences in capsid proteins can modulate the efficiency with which different capsids deliver genes to different cells, thus allowing different AAV capsids to be selected to most effectively target particular cell types.

The therapeutic gene sequence that enters the targeted cell includes both the protein coding region and an engineered promoter sequence that is used to drive functional gene expression. These engineered promoters may be designed to drive different levels of gene expression or to limit gene expression to specific cell types. Additional aspects of the transgene sequence may be engineered for optimal gene expression, such as codon usage and synthetic introns, which may enhance levels of therapeutic protein expression.

Gene therapy can be used to address monogenic diseases, which result in mutations in a single gene in a patient's genome. In such cases, the viral vector is used to deliver a normal copy of the gene to the cells that are defective due to the lack of the gene function. The normal gene then drives production of the missing protein and offers a therapeutic benefit in patients with the disease. This gene replacement approach underlies all of our IRD programs.

In addition to replacing a gene that is defective or missing in a monogenic disease, gene therapy can also provide a therapeutic impact by adding a particular new gene function to cells and thereby change cell behavior and function in other types of diseases. This is the aim of our salivary gland programs, where our treatment is designed to promote water to flow through otherwise impermeable cells in damaged salivary glands and increase saliva flow into the mouth. Additionally, gene therapy may be used to deliver a therapeutic protein that may block a disease pathway or enhance a deficient cellular pathway in multifactorial diseases such as wet AMD and neurodegenerative diseases, including ALS and Alzheimer's disease.

Importantly, AAV vectors enable targeting of therapeutic genes to non-dividing cells, in which they are thought to remain for the rest of the cell's life. This means that a single treatment may offer patients a durable effect and long-term benefit. The specific cells of the eye, salivary gland and the neurons that we target in our current gene therapy programs are largely non-dividing cells and preclinical evidence has shown that they can be effectively targeted by the specific AAV capsids that we use, enabling us to potentially achieve a durable impact on each of the diseases that we treat.

Our Gene Regulation Platform

We have developed a potentially transformative technology designed to precisely and specifically control gene therapy expression levels via dose-response to orally delivered small molecules. The aim of this gene regulation platform is to transform gene therapy into a generalizable mechanism for the delivery of biologic drugs. The idea is that

the gene encoding a particular biologic drug or a therapeutic antibody or peptide would be delivered to target cells in the body, but these transgenes would only be activated in the presence of a specific, proprietary small molecule. The therapeutic protein would be manufactured by the patient's body only in the presence of the small molecule so that intermittent production of the therapeutic protein would be achieved by dosing with the small molecule drug.

This temporal regulation of gene expression by exogenous small molecules has long been a goal of gene therapy researchers. The ability to regulate transgenes by introducing temporal control has the potential to transform the gene therapy field and the biologics industry as a whole. Our approach focuses on riboswitches to regulate gene expression rather than on the modulation of transcription factor activity.

Riboswitches are pieces of RNA that fold into alternative shapes depending on the binding of a specific small molecule to that RNA sequence. One RNA shape allows the gene containing the riboswitch to be active, while the alternative shape inactivates the gene. Riboswitches are used extensively by bacteria, but none have been identified in mammalian cells to date.

We designed *de-novo* mammalian riboswitches that we have observed respond to small molecules, and demonstrated the ability to switch genes on and off in mammalian cells and *in vivo* in mice and non-human primates. Our riboswitch contains a stretch of RNA sequence, called an aptamer, that binds to a specific small molecule. The riboswitch is inserted into the therapeutic transgene cDNA. In the absence of the specific small molecule, the unbound riboswitch folds into the shape that drives the destruction of the RNA message and no therapeutic protein is produced in the absence of the small molecule. However, when the small molecule is present and binds to the riboswitch it adopts the alternative RNA shape, causing stable messages to be formed and the therapeutic protein to be produced.

One of the features of our mammalian riboswitch is its unprecedented dynamic range of greater than 5,000-fold. We believe this technology is viable for a therapeutic product and is also the first instance of a proprietary system for screening randomized aptamers and small molecules within mammalian cells for functional interactions.

Using our proprietary technology, we have demonstrated the ability to regulate multiple genes *in vitro* and *in vivo* in multiple tissue types using multiple small molecules.

Using this technology *in vivo*, we have delivered ongoing efficacious levels of multiple therapeutic antibodies with a daily small molecule dose.

We have also delivered peptides and growth factors such as erythropoietin (EPO), human growth hormone (hGH), and parathyroid hormone (PTH) - rescuing hematocrit, little mouse growth or calcium to physiological levels, respectively, with daily oral dosing of our small molecule. In addition, we have now delivered combinations of gut peptides such as GLP-1, GIP glucagon, amylin, PYY and leptin, and we have shown that the efficacy with respect to glucose control is better than constitutively active expression of those peptides.

In cell therapy, we can control any chimeric antigen receptor (CAR) or receptor or cell fate determining factor to a specific level at a specific time, thus allowing us to precisely control the cell fate of transplanted cells. We can knock our regulation mechanism into T-cells to regulate CAR expression in CAR-T, and have demonstrated reduced exhaustion, improved T-cell profile, improved cytotoxicity, and 3-4x increased potency in tumor killing, *in vivo*, compared to existing CAR-T therapies.

For gene editing nucleases, we can very tightly regulate nuclease expression from 0% to close to 100% activity using our small molecules, allowing transient expression of DNA editors to achieve efficient editing, avoiding undesirable constitutive expression of the nuclease.

The riboswitch platform provides the ability to express any mRNA and therefore any protein or peptide in the body on an ongoing basis via the dosing of an oral pill. We are now applying this to metabolic peptides that are agonists

of muscle metabolism and fat browning – which are not readily made sufficiently stable to be injectable recombinant drugs. This opens an entire array of targets that are not currently druggable, particularly in the area of metabolism where many of the known peptide agonists have proven difficult to address pharmaceutically. We express the natural peptide sequence that is the most physiologically active, without the need for modification to extend the half-life, or manufacturing outside the body.

In October 2023, we announced that under the terms of the Investment Agreement we entered into with Sanofi and Sanofi Foreign Participations, Sanofi has a right of first negotiation for use of our riboswitch gene regulation technology for certain Immunology and Inflammation (I&I), including modulation of IL-4 and IL-13, and Central Nervous System (CNS) targets, as well as for GLP-1 and other gut peptides for metabolic disease, and for our Phase 2 xerostomia program.

Our Manufacturing Capabilities

We own and operate a GMP manufacturing facility situated in London, United Kingdom. Supporting our global approach to clinical development and market supply, we designed the 29,000 square foot facility to meet multiple regulatory standards, including the MHRA, EMA and FDA standards.

Our London facility is flexible and scalable, with eleven independent air handling units, two cell culture suites and three separate viral vector production suites, which allows us to produce multiple product candidates in parallel, as well as sequentially at different scales. This allows us to accommodate up to three independent parallel manufacturing streams of viral vector products that are isolated within dedicated production areas.

Our London manufacturing facility includes an integrated analytical department and in-house analytical tool kit that allows for in-house release of clinical and commercial manufactured products. It is also equipped with dedicated areas for microbiology, molecular biology, and cell-based analytics. Our analytical department can perform product related assays, allowing us to retain and gain expertise that is normally lost to third parties. The close integration allows for rapid turnaround and flexibility in scheduling of key assays, reducing lead times for product candidate releases. Further, our dedicated product fill and finish suite allows us to manufacture a full range of clinical and commercial products under one roof and in our control.

Our second, large scale GMP viral vector manufacturing facility and our first GMP plasmid and DNA production facility in Shannon, Ireland came online in 2022. The campus encompasses 150,000 square feet and contains three facilities, one built to be flexible and scalable for viral vector production for clinical and commercial supply, in addition, a facility to manufacture plasmid DNA – the critical starting material for producing gene therapy products – and thirdly, a QC hub performing advanced biochemical quality control testing for MeiraGTx clinical and commercial programs.

We believe that building a second viral vector manufacturing facility and bringing GMP plasmid and DNA production, as well as QC analytics, in-house provides greater flexibility and efficiency as we advance our product candidates through development, and should they be approved, commercial production.

We have more than 200 highly trained multidisciplinary staff on our manufacturing team with backgrounds in a diverse array of manufacturing sciences, technologies, analytics and production working together to expedite delivery of gene therapy products.

We believe our facilities can supply our current clinical and preclinical programs, as well as our third party supply obligations, through regulatory approval and, should they be approved, provide sufficient capacity for commercial production. Strategically, we believe our facilities will minimize our dependence on third-party contract manufacturers, which we believe provides a significant strategic, clinical and commercial advantage, as well as significantly reduce the cost of goods sold for our programs.

We have identified and licensed a proprietary HEK-293 cell line that is well characterized and that we have banked in hundreds of vials. The specific cell line, size of the bank, culture media, and cryopreservation agents have been selected to facilitate bridging between process development platforms and targets. Our HEK-293 cells are suitable for both the adherent culture platform and the bioreactor process. We believe the ability to use the same cell line throughout the product and process development lifecycle will allow us to use a bracketed approach to process validation and comparability, which we believe may reduce the time and costs related to their implementation.

Our significant investment in the development of our internal manufacturing capacity and expertise to allow for better control over our process development timelines, costs, product quality and intellectual property provides us with a key competitive advantage.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. This is true in the field of gene therapy generally, and in the treatments for our key disease areas. While we believe that the strength of our team, gene therapy expertise, scientific knowledge and intellectual property provide us with competitive advantages, we face competition from several sources, including large and small biopharmaceutical companies, academic research institutions, government agencies and public and private research institutions. Not only must we compete with other companies that are focused on gene therapy, but any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and product marketing than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, clinical programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

There are other organizations working to improve existing therapies or to develop new therapies for our initially selected disease indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success for our product candidates, if approved. These efforts include Luxturna, marketed by Spark Therapeutics, Inc., which has been approved to treat *RPE65*-associated retinal dystrophy. We are not aware of any other gene therapy product candidates in clinical development targeting xerostomia. We are aware of other ALS gene therapies utilizing different treatment mechanisms to treat different genetically defined subsets of ALS patients, as well as gene therapy product candidates being developed for the treatment of Parkinson's disease, including those being developed by Voyager Therapeutics, Inc. and Eli Lilly and Company.

We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Our success depends in large part upon our ability to secure and maintain proprietary protection for our technologies and products and to operate without infringing the proprietary rights of others. Our policy is to protect our proprietary position by, among other methods, filing or collaborating with our licensors to file U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development

and implementation of our business. We also use other forms of protection, such as confidential information and trademark protection, particularly where we do not believe patent protection is appropriate or obtainable. Our patent portfolio comprises a combination of issued patents and pending patent applications that are owned or licensed from third parties. In addition, we also evaluate opportunities to sublicense our portfolio of patents and patent applications that we own or exclusively license, and we may enter into such licenses from time to time.

As of December 31, 2024, we own, co-own, or have an exclusive license to 661 United States and foreign issued or allowed patents and 533 patent applications, pending in the United States and internationally. For any individual patent, the term depends on the applicable law in the country in which the patent is granted. In most countries where we have filed patent applications or in-licensed patents and patent applications, patents have a term of 20 years from the application filing date or earliest claimed non-provisional priority date. In the United States, the patent term is 20 years but may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a U.S. patent may also be lengthened by a patent term adjustment, in order to address administrative delays by the United States Patent and Trademark Office in granting a patent. In the United States, the term of a patent that covers an FDA-approved drug or biologic may be eligible for patent term extension in order to restore the period of a patent term lost during the premarket FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the natural expiration of the patent. The patent term restoration period is generally equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, subject to certain exceptions. Only one patent may be extended for a regulatory review period for any product, and the application for the extension must be submitted prior to the expiration of the patent. In the future, we may decide to apply for restoration of patent term for one of our currently owned or licensed patents to extend its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant Biologics License Application.

Company-Owned Intellectual Property

We own eight patent families relating to gene regulation platform technologies developed by us with a combined 187 United States and foreign issued patents and 129 pending patent applications.

The first patent family includes 58 issued patents in the United States (two patents), African Regional Intellectual Property Organization, Albania, Australia (two patents), Austria, Belgium, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Eurasian Patent Organization, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Ireland, Israel (two patents), Italy, Japan (two patents), Republic of Korea, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Monaco, Netherlands, New Zealand, North Macedonia, Norway, Philippines, Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Africa (two patents) Spain, Sweden, Switzerland/Liechtenstein, Turkey and the United Kingdom and 20 pending patent applications with claims directed to compositions of matter and methods of use in the United States, African Regional Intellectual Property Organization, Australia, Brazil, Canada, China, Egypt, Eurasian Patent Organization, European Patent Organization, Hong Kong (two applications), Indonesia, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Singapore, South Africa and Vietnam. Patents issued from this family are expected to expire February 2, 2036, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

The second patent family includes 48 issued patents in the United States, Albania, Australia, Austria, Belgium, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Monaco, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland/Liechtenstein, Turkey and the United Kingdom and 15 pending patent applications with claims directed to compositions of matter and methods of use in the United States, African Regional Intellectual Property Organization, Brazil, Canada, Egypt, Eurasian Patent Organization, India, Indonesia, Republic of Korea, New Zealand, Philippines (two applications), South Africa and Vietnam (two applications). Patents issued from

this family are expected to expire February 2, 2037, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

The third patent family includes 11 issued patents in the United States, African Regional Intellectual Property Organization, Australia, China, Eurasian Patent Organization, India, Indonesia, Japan, Malaysia, Mexico and Singapore and 12 pending patent applications with claims directed to compositions of matter and methods of use in the United States, Brazil, Canada, Egypt, European Patent Organization, Hong Kong, Israel, Republic of Korea, New Zealand, Philippines, South Africa and Vietnam. Patents issued from this family are expected to expire February 2, 2037, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

The fourth patent family includes 51 issued patents in the United States, Albania, Australia, Austria, Belgium, Bulgaria, Canada, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Eurasian Patent Organization, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Republic of Korea, Latvia, Lithuania, Luxembourg, Malta, Malaysia, Mexico, Monaco, Netherlands, New Zealand, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland/Liechtenstein, Turkey and the United Kingdom and 10 pending patent applications with claims directed to compositions of matter and methods of use in the United States, African Regional Industrial Property Organization, Australia, Brazil, Egypt, New Zealand, Philippines, Singapore, South Africa and Vietnam. Patents issued from this family are expected to expire August 3, 2037, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

The fifth patent family includes nine issued patents in the United States, African Regional Industrial Property Organization, Australia, China, Indonesia, Japan, Republic of Korea, Mexico and Philippines, and 16 pending patent applications with claims directed to compositions of matter and methods of use in the United States, Australia, Brazil, Canada, Egypt, Eurasian Patent Organization, European Patent Organization, Hong Kong, India, Israel, Malaysia, New Zealand (two applications), Singapore, South Africa and Vietnam. Patents issued from this family are expected to expire on March 2, 2038, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

The sixth patent family includes nine issued patents in African Regional Industrial Property Organization, China, Indonesia, Israel, Japan, Republic of Korea, Malaysia, Mexico and New Zealand and 14 pending patent applications with claims directed to compositions of matter and methods of use in the United States, Australia, Brazil, Canada, Egypt, Eurasian Patent Organization, European Patent Organization, Hong Kong, India, New Zealand, Philippines, Singapore, South Africa and Vietnam. Patents issued from this family are expected to expire on February 21, 2038, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

The seventh patent family includes one issued patent in Japan and 21 pending patent applications with claims directed to compositions of matter and methods of use in the United States, African Regional Industrial Property Organization, Australia, Brazil, Canada, China, Egypt, Eurasian Patent Organization, European Patent Organization, Hong Kong, India, Indonesia, Israel, Republic of Korea, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa and Vietnam. Patents issued from this family are expected to expire on March 24, 2041, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

The eighth patent family includes 21 pending applications with claims directed to compositions of matter and methods of use in the United States of America, African Regional Industrial Property Organization, Australia, Brazil, Canada, China, Egypt, Eurasian Patent Organization, European Patent Convention, India, Indonesia, Israel, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa, and Vietnam. Patents issued from this family are expected to expire on December 15, 2042, not including any patent term adjustments that may extend the patent term in certain jurisdictions.

Licensed Intellectual Property

Certain of our issued patents and pending patent applications are exclusively licensed to us from UCLB, Brandeis University ("Brandeis") and the National Institute of Dental and Craniofacial Research ("NIDCR").

UCLB

The UCLB portfolio includes two licensed patent families relating to our *RPE65*, *CNGA3* and dry AMD gene therapy programs with a combined 150 United States and foreign issued patents and 30 pending patent applications.

The first patent family, with claims directed to compositions of matter and methods of use relating to our *RPE65* program, and the AAV-RPE65 product candidate includes 52 issued patents in the United States (two patents), Albania, Australia, Austria, Belgium, Bulgaria, Canada, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Ireland, Israel (two patents), Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Malaysia, Mexico, Monaco, Netherlands, New Zealand, North Macedonia, Norway, Philippines, Poland, Portugal, Romania, San Morino, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland/Liechtenstein, Turkey and the United Kingdom and 7 pending patent applications in the United States, Brazil, European Patent Organization, Hong Kong, Mexico, Nigeria and Thailand. Patents issued from this family are expected to expire February 8, 2036, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

The second patent family includes 44 issued patents in the United States, African Regional Intellectual Property Organization, Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Eurasian Patent Convention, Finland, France, Germany, Greece, Hungary, Iceland, Indonesia, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, New Zealand, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland/Liechtenstein, Turkey and United Kingdom and 16 pending patent applications with claims directed to compositions of matter and methods of use relating to our achromatopsia program and the AAV-CNGA3 product candidate in the United States, Australia, Brazil, Canada, China, Egypt, Hong Kong, India, Israel, Republic of Korea, Malaysia, Mexico, New Zealand, Philippines, South Africa and Vietnam. Patents issued from this family are expected to expire January 14, 2039, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

The third patent family, with claims directed to compositions of matter and methods of use relating to our dry AMD gene therapy program, includes 54 issued patents in African Regional Intellectual Property Organization, Albania, Austria, Australia (two patents), Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Eurasian Patent Organization, Finland, France, Germany, Greece, Hong, Kong, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Japan, Republic of Korea, Latvia, Lithuania, Luxembourg, Malta, Malaysia, Mexico, Monaco, Netherlands, New Zealand, Nigeria, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Singapore (two patents), Slovakia, Slovenia, Spain, South Africa, Sweden, Switzerland/Liechtenstein, Turkey and the United Kingdom and seven pending applications in the United States, Brazil, China, Hong Kong, Philippines, Thailand and Vietnam. Patents issued from this family are expected to expire February 19, 2036, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

On December 20, 2023, we and MeiraGTx UK II Limited sold and assigned to Johnson & Johnson Innovative Medicine the rights to a fourth patent family related to the RPGR Product, which had been previously licensed from UCLB.

Brandeis

The licensed Brandeis portfolio includes one patent family with claims directed to compositions of matter and methods of use relating to our ALS gene therapy program and the AAV-UPF1 product candidate.

This patent family includes 17 issued patents in the United States (two patents), Austria, Australia, Belgium, Denmark, France, Germany, Hong Kong, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland/Liechtenstein and the United Kingdom and 4 pending patent applications in the United States, Canada European Patent Organization and Hong Kong. Patents issued from this family are expected to expire October 8, 2033, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

NIDCR

The exclusively licensed NIDCR portfolio includes two patent families.

The first patent family has claims directed to compositions of matter and methods of use relating to our Sjogren's Syndrome gene therapy program. This patent family includes 16 issued patents in the United States, Australia, Austria, Belgium, Canada, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland/Liechtenstein and the United Kingdom. Patents issued from this family are expected to expire August 30, 2033, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

The second patent family has claims directed to methods of use for our radiation-induced salivary dysfunction gene therapy program. This patent family includes 18 pending applications in the United States of America, African Regional Industrial Property Organization, Australia, Brazil, Canada, China, Eurasian Patent Organization, European Patent Convention, Hong Kong, Israel, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Philippines, Singapore, and South Africa. Patents issued from this family are expected to expire August 4, 2042, not including any patent term extensions or adjustments that may extend the patent term in certain jurisdictions.

License Agreements

License Agreements with UCLB

We previously entered into several license agreements with UCLB, covering the following inherited retinal disease programs: (a) ACHM caused by mutations in CNGB3; (b) ACHM caused by mutations in CNGA3; (c) XLRP caused by mutations in RPGR; and (d) RPE65-mediated IRD (together, the "Licensed Gene Therapy Programs"). The terms of these license agreements were set forth in (i) the license agreement, dated February 4, 2015, as amended, between Athena Vision Ltd. and UCLB (the "First UCLB License Agreement"); (ii) the license agreements, dated July 29, 2017, as amended, between MeiraGTx UK II Limited and UCL Business Plc (the "Second UCLB License Agreement"); and (iii) the license agreement, dated March 15, 2018, among MeiraGTx Limited, MeiraGTx UK II Limited and UCL Business Plc (the "Third UCLB License Agreement" and, collectively, the "prior UCLB license agreements"). In January and February 2019, we amended and restated the prior UCLB license agreements to establish a new standalone license agreement (each, a "Stand-Alone UCLB Agreement") for each of the Licensed Gene Therapy Programs. We have removed from each of the Stand-Alone UCLB Agreements our obligation to pay UCLB a share of certain sublicensing revenues as was provided under the First UCLB License Agreement and have aligned the material terms of the Stand-Alone UCLB Agreements to track those under the Third UCLB License Agreement as previously disclosed and a summary of which is set forth below as is now reflected in each of the Stand-Alone UCLB Agreements.

Under the terms of the Third UCLB License Agreement, we paid an initial upfront payment of £6,994, and issued to UCLB £100,000 of our ordinary shares.

Under each of the Stand-Alone UCLB Agreements, UCLB granted us an exclusive, worldwide, and sublicensable license under certain intellectual property rights controlled by UCLB relating to one of the Licensed Gene Therapy Programs to develop and commercialize licensed products in a relevant field of gene therapy. We must use diligent efforts to develop and commercialize the licensed products.

Under the terms of each Stand-Alone UCLB Agreement, we are required to pay UCLB sales milestone payments of up to a total of £39.8 million in the aggregate and an annual management fee of £50 thousand until certain royalty payments have been paid. Additionally, pursuant to the Stand-Alone UCLB Agreement related to CNGB3, we paid UCLB an upfront payment of £1.5 million and issued £1.5 million of the Company's ordinary shares.

Commencing on the first commercial sale of licensed products under each Stand-Alone UCLB Agreement, we must make low single-digit percentage royalty payments to UCLB on net sales of such products. Our royalty obligations under each agreement continue on a licensed product-by-licensed product and country-by-country basis until the latest to occur of the expiration of the last valid claim of a patent claiming such licensed product in such country, the expiration of any regulatory exclusivity for all licensed products in such country, or the tenth anniversary of first commercial sale of such licensed product in such country.

Each Stand-Alone UCLB Agreement will remain in effect on a country-by-country basis until the expiration of the last payment obligation in such country. Each Stand-Alone UCLB Agreement may be terminated: (a) by either party in the event of the other party's material breach that remains uncured for 30 days (or for 14 days in the case of breaches related to payment obligations), (b) by either party for the other party's insolvency, (c) immediately by UCLB if we are in persistent breach of the agreement and the parties fail to agree upon a mechanism to remedy such persistent breach (or we do not comply with such agreed upon mechanism), or (d) immediately by UCLB if we undergo certain change of control events or if we enter into a sublicense with certain prohibited persons, which may adversely affect UCL's and/or UCLB's reputation. Each Stand-Alone UCLB Agreement may also be terminated or converted to a non-exclusive license by UCLB upon three months' notice if we, based on an independent expert determination, fail to use diligent efforts to develop and commercially exploit licensed products and do not cure such failure within a certain cure period.

The First UCLB License Agreement had also included an option to the dry AMD gene therapy program. This option was exercised under a separate license agreement dated March 23, 2020.

As noted above, on December 20, 2023, we and MeiraGTx UK II Limited entered into and consummated an Asset Purchase Agreement with Johnson & Johnson Innovative Medicine pursuant to which we sold and assigned to Johnson & Johnson Innovative Medicine, and Johnson & Johnson Innovative Medicine purchased and assumed, the UCLB RPGR License Agreement relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the Asset Purchase Agreement. Johnson & Johnson Innovative Medicine is responsible for any royalty or milestone amounts that become payable on the RPGR Product under the UCLB RPGR License Agreement.

License Agreement between BRI-Alzan Inc. and Brandeis

In May 2013, BRI-Alzan Inc., or BRI-Alzan, entered into a license agreement with Brandeis, or the Brandeis Agreement. On December 31, 2015, we entered into an Agreement and Plan of Merger, or the BRI-Alzan Merger Agreement, with BRI-Alzan, and the Brandeis Agreement was assigned to us as a result of such merger. Pursuant to the terms of the BRI-Alzan Merger Agreement, we agreed to make cash payments to the sellers of BRI-Alzan upon the achievement of certain milestones, subject to an aggregate cap of $4.5 million. In addition, we agreed to make low single-digit percentage royalty payments to the sellers of BRI-Alzan on net sales of any product for the therapeutic or prophylactic treatment of ALS that is covered by a valid claim of the patent rights licensed under the Brandeis Agreement. The BRI-Alzan Merger Agreement includes customary confidentiality, indemnification, non-competition and non-solicitation provisions.

Pursuant to the Brandeis Agreement, Brandeis granted us an exclusive, worldwide license under certain patent rights with claims directed to compositions of matter and methods of use relating to our ALS gene therapy program and the AAV-UPF1 product candidate to develop and commercialize licensed products.

We must use commercially reasonable efforts to develop and commercialize licensed products. We also acquired non-exclusive, worldwide licenses to certain know-how controlled by Brandeis to exploit licensed products. We are required to pay Brandeis developmental and regulatory milestone payments of up to a total of $1.0 million in the aggregate. We are also required to pay Brandeis annual license maintenance fees ranging from $15,000 to $100,000 depending on the development stage of the licensed product. Commencing on the first commercial sale of licensed products, we must make low single-digit percentage royalty payments to Brandeis on net sales of such products. In addition, we must pay Brandeis mid-teen percentages of sublicensing revenues.

The Brandeis Agreement will remain in effect on a country-by-country basis until the earlier of: (a) 1 year after the date that we, our affiliates or sublicensees last sell any licensed product in such country or (b) until the expiration of the last–to-expire of the licensed patent rights in such country. The Brandeis Agreement may be terminated by Brandeis for our insolvency or for our material breach that remains uncured for 60 days (or for 30 days in the case of breaches related to payment obligations). Such material breach may be cured only once in any 12-month period. Brandeis may also terminate any license granted under the Brandeis Agreement if we fail to timely achieve certain regulatory milestone events.

Trade Secrets

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive advantage. We require inventors who are identified on any company-owned patent applications to assign rights to us. We also rely on confidentiality agreements with our employees, consultants and other advisors to protect our proprietary information. Our policy is to require third parties that receive material confidential information to enter into confidentiality agreements with us.

Trademarks

Our trademark MeiraGTx is the subject of registrations and/or pending applications in the U.S., UK and EU.

Government Regulation and Product Approval

Governmental authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing, post-approval monitoring and reporting and export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, are extensive and require the expenditure of substantial time and financial resources.

FDA Approval Process

We expect our product candidates to be regulated as biologics. Biological products, including gene therapy products, are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and other federal, state, local and foreign statutes and regulations. Both the FDCA and the PHSA and their corresponding regulations govern, among other things, the research, development, safety, testing, packaging, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biological products.

U.S. Biological Products Development Process

Our products must be approved by the FDA through the BLA process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical studies, sometimes referred to as preclinical laboratory tests, and preclinical studies and applicable requirements for the humane use of laboratory animals and formulation studies in accordance with applicable regulations, including good laboratory practices, or GLPs;
- submission to the FDA of an IND which must become effective before clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation and submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, potency and efficacy from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current GMP, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA;
- FDA review and approval, or licensure, of the BLA prior to any commercial marketing or sale of the product in the United States; and
- compliance with any post-approval requirements, including the potential requirement to conduct post-approval studies.

Before testing any biological product candidate, including a gene therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of certain preclinical tests must comply with certain federal regulations and requirements, including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing and controls, information about product chemistry, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing, such as reproductive toxicity tests and carcinogenicity in animals, may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, after which human clinical trials may begin unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a

biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

In addition to the IND submission process, sponsors of certain human clinical trials of cells containing recombinant or synthetic nucleic acid molecules, including human gene transfer studies, are subject to evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution, pursuant to the National Institutes of Health's Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. The IBC assesses the safety of the research and identifies any potential risk to the public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, the efficacy measurements to be evaluated and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2. The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the safety and efficacy of a biological product. In some instances, a single Phase 3 trial, together with other confirmatory evidence may be sufficient to support a BLA submission. Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-

up. The FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or permanently discontinue a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or the clinical trial is not being conducted in accordance with FDA regulations. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. The FDA and the IRB may also halt, terminate or impose other conditions if either believes the patients are subject to unacceptable risk.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP and cGMP requirements, as applicable. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing and distribution of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture, pharmacology, chemistry and controls of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

A sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must

submit an initial Pediatric Study Plan, or PSP, within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include, among other things, an outline of the pediatric study or studies that the sponsor plans to conduct, including to the extent practicable study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information, along with any other information specified in FDA regulations. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may grant deferrals for submission of data or full or partial waivers. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan drug designation has been granted.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first human drug application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application is also subject to an initial review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA's goal is to complete the review of standard BLAs within ten months after it accepts an application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification.

The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. Under the current PDUFA guidelines, the FDA has committed to reviewing such resubmissions in two or six months of receipt depending on the type of information included.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a REMS, to ensure the benefits of the product outweigh its potential risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The requirement for a REMS can materially affect the potential market and profitability of the product.

Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. Changes to some of the conditions established in an approved BLA, including changes in indications, product labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs. The FDA may require one or more Phase 4 post-market studies or surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and marketing the drug or biologic for this type of disease or condition will be recovered from its sales in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and BLA user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application, including a full BLA, to market the same drug or biologic for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan drug-designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different disease or condition for which the orphan product has

exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new biological product candidates that meet certain criteria. Specifically, biological product candidates are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

In addition, the FDA established a Breakthrough Therapy designation which is intended to expedite the development and review of products that are intended to treat serious or life-threatening diseases or conditions. A Breakthrough Therapy-designated product candidate is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of Fast Track designation, as well as more intensive FDA interaction and guidance.

Any product candidate submitted to the FDA for marketing, including a product that has received a Fast Track or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An application seeking marketing approval for a biologic product is eligible for priority review if the biologic has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or there is potential for a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. Priority review means the FDA's goal is to take action on an application within six months (compared to 10 months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than the irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require that the sponsor perform adequate and well-controlled confirmatory clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require that such confirmatory trials are underway prior to granting any accelerated approvals. Failure to conduct required confirmatory trials in a timely manner, or to confirm a clinical benefit

during post-marketing trials, will allow the FDA to withdraw the approved biologic product from the market on an expedited basis. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Furthermore, as part of its implementation of the 21st Century Cures Act, the FDA established the Regenerative Medicine Advanced Therapy, or RMAT, designation, to facilitate an efficient development program for, and expedite review of, certain drugs and biological products. A biological product is eligible for RMAT designation if it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions, and is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the biological product has the potential to address unmet medical needs for such a disease or condition. Like Breakthrough Therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

Fast Track designation, priority review, accelerated approval, Breakthrough Therapy designation and RMAT designation do not change the standards for approval but may expedite the development or approval process. Even if these designations are received, the FDA may later decide that a product candidate no longer meets the conditions for qualification.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics for the prevention and treatment of rare pediatric diseases. A "rare pediatric disease" is defined to include a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged 18 years of age or younger and the disease affects fewer than 200,000 individuals in the U.S., or affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a priority review voucher upon approval of its BLA. If a priority review voucher is received, it may be sold or transferred an unlimited number of times. The FDA's rare pediatric disease priority voucher program began to sunset on December 20, 2024, after Congress failed to pass a continuing resolution package that included its reauthorization. Under the amended statutory sunset provisions, after December 20, 2024, the FDA may award a priority review voucher for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug and if that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. Congress may vote to reauthorize this program, but its future remains unknown at this time.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to rigorous and extensive FDA regulation including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, manufacturing, and marketing and promotion. Biological products may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe a product for uses in patient populations that are not described in the product's approved labeling, or "off-label" uses, manufacturers may only promote a product for the approved indications and in accordance with the provisions of the approved label of such product. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of "off-label" uses, and a company that is found to have improperly promoted "off-label" uses may be subject to significant liability.

After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Manufacturers are also required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

The FDA may require one or more Phase 4 post-market trials or surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject

to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business, which may constrain the financial arrangements and relationships through which we conduct our research, as well as, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims and transparency laws and regulations regarding drug pricing and payments or other transfers of value made to physicians and other licensed healthcare professionals. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance and imprisonment.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

In March 2010, the Patient Protection and Affordable Care Act, or the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which was temporarily suspended from May 1, 2020 through March 31, 2022, and reduced payments to several types of Medicare providers. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. The Centers for Medicare & Medicaid Services, or CMS, has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

U.S. Data Privacy and Security Laws

In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA, and federal and state and consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state laws, such as the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977, or FCPA, prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business or secure any improper advantage, or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any

employee or official of a foreign government or public international organization, or political party, political party official, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA also includes employees and officials of state-owned or controlled enterprises, which may include healthcare professionals in many countries. Equivalent laws have been adopted in other foreign countries that impose similar obligations.

Government Regulation Outside of the United States

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions, for instance in the UK or EU, governing, among other things, clinical trials, marketing authorizations, or MAs, post-MA requirements and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. In addition, ethical, social and legal concerns about gene therapy, genetic testing, genetic research and gene-editing technology, could result in additional regulations restricting or prohibiting the processes we may use.

Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing, promotion and reimbursement vary from country to country. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-Clinical Studies and Clinical Trials

Similar to the United States, the various phases of non-clinical and clinical research abroad are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both *in vitro* and *in vivo*, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Human Use, or ICH, guidelines on GCPs, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products, or ATMPs. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity within the EU to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and

supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with GMP. Other national and EU-wide regulatory requirements may also apply.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical trials, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorizations

In the EU, medicinal products can only be placed on the market after obtaining an MA. To obtain regulatory approval of an investigational chemical or biological product in the EU, we must submit an MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs – "Centralized MAs" and "National MAs."

"Centralized MAs" are issued by the European Commission through the centralized procedure, based on the opinion of the CHMP of the EMA, and are valid across the entire territory of the EU. The centralized procedure is compulsory for certain types of product candidates, such as: (i) medicinal products derived from biotechnology processes, such as genetic engineering, (ii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative or autoimmune diseases, and other immune dysfunctions and viral diseases, (iii) designated orphan medicines and (iv) ATMPs, such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of advanced therapy medicinal products, or ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which an MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft

opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in an MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs. Although these guidelines are not legally binding, we believe that our compliance with them is likely necessary to gain and maintain approval for any of our product candidates.

Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this opinion is favorable, the Commission may then adopt a decision to grant an MA.

"National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the European Commission or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal

In exceptional cases, the CHMP might perform an accelerated review of an MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicine, or PRIME, scheme, which provides incentives similar to the Breakthrough Therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, the European Commission may grant a so-called "conditional MA" prior to obtaining the comprehensive clinical data required for a full MA. Such conditional MAs may be granted for product candidates (including medicines designated as orphan medicinal products), if (i) the risk-benefit balance of the product candidate is positive, (ii) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (iii) the product fulfills an unmet medical need and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional MA may contain specific obligations to be fulfilled by the MA holder, including obligations with respect

to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional MAs are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The MA can be converted into a standard MA once the MA holder fulfils the obligations that were imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional MA.

The European Commission may also grant a so-called "marketing authorization under exceptional circumstances." Such MA is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, MAs under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

An MA under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual reassessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the MA being suspended or revoked. The renewal of an MA of a medicinal product under exceptional circumstances, however, follows the same rules as a "normal" MA. Thus, an MA under exceptional circumstances is granted for an initial five years, after which the authorization will become valid indefinitely, unless the EMA decides that safety grounds merit one additional five-year renewal. An MA under exceptional circumstances should not be granted when a conditional MA is more appropriate.

The EU medicines rules expressly permit the EU member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products we have in development do not make use of embryonic stem cells, it is possible that the national laws in certain EU member states may prohibit or restrict us from commercializing our products, even if they have been granted an MA.

Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving MA, reference products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period may be extended to a maximum of eleven years if during the first eight years of those ten years, the MA holder obtains an authorization for one or more

new therapeutic indications, which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit over existing therapies. However, there is no guarantee that a product will be considered by the EU regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product may be designated as orphan if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition.

Orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized MA procedure. The application for orphan designation must be submitted before the MAA. The applicant will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the MA is submitted. Upon grant of an MA and assuming the requirement for orphan designation are also met at the time the MA is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that regulatory authorities cannot accept another MA or grant an MA or accept an application to extend an existing MA in respect of a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the orphan designation threshold. Additionally, an MA may be granted to a similar product for the same indication at any time if (1) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior, (2) the applicant consents to a second orphan medicinal product application; or (3) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product candidate for which an MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation

to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for a six-months supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity is granted.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Iceland, Liechtenstein and Norway.

Pricing and Reimbursement

Even if a medicinal product obtains an MA in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Governments influence the price of medicinal products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be

marketed once a reimbursement price has been agreed to by the government. Member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

Healthcare Reform

Political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products, once approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution and parallel trade. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of medicinal products in one EU member state could affect the price in other EU member states.

Health Technology Assessment, or HTA, of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product (i.e., oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030). The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early,

and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Brexit and the Regulatory Framework in the United Kingdom

The UK formally left the EU on January 31, 2020, commonly referred to as "Brexit". Since the end of the Brexit transition period on January 1, 2021, and the implementation of the Windsor Framework on January 1, 2025, the UK has not generally been directly subject to EU laws with respect to medicinal products. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain (England, Scotland and Wales), however, new legislation such as the CTR is not applicable in Great Britain.

Since January 1, 2021, the MHRA has been the UK's standalone medicines and medical devices regulator. As a result of the Protocol on Ireland and Northern Ireland, different rules applied in Northern Ireland than in Great Britain; broadly, Northern Ireland continued to follow the EU regulatory regime. However, on January 1, 2025 a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes, and EU labeling and serialization requirements in relation to Northern Ireland, and introduces a UK-wide licensing process for medicinal products.

UK Clinical Trials

It is currently unclear to what extent the UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from pre-existing EU legislation (as implemented into UK law, through secondary legislation), and after Brexit, EU laws on clinical trials (including the CTR) are not directly applicable in Great Britain (i.e., the UK excluding Northern Ireland). The extent to which the regulation of clinical trials in the UK will mirror the CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026. Under the terms of the Protocol on Ireland and Northern Ireland, provisions of the CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products currently apply in Northern Ireland.

UK Marketing Authorizations

MAs in the UK are governed by the UK's Human Medicines Regulations 2012 (as amended). All existing centralized procedure MAs were automatically converted into UK MAs effective in Great Britain (only), free of charge on January 1, 2021 (unless MA holders opted out of this scheme). Under the terms of the Windsor Framework, these MAs became valid for the whole of the UK from January 1, 2025. In order to use the centralized procedure to obtain an MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore, since Brexit, companies established in the UK can no longer use the centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to market products in the UK. Applications are governed by the UK's Human Medicines Regulations 2012 (as amended) and are made electronically through the MHRA Submissions Portal. In addition, an international recognition procedure, or IRP, has applied since January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new UK MA. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (i.e., the regulators in Australia, Canada, Switzerland, Singapore, Japan, the U.S. and the EU). The MHRA will conduct a

targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update an MA in the UK. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60-day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval has not been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals. In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance, to proceed with only one additional 5-year renewal. Any authorization which is not followed by the actual placing of the medicinal product on the market in the UK within 3 years shall cease to be in force.

Post Brexit, the MHRA has updated various aspects of the regulatory regime for medicines in the UK, including: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicines; updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for MAs in the UK and a rolling review process for MAAs (rather than a consolidated full dossier submission).

The UK's Human Medicines Regulations 2012 (as amended) allow the MHRA to grant an MA under exceptional circumstances in the UK. Such MA is intended for products for which the applicant can show that it is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use because the condition to be treated is rare or because collection of full information is not possible or is unethical. This type of MA is similar to the MA under exceptional circumstances granted by the European Commission. Since the end of the Brexit transition period on January 1, 2021, applications for MAs under exceptional circumstances in Northern Ireland were required to be submitted to the EMA. However, since the implementation of the Windsor Framework on January 1, 2025, such applications are now required to be submitted to the MHRA that will grant UK-wide MAs under exceptional circumstances. The MHRA may take into account an MA under exceptional circumstances granted by the European Commission or by a competent authority in another jurisdiction when determining an application for an MA under exceptional circumstances, but the final decision on the approval of such application will rest with the MHRA. The MHRA is likely to impose specific obligations on the holder of an MA under exceptional circumstances (i.e., to provide information on the safe and effective use of the product). The MHRA will communicate these obligations to the applicant during its review of the application. This authorization route does not normally lead to a standard MA.

UK Orphan Designation

Post-Brexit, the UK has retained the EU Regulation which governs the designation of medicinal products as orphan medicinal products and which establishes incentives thereto (Regulation (EC) No. 141/2000) as part of UK law by virtue of the EU (Withdrawal) Act 2018.

There is no pre-MA orphan designation in the UK. The MHRA reviews applications from companies for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in the UK.

UK Specials Regulation

The UK's Human Medicines Regulations 2012 (as amended) allow for the manufacture and supply of medicinal products not authorized for marketing to patients with special needs at the request of the healthcare professional responsible for the patient's care (these products are referred to as "specials"). A special may only be

supplied: (i) in response to an unsolicited order from a healthcare professional responsible for the care of the patient, (ii) if the product is manufactured and assembled in accordance with the specifications of that healthcare professional to fulfil the special needs of the individual patient which cannot be met by products already authorized for marketing, and (iii) if the product is manufactured under a specials license granted by the UK's MHRA.

Manufacturing a special also imposes a five year record retention requirement subject to review by the MHRA, including details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware, as well as a continuing obligation to notify the MHRA of any suspected adverse reaction to the medicinal product which is a serious adverse reaction.

Privacy and Data Protection Laws

We are also subject to laws and regulations in non-U.S. countries in which we are established or in which we run clinical trials, as well as countries in which we may sell, market and distribute products for which we obtain marketing approval. These laws and regulations cover data privacy and the protection of health-related and other personal data. Laws and regulations in the EU and other jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal data, and have generally become more stringent over time.

For example, the EU General Data Protection Regulation, or GDPR, imposes strict requirements for processing the personal data of individuals within the EEA or in the context of our activities in the EEA. The GDPR allows EU member states to make additional laws and regulations further regulating the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of a noncompliant undertaking in the preceding financial year, whichever is higher, and other administrative penalties and may expose us to compensation claims from affected individuals.

Further, from January 1, 2021, we are subject to the GDPR and also the UK General Data Protection Regulation, which, together with the amended UK Data Protection Act 2018 (collectively, the UK GDPR), retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of £17.5 million or 4% of the total worldwide annual turnover of a noncompliant undertaking for the preceding financial year. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and it continues to remain under review by the Commission during this period.

Employees

As of December 31, 2024, we had 381 employees, 375 of which are full-time employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

MeiraGTx Holdings plc was formed on May 1, 2018 under the laws of the Cayman Islands. Our predecessor, MeiraGTx Limited, a limited company under the laws of England and Wales, was formed on March 20, 2015. In

connection with our initial public offering ("IPO"), we reorganized whereby MeiraGTx Limited became a wholly owned subsidiary of MeiraGTx Holdings plc.

Available Information

Our website can be found at *http://www.meiragtx.com*. From time to time, we may use our website as a channel of distribution of material company information. Financial and other material information is routinely posted and accessible under the Investors and Media section of our website at *http://www.meiragtx.com*.

We file annual, quarterly and current reports, proxy statements and other information with the U.S. Securities and Exchange Commission ("SEC"). Our SEC filings are available to the public over the Internet at the SEC's website at *http://www.sec.gov*. Our SEC filings are also available without charge under the Investors and Media section of our website at *http://www.meiragtx.com*. We make this information available on our website as soon as reasonably practicable after we electronically file such information with, or furnish it to, the SEC. Our website and the information contained on or connected to that site are not incorporated into this Form 10-K.

ITEM 1A. RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Form 10-K. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our ordinary shares could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future, and may never achieve or maintain profitability.

We are a clinical stage company with limited operating history. We were formed and began operations in 2015. We have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses since inception, including net losses of approximately $147.8 million and $84.0 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $702.0 million. Since our inception, we have devoted substantially all of our resources to developing our technology platform, establishing our viral vector manufacturing facilities and plasmid and DNA production facility, developing manufacturing processes, advancing the product candidates in our ophthalmology, salivary gland and neurodegenerative disease programs, research and development activities, including our riboswitch gene regulation platform technology, building our intellectual property portfolio, organizing and staffing our company, developing our business plans, raising capital, securing debt financing and providing general and administrative support for these operations. We have not yet demonstrated an ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approval, manufacture product at a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Given the length of time typically needed to develop a new drug from the time it enters Phase 1 clinical trials to when it is approved for treating patients, if ever, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing genetic medicine products.

We expect to continue to incur significant expenses and additional operating losses for the foreseeable future as we seek to advance product candidates through preclinical and clinical development, expand our research, development and manufacturing activities, develop new product candidates, build and expand our intellectual product portfolio, complete clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products.

Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time, including the ongoing Phase 2 AQUAx2 clinical trial of AAV-hAQP1 for the treatment of patients with radiation-induced xerostomia. In addition, we expect to continue incurring increasing research and development costs associated with our clinical activities for AAV-GAD for the treatment of Parkinson's disease and research, preclinical and clinical activities for our riboswitch platform. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with gene therapy product development, we are unable to accurately predict the timing or amount of increased expenses or whether we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability.

Before we generate any revenue from product sales, each of our programs and product candidates will require additional preclinical and/or clinical development, potential regulatory approval in multiple jurisdictions, manufacturing, building of a commercial organization, substantial investment and significant marketing efforts. Our expenses could increase beyond expectations if we are required by the FDA, MHRA, EMA, or other regulatory authorities to perform preclinical studies and clinical trials in addition to those that we currently anticipate. These risks are further described under "—Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval" and "—Risks Related to Commercialization." As a result, we expect to continue to incur net losses for the foreseeable future. These net losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance. If we are unable to develop and commercialize one or more of our product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our equity securities will be adversely affected.

There is no guarantee that we will receive in a timely fashion or at all the additional milestone payments contemplated under the Asset Purchase Agreement or the revenues associated with our manufacture of the commercial supply of the RPGR Product under the Supply Agreement.

On December 20, 2023, we and MeiraGTx UK II Limited entered into and consummated the Asset Purchase Agreement with Johnson & Johnson Innovative Medicine pursuant to which we sold and assigned to Johnson & Johnson Innovative Medicine, and Johnson & Johnson Innovative Medicine purchased and assumed, the UCLB RPGR License Agreement relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the Asset Purchase Agreement. MeiraGTx UK II Limited and Johnson & Johnson Innovative Medicine also entered into a Supply Agreement on December 20, 2023 pursuant to which MeiraGTx UK II Limited, together with its affiliates, will manufacture commercial supply of the RPGR Product for Johnson & Johnson Innovative Medicine for an initial term of four years, with Johnson & Johnson Innovative Medicine having an option to extend the Supply Agreement for a fifth year upon written notification to us.

Under the Asset Purchase Agreement, Johnson & Johnson Innovative Medicine paid us a non-refundable upfront cash purchase price of $65.0 million in December 2023. Additionally, pursuant to and subject to the terms and conditions set forth in the Asset Purchase Agreement, Johnson & Johnson Innovative Medicine agreed to pay us future contingent consideration of up to an aggregate of $350.0 million, as follows: (i) a milestone payment of $50.0 million in connection with the achievement of the initiation of the extension study for the Phase 3 LUMEOS clinical trial for the RPGR Product; (ii) $10.0 million upon completion of certain specified development services for the drug substance for the RPGR Product; (iii) $5.0 million upon completion of certain specified development services for the drug product for the RPGR Product; (iv) $175.0 million upon the first commercial sale of an RPGR Product in the United States; (v) $75.0 million upon the first commercial sale of an RPGR Product in at least one of the United Kingdom, France,

Germany, Spain and Italy; (vi) $25.0 million upon completion of the transfer of certain manufacturing technology for drug substance and drug product from us to Johnson & Johnson Innovative Medicine; and (vii) $10.0 million upon regulatory approval of a Johnson & Johnson Innovative Medicine-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. As of December 31, 2024, we have received $60.0 million in milestone payments from Johnson & Johnson Innovative Medicine.

In connection with the sale and assignment of the UCLB RPGR License Agreement relating to the research, development, manufacture and exploitation of the RPGR Product to Johnson & Johnson Innovative Medicine, Johnson & Johnson Innovative Medicine has control and broad discretion over all aspects of the development and commercialization of the RPGR Product and we will have little, if any, influence over how such activities will be conducted. Johnson & Johnson Innovative Medicine will also be responsible for seeking regulatory approval and initiating the first commercial sale in the relevant jurisdictions of the RPGR Product, as well as obtaining regulatory approval of its manufacturing facilities in the relevant jurisdictions for the purposes of conducting commercial manufacture of the RPGR Product. These regulatory approvals and initiation of the first commercial sales in the relevant jurisdictions would entitle us to receive milestone payments up to an aggregate of $260.0 million. Our receipt of these milestones is dependent on Johnson & Johnson Innovative Medicine's ability to successfully develop and commercialize the RPGR Product and obtain the necessary regulatory approvals for its manufacturing facilities. If these regulatory approvals or commercial sales do not occur in a timely fashion or at all, then such milestone payments, and any revenues we may receive from manufacturing commercial supply of the RPGR Product, may be delayed or we may not receive such payments. Additionally, certain of these milestone based payments are payable upon our achievement of the specified development services, completion of the transfer of certain manufacturing technology to Johnson & Johnson Innovative Medicine and our ability to manufacture sufficient commercial supply of the RPGR Product in a timely fashion. In the event we are not successful in completing these activities in a timely fashion or at all, we will not receive the milestone payments associated with the relevant milestone under the Asset Purchase Agreement or receive revenue for commercial supply of the RPGR Product under the Supply Agreement. In each of these circumstances, our anticipated cash inflows from these activities would be reduced or eliminated, which would have an adverse effect on our revenue and financial position.

We will require additional capital to fund our operations, which may not be available on acceptable terms, if at all.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our product candidates, as well as continue to expand our manufacturing and supply chain capabilities. This will require additional capital, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Our ability to raise additional capital when needed has been and may in the future be adversely affected by external factors beyond our control, including changes in the political climate, geopolitical actions, changes in market interest rates, potential reforms and changes to government regulations, the effect of healthcare reform legislation, including those that may limit pricing of pharmaceutical products and drugs, market prices and conditions, prospects for favorable or unfavorable clinical trial results, new product initiatives, the manufacturing and distribution of new products, product safety and efficacy issues, new collaborations and strategic alliances and licensing arrangements. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing has diverted and may in the future divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

Our operations have consumed significant amounts of cash since inception. As of December 31, 2024, our cash, cash equivalents and restricted cash were $105.7 million. In addition, we expect to receive $0.7 million from receivables from Johnson & Johnson Innovative Medicine during the first quarter of 2025 in connection with transition services we provided to Johnson & Johnson Innovative Medicine. Based on our cash, cash equivalents, accounts receivable – related

party and tax incentive receivable at December 31, 2024, together with the proceeds from the anticipated closing of the strategic collaboration with Hologen Ltd, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2027 and to repay our debt obligation of $75.0 million to Perceptive (due in August 2026). This estimate does not include the $285.0 million in milestones we are eligible to receive under the Asset Purchase Agreement upon first commercial sale of an RPGR Product in the United States and in at least one of the United Kingdom, France, Germany, Spain and Italy, for completion of the transfer of certain manufacturing technology to Johnson & Johnson Innovative Medicine and upon regulatory approval of a Johnson & Johnson Innovative Medicine-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to spend more than expected or consume capital significantly faster than we currently anticipate, such as inflation or other factors that may significantly increase our business costs. Because the length of time and activities associated with successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the progress, timing, costs and results of our clinical development for our radiation-induced xerostomia product candidate, AAV-hAQP1, and for our product candidate for the treatment of Parkinson's disease, AAV-GAD;
- the progress, timing, costs and results of our ongoing clinical development for our AAV-AIPL1 gene therapy product candidate, our CNGB3 achromatopsia gene therapy product candidate, AAV-CNGB3, for our CNGA3 achromatopsia gene therapy product candidate, AAV-CNGA3, and for our RPE65-associated retinal dystrophy product candidate, AAV-RPE65;
- the development of our product candidate for the treatment of ALS, AAV-UPF1, for our product candidate for the treatment of xerostomia associated with Sjogren's syndrome, AAV-hAQP1, and our product candidate for the treatment of neovascular age related macular degeneration, or wet AMD;
- the development of our potentially transformative riboswitch gene regulation platform technology designed to precisely and specifically control gene therapy expression levels via dose-response to orally delivered small molecules;
- the extent to which we receive the milestone payments under the Asset Purchase Agreement with Johnson & Johnson Innovative Medicine;
- continuing our current research programs and our preclinical development of product candidates from our current research programs;
- seeking to identify, assess, acquire and/or develop additional research programs and additional product candidates;
- the preclinical testing and clinical trials for any product candidates we identify and develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, MHRA, EMA and other regulatory authorities;
- the cost of expanding and protecting our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;

- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our product candidates;
- the effect of competing technological and market developments;
- the cost of further developing and scaling our manufacturing facilities and processes;
- the cost and timing of completion of commercial-scale manufacturing facilities and activities;
- the cost of making royalty, milestone or other payments under current and any future in-license agreements;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the extent to which we in-license or acquire rights to other products, product candidates and technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our products; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

Raising additional capital through the sale of equity or convertible debt securities will dilute your ownership interest, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. For example, in connection with entering into the Financing Agreement (as defined below), we issued warrants to Perceptive (as defined below), to purchase 400,000 ordinary shares at an exercise price of $15.00 per share and 300,000 ordinary shares at an exercise price of $20.00 per share. Additional debt financing or preferred equity financing, if available, may involve agreements that include covenants further limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We may not have sufficient cash flows or cash on hand to satisfy our debt obligations or covenants under our financing arrangements, or we may not be able to effectively manage our business in compliance with such covenants.

On August 2, 2022, we, as borrower, and our wholly-owned subsidiaries MeiraGTx UK II Limited and MeiraGTx Ireland DAC, as guarantors (the "Subsidiary Guarantors"), entered into a senior secured financing arrangement (the "Financing Agreement") by and among us, the Subsidiary Guarantors, the lenders and other parties from time to time party thereto and Perceptive Credit Holdings III, LP, as administrative agent and lender ("Perceptive"). On December 19, 2022, the Financing Agreement was converted to a notes purchase agreement and guaranty (as converted, the "Notes Purchase Agreement") between the same parties and under substantially the same terms and conditions as the Financing Agreement, subject to certain customary note constitution terms. We and the Subsidiary Guarantors entered into a Consent and Amendment with Perceptive on August 10, 2023 (the "First Consent

and Amendment), and we and the Subsidiary Guarantors entered into a second Consent and Amendment with Perceptive on December 20, 2023 (the "Second Consent and Amendment"). The Notes Purchase Agreement provides for an initial $75.0 million notes issuance (the "Tranche 1 Notes"). Pursuant to the First Consent and Amendment, we were able to request in our sole discretion, and Perceptive agreed to subscribe to purchase upon such request, an additional $25.0 million notes issuance (the "Tranche 2 Notes", together with the Tranche 1 Notes, the "Notes") at any time before August 2, 2024, subject to the terms of the Notes Purchase Agreement. Previously, the Company's request for issuance of the Tranche 2 Notes was to be determined at Perceptive's sole discretion. Under each of the First Consent and Amendment and the Second Consent and Amendment, the Notes Purchase Agreement was also amended to increase the applicable early redemption fee. The Notes incur interest, subject to certain provisions therein, at a fluctuating rate per annum equal to 10.00% plus the secured overnight financing rate administered by the Federal Reserve Bank of New York for a one-month tenor, subject to a 1.00% floor. The Notes Purchase Agreement matures on August 2, 2026 and is interest-only during the term. The Notes Purchase Agreement also contains various restrictions and covenants, including, among other things, covenants regarding the incurrence of additional indebtedness, limitations on liens, limitations on certain investments, limitations on making distributions, dividends and other payments, mergers, consolidations and acquisitions, dispositions of assets, maintenance of at least $3.0 million in a U.S. bank account, transactions with affiliates, changes to governing documents, changes to certain agreements and leases and changes in control. Our obligations under the Notes Purchase Agreement are secured by our London, UK and Shannon, Ireland manufacturing facilities, $3.0 million of our cash and the bank accounts of the Subsidiary Guarantors, and the issued and outstanding equity interests of the Subsidiary Guarantors.

There can be no assurance that our cash and cash equivalents available under the Notes Purchase Agreement and under any future financings, together with any funds generated by our operations, will be sufficient to satisfy our debt payment obligations. Our inability to generate funds, obtain financing sufficient to satisfy our debt payment obligations or remain in compliance with the debt covenants may result in such obligations being accelerated by our lenders, which would likely have a material adverse effect on our business, financial condition and results of operations.

The covenants may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry, or take future actions. Additionally, our ability to comply with these restrictive covenants may be impacted by events beyond our control, such as economic conditions or major central bank policy actions. Our Notes Purchase Agreement provides that our breach or failure to satisfy certain covenants constitutes an event of default. Upon the occurrence of an event of default, in addition to an increase in the rate of interest on the Notes of 3% per annum, Perceptive could elect to declare all amounts outstanding thereunder to be immediately due and payable, proceed against the assets we provided as collateral, and, if such debt were accelerated, we may not have sufficient cash on hand or be able to sell sufficient collateral to repay it, which would have an immediate adverse effect on our business and operating results. This could potentially cause us to cease operations and result in a complete loss of your investment in our ordinary shares**.**

Our review of potential strategic transactions may not result in an executed or consummated transaction or other strategic alternative and may not result in anticipated benefits to us or our shareholders, and the process of reviewing strategic transactions or its conclusion could be disruptive and distracting to our business operations and management.

We have, and may continue to, opportunistically identify and evaluate strategic opportunities regarding our assets. For example, in October 2023, we entered into the Investment Agreement with Sanofi Foreign Participations, pursuant to which, among other things and subject to the terms and conditions specified therein, we issued an aggregate of 4,000,000 ordinary shares, at a purchase price of $7.50 per share for gross proceeds of $30.0 million. Sanofi also received a right of first negotiation (ROFN) for the use of our riboswitch gene regulation technology for certain Central Nervous System (CNS) and Immunology and Inflammation (I&I) targets, including IL-4 and IL-13, as well as for GLP-1 and other gut peptides for obesity, and for our Phase 2 xerostomia program. In addition, in December 2023, we announced the transaction with Johnson & Johnson Innovative Medicine, as described above. There can be no assurance that we will be successful in our efforts to pursue or advance such options, or identify similar opportunities, or that any potential transaction would be consummated or, if consummated, will provide the anticipated benefits to us or otherwise enhance shareholder value. Any such potential transaction would be dependent upon a number of factors beyond our control, including, without limitation, market conditions, industry trends, the interest of third parties in our assets and whether the terms of any strategic transaction would be acceptable to us. The process of reviewing potential strategic alternatives is time consuming and may be distracting and disruptive to our business operations and long-term planning, which may cause concern to our current or potential customers, employees, investors, strategic partners and other constituencies and may have a material impact on our business and operating results or result in increased volatility in our share price.

We are heavily dependent on the success of our product candidates, which are still in development, and if none of them receive regulatory approval or are successfully commercialized, our business may be harmed.

Our future success and ability to generate product revenue is substantially dependent on our ability to successfully develop, manufacture, obtain regulatory approval for and successfully commercialize our product candidates. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We have invested and expect to continue to invest a meaningful portion of our efforts and expenditures over the next few years in the development of AAV-hAQP1, AAV-GAD, AAV-AIPL1 and our riboswitch gene regulation technology platform, as well as potentially AAV-CNGB3, AAV-CNGA3, AAV-RPE65, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, manufacturing sufficient supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales. We cannot be certain that our product candidates will be successful in clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Even if we receive approval to market our product candidates from the FDA, MHRA or other regulatory bodies, we cannot be certain that our product candidates will be successfully commercialized by us or any of our collaborators, widely accepted in the marketplace or more effective than other commercially available alternatives. Additionally, the research, testing, manufacturing, labeling, approval, sale, marketing and distribution of gene therapy products are and will remain subject to extensive and evolving regulation by the FDA, MHRA and other regulatory authorities. We are not permitted to market our product candidates in the United States until they receive approval of a BLA from the FDA, we cannot market them in the UK or EU until we receive approval for an MA, from the MHRA or European Commission, respectively, and we cannot market them in other countries until we receive any other required regulatory approval in those countries.

Because some of our product candidates are based on similar technology, if any of our product candidates show unexpected adverse events or a lack of efficacy in the indications we intend to treat, or if we experience other regulatory or developmental issues, our development plans and business could be significantly harmed. Further, competitors may be developing products with similar technology and may experience problems with their products that could identify problems that would potentially harm our business.

We may not be successful in our efforts to identify additional product candidates.

Part of our strategy involves identifying novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate may be too complex and difficult to navigate successfully or economically.

In addition, we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify additional suitable product candidates for clinical development, this would adversely impact our business strategy and our financial position and share price and could potentially cause us to cease operations.

Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval

It is difficult to predict the time and cost of product candidate development on our novel gene therapy platform. A limited number of gene therapies have been approved in the United States or in Europe.

We have concentrated a portion of our research and development efforts on our gene therapy platform, which uses both transduction and gene control technology. Our future success depends on the successful development of these novel therapeutic approaches. To date, a limited number of products that utilize gene transfer have been approved in the United States or Europe.

Our gene therapy platform is based on a suite of viral vectors which we can deploy with gene therapy constructs, which relies on the ability of AAV to efficiently transmit a therapeutic gene to certain kinds of cells. The mechanism of action by which these vectors target particular tissues is still not completely understood. Therefore, it is difficult for us to determine that our vectors will be able to properly deliver gene transfer constructs to enough tissue cells to reach therapeutic levels. We cannot be certain that animal models will exist for some of the diseases we expect to pursue, that our viral vectors will be able to meet safety and efficacy levels needed to be therapeutic in humans or that they will not cause significant adverse events or toxicities. Furthermore, prior work conducted by a third party in non-human primates suggests that intravenous, or IV, delivery of certain AAV vectors at very high doses may result in severe toxicity. The indications that we target do not use IV administration for viral vector delivery and do not use doses as high as those tested in these publications, and to date we have not observed the severe toxicities described in these publications with the naturally occurring AAV vectors that we use. However, we cannot be certain that we will be able to avoid triggering toxicities in our future preclinical studies or clinical trials. Any such results could impact our ability to develop a product candidate. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our gene therapy platform, or any similar or competitive gene therapy platforms, will result in the identification, development, and regulatory approval of any product candidates, or that other gene therapy technologies will not be considered better or more attractive. There can be no assurance that any development problems we experience in the future related to our gene therapy platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or clinical trials or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

In addition, because our gene regulation technology is still in the research stage, we have not yet been able to assess safety in humans, and there may be long-term effects from treatment that we cannot predict at this time.

Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel gene therapy product candidates we develop are not entirely clear and may change. Within the broader genetic medicine field, a limited number of therapeutic products have received approval from the FDA or an MA from the MHRA and European Commission. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products, which could impact the timing and cost of any regulatory approval. For example, in the United States, the FDA has established the Office of Therapeutic Products within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials may also be subject to review and oversight by an institutional biosafety committee and/or an institutional review board, or IRB, which are local institutional committees or boards, as applicable, that review, approve and oversee basic and clinical research conducted at the institution participating in the clinical trial.

In the EU, the EMA's Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety, and efficacy of ATMPs. ATMPs include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for MA for a gene therapy medicinal candidate that is submitted to the EMA. In the EU, the development and evaluation of a gene therapy product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and MA for gene therapy products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any gene therapy product candidate we may develop, but that remains uncertain at this point.

Post Brexit, MAAs for ATMPs in the UK are regulated nationally and assessed in accordance with the general provisions in place for the licensing of medicines, taking the specific requirements for this group of medicines into account. Definitions for individual classes of ATMPs remain unchanged and classification of ATMPs are undertaken by the MHRA. Data, traceability, exemptions from licensing, packaging and post-authorization requirements remain in line with EU requirements transposed into UK law. However, if the EMA issues new guidance on ATMPs going forward, there is a risk of regulatory divergence with the MHRA and separate procedures and standards with which we may need to comply.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, MHRA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene regulation technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, MHRA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel treatments for diseases or conditions in which there may be limited clinical experience with novel endpoints and methodologies, there is heightened risk that the FDA, MHRA, EMA or other regulatory bodies may not consider the clinical trial endpoints we pursue to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. The prospectively designed natural history studies with the same endpoints as our corresponding clinical trials may not be accepted by the FDA, MHRA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

Clinical trials are expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive, can take many years to complete and is subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our future clinical trials are completed as planned, we cannot be certain that their

results will support the safety and effectiveness of our product candidates for their targeted indications. Our future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA, MHRA, EMA or other regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA, MHRA, EMA or other regulatory authorities for support of an MAA, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

To date, we have not completed any clinical development programs required for the approval of any of our product candidates. Although we are currently conducting several clinical development programs, we may experience delays in conducting any clinical trials and we do not know whether our ongoing and future clinical trials will begin on time, need to be redesigned, be able to recruit and enroll patients on time or be completed on schedule, or at all. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching consensus with the FDA, MHRA or other regulatory authorities as to the design or implementation of our clinical trials and obtaining regulatory allowance or approval to commence a clinical trial;
- inability to reach an agreement on acceptable terms with clinical trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- our inability to recruit and train clinical trial investigators with the appropriate competencies and experience to conduct the clinical trials, administer our product candidates and oversee clinical trial staff;
- delays in obtaining IRB or ethics committee approval or positive opinion at each site;
- inability to recruit suitable patients to participate in a clinical trial;
- inability to develop and validate any companion diagnostic we may decide to use in connection with a clinical trial, if applicable;
- delays in sufficiently developing, designing and manufacturing equipment or medical devices used to administer our product candidates in our clinical trials, if applicable;
- patients not completing a clinical trial or returning for post-treatment follow-up;
- clinical sites, CROs, or other third parties deviating from trial protocol or dropping out of a trial;

- failures to conduct clinical trials in accordance with good clinical practice, or GCP, requirements, or other applicable regulatory guidelines;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate;
- having an insufficient number of clinical trial sites; or
- inability to manufacture sufficient quantities of our product candidates for use in clinical trials, or to manufacture such product candidates to acceptable quality standards.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:

- we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- business interruptions resulting from geopolitical actions, including war and terrorism, or a widespread health emergency, or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability; and
- any future collaborators that conduct clinical trials may face any of the above issues, and they may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other

testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA, MHRA or other foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, MHRA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Our product candidates will require extensive clinical testing before we are prepared to submit a BLA or MAA for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, MHRA, EMA or other regulatory authorities on our clinical development program, and the FDA, MHRA, EMA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. For example changes in the leadership of the FDA and other federal agencies under the current presidential administration or reductions in funding, operations, staffing and policies of the FDA and other federal agencies could impact our clinical development plans and timelines.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the

EU has evolved over recent years. As of January 2025, clinical trials (and related applications) in the EU are now fully subject to the provisions of the CTR, which allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state and provides for a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from pre-existing EU legislation (as implemented into UK law, through secondary legislation). The extent to which the regulation of clinical trials in the UK may mirror the (EU) CTR in the long term is not yet certain. In December 2024, the UK government introduced a legislative proposal which, if implemented, could provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The legislation may not be approved or could be approved with amendment, and any adoption into UK law may not be until early 2026. Under the terms of the Protocol on Ireland and Northern Ireland, provisions of the (EU) CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products currently apply in Northern Ireland. A decision by the UK not to closely align its regulations with the new approach adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted.

Pandemics, epidemics or outbreaks of an infectious disease have impacted and may in the future materially and adversely impact our business, including our preclinical studies, clinical trials, manufacturing capabilities and regulatory approvals.

We have and may in the future experience disruptions from pandemics, epidemics or outbreaks of an infectious disease that could severely impact our business, preclinical studies, clinical trials and laboratory and manufacturing activities, including, for example, delays or difficulties in enrolling patients in our clinical trials, delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, diversion of healthcare resources away from the conduct of clinical trials, interruption of key clinical trial activities due to limitations on travel imposed or recommended by regulatory authorities or others, interruption or delays in the operations of the FDA, MHRA, EMA or other regulatory authorities, interruption of, or delays in, the manufacturing of our product candidates, interruptions in preclinical studies due to restricted or limited operations at our laboratory facilities, limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, and interruption or delays to our sourced discovery and clinical activities. For example, as a result of the COVID-19 pandemic, we restricted onsite activities and also experienced some delays in enrolling, treating and monitoring patients in our clinical trials, as well as limited disruptions to our supply chain.

The extent to which any future outbreaks or any variants of COVID-19 or another pandemic may impact our business, preclinical studies, clinical trials and laboratory and manufacturing activities will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of any pandemic, the timing, distribution and effectiveness of vaccines, vaccination rates, travel restrictions and physical distancing requirements in the countries where we do business, business closures or business disruptions, and the effectiveness of actions taken in the countries where we do business to contain and treat any such disease, respond to the reduction in global economic activity and resume normal economic and operating conditions. If we or any of the third parties with whom we engage experience prolonged shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Furthermore, the magnitude of the economic impact of any pandemic including sustained inflation, supply chain

disruptions, and major central bank policy actions may result in significant disruption of global financial markets, which could materially affect our performance, financial condition, results of operations, and cash flows, as well as our ability to raise additional capital. Additionally, major central bank policy actions may have a negative impact on our payment obligations under the Notes Purchase Agreement.

The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included, or supporting the information, in our SEC filings and other materials should be viewed with caution. Further, the data and statistical information included, or supporting the information, in our SEC filings and other materials, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

The use of such data involves risks and uncertainties and is subject to change based on various factors. Our estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of the diseases we seek to address. The number of patients with the diseases we are targeting in the United States, the UK, the EU and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or access, all of which would harm our results of operations and our business.

Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact public perception of our current and future product candidates.

Our potential therapeutic products involve introducing genetic material into patients' cells. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. For example, on November 28, 2023, the FDA announced that it was investigating reports of T-cell malignancies, including CAR- positive lymphoma, in patients who received treatment with BCMA- or CD19-directed autologous CAR-T cell immunotherapies, and in January 2024, the FDA required the manufacturers of certain CAR-T therapies to add boxed warnings to product labeling cautioning against the risk of T-cell malignancies. Although none of our current product candidates utilize the same technology as these CAR-T immunotherapies, our product candidates use a viral delivery system. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates

or the halting of clinical trials, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy and we cannot assure that it will not occur in any of our planned or future clinical trials. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. If any such adverse events occur, commercialization of our product candidates or further advancement of our clinical trials could be halted or delayed, which would have a negative impact on our business and operations.

We may fail to maintain the benefits of certain regulatory designations that we have obtained for our product candidates, and may in the future seek and fail to obtain such designations for other of our current or potential future product candidates. Even if such designations are obtained, they may not lead to faster development or regulatory review or approval, and they do not increase the likelihood that our product candidates will receive marketing approval.

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of drugs and biological products that meet certain criteria. For example, the FDA has a Fast Track designation program that is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, investigational drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the application may be eligible for priority review. In addition, the Fast Track product may be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. Even if Fast Track designation is granted, it may be rescinded if the product no longer meets the qualifying criteria. In August 2018, AAV-CNGB3 was issued Fast Track designation by the FDA for the treatment of achromatopsia caused by CNGB3 mutations. In January 2021, AAV-CNGA3 was issued Fast Track designation by the FDA for the treatment of achromatopsia caused by CNGA3 mutations.

Similarly, the EMA has established the PRIME scheme to expedite the development and review of product candidates that show a potential to address to a significant extent an unmet medical need, based on early clinical data. In February 2018, AAV-CNGB3 in the treatment of achromatopsia associated with defects in CNGB3 was admitted to the PRIME scheme of the EMA.

A sponsor may also seek an RMAT designation for its product candidates. In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act. A biological product is eligible for RMAT designation if it qualifies as an RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions, and is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the biological product has the potential to address unmet medical needs for such a disease or condition. In a February 2019 guidance, the FDA also stated that certain gene therapies that lead to a sustained effect on cells or tissues may meet the definition of a regenerative medicine therapy. RMAT designation provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review, provided the applicable criteria are met. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory

data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy. In December 2024, the FDA granted RMAT designation to AAV-hAQP1 for the treatment of grade 2 or 3 radiation-induced xerostomia.

Such regulatory designations are within the discretion of the FDA, MHRA, EMA and other regulatory authorities. Accordingly, even if we believe one of our product candidates meets the criteria for such regulatory programs and we seek such designations, the FDA, MHRA, EMA or other applicable regulatory authority may disagree and instead determine not to make such designation for such product candidate. We cannot be sure that our evaluation of our product candidates as qualifying for such regulatory designations will meet the regulatory authority's expectations. In any event, the receipt of such regulatory designations for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional regulatory procedures and does not assure ultimate approval by the regulatory authorities. In addition, even if additional product candidates are granted such regulatory designations, the regulatory authority may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened, as applicable.

We have received orphan drug designation and orphan designation from the FDA and European Commission, respectively, for AAV-CNGB3, AAV-CNGA3, AAV-RPE65, AAV-AIPL1, AAV-RDH12 and orphan drug designation from the FDA for AAV-hAQP1 and AAV-BBS10, and we may seek orphan drug designation or orphan designation for additional product candidates in the future, but any orphan drug designations or orphan designations we have received or may receive in the future may not confer marketing exclusivity or other expected benefits.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the European Commission grants orphan designation on the basis of the EMA's Committee for Orphan Medicinal Products opinion. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment, of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for qualified clinical testing, and user-fee waivers. In addition, if a product receives the first FDA approval of that drug for the disease or condition for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the rare disease or condition. Under the FDA's regulations, the FDA will deny orphan drug exclusivity to a designated drug upon approval if the FDA has already approved another drug with the same principal molecular structural features, in the case of a biologic, for the same indication, unless the drug is demonstrated to be clinically superior to the previously approved drug. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized MA procedure. Moreover, upon grant of an MA and assuming the requirement for orphan designation are also met at the time the MA is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. This period may be reduced to six years if, at the end of the fifth year, the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market

exclusivity, or where the prevalence of the condition has increased above the orphan designation threshold. In the EU, an MA for an orphan designated product will not be granted if a similar product has been approved in the EU for the same therapeutic indication, unless the applicant can establish that (i) its product, although similar to the orphan medicinal product already authorized is safer, more effective or otherwise clinically superior; (ii) the MA holder for the orphan medicinal product grants its consent; or (iii) if the MA holder of the orphan medicinal product is unable to supply sufficient quantities of product. A similar medicine is a product containing a similar active substance or substances as those contained in an already authorized product. Similar active substance is defined as an identical active substance, or an active substance with the same principal molecular structural features (but not necessarily all of the same molecular features) and which acts via the same mechanism.

There is no pre-MA orphan designation in the UK. The MHRA reviews applications from companies for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in the UK.

We have obtained orphan drug designation from the FDA and orphan designation from the European Commission for AAV-CNGB3 for the treatment of achromatopsia caused by mutations in the *CNGB3* gene, for AAV-CNGA3 for the treatment of achromatopsia due to autosomal-recessive *CNGA3* gene mutations, for AAV-RPE65 for the treatment of Leber congenital amaurosis, for AAV-AIPL1 for the treatment of inherited retinal dystrophy due to defects in *AIPL1* gene and for AAV-RDH12 for the treatment of retinol dehydrogenase 12 (RDH12) mutation-associated retinal dystrophy, and we obtained orphan drug designation from the FDA for AAV-hAQP1 for the treatment of grade 2 and grade 3 late xerostomia from parotid gland hypofunction caused by radiotherapy and for AAV-BBS10 for the treatment of Bardet-Biedel syndrome (BBS) due to *BBS10* mutations. We may seek orphan drug designation and orphan designation for other current and future product candidates. Even with orphan drug designation and orphan designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, which could prevent us from marketing our product candidates if another company is able to obtain orphan drug exclusivity before we do. In addition, exclusive marketing rights in the United States and the EU may be unavailable if we seek approval for a disease or condition broader than the orphan drug-designated and orphan-designated disease or condition or may be lost in the United States or EU if the FDA or foreign authorities later determine that the request for designation was materially defective or if we are unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition following approval.

Further, even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect our product candidates from competition because different biologics with different active principal molecular structural features can be approved for the same disease or condition. In addition, the FDA can subsequently approve products with the same principal molecular structural features, in the case of a biologic, for the same disease or condition if the FDA concludes that the later product is safer, more effective, makes a major contribution to patient care, or if the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Likewise, in the EU and UK, the European Commission or MHRA, respectively, can authorize a similar product for the same therapeutic indication, if it concludes that the later product is safer, more effective or clinically superior; if the MA holder for the initial orphan medicinal product grants its consent; or if such MA holder is unable to supply sufficient quantities of the product. Neither orphan drug designation nor orphan designation shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation and orphan designation for other existing and future product candidates, we may never receive such designations.

The FDA has granted rare pediatric disease designation to a number of our gene therapy product candidates, however, there is no guarantee that FDA approval of any of these gene therapy candidates will result in a priority review voucher.

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease drugs and biologics intended to treat certain orphan diseases affecting fewer than 200,000 patients in the U.S., the serious or life-threatening manifestations of which primarily affect individuals aged 18 years of age or younger, or affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. of such drug. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" that meets certain criteria may be eligible to receive a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor, and such priority review vouchers have recently sold for between $100 million to $158 million. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

The FDA has granted us rare pediatric disease designation for AAV-AIPL1 for the treatment of Leber congenital amaurosis (LCA4) retinal dystrophy, AAV-BBS10 for the treatment of BBS due to *BBS10* mutations, AAV-RDH12 for the treatment of Leber congenital amaurosis (LCA) and early-onset severe retinal dystrophy (EOSRD), AAV8-RK-RetGC for the treatment of patients with Leber congenital amaurosis due to *GUCY2D* mutations (LCA1), AAV-RPE65 for the treatment of inherited retinal dystrophy due to biallelic *RPE65* mutations, AAV-CNGB3 for the treatment of achromatopsia caused by mutations in the *CNGB3* gene and AAV-CNGA3 for the treatment of achromatopsia caused by mutations in the *CNGA3* gene. There is no guarantee that we will be able to obtain a priority review voucher, even if one or more of these gene therapy product candidates is approved by the FDA. Under the current statutory provisions, the FDA may not award a rare pediatric disease priority review voucher to sponsors of marketing applications unless the drug has received rare pediatric disease designation as of December 20, 2024 and is approved by the FDA no later than September 30, 2026. Even though we received rare pediatric disease designation by the current statutory deadline of December 20, 2024 for all of these gene therapy product candidates except AAV8-RK-RetGC, which received such designation in January 2025, we may not receive a voucher for such gene therapy product candidates if we do not obtain approval by September 2026. It is possible that Congress may retroactively extend the date by which a rare pediatric disease-designated drug may be designated as such to be eligible for a priority review voucher, or extend the date by which a rare pediatric disease-designated drug must obtain approval in order to receive a priority review voucher, but even if such legislation is enacted, we may not obtain approval by that date, and even if we do, we may not obtain a priority review voucher.

We and our contract manufacturers for plasmid are subject to significant regulation with respect to manufacturing our products. Our manufacturing facilities and the third-party manufacturing facilities which we rely on may not continue to meet regulatory requirements and have limited capacity.

We currently have relationships with a limited number of suppliers for the manufacturing of plasmid, a component of our viral vectors and product candidates. We also have GMP manufacturing facilities in London, United Kingdom and Shannon, Ireland, which we expect can supply our current clinical and preclinical programs, as well as our third party supply obligations, through regulatory approval and, should they be approved, provide sufficient capacity for their commercial production. However, if we experience slowdowns or problems with our facilities or are unable to establish or scale our internal manufacturing capabilities, we will need to continue to contract with manufacturers that can produce the preclinical, clinical and commercial supply of our products. Each supplier may require licenses to

manufacture such components if such processes are not owned by the supplier or in the public domain and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for components of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis. Generally, our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must successfully complete a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or the product candidates that we manufacture for third parties. In addition, certain regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the product candidates that we manufacture for third parties or the associated quality systems for compliance with the regulations applicable, if and when approved, to the activities being conducted. If these facilities do not successfully complete a pre-approval plant inspection, FDA, MHRA or other regulatory approval of the product candidates will not be granted.

If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA, MHRA or other regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA and/or MAA supplement which could result in further delay. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for clinical or commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

Any contamination in our manufacturing process, shortages of raw materials or failure of our plasmid supplier to deliver necessary components, or other issues with the manufacturing process, could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. In addition, our manufacturing process is complex, and the manufacturing batch cycle period can be several weeks long.

Each batch cycle may not yield planned quantities or meet the required standards. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates, failure of manufacturing equipment or systems or other issues with our manufacturing process, could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Expanding our manufacturing capacity has and will continue to be costly and we may be unsuccessful in doing so in a timely manner, which could delay our current and future clinical development programs, or delay the commercialization of our product candidates.

In addition to our existing manufacturing facilities in London, United Kingdom and Shannon, Ireland, we may lease, operate, purchase, or construct additional facilities to supply our clinical and preclinical programs, as well as to meet our third party supply obligations, or conduct expanded manufacturing or other related activities in the future. Expanding our manufacturing capacity to produce the preclinical, clinical and commercial supply of our products and their components, as well as our obligations under the Supply Agreement with Johnson & Johnson Innovative Medicine if the RPGR Product is successfully commercialized, has required and will continue to require substantial additional expenditures, time, and various regulatory approvals and permits, as well as hiring, training and retraining employees and managerial personnel to staff our manufacturing and supply chain operations. Start-up costs can be large and may exceed our expectations, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates for use in clinical trials and, should they be approved, to supply the commercial market at reasonable costs and in compliance with applicable regulatory requirements. We may not successfully expand, establish or sustain sufficient manufacturing capabilities or manufacture our products economically or in compliance with GMP and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet the requirements of our clinical programs or to meet potential commercial demand for our product candidates. This could also delay or require us to discontinue one or more of our clinical development programs or could interfere with our efforts to successfully commercialize our products. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. This may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. The enrollment of patients depends on many factors, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial’s primary endpoints;
- the proximity of patients to study sites;
- the design of the trial or side effects that may arise in development;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or widespread health emergencies, or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability.

In addition, other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or approved products for the same clinical indications (such as Luxturna marketed by Spark Therapeutics, Inc. for the treatment of RPE65-associated retinal disease) may reduce the number and type of patients available to us. Furthermore, although we have conducted and may in the future conduct natural history studies to better characterize the patient populations we seek to address, any natural history studies we may undertake could fail to provide us with patients for our clinical trials, because patients enrolled in the natural history studies may not be good candidates for our clinical trials or may choose to not enroll in our clinical trials.

Our product candidates may cause serious adverse events or undesirable side effects or have other properties which may delay or prevent their regulatory approval, limit the commercial profile of an approved label, or, result in significant negative consequences following marketing approval, if any.

Serious adverse events or undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, MHRA or other authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics, including death. A risk in any gene therapy product based on viral vectors is the risk of insertional mutagenesis.

If unacceptable side effects or deaths arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, the DSMB, or other regulatory bodies could suspend or terminate our clinical trials or the FDA, MHRA or other regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Undesirable side effects or deaths in clinical trials with our product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical trials, to require additional studies, or otherwise to delay or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients or similar risk management measures;
- the product could become less competitive;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.

Results from previous preclinical studies or clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate.

Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for drugs and biologic products proceeding through clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval, which could negatively impact our business, financial condition, results of operations and prospects.

The regulatory approval processes of the FDA, MHRA, competent authorities in the EU and other regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, MHRA, European Commission and other regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not expected before early 2026. The revisions may however have a significant impact on the pharmaceutical industry in the long term.

We have not obtained regulatory approval for any product candidate and it is possible that none of our product candidates in clinical programs or any other product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States, the UK or the EU until we receive regulatory approval of a BLA from the FDA or of an MAA from the MHRA or European Commission, respectively. It is possible that the FDA may refuse to accept for substantive review any BLAs, or the MHRA or EMA any of our MAAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates.

Prior to obtaining approval to commercialize a product candidate in the United States, the UK, the EU or elsewhere, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, MHRA, EMA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses, or with respect to biologics in the United States, that such product candidates are safe, pure, and potent for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, MHRA, European Commission or other regulatory authorities. The FDA, MHRA or EMA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. Depending on the extent of these or any other FDA, MHRA or EMA required studies, approval of any regulatory approval applications that we submit may be delayed by several years, or may require us to expend significantly more resources than we have available.

Of the large number of potential products in development, only a small percentage successfully complete the FDA, MHRA, or other foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Even if we obtain FDA, MHRA or European Commission approval for our product candidates in the United States, UK or EU, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States, the MHRA in the UK or the competent authorities in the EU does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we receive regulatory approval of one or more of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA, MHRA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with GMP and similar requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post-approval.

The FDA, MHRA and other regulatory authorities closely regulate the post-approval marketing and promotion of genetic therapy medicines to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA, MHRA and other regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the U.S. federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. Similar risks apply in foreign jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, including adverse events of unanticipated severity or frequency, or with our manufacturing processes or third-party manufacturers, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or holds on clinical trials;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's and foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary

data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from these trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data become available. Adverse differences between interim data and topline, preliminary, or final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our ordinary shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government or regulatory agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed, approved or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, disruptions caused by global health concerns, ability to hire and retain key personnel, including those with experience relating to novel gene therapy product candidates, acceptance of the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other government or regulatory agencies such as the EMA, following its relocation to Amsterdam and related reorganization (including staff changes), may also slow the time necessary for new product candidates to be reviewed and/or approved, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current presidential administration has threatened to

lay off thousands of federal health workers, including at the FDA, which may delay review times for approval of our product candidates and impact our ability to correspond with the FDA regarding the development of our programs in a timely fashion.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the UK, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a licensure framework for follow on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which was temporarily suspended from May 1, 2020 through March 31, 2022, and reduced payments to several types of Medicare providers. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In August 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare beginning in 2026, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. For that and other reasons, it is currently unclear how the IRA will be effectuated. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

In the UK and EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the UK or the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the UK and the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in the UK and in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted in the EU. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product (i.e., oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030). The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

In markets outside of the United States, the UK and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the UK the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse laws and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person

or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and

- similar healthcare laws and regulations in the UK, EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to regulation and other legal obligations relating to data privacy and protection. Compliance with these requirements is complex and costly. The actual or perceived failure to comply with such obligations could materially harm our business.

The global data protection landscape is continually evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, access to, confidentiality, disclosure, storage, processing, retention and security of personal information such as information that we may collect in connection with clinical trials in the U.S. and abroad.

In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, healthcare clearinghouses and certain healthcare providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. Most healthcare providers, including research institutions and other vendors from which we may obtain health-related information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. For example, the CCPA requires covered businesses that process the personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have been passed in other states, and are continuing to be proposed at the state and the federal level, reflecting a

trend toward more stringent privacy legislation in the United States. HIPAA, the CCPA and other domestic privacy and data protection laws and regulations may increase our compliance costs and potential liability.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, the GDPR imposes stringent requirements for processing the personal data of individuals within the EEA or in the context of our activities within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and, among other things, potential fines for noncompliance of up to €20 million or up to 4% of the total worldwide annual turnover of the relevant undertaking in the preceding financial year, whichever is higher, and other administrative penalties.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S. Case law from the Court of Justice of the European Union states that reliance on the standard contractual clauses – a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism – alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. The European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF") on July 10, 2023, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the adequacy of the DPF as an approved GDPR transfer mechanism to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. If, owing to the restriction or perceived restriction of personal data transfers, we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, we are subject to the UK GDPR, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant undertaking's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. UK privacy law has been, and continues to be, subject to scrutiny and proposed changes. This could affect the ease of data transfers between the EEA and the UK in the future. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, as well as our contractual obligations and other legal obligations, relating to data privacy and security, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction and/or organization to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy data and security concerns, even if unfounded, could result in additional costs, claims by and liability to third parties, government investigations and enforcement actions, damage to our reputation, and other adverse affects on our business, financial condition and results of operations.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we

fail to comply with such laws and regulations, we could be subject to fines or other sanctions. Additionally, if environmental regulations are enacted that restrict our ability to use one or more of the materials or compounds necessary to manufacture our product candidates, and we are unable to find suitable alternatives or such alternatives require additional testing or will extend the manufacturing timeline, then we may be unable to manufacture our product candidates in a timely manner, or at all.

We may be subject to environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production efforts or those of our third-party manufacturers may be interrupted or delayed.

Due to our international operations, we are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses.

Our operations are subject to anti-corruption laws, including the UK Bribery Act 2010, or Bribery Act; the U.S. Foreign Corrupt Practices Act, or FCPA; and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA, and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed by, or providing prohibited payments or anything else of value to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA, or local anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which any of our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We also are subject to other laws and regulations governing any international operations, including regulations administered by the governments of the UK and the U.S., and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, or, collectively, the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA, or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA, and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement, and other sanctions and remedial measures and legal expenses. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws, or Trade Control laws by UK, U.S., or other authorities, even if it is ultimately determined that we did not violate such laws, could be costly and time-consuming, require significant personnel resources, and harm our reputation.

We have established internal controls to detect and prevent violations of applicable anti-corruption laws and to remedy any weaknesses identified. There can be no assurance, however, that the policies and procedures will be followed at all times or effectively detect and prevent violations of the applicable laws by one or more of our employees, consultants, agents, or collaborators and, as a result, we could be subject to fines, penalties, or prosecution.

Risks Related to Commercialization

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new gene therapy products is highly competitive. Moreover, the gene regulation and manufacturing fields are characterized by rapidly changing technologies and a strong emphasis on intellectual property. We may face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs, including inherited retinal diseases and neurodegenerative diseases. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Differences in the scientific approaches may create confusion or uncertainty among clinical trial investigators or patient populations, which could delay or hinder enrollment or initiation of our clinical trials.

Our platform and products focus on the development of gene therapies and gene regulation technology. In 2017, the FDA approved the first gene treatment for RPE65-associated retinal disease, Luxturna, a commercially available product developed by Spark Therapeutics, Inc., which was purchased by Roche. There are a number of other companies developing ocular gene therapy products, including Applied Genetic Technologies Corporation, and 4D Molecular Therapeutics, Inc. There are a number of companies developing gene therapy products for neurodegenerative diseases, including Voyager Therapeutics, Inc., Brain Neurotherapy Bio, Inc., and Eli Lilly and Company. In addition to competition from other gene therapies, any products we may develop may also face competition from other types of therapies, such as small molecule, antibody, or protein therapies. Many of our current or potential competitors, either alone or with their collaboration partners, have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific, manufacturing and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop, limiting demand or the price we are able to charge, or that could render any products that we may develop obsolete or non-competitive. Our competitors also may obtain FDA, MHRA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our products or procedures using our products, could reduce physician utilization of our products if approved. Assuming there is such coverage by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the UK, the EU or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many

countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our product candidates for sale at competitive prices;
- the convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support, and publicity concerning our products or competing products and treatments;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- product labeling or product insert requirements of the FDA, MHRA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenues for a substantial period, the failure of these product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates or realizing the synergies in the target indications of our programs, even if they are approved.

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so or we may seek collaborative arrangements or external funding to commercialize our product candidates. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of such capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates. Additionally, if any commercial launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may not have the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain markets. Therefore, our future sales in these markets will largely depend on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We may pursue collaborative arrangements regarding the sale and marketing of AAV-hAQP1, AAV-GAD, our IRD programs, our riboswitch gene regulation platform technology or other future gene therapy programs, if approved, for the United States and/or certain markets overseas; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces.

If we are unable to build our own sales force or negotiate or maintain a collaborative relationship for the commercialization of our product candidates, we may be forced to delay potential commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities internationally, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

Some indications targeted by our ophthalmology programs are rare, but we anticipate realizing synergies in commercializing our IRD product candidates, should they be approved. Failure to realize synergies in our sales, marketing and distribution efforts may harm our commercialization efforts.

If we or our collaborators are unable to establish or maintain adequate sales, marketing and distribution capabilities, we will not be successful in commercializing our product candidates and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If any of our products are commercialized outside of the United States, the UK or the EU, a variety of risks associated with international operations could adversely affect our business.

If any of our products are approved for commercialization, we have entered into, and intend to enter into, agreements with third parties to market them in certain jurisdictions outside the United States, the UK and the EU. We expect that we and our third-party collaborators will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug and biologic approvals and rules governing drug and biologic commercialization in foreign countries;
- tighter restrictions on data privacy and security and the collection and use of patient data;
- reduced or loss of protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- business interruptions resulting from geopolitical actions, including war and terrorism, or widespread health emergencies, or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the FCPA, the Bribery Act and similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- workforce uncertainty in countries where labor unrest is more common than in the United States and compliance with tax, employment, immigration and labor laws for employees living or traveling abroad.

We have no prior experience in these areas and we may rely on other third parties to help us establish our international commercialization operations. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we and our third-party collaborators will need to comply. If we are unable to successfully manage the challenges of international expansion and operations, our business and operating results could be harmed.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed by the FDA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Jurisdictions outside the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Risks Related to Our Dependence on Third Parties

If our GMP manufacturing facilities are unable to supply our product candidates for all of our current preclinical, clinical and potential commercial needs, including our third party supply obligations, we will be forced to seek out third-party manufacturers. We currently contract with third parties for the manufacture of plasmid used in producing product candidates. Relying on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We produce our product candidates in our GMP viral vector manufacturing facility in London, UK, completed in early 2018, and our second, large scale GMP viral vector manufacturing facility and our first GMP plasmid and DNA production facility came online in 2022 in Shannon, Ireland. However, if our current facilities are damaged, suffer any form of delay or regulatory challenges, we experience slowdowns or problems with our facilities or we are unable to scale our internal manufacturing capabilities to meet demand for our product candidates, we will need to contract with third-party manufacturers to produce our product candidates. We have also agreed to manufacture commercial supply of the RPGR Product for Johnson & Johnson Innovative Medicine, if and when approved, under the Supply Agreement. If we fail to meet our obligations under the Supply Agreement, we may not be able to find a third-party manufacturer suitable to us or Johnson & Johnson Innovative Medicine to perform such manufacturing obligations, which could negatively impact our receipt of revenues under the Supply Agreement. While we now have our own plasmid manufacturing capabilities in our Shannon, Ireland facilities, we also rely on third-party manufacturers from time to time for the manufacture of plasmid used in the production of some product candidates. We do not have a long-term supply agreement with any of the third-party manufacturers, and we purchase our required supply on a purchase order basis.

We and our third-party manufacturers may also encounter difficulties or delays in manufacturing of our product candidates or the plasmid used in the production of our product candidates. Geopolitical actions, natural disaster or a widespread health emergency could impact our supply chain. To the extent that we or our third-party manufacturers are located in geographies affected by these matters, it may result in the temporary closing of manufacturing facilities and may increase the costs associated with manufacturing our product candidates.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party, including failure to provide appropriate quantities in a timely manner;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

We and our third-party manufacturers may not be able to comply with GMP regulations or similar regulatory requirements that might be required by the FDA, MHRA or EMA. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could adversely affect supplies of our candidates and harm our business, financial condition, results of operations, and prospects.

Any therapies that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under GMP or similar regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or any components required for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We have in the past, and may in the future, collaborate with third parties for the development, manufacture and commercialization of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

We have entered into collaboration agreements with third parties for the development and commercialization of our product candidates, including the Collaboration Agreement with Johnson & Johnson Innovative Medicine for the development and commercialization of AAV-CNGB3, AAV-CNGA3 and bota-vec, which Collaboration Agreement was terminated in December 2023 in connection with our entering into the Asset Purchase Agreement with Johnson & Johnson Innovative Medicine. In addition, in October 2023 we provided Sanofi and its affiliates with a right of first negotiation for use of our riboswitch gene regulation technology for certain Immunology and Inflammation (I&I), including modulation of IL-4 and IL-13, and Central Nervous System (CNS) targets, as well as for GLP-1 and other gut peptides for metabolic disease, and for our Phase 2 xerostomia program, under the Investment Agreement. We may seek additional collaborative relationships in the future. Failure to obtain a collaborative relationship for our product

candidates may significantly impair their commercial potential. We also may need to enter into collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, such as:

- a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may not devote sufficient capital or resources towards our product candidates;
- a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our product candidate;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaboration partner may terminate a strategic alliance;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our products or technology in such a way as to make us subject to litigation with a third party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

We have relied, and we expect to continue to rely, on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if these third parties perform in an unsatisfactory manner, our business could be harmed.

We expect to rely on CROs, clinical trial sites, and other vendors to ensure our preclinical studies and clinical trials are conducted properly and on time. We may also engage third parties such as clinical data management organizations, medical institutions and clinical investigators to conduct or assist in our clinical trials or other preclinical and clinical research and development work. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our third-party service providers' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with applicable protocol, legal, quality, regulatory and scientific standards, including among other things, GCP requirements for clinical trials and GLP requirements for certain preclinical studies. Our reliance on these third parties does not relieve us of our regulatory responsibilities. For example, we are conducting the Phase 2 AQUAx2 clinical trial of AAV-hAQP1 for the treatment of patients with radiation-induced xerostomia at multiple clinical trial sites in North America and the United Kingdom. If any locations terminate the clinical trial, we may be required to find another party to conduct any new trials. We may be unable to find a new party to conduct new trials of our product candidates or obtain clinical supply of our product candidates or AAV vectors for such trials. If we elect to internalize some or all activities related to the conduct of our preclinical studies or clinical trials that are currently performed by our third-party service providers, or if we are required to do so due to a service provider's termination of our relationship, then we may be required to source additional technology and personnel in order to perform the relevant activities. We may be unsuccessful in our efforts to internalize some or all relevant activities, either on the desired timeline or at all.

Our third-party service providers are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time, attention, expertise and resources to our clinical and nonclinical programs. These third-party service providers may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our third-party service providers do not successfully carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our preclinical studies or clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates could be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

Risks Related to Intellectual Property

We depend on proprietary technology licensed from others. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.

We currently in-license certain intellectual property from research institutions, universities and other third parties. We may also enter into additional agreements, including license agreements, with other parties in the future that

impose diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us. If we fail to comply with our obligations to any of our current or future collaborators, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may rely on other third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than if we conduct them ourselves. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

If we are unable to obtain and maintain patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our proprietary technologies, product candidate development programs and product candidates. Our success depends in part on our ability to secure and maintain patent protection in the United States and other countries with respect to our current product candidates and any future product candidates we may develop. We seek to protect our proprietary position by filing or collaborating with our licensors to file patent applications in the United States and abroad related to our proprietary technologies, development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain.

It is also possible that we might fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our proprietary products and technology, including current product candidates, any future product candidates we may develop, and our gene regulation technology in the United States or in other countries, in whole or in part. Alternately, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. For example, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States

and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Even if patents do successfully issue and even if such patents cover our current product candidates, any future product candidates we may develop and our gene regulation technology, third parties may challenge their validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any of our product candidates or gene regulation technology. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and our gene regulation technology under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our current or future product candidates or technology, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our ability to commercialize future product candidates. Any such outcome could harm our business.

The patent position of biotechnology and pharmaceutical companies is uncertain, involves complex legal and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our product candidates, prohibit our use of proprietary technology or sale of products or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary

rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and *inter partes* reviews, and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review and *inter partes* review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents, and the holders of any such patents may be able to prohibit our use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license.

In addition, defending such claims would cause us to incur substantial expenses and, if we are not successful in defending such claims, it could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially include increased damages (possibly treble damages) and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Competitors may infringe our patents or other intellectual property. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal

responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop, manufacture and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, the UK, the EU and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, the UK, the EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could be filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the UK, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the biotechnology and genetic medicine industries involve both technological complexity and legal complexity. In addition, the Leahy-Smith America Invents Act, or the AIA, which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent

applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant of the time from invention to filing of a patent application and diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

In addition, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents that may be important for our business.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States, the UK or the EU. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States, the UK and the EU, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke

third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts, or the efforts of our licensors or collaborators, to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. In the UK and the EU, our product candidates may be eligible for term extensions based on similar legislation. In each of these jurisdictions, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be essentially shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction in revenue from applicable products could be substantial.

Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as

alternatives or replacements for any of our technologies without infringing our intellectual property rights;

- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;

- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;

- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;

- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; and

- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and confidential know-how are difficult to protect, and we have limited control over the protection of trade secrets and confidential know-how used by our licensors, collaborators and suppliers. Because we have relied in the past on third parties to manufacture our product candidates, because we may continue to do so in the future, and because we expect to collaborate with third parties on the development of our current product candidates and any future product candidates we develop, we may, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Under such circumstances, trade secrets and confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may also be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or

confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademark MeiraGTx is the subject of registrations and/or pending applications in the EU, UK and United States. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We may need to license or acquire additional intellectual property from third parties, and such intellectual property may not be available or may not be available on commercially reasonable terms.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve product candidates or equipment that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compositions and pre-existing pharmaceutical compositions. These pharmaceutical products may be covered by intellectual property rights held by others. We may be required by the FDA, MHRA, EMA or other foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

Risks Related to Employee Matters and Managing Growth

We may need to increase or decrease the size of our organization, and we may experience difficulties in managing those organizational changes, which could disrupt our operations.

As of December 31, 2024, we had 381 employees. If we seek to expand our organization, we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in

our infrastructure, give rise to operational mistakes, loss of business opportunities or strategic opportunities related to our assets, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy. Many of the biotechnology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited. Alternatively, if we seek to decrease the number of employees in our organization in the future in response to adverse business events, it may lead to additional unanticipated attrition. If our future staffing is inadequate because of additional unanticipated attrition or because we failed to retain the staffing level required to accomplish our business objectives, we may be delayed or unable to continue the development of our product candidates, which could impede our ability to generate revenues and achieve or maintain profitability.

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Alexandria Forbes, Ph.D., our President and Chief Executive Officer, Rich Giroux, our Chief Operating Officer and Chief Financial Officer and Stuart Naylor, Ph.D., our Chief Development Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have formal employment agreements with certain of our executive officers, these agreements do not prevent them from terminating their employment with us at any time and, for certain of our executive officers, entitle them to receive severance payments in connection with their voluntary resignation of employment.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had

unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant time, costs and diversion of management resources to defend the related litigation;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our product candidates, if approved for commercial sale; and
- loss of revenue.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, clinical product and clinical trial liability, employment practices liability, property, transit, auto, workers' compensation, umbrella, cyber and directors' and officers' insurance. Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and restrictive, and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for our product candidates or manufacture commercial products for third parties, we intend to acquire insurance coverage to include, as necessary, the sale, manufacture and supply of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Operating as a public company may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. If we are unable to maintain existing insurance with adequate levels of coverage, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors, and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) applicable laws and regulations of the FDA, MHRA, EMA and other regulatory or governmental authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy and security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Our business and operations may suffer in the event of system failures and our systems and those of our business partners and service providers may be vulnerable to cybersecurity risks.

Our information technology, or IT, systems, including manufacturing systems, as well as those of our business partners and service providers, are vulnerable to damage from computer viruses, unauthorized access, hardware and software failures, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur, it could result in a material disruption of our product candidate development programs or manufacturing operations. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. A significant interruption to our manufacturing operations could delay the completion of clinical trials and increase the costs of those trials, or impede our ability to meet any third party supply obligations. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

In the ordinary course of our business, we, our business partners and our service providers collect, process and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees. The secure processing, maintenance and transmission of this information is critical to our operations. Increased cybersecurity threats pose a risk to this information, in addition to our and our business partners' and service providers' systems and networks. Cybersecurity threats including state-sponsored attacks, ransomware, phishing, insider threats, supply chain compromises, and vulnerabilities in cloud-based services, are increasing in frequency, sophistication, persistence and severity. Attackers, ranging from criminal organizations to nation-state actors, may target our systems for financial, competitive, or political

motives. We may also face increased cybersecurity risks due to our reliance on internet technology and by allowing some of our employees to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Despite our security measures, our IT and infrastructure may be vulnerable to cyber-attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions that could have a negative impact, including loss or destruction of data, including confidential or critical business information. In addition, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully effective in protecting our systems and information. Although, to our knowledge, we have not experienced any such material security breach to date, we may experience cybersecurity incidents such as malware infections, ransomware, phishing attempts, thefts of personal, confidential, proprietary or other critical business information and other attempts at compromising our IT that are typical for a company of our size in our market. Any security breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, result in significant expenses in implementing future security measures and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and financial results, and delay clinical development of our product candidates.

Risks Related to Our Ordinary Shares

The market price of our ordinary shares may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our ordinary shares.

Our share price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your ordinary shares at or above your purchase price. The market price for our ordinary shares may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- developments related to our existing or any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;

- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the impact of any potential strategic transactions related to our assets;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines, recommendations by securities analysts or shifting investor perceptions;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- changes in accounting principles; and
- the other factors described in this "Item 1A. Risk Factors" section and elsewhere in this Form 10-K.

In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a security has been volatile, holders of that security have sometimes instituted securities class action litigation against the issuer. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If any of the holders of our ordinary shares were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities. Broad market and industry factors may negatively affect the market price of our ordinary shares, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause the price of our ordinary shares to decline rapidly and unexpectedly. If the market price of our ordinary shares does not exceed your purchase price, you may not realize any return on your investment in us and may lose some or all of your investment.

We may raise additional capital pursuant to our shelf registration statement, including through our "at-the-market" offering program, or through additional public or private placements, any of which could substantially dilute the investment of our stockholders.

Sales of a substantial number of our ordinary shares in the public market could dilute your ownership interest. Pursuant to an "at-the-market" sales agreement we entered into with BofA Securities, Inc., or BofA, in December 2023, we may sell from time to time, ordinary shares having an aggregate offering price of up to $100.0 million through BofA, acting as our agent. During the year ended December 31, 2024, the Company raised gross proceeds of $8.4 million through the sale of 1,508,517 ordinary shares pursuant to an "at-the-market" equity offering program. Whether we choose to affect future sales under the "at-the-market" equity offering program will depend on a number of factors, including, among others, market conditions and the trading price of our ordinary shares relative to other sources of capital. The issuance from time to time of ordinary shares through our "at-the-market" equity offering program or in any other equity offering, or the perception that such sales may occur, could have the effect of depressing the market price of our ordinary shares.

Our executive officers, directors and principal shareholders, if they choose to act together, have the ability to significantly influence all matters submitted to shareholders for approval.

As of December 31, 2024, our executive officers, directors and shareholders who owned more than 5% of our outstanding ordinary shares and their respective affiliates, in the aggregate, hold ordinary shares representing approximately 56.5% of our outstanding ordinary shares. In addition, in connection with entering into the Financing Agreement, we issued to an affiliate of Perceptive Advisors, LLC, our largest shareholder that employs a director serving on our board, warrants to purchase an aggregate of 700,000 of our ordinary shares.

As a result, if these shareholders choose to act together, they would be able to significantly influence all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors, the composition of our management and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination that other shareholders may desire. Any of these actions could adversely affect the market price of our ordinary shares.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our ordinary shares less attractive to investors.

We are a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting ordinary shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting ordinary shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, not being required to provide selected financial data, supplemental financial information or risk factors.

We may choose to take advantage of some, but not all, of the available exemptions for smaller reporting companies. We cannot predict whether investors will find our ordinary shares less attractive if we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Anti-takeover provisions in our organizational documents and Cayman Islands law may discourage or prevent a change of control, even if an acquisition would be beneficial to our shareholders, which could depress the price of our ordinary shares and prevent attempts by our shareholders to replace or remove our current management.

Our memorandum and articles of association contain provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. Our board of directors is divided into three classes with staggered, three-year terms. Our board of directors has the ability to designate the terms of and issue preferred shares without shareholder approval. We are also subject to certain provisions under Cayman Islands law that could delay or prevent a change of control. Together these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our ordinary shares.

There may be difficulties in enforcing foreign judgments against our management or us.

Certain of our directors and management reside outside the United States. A significant portion of our assets and such persons' assets are located outside the United States. As a result, it may be difficult or impossible for investors to effect service of process upon us within the United States or other jurisdictions, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

In particular, investors should be aware that there is uncertainty as to whether the courts of the Cayman Islands or any other applicable jurisdictions would recognize and enforce judgments of U.S. courts obtained against us or our directors or management predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States or entertain original actions brought in the Cayman Islands or any other applicable jurisdiction's courts against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

The rights of our shareholders differ from the rights typically offered to shareholders of a U.S. corporation.

Our corporate affairs and the rights of holders of ordinary shares are governed by Cayman Islands law, including the provisions of the Cayman Islands Companies Act (as amended), or the Companies Act, the common law of the Cayman Islands and by our memorandum and articles of association. We are also subject to the federal securities laws of the United States. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, the decisions of whose courts are of persuasive authority, but are not binding on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are different from what they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a different body of securities laws as compared to the United States, and certain states, such as Delaware, may have more fully developed and judicially interpreted bodies of corporate law. In addition, Cayman Islands companies may not have standing to initiate a shareholders derivative action in a Federal court of the United States.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a United States company.

We expect to be treated as resident in the UK for tax purposes, but may be treated as a dual resident company for UK tax purposes.

Our board of directors conducts our affairs so that the central management and control of the company is exercised in the UK. As a result, we expect to be treated as resident in the UK for UK tax purposes. Accordingly, we expect to be subject to UK taxation on our income and gains, except where an exemption applies.

However, we may be treated as a dual resident company for UK tax purposes. As a result, our right to claim certain reliefs from UK tax may be restricted, and changes in law or practice in the UK could result in the imposition of further restrictions on our right to claim UK tax reliefs.

We may be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in our ordinary shares.

Based on the current and anticipated value of our assets, including goodwill, and the current and anticipated composition of our income, assets and operations, we do not believe we were a PFIC for the taxable year ended on December 31, 2024, and do not expect to be a PFIC for the current taxable year. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you that the U.S. Internal Revenue Service, or the IRS, will not take a contrary position. Furthermore, a separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. Accordingly, we cannot assure you that we were not a PFIC for our taxable year ended on December 31, 2024 or that we will not be a PFIC for our current taxable year or any future taxable year. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The value of our assets generally is determined by reference to the market price of our ordinary shares, which may fluctuate considerably. In addition, the composition of our income and assets is affected by how, and how quickly, we spend any cash we raise. If we were to be classified as a PFIC for any taxable year during which a U.S. holder holds our ordinary shares, certain materially adverse U.S. federal income tax consequences could apply to such U.S. holder.

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. holder of our ordinary shares is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, such U.S. holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). If our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether we are treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations from starting with respect to your U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. holders of our ordinary shares should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares.

Changes in tax laws or challenges to our tax position could adversely affect our results of operations and financial condition.

We are subject to complex tax laws that are subject to change or differing interpretations, including on a retroactive basis. Any such changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate could adversely affect our tax position, including our effective tax rate or tax payments.

We have significant U.S. federal and state net operating losses, or NOLs, and UK and Ireland carryforward tax losses which we may not be able to realize or which may be restricted under applicable law. We also benefit from certain tax incentive regimes, such as research and development tax credits. Any adverse change to these regimes, the application thereof or challenges to the tax position we have adopted under these rules could adversely affect our results of operations and financial condition.

As of December 31, 2024, we had federal and state NOL carryforwards in the United States of $74.3 million and $19.3 million, respectively, and cumulative carryforward tax losses in the UK of $203.7 million, which we expect to be available to reduce future taxable income subject to any relevant restrictions (including those in the U.S. and UK that limit the percentage of taxable income that can be reduced by NOLs and carried forward losses). As of December 31, 2024, cumulative carryforward tax losses in Ireland were $78.3 million. U.S. federal NOLs generated after December 31, 2017 are not subject to expiration but such NOLs may only offset 80% of taxable income for taxable years beginning after December 31, 2020. U.S. federal NOLs generated prior to December 31, 2017 may only be carried forward for 20 years. As of December 31, 2024, we also had orphan drug and research and development credits in the U.S. in the amount of $22.5 million, both of which may be carried forward for 20 years and are expected to begin expiring in 2035 if not utilized. We also had research and development credits in the UK of $1.9 million, which may be carried forward indefinitely until utilized. The UK and Ireland carryforward tax losses will continue indefinitely, subject to relevant restrictions, under current jurisdictional tax law.

The NOLs and carryforward tax losses are subject to review and possible adjustment by the applicable tax authorities. Additionally, carryforward tax losses, and research and development tax credits, may become subject to limitations in the event of certain cumulative changes in the ownership interest of significant shareholders, as determined under Sections 382 of the United States Internal Revenue Code, as well as the Corporation Tax Act 2010 Part 14 under the UK tax rules and the Taxes Consolidation Act 1997 (TCA 1997) under the Ireland tax rules. This could limit the amount of NOLs or carryforward tax losses that we can utilize annually to offset future taxable income or tax liabilities. We have conducted a review of changes in the ownership interest of significant shareholders and determined that as of August 2024, there were no limitations in the UK. However, for U.S. purposes, we determined that a change of ownership occurred in April 2016 and again in June 2018, but there was not a limit for utilizing these losses to offset the 2022 income. We have performed a 382 analysis through August 2024 and no additional change of ownership has occurred. Subsequent ownership changes and changes to the U.S. federal or state or UK tax rules in respect of the utilization of NOLs and carryforward tax losses may further affect the limitation in future years.

General Risk Factors

We may engage in acquisitions that could disrupt our business, cause dilution to our shareholders or reduce our financial resources.

We have, and may in the future, enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our ordinary shares or other equity securities to the shareholders of the acquired company, which would reduce the percentage ownership of

our existing shareholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Exchange rate fluctuations may adversely affect our results of operations and financial condition.

Owing to the international scope of our operations, fluctuations in exchange rates may adversely affect us, particularly between the U.S. dollar on the one hand, and the pound sterling and euro on the other hand. As a result, our business and the market price of our securities may be affected by such fluctuations, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Our management team has broad discretion as to the use of the net proceeds from public and private equity or debt financings and the investment of these proceeds may not yield a favorable return. We may invest the proceeds in ways with which our shareholders disagree.

We have broad discretion in the application of any net proceeds we have received in the past or may receive in the future pursuant to existing or future equity and debt financings, including under our "at-the-market" equity offering program. Shareholders may not agree with our decisions, and our use of the proceeds and our existing cash and cash equivalents may not improve our results of operation or enhance the value of our ordinary shares. Our ability to apply certain proceeds may be restricted. For example, in August 2024, we conducted an equity financing by selling an aggregate of 12.75 million ordinary shares at a price of $4.00 per share for gross proceeds of $51.0 million. Our failure to apply any such funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the market price of our ordinary shares to decline. In addition, until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value. Additionally, our existing cash and cash equivalents are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crises. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

We incur substantial costs as a result of operating as a public company, and our management is required to devote substantial time to new and existing compliance initiatives and corporate governance practices.

As a public company, and particularly since we no longer qualify as an emerging growth company and if we no longer qualify as a smaller reporting company or a non-accelerated filer in the future, we incur and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, The Nasdaq Global Select listing requirements and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we are a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess

and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we, or our independent registered public accounting firm, if we no longer qualify as a non-accelerated filer, will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. If we identify one or more material weaknesses or determine we have inadequate internal controls, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If securities or industry analysts cease to publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our ordinary shares, our share price and trading volume could decline.

The trading market for our ordinary shares relies in part on the research and reports that industry or securities analysts publish about us or our business. We do not control these analysts. Furthermore, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our share performance, or if any of our preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our share price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Expectations relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from the SEC, foreign regulators, stock exchanges, certain investors and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance factors. The SEC has adopted rules regarding new climate-related disclosure, which have been stayed by the SEC pending the outcome of pending litigation challenging the new rules. Some investors may use these and other environmental, social and governance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and disclosures relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have varied and in some cases inconsistent standards. In addition, the criteria by which companies' corporate responsibility practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy such new criteria or do not meet the criteria of a specific third-party provider, some investors may conclude that our policies with respect to corporate responsibility are insufficient. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies. Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate or disclose certain initiatives and goals regarding environmental, social and governance matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals or be subject to litigation for such failures. If we fail to satisfy the expectations of investors and other stakeholders or our initiatives are not executed as planned, our reputation and financial results could be adversely affected.

Because we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

Under Cayman Islands law, we may only make distributions by way of dividend out of profits, or out of our share premium account (provided that immediately following the date that the dividend is proposed to be paid we are

able to pay our debts as they fall due in the ordinary course of business). We have never declared or paid any cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the Notes Purchase Agreement prohibits us from paying dividends during its term and the terms of existing and future financing agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our ordinary shares would be your sole source of gain on an investment in our ordinary shares for the foreseeable future. See the "Dividend Policy" section of this Form 10-K for additional information.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We have implemented and maintain a cybersecurity risk management program that includes processes designed for the identification, assessment and mitigation of cybersecurity risks in order to protect the confidentiality, integrity and availability of our critical systems and information. We have designed and assessed our program based on the Center for Internet Security (CIS) Controls standard and the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF).

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- security controls and mitigation measures designed to manage and mitigate material risks from cybersecurity threats to our critical systems and information;
- an IT and security team responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls and mitigation measures, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, IT and security personnel and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a risk-based approach to identifying and overseeing third party cybersecurity risks, including evaluating the cybersecurity processes of service providers and other vendors, and reviewing available security certifications and independent audit reports.

Although, to our knowledge, we have not experienced any material cybersecurity breach to date, we may experience cybersecurity incidents and face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations or financial condition. For more information regarding how cybersecurity risks may affect us, see "Item 1A Risk Factors."

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated oversight of cybersecurity and other IT risks to the Audit Committee. The Audit Committee oversees management's implementation of our cybersecurity risk management program.

The Audit Committee receives reports from management on our cybersecurity risks at least semi-annually. In addition, management updates the Audit Committee regarding cybersecurity matters, as necessary, including any material cybersecurity incidents, as well as any incidents with lesser impact potential. The Audit Committee reports to the full Board regarding its activities and the full Board periodically receives briefings from management on our cybersecurity risk management program.

Our management team is responsible for assessing and managing risks from cybersecurity threats. The Vice President, Global IT and Senior Vice President, Risk and Internal Controls have primary responsibility for our overall cybersecurity risk management program and supervise both our internal cybersecurity personnel and our external cybersecurity consultants. They provide briefings to the management team, including the Chief Financial Officer/Chief Operating Officer and the General Counsel and Secretary, as well as the Board and the Audit Committee. Their briefings include topics such as threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us. The briefings also cover alerts and reports produced by security tools deployed in our IT environment. Our Vice President, Global IT has over 20 years' experience leading teams in cybersecurity, and designing and securing critical IT infrastructure in the healthcare, biotech and sports entertainment sectors. Our Senior Vice President, Risk and Internal Controls has more than 30 years' experience designing, implementing and leading risk management, internal control and compliance programs, including cybersecurity, data privacy and business resilience, in global organizations.

ITEM 2. PROPERTIES

Our principal office is located at 450 East 29th Street, New York, New York, USA, where we lease 22,721 square feet of office and laboratory space. We lease this office space under a lease that terminates on October 31, 2026.

We own a long leasehold interest in the ground rights where our 29,000 square foot GMP viral vector manufacturing facility is located, at 92 Britannia Walk, London, United Kingdom. The long leasehold interest expires in 2126, and there is no facility rent due. We also own the buildings housing our second, large scale GMP viral vector manufacturing facility and our first GMP plasmid and DNA production facility located in Buildings 2 and 3, Block K, Airport Avenue, Shannon Free Zone, Shannon Ireland. The Shannon campus encompasses an aggregate of 150,000 square feet. We entered into a lease for each property providing for a long leasehold interest that expires in 2211.

Additionally, we lease an 11,306 square foot office facility located at 34-38 Provost Street, London, United Kingdom and 6,679 square feet of laboratory facilities at 15 Ebenezer Street, London, United Kingdom. The office space lease terminates on September 8, 2029 and the laboratory leases terminate on May 24, 2027.

ITEM 3. LEGAL PROCEEDINGS

We are not subject to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our ordinary shares trade on the Nasdaq Global Select Market under the symbol "MGTX."

Holders of Record

As of February 28, 2025, there were 51 holders of record. The actual number of shareholders of our ordinary shares is greater than this number of record holders and includes shareholders who are beneficial owners but whose ordinary shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose ordinary shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our ordinary shares. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the Notes Purchase Agreement prohibits us from paying dividends during its term and the terms of existing and future financing agreements may also preclude us from paying dividends. However, if we do pay a cash dividend on our ordinary shares in the future, we will only pay such dividend out of our profits or share premium (subject to solvency requirements) as permitted under Cayman Islands law.

Recent Sales of Unregistered Securities

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and operating results together with our financial statements and the related notes appearing in this Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those set forth in the section of this Form 10-K captioned "Item 1A. Risk Factors" and elsewhere in this Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis. For convenience of presentation some of the numbers have been rounded in the text below.

Overview

We are a vertically integrated, clinical-stage genetic medicines company with a broad pipeline of late-stage clinical programs, including Parkinson's disease, radiation-induced xerostomia and AIPL1-associated retinal dystrophy. Our clinical programs use targeted local delivery of small doses of genetic medicines to treat both inherited and more common conditions with severe unmet need. The successful development of the clinical pipeline is supported by our internal end-to-end manufacturing capabilities. We have two GMP viral vector production facilities, internal plasmid production for GMP, as well as an in-house Quality Control hub for stability and release, all fit for IND through

commercial supply. In addition, we have developed a proprietary manufacturing platform with leading yield and quality aspects and commercial readiness. Our core capabilities in viral vector and capsid optimization allow increased potency, decreased dose and significantly reduced cost of goods for our genetic medicines. We have developed a potentially transformative gene regulation platform using bespoke synthetic riboswitch technology invented in-house that allows for the precise, dose-responsive control of any transgene under the control of oral small molecules. We are focusing the riboswitch platform on *in vivo* delivery of biologic therapeutics such as the metabolic peptides GLP-1, GIP, glucagon, amylin, PYY and leptin via oral small molecules, as well as cell therapy for oncology and autoimmune diseases, and long-term intractable pain. We have developed unique comprehensive technology capabilities to apply genetic medicine to more common diseases, increasing efficacy, addressing novel targets, and expanding access in some of the largest disease areas where the unmet need remains high.

We are an exempted company incorporated under the laws of the Cayman Islands in 2018, and prior to that, we commenced operations as MeiraGTx Limited, a private limited company incorporated under the laws of England and Wales in 2015. Our discussion of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). Since our formation, we have devoted substantially all of our resources to developing our technology platform, establishing our viral vector manufacturing facilities and our GMP plasmid and DNA production facility and developing manufacturing processes, advancing the product candidates in our ophthalmology, salivary gland and neurodegenerative disease programs, building our intellectual property portfolio, organizing and staffing our company, developing our business plan, raising capital, and providing general and administrative support for these operations. To date, we have financed our operations primarily with cash on hand and proceeds from the sales of our Series A ordinary shares, Convertible Preferred C Shares and ordinary shares, debt financing and upfront and milestone payments in connection with the Collaboration Agreement and Asset Purchase Agreement. Through December 31, 2024, we received gross proceeds of approximately $622.3 million from sales of our ordinary shares, Series A ordinary shares and convertible preferred C shares, gross proceeds of approximately $75.0 million from issuance of debt, $130.0 million from the Collaboration Agreement with Johnson & Johnson Innovative Medicine, and $125.0 million from the Asset Purchase Agreement with Johnson & Johnson Innovative Medicine. As of December 31, 2024, we had cash, cash equivalents and restricted cash of $105.7 million, as well as $0.7 million we expect to receive from Johnson & Johnson Innovative Medicine in the first quarter of 2025 in connection with the PPQ and transition services we provided to Johnson & Johnson Innovative Medicine.

We are a clinical stage company and have not generated any product revenues to date. We have ongoing clinical development programs and a broad pipeline of preclinical programs. Since inception, we have incurred significant operating losses. Our net losses for the years ended December 31, 2024 and 2023 were $147.8 million and $84.0 million, respectively. As of December 31, 2024, we had an accumulated deficit of $702.0 million. We do not expect to generate revenue from sales of products unless and until we successfully initiate and complete clinical development and obtain regulatory approval for any product candidates, or satisfy our third party obligations. Under the Collaboration Agreement, we received an upfront payment in the amount of $100.0 million in March 2019 and a milestone payment in the amount of $30.0 million in December 2021. Additionally, pursuant to the Collaboration Agreement, we received research and development funding for certain research, manufacturing and clinical development costs. On December 20, 2023, we entered into an Asset Purchase Agreement with Johnson & Johnson Innovative Medicine pursuant to which the Company sold and assigned to Johnson & Johnson Innovative Medicine a License Agreement between the Company and UCLB relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the Asset Purchase Agreement. In connection with entering into the Asset Purchase Agreement, we entered into a Termination Agreement with Johnson & Johnson Innovative Medicine terminating the Collaboration Agreement. The Company and Johnson & Johnson Innovative Medicine also entered into a Supply Agreement on December 20, 2023 pursuant to which the Company agreed to manufacture and supply the RPGR Product for Johnson & Johnson Innovative Medicine. In December 2023, we received a non-refundable upfront payment of $65.0 million in connection with the Asset Purchase Agreement. During the year ended December 31, 2024, we received $60.0 million in milestone payments under the Asset Purchase Agreement.

Our total operating expenses were $197.5 million and $151.1 million for the years ended December 31, 2024 and 2023, respectively. We expect to continue incurring increasing costs associated with our clinical activities for AAV-hAQP1 for the treatment of radiation-induced xerostomia and xerostomia associated with Sjogren's syndrome, AAV-GAD for the treatment of Parkinson's disease, as well as costs associated with the delivery of services under the Asset Purchase and related agreements. We also incurred expenses during the year ended December 31, 2024 and expect to continue to incur expenses related to research activities in additional therapeutic areas to expand our pipeline, developing our potentially transformative gene regulation technology, hiring additional personnel as needed in manufacturing, research, clinical operations, quality and other functional areas, and associated cash and share-based compensation expense, as well as the further development of internal manufacturing capabilities and capacity and other associated costs including the management of our intellectual property portfolio.

On May 3, 2023, we entered into a securities purchase agreement with certain accredited investors, pursuant to which we, in a private placement, agreed to issue and sell an aggregate of 10,773,913 ordinary shares at a purchase price of $5.75 per share, for gross proceeds of approximately $62.0 million. The closing occurred on May 5, 2023.

On October 30, 2023, we entered into the Investment Agreement with Sanofi Foreign Participations, and solely for the limited purposes set forth therein, Sanofi, pursuant to which, among other things and subject to the terms and conditions specified therein, we issued an aggregate of 4,000,000 ordinary shares of the Company at a purchase price of $7.50 per share for gross proceeds of $30.0 million. The Investment Agreement also provides Sanofi Foreign Participations and its affiliates with a right of first negotiation for use of our riboswitch gene regulation technology for certain Immunology and Inflammation (I&I), including modulation of IL-4 and IL-13, and Central Nervous System (CNS) targets, as well as for GLP-1 and other gut peptides for metabolic disease, and for our Phase 2 xerostomia program, in each case, on the terms set forth therein.

On December 20, 2023, we entered into an Asset Purchase Agreement with Johnson & Johnson Innovative Medicine pursuant to which the Company sold and assigned to Johnson & Johnson Innovative Medicine a License Agreement between the Company and UCLB relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the APA. In connection with entering into the Asset Purchase Agreement, we entered into a Termination Agreement with Johnson & Johnson Innovative Medicine terminating the Collaboration Agreement. The Company and Johnson & Johnson Innovative Medicine also entered into a Supply Agreement on December 20, 2023 pursuant to which we agreed to manufacture and supply the RPGR Product for Johnson & Johnson Innovative Medicine. Under the Asset Purchase Agreement, Johnson & Johnson Innovative Medicine paid the Company a non-refundable upfront cash payment of $65.0 million in December 2023. Additionally, pursuant to and subject to the terms and conditions set forth in the Asset Purchase Agreement, Johnson & Johnson Innovative Medicine agreed to pay the Company future contingent consideration of up to an aggregate of $350.0 million, as follows: (i) a milestone payment of $50.0 million in connection with the achievement of the initiation of the extension study for the Phase 3 LUMEOS clinical trial for the RPGR Product; (ii) $10.0 million upon completion of certain specified development services for the drug substance for the RPGR Product; (iii) $5.0 million upon completion of certain specified development services for the drug product for the RPGR Product; (iv) $175.0 million upon the first commercial sale of an RPGR Product in the United States; (v) $75.0 million upon the first commercial sale of an RPGR Product in at least one of the United Kingdom, France, Germany, Spain and Italy; (vi) $25.0 million upon completion of the transfer of certain manufacturing technology for drug substance and drug product from the Company to Johnson & Johnson Innovative Medicine; and (vii) $10.0 million upon regulatory approval of a Johnson & Johnson Innovative Medicine-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. As of December 31, 2024, we have received $60.0 million in milestone payments from Johnson & Johnson Innovative Medicine. Johnson & Johnson Innovative Medicine is also responsible for any royalty or milestone amounts that become payable on the RPGR Product under the UCLB RPGR License Agreement.

In December 2023, we entered into an "at-the-market" sales agreement with BofA Securities, Inc., or BofA, pursuant to which we may sell from time to time, ordinary shares having an aggregate offering price of up to $100.0 million through BofA, acting as our agent. During the year ended December 31, 2024, we raised gross proceeds of $8.4

million through the sale of 1,508,517 ordinary shares pursuant to an "at-the-market" equity offering program. Under the "at-the-market" equity program which is currently effective and may remain available for us to use in the future, we may sell an additional $91.6 million of ordinary shares. Whether we choose to affect future sales under the "at-the-market" equity offering program will depend on a number of factors, including, among others, market conditions and the trading price of our ordinary shares relative to other sources of capital.

On August 12, 2024, we entered into an underwriting agreement with BofA in connection with the issuance and sale by the Company in a public offering of 12,500,000 of our ordinary shares at a public offering price of $4.00 per share, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 (Registration No. 333-276183) and a related prospectus supplement filed with the SEC. The closing of the offering occurred on August 13, 2024. We received gross proceeds from the offering of $50.0 million and incurred underwriting discounts and commissions and estimated offering expenses of approximately $1.9 million.

On August 12, 2024, the Company agreed to sell shares to an accredited investor (the "Investor") through a private placement rather than through the public offering and as a result, on August 23, 2024, we entered into a securities purchase agreement with the Investor, pursuant to which we, in a private placement, agreed to issue and sell to the Investor 250,000 ordinary shares at a purchase price of $4.00 per share, for gross proceeds of $1.0 million (the "Private Placement"). The closing of the Private Placement occurred on August 29, 2024.

We will require additional capital in the future, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our product candidates. Furthermore, we expect to continue incurring costs associated with being a public company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

Based on our cash, cash equivalents, accounts receivable – related party and tax incentive receivable at December 31, 2024, together with the proceeds from the anticipated closing of the strategic collaboration with Hologen Ltd, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2027 and to repay our debt obligation of $75.0 million to Perceptive (due in August 2026). This estimate does not include the $285.0 million in milestones we are eligible to receive under the Asset Purchase Agreement upon first commercial sale of an RPGR Product in the United States and in at least one of the United Kingdom, France, Germany, Spain and Italy, for completion of the transfer of certain manufacturing technology to Johnson & Johnson Innovative Medicine and upon regulatory approval of a Johnson & Johnson Innovative Medicine-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. See "Liquidity and Capital Resources." Because of the numerous risks and uncertainties associated with the development of our product candidates, any future product candidates, our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Any future debt financing or preferred equity or other financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital

expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interests.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Highlights and Recent Developments

Strategic Collaboration with Hologen AI:

- We will receive $200 million in upfront cash consideration at closing.
- We and Hologen will form a joint venture, Hologen Neuro AI Ltd, with additional committed funding from Hologen of up to $230 million into the joint venture to finance the development of the AAV-GAD program in Parkinson's disease to commercialization, as well as other locally-delivered therapies to the CNS.
- The joint venture, Hologen Neuro AI Ltd, will use Hologen's proprietary multi-modal generative foundation models (LMMs).
- We will hold a 30% ownership in the joint venture and will lead all clinical development and manufacturing.
- Hologen Neuro AI Ltd will enter into both clinical and commercial manufacturing supply agreements with us for exclusive manufacturing of AAV-GAD and other locally-delivered genetic medicines targeting the CNS.
- Hologen will own a minority stake in our manufacturing subsidiary and will contribute a portion of the annual funding and deploy Hologen's world leading generative AI capabilities to further accelerate the optimization of our proprietary manufacturing capabilities.

AAV-GAD for the Treatment of Parkinson's Disease:

- Announced positive data in October 2024 from randomized, sham-controlled clinical bridging study of AAV-GAD for the treatment of Parkinson's disease.
- The primary study objective of safety and tolerability was met.
- Significant and clinically meaningful improvements from baseline demonstrated for key efficacy endpoints at 26 weeks.
- Significant improvement of 18 points in Unified Parkinson's Disease Rating Scale (UPDRS) Part 3 in the high dose group at 26 weeks (p=0.03).
- Significant improvement in the Parkinson's Disease Questionnaire (PDQ-39) score, a key quality of life measure, for both the high and low dose groups at 26 weeks.

AAV2-hAQP1 for the Treatment of Xerostomia:

- In December 2024, we were granted RMAT Designation by the FDA for AAV2-hAQP1 for the treatment of Grade 2/3 RIX.
- RMAT designation includes the benefits of the Fast Track and Breakthrough Therapy designations, allows frequent regulatory interactions with the FDA, and potential routes to accelerated approval and Priority Review.

- We have gained alignment with the FDA on requirements for the ongoing Phase 2 AQUAx2 clinical trial for Grade 2/3 RIX to be considered a pivotal trial in support of a potential BLA filing based on the use of material manufactured using our proprietary production process and in-house manufacturing.
- Data from our Phase 1 AQUAx clinical trial were presented in an oral session at the American Academy of Oral Medicine (AAOM) 2024 annual meeting in April 2024, demonstrating that treatment with AAV2-hAQP1 resulted in significant improvements across three different patient-reported outcomes and in saliva production, with no treatment-related serious adverse events or dose-limiting toxicities reported. These data underpinned this successful RMAT designation.
- The Phase 2 AQUAx2 (NCT05926765) randomized, double-blind, placebo-controlled study continues to enroll and dose participants at multiple sites in the U.S., Canada and the U.K.
- The RMAT designation will allow us to benefit from increased interactions with the FDA to further accelerate the development pathway and potential BLA filing based on data from the ongoing pivotal study in 2026.

AAV-AIPL1 Specials License in the UK:

- In February 2025, we announced that data demonstrating the efficacy of rAAV8.*hRKp.AIPL1* for the treatment of LCA4 were published in *The Lancet* in a paper titled, "*Gene therapy in children with AIPL1-associated severe retinal dystrophy: an open-label, first-in-human interventional study*".
- As disclosed in the paper, 4 out of 4 young children with the AIPL1-associated retinal dystrophy, LCA4, benefited substantially from unilateral subretinal administration of rAAV8.hRKp.*AIPL1* with improved visual acuity, functional vision, and protection against progressive retinal degeneration.
- Following the strong safety and substantial efficacy demonstrated in this first cohort of 4 children treated unilaterally, a further 7 children were treated bilaterally, and all showed substantial benefit from treatment with rAAV8.*hRKp.AIPL1*.
- Meaningful responses were observed in 11 out of 11 LCA4 children treated to date with rAAV8.*hRKp.AIPL1*.
- Following recent meetings with the MHRA, we intend to submit a Marketing Authorization Application (MAA) under exceptional circumstances for rAAV8.*hRKp.AIPL1* based on the results from the 11 treated children with no further clinical data required.
- We have aligned on an expedited CMC package to support approval.
- We are also currently engaging with the FDA to discuss a parallel path forward for expedited approval in the U.S., as well as other global regulatory agencies.
- The Offices of Orphan Products Development and Pediatric Therapeutics of the FDA has granted RPDD to AAV8-RK-AIPL1 for the treatment of LCA4 retinal dystrophy.
- In addition, three of our other IRD programs gained RPDD: AAV8-RK-BBS10 for the treatment of Bardet-Biedl syndrome (BBS) due to BBS10 mutations; AAV5-RDH12 for the treatment of RDH12 associated retinal dystrophy; and AAV8-RK-RetGC for the treatment of Leber congenital amaurosis due to GUCY2D mutations.

An RPDD may be granted by the FDA to drugs and biologics intended to treat certain orphan diseases affecting fewer than 200,000 patients in the U.S., the serious or life-threatening manifestations of which primarily affect individuals aged 18 years or younger. Under the FDA's Rare Pediatric Disease Priority Review Voucher (PRV) program, a sponsor that receives approval for a biologics license application for a rare pediatric disease may be eligible to receive a voucher for a priority review of a subsequent marketing application for a different product. PRVs may be used by the sponsor or sold to another sponsor for their use and have recently been sold for between $100 million to $158 million.

Botaretigene Sparoparvovec for the Treatment of XLRP:

- Data from the Phase 3 LUMEOS trial of botaretigene sparoparvovec (bota-vec) for the treatment of X-linked retinitis pigmentosa in collaboration with Johnson & Johnson Innovative Medicine is expected in 2025. We are eligible to receive up to $285 million upon the first commercial sales of bota-vec in the U.S. and EU and manufacturing tech transfer.

- We also entered into a commercial supply agreement with Johnson & Johnson Innovative Medicine for bota-vec manufacturing, which we anticipate will generate additional revenue during the product launch.

Riboswitch Gene Regulation Technology Platform for *in vivo* Delivery:

- We continue to progress our riboswitch technology platform in multiple potential indications, with an initial focus on obesity and metabolic disease and CAR-T for oncology and autoimmune disease.
- We continue to generate compelling preclinical data with metabolic peptides and hormones, including incretins, myokines and leptin, which suggests greater efficacy on weight loss as well as a positive impact on fat to muscle ratio with certain novel combinations of peptides.
- Preclinical data mentioned above as well as new data on chronic pain therapies is informing the decision for our first INDs using our riboswitch small molecule platform.
- We are in dialogue with regulatory agencies and intend to initiate first-in-human studies using the riboswitch platform in 2025.

Manufacturing:

United Kingdom (MeiraGTx UK II Ltd.)

Our UK manufacturing facility holds two authorizations issued by the MHRA:

- MIA(IMP) Licence (MIA(IMP) 45522) – Authorizing manufacturing, fill-finish, and QC testing of Investigational Medicinal Products (IMPs).
- Specials Licence (MS 45522) – Authorizing manufacturing, fill-finish, and QC testing of 'Special' medicinal products.

The UK facility was inspected in May 2024, and the licences were successfully renewed. The outcome of this inspection confirmed that the site was found to be in compliance with GMP requirements for Investigational Medicinal Products (IMPs) and was operating at the required compliance level to support an application for a commercial MIA licence. We plan to submit this application in the second quarter of 2025.

Ireland (MeiraGTx Ireland DAC)

Our Shannon facility holds two authorizations issued by Ireland's Health Products Regulatory Authority (HPRA):

- MIA Licence (M1316) – Authorizing QC testing of commercial products (awarded June 2023).
- MIA(IMP) Licence (IMP13221) – Authorizing QC testing of Investigational Medicinal Products (IMPs) (awarded September 2023/QC and 2025/MFG).

The QC laboratory is actively undertaking release and stability testing on PPQ batches.

The latest HPRA inspection in February 2025 was highly successful—both QC licences were renewed, and viral vector manufacturing was added to the MIA(IMP) licence. This means the Shannon site can manufacture material for use in clinical trials, a first-of-its-kind licence for a gene therapy facility in Ireland.

Strategic Investment from Sanofi:

- On August 12, 2024, Sanofi purchased $30 million of ordinary shares of the Company.
- Sanofi holds a right of first negotiation (ROFN) for the use of our riboswitch gene regulation technology for certain Central Nervous System (CNS) and Immunology and Inflammation (I&I) targets, including IL-4 and IL-13, as well as for GLP-1 and other gut peptides for obesity, and for our Phase 2 xerostomia program.

Components of Our Results of Operations

Service Revenue – Related Party

Our service revenue consisted of the process performance qualification ("PPQ") services performed in connection with the Asset Purchase Agreement and related agreements.

License Revenue – Related Party

Our license revenue consisted of the amortization of the upfront and milestone payments we received in connection with the Collaboration Agreement.

Operating Expenses

Our operating expenses since inception have consisted primarily of general and administrative costs and research and development costs. Beginning in 2024, we incurred expenses classified as cost of service revenue – related party performed in connection with the Asset Purchase Agreement and related agreements.

Cost of Service Revenue – Related Party

Our cost of service revenue consisted of the PPQ services performed in connection with the Asset Purchase Agreement and related agreements.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation, for personnel in our executive, finance, legal, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and office facility-related expenses, which include direct depreciation costs.

We have incurred and expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; maintaining and protecting our intellectual property portfolio; and investor and public relations costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- employee-related expenses, including salaries, benefits and travel of our research and development personnel;

- expenses incurred in connection with third-party vendors that conduct clinical and preclinical studies and manufacture the drug product for the clinical trials and preclinical activities;
- acquisition and impairment of in process research and development;
- costs associated with clinical and preclinical activities including costs related to facilities, supplies, rent, insurance, certain legal fees, share-based compensation, and depreciation; and
- expenses incurred with the development and operation of our manufacturing facilities.

We expense research and development costs as incurred.

Research and development activities are central to our business model. We expect to continue incurring increasing research and development costs associated with our clinical activities for AAV-hAQP1 for the treatment of radiation-induced xerostomia and xerostomia associated with Sjogren's syndrome, as well as for AAV-GAD for the treatment of Parkinson's disease. In addition, we expect to continue to incur expenses related to research activities in additional therapeutic areas to expand our pipeline and develop our potentially transformative gene regulation technology.

We cannot determine with certainty the duration and costs of future clinical trials of our product candidates or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of our existing product candidates or any other product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our existing product candidates, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including the safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another U.S. or foreign regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

Other Non-Operating Income (Expense)

Other non-operating income (expense) includes the following:

Foreign Currency (Loss) Gain

Our consolidated financial statements are presented in U.S. dollars, which is our reporting currency. The financial position and results of operations of our subsidiaries are measured using the foreign subsidiaries' local currency as the functional currency, either the pound sterling or the euro. These entities' cash accounts holding U.S. dollars and intercompany payables and receivables are remeasured based upon the exchange rate at the date of remeasurement with the resulting gain or loss included in the consolidated statement of operations and comprehensive loss.

Interest Income

Interest income is comprised on interest earned on our interest-bearing bank accounts.

Interest Expense

Interest expense consists of interest expense and amortization of the debt discount in connection with the debt financing described in Note 13 to our consolidated financial statements.

Gain on Sale of Nonfinancial Assets

The gain on sale of nonfinancial assets represents the value allocated to the nonfinancial assets sold and assigned to Johnson & Johnson Innovative Medicine including the UCLB RPGR License Agreement relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets pursuant to the Asset Purchase Agreement, net of carrying value.

Other Comprehensive Loss

Other comprehensive loss includes the following:

Foreign Currency Translation Loss

Expenses of subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Assets and liabilities have been translated at the rates of exchange on the consolidated balance sheet date. The resulting translation gain adjustments are recorded directly as a separate component of shareholders' equity and as other comprehensive loss on the consolidated statements of operations and comprehensive loss.

Critical Accounting Policies and Use of Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgements that affect the reporting amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgements, including those related to license and collaboration revenue, share-based compensation and accrued expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying value of assets and liabilities that are not readily apparent from our sources. Actual results may differ from these estimates under different assumptions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing in this Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Collaboration Arrangements

We evaluate our collaborative arrangements pursuant to Accounting Standards Codification ("ASC") 808, *Collaborative Arrangements* ("ASC 808") and ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). We consider the nature and contractual terms of collaborative arrangements and assess whether the arrangement involves a joint operating activity pursuant to which we are an active participant and are exposed to significant risks and rewards with respect to the arrangement. If we are an active participant and exposed to significant risks and rewards with respect to the arrangement, we account for the arrangement as a collaboration under ASC 808.

ASC 808 does not address recognition or measurement matters related to collaborative arrangements. Payments between participants pursuant to a collaborative arrangement that are within the scope of other authoritative accounting literature on income statement classification are accounted for using the relevant provisions of that literature. If we conclude that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, we recognize our allocation of the shared costs incurred with respect to the jointly conducted activities pursuant to ASC 730, *Research and Development* ("ASC 730"). If we concluded that some or all aspects of the arrangement represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606. If the payments are not within the scope of other authoritative accounting literature, the income statement classification for the payments is based on an analogy to authoritative accounting literature or if there is no appropriate analogy, a reasonable, rational and consistently applied accounting policy election. Payments received from a collaboration partner to which this policy applies may include upfront payments in respect of a license of intellectual property, development and commercialization-based milestones, and royalties.

Revenue Recognition

We evaluate the promised goods or services to determine which promises, or group of promises, represent performance obligations in our contracts with customers. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, we consider the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, we must develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

When we conclude that a contract should be accounted for as a combined performance obligation and recognized over time, we must then determine the period over which revenue should be recognized and the method by which to measure revenue. We generally recognize revenue using a cost-based input method.

At inception, we determine whether contracts are within the scope of ASC 606 or other topics. For contracts that are determined to be within the scope of ASC 606, we recognize revenue when the customer or collaborator obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition, we perform the following five steps:

i. identify the contract(s) with a customer;

ii. identify the performance obligations in the contract;

iii. determine the transaction price;

iv. allocate the transaction price to the performance obligations within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when we determine that it is probable we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

At contract inception, we assess the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services for our arrangements typically consist of a license to our intellectual property and research, development and manufacturing services. We may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

We determine transaction prices based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, we estimate the probability and extent of consideration we expect to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. We then consider any constraints on the variable consideration and include in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We then allocate the transaction price to each performance obligation based on the relative standalone selling price and recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

If there are multiple performance obligations, we allocate the transaction price to each performance obligation based on their estimated standalone selling prices (“SSP”). We estimate the SSP for each performance obligation by considering information such as market conditions, entity-specific factors, and information about our customer that is reasonably available. We consider estimation approaches that allow us to maximize the use of observable inputs. These estimation approaches may include the adjusted market assessment approach, the expected cost plus a margin approach or the residual approach. We also consider whether to use a different estimation approach or a combination of approaches to estimate the SSP for each performance obligation. Developing certain assumptions (e.g., treatable patient population, expected market share, probability of success and product profitability, and discount rate based on weighted-average cost of capital) to estimate the SSP of a performance obligation requires significant judgment.

We record amounts as contract assets when the right to consideration is deemed unconditional. Contract assets are reclassified as accounts receivable once billed. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our consolidated balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance

sheet date are classified as deferred revenue – related party, current. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue – related party.

Our collaboration and revenue arrangements include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, we evaluate each milestone to determine when and how much of the milestone to include in the transaction price. We first estimate the amount of the milestone payment that we could receive using either the expected value or the most likely amount approach. We primarily use the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, we consider whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty.) We update the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

Research and Development Services: Under the Collaboration Agreement, we incurred research and development costs, with Johnson & Johnson Innovative Medicine responsible for up to 100% of the costs, depending on the type of research and development services being performed. We recorded costs associated with the development activities as research and development expenses in the consolidated statements of operations and comprehensive loss consistent with ASC 730. The reimbursement of the research and development costs by Johnson & Johnson Innovative Medicine was representative of the joint risk sharing nature of the arrangement. We considered the guidance in ASC 808 and recognize the payments received from Johnson & Johnson Innovative Medicine as a reduction to research and development expense when the related costs are incurred. Under the Asset Purchase Agreement, research and development services (PPQ services) are recorded as incurred under cost of service revenue – related party.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Customer Options: Customer options are evaluated at contract inception to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the standalone selling price. As a practical alternative to estimating the standalone selling price of a material right when the underlying goods or services are both (i) similar to the original goods or services in the contract and (ii) provided in accordance with the terms of the

original contract, we allocate the total amount of consideration expected to be received from the customer to the total goods or services expected to be provided to the customer. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

Research and Development

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and travel of our research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical and preclinical studies and manufacture the drug product for the clinical studies and preclinical activities; acquisition of in-process research and development; facilities; supplies; rent, insurance, certain legal fees, stock-based compensation, depreciation and other costs associated with clinical and preclinical activities and regulatory operations. Research funding under collaboration agreements and refundable research and development credits / tax credits received are recorded as an offset to these costs.

Costs for certain development activities, such as outside research programs funded by us, are recognized based on an evaluation of the progress to completion of specific tasks with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

Share-Based Compensation

Options

We grant share options to employees, non-employee members of our board of directors and non-employee consultants as compensation for services performed. Share-based compensation are accounted for in accordance with ASC 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all share-based payments, including grants of share options, to be recognized in the statement of operations and comprehensive loss based on their grant date fair values. The grant date fair value of share options is estimated using the Black-Scholes option valuation model.

Using this model, fair value is calculated based on assumptions with respect to (i) the fair value of our ordinary shares on the grant date; (ii) expected volatility of our ordinary share price, (iii) the periods of time over which recipients are expected to hold their options prior to exercise (expected term), (iv) expected dividend yield on our ordinary shares, and (v) risk-free interest rates.

The expected term of share options granted to the optionees is determined using the average of the vesting period and contractual life of the option, an accepted method for our Company's option grants under the SEC Staff Accounting Bulletin No. 107 and No. 110, *Share-Based Payment*.

Expected volatility is based on an analysis of our Company and guideline companies in accordance with ASC 718. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. Risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the option's expected term.

Restricted Share Units

The Company grants restricted share units ("RSUs") to employees, non-employee members of our board of directors and non-employee consultants as compensation for services performed. Awards of RSUs are accounted for in accordance with ASC 718. ASC 718 requires all share-based payments, including grants of RSUs, to be recognized in

the consolidated statement of operations and comprehensive loss based on their grant date fair values. The grant date fair value of RSUs is determined using the closing market price of the Company's ordinary shares on the date of grant.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

	2024	2023	Change
		(in thousands)	
Revenues:			
Service revenue - related party	$ 33,279	$ —	$ 33,279
License revenue - related party	—	14,017	(14,017)
Total revenue	33,279	14,017	19,262
Operating expenses:			
Cost of service revenue - related party	23,791	—	23,791
General and administrative	54,216	47,293	6,923
Research and development	119,484	103,785	15,699
Total operating expenses	197,491	151,078	46,413
Loss from operations	(164,212)	(137,061)	(27,151)
Other non-operating income (expense)			
Foreign currency (loss) gain	(2,886)	9,300	(12,186)
Interest income	4,145	2,272	1,873
Interest expense	(13,272)	(13,245)	(27)
Gain on sale of nonfinancial assets	28,434	54,208	(25,774)
Fair value adjustments	—	499	(499)
Net loss	$ (147,791)	$ (84,027)	$ (63,764)
Other comprehensive loss:			
Foreign currency translation loss	(2,284)	(7,482)	5,198
Comprehensive loss	$ (150,075)	$ (91,509)	$ (58,566)

Service Revenue – Related Party

Service revenue was $33.3 million for the year ended December 31, 2024, due to progress of PPQ services under the Asset Purchase Agreement and related agreements. There was no service revenue for the year ended December 31, 2023.

License Revenue – Related Party

There was no license revenue for the year ended December 31, 2024, compared to $14.0 million for the year ended December 31, 2023. The decrease is due to the termination of the Collaboration Agreement concurrent with the execution of the Asset Purchase Agreement.

Cost of Service Revenue – Related Party

Cost of service revenue was $23.8 million for the year ended December 31, 2024, due to progress of PPQ services under the Asset Purchase Agreement and related agreements. There was no cost of service revenue for the year ended December 31, 2023.

General and Administrative Expenses

General and administrative expenses were $54.2 million for the year ended December 31, 2024, compared to $47.3 million for the year ended December 31, 2023. The increase of $6.9 million was primarily due to an increase of $2.1 million in professional fees, and the remaining $4.8 million was related to other general and administrative costs, none of which were individually significant.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2024 and 2023 were as follows (in thousands):

	For the Years Ended December 31, 2024	2023	Change
Clinical Programs			
Botaretigene sparoparvovec	$ 1,250	$ 55,518	$(54,268)
AAV-hAQP1	17,307	15,772	1,535
AAV-CNGB3 / AAV-CNGA3	(969)	2,184	(3,153)
AAV-GAD	6,411	7,598	(1,187)
Other ocular diseases	1,763	—	1,763
Manufacturing	53,445	50,221	3,224
Preclinical Programs			
Gene regulation	10,509	8,324	2,185
Neurodegenerative diseases	1,608	2,242	(634)
Preclinical ocular diseases	2,474	2,849	(375)
Other research and development expenses	25,686	29,506	(3,820)
Gross research and development expenses	119,484	174,214	(54,730)
Johnson & Johnson Innovative Medicine reimbursement	—	(70,429)	70,429
Research and development expenses	$ 119,484	$ 103,785	$ 15,699

Clinical program expenses represent the direct costs for each clinical trial plus the cost of the clinical trial material charged from the manufacturing costs.

Manufacturing expenses represent the costs to manufacture clinical trial material, including payroll, facilities, manufacturing supplies, raw materials, quality control and quality assurance. Upon completion of the manufacture of a batch of clinical trial material, the standard cost of manufacturing the batch of clinical trial material is charged to the clinical programs.

Preclinical program expenses represent the direct costs for each group of preclinical programs.

Other research and development expenses represent costs that are not allocated to a specific clinical or preclinical program, such as payroll and payroll related costs, share-based compensation, travel, rent and facilities costs, depreciation and other non-program specific expenses.

Research and development expenses for the year ended December 31, 2024 were $119.5 million, compared to $103.8 million for the year ended December 31, 2023. The increase of $15.7 million was primarily due to an increase in manufacturing costs of $3.2 million, preclinical expenses of $1.2 million and a reduction in reimbursements from Johnson & Johnson Innovative Medicine of $70.4 million as the reimbursement for the year ended December 31, 2023 was in connection with research funding provided under the Collaboration Agreement, which was terminated on December 20, 2023. These increases were partially offset by a decrease of $55.3 million in clinical trial expenses primarily related to bota-vec as Johnson & Johnson Innovative Medicine is now primarily funding the research and development related to this program as a result of the Asset Purchase Agreement and $3.8 million of other research and development expenses.

Foreign Currency (Loss) Gain

Foreign currency loss was $2.9 million for the year ended December 31, 2024 compared to a gain of $9.3 million for the year ended December 31, 2023. The change of $12.2 million was primarily due to the restructuring and payment of certain intercompany receivables and payables during the year ended December 31, 2023. Foreign currency gains and losses subsequent to the restructuring are recorded as a part of accumulated other comprehensive income.

Interest Income

Interest income was $4.1 million for the year ended December 31, 2024 compared to $2.3 million for the year ended December 31, 2023. The increase was due to higher interest rates and cash balances during 2024.

Interest Expense

Interest expense was $13.3 million for each of the years ended December 31, 2024 and 2023.

Gain on Sale of Nonfinancial Assets

The gain on sale of nonfinancial assets was $28.4 million for the year ended December 31, 2024 compared to $54.2 million for the year ended December 31, 2023. This decrease was a result of a lower value of transaction consideration recognized in connection with the Asset Purchase Agreement during the year ended December 31, 2024 compared to the year ended December 31, 2023.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. For the year ended December 31, 2024, we used $104.5 million in cash flows from operations. We did not generate positive cash flows from operations during the year and there are no assurances that we will generate positive cash flows in the future. Additionally, there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our product candidates. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will increase in connection with conducting preclinical studies and clinical trials for our product candidates, building out internal capacity to have products manufactured to support preclinical studies and clinical trials as well as to manufacture commercial products, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result of these incurred and expected expenses we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

We do not currently have any approved products and have never generated any revenue from product sales. We have historically financed our operations primarily through cash on hand and proceeds from the sale of our ordinary shares, series A ordinary shares and convertible preferred C shares and upfront and milestone payments from

collaboration agreements. On December 20, 2023, we entered into an Asset Purchase Agreement with Johnson & Johnson Innovative Medicine pursuant to which the Company sold and assigned to Johnson & Johnson Innovative Medicine a License Agreement between the Company and UCLB relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the Asset Purchase Agreement. In connection with entering into the Asset Purchase Agreement, we entered into a Termination Agreement with Johnson & Johnson Innovative Medicine terminating the Collaboration Agreement. The Company and Johnson & Johnson Innovative Medicine also entered into a Supply Agreement on December 20, 2023 pursuant to which the Company agreed to manufacture and supply the RPGR Product for Johnson & Johnson Innovative Medicine. During the year ended December 31, 2024, we received $60.0 million in milestone payments under the Asset Purchase Agreement.

Additionally, on August 2, 2022, we, as borrower, and our Subsidiary Guarantors, entered into a Financing Agreement by and among us, the Subsidiary Guarantors, the lenders and other parties from time to time party thereto and Perceptive, as administrative agent and lender. On December 19, 2022, the Financing Agreement was converted to a Notes Purchase Agreement between the same parties and under substantially the same terms and conditions as the Financing Agreement, subject to certain customary note constitution terms.

The Notes Purchase Agreement provides for the issuance of the Tranche 1 Notes in an initial amount of $75.0 million. Pursuant to the First Consent and Amendment, we were able to request, in our sole discretion, and Perceptive agreed to subscribe to purchase upon such request, the issuance of the Tranche 2 Notes in an additional amount of $25.0 million at any time before August 2, 2024 subject to the terms of the Notes Purchase Agreement. Previously, our request for the issuance of the Tranche 2 Notes was to be determined at Perceptive's sole discretion. The Notes Purchase Agreement matures on August 2, 2026 and is interest-only during the term. We have the option to redeem outstanding principal notes at any time along with an applicable early redemption fee. Under each of the First Consent and Amendment and the Second Consent and Amendment, the Notes Purchase Agreement was amended to increase the applicable early redemption fee. Outstanding amounts under the Notes Purchase Agreement bear interest at a fluctuating rate per annum equal to 10.00% plus the secured overnight financing rate administered by the Federal Reserve Bank of New York for a one-month tenor, subject to a 1.00% floor.

Our obligations under the Notes Purchase Agreement are secured by our London, UK and Shannon, Ireland manufacturing facilities, $3.0 million of our cash and the bank accounts of the Subsidiary Guarantors, and the issued and outstanding equity interests of the Subsidiary Guarantors.

The Notes Purchase Agreement imposes certain covenants and restrictions on us and the Subsidiary Guarantors, including restrictions pertaining to: (i) the incurrence of additional indebtedness, (ii) limitations on liens, (iii) limitations on certain investments, (iv) making distributions, dividends and other payments, (v) mergers, consolidations and acquisitions, (vi) dispositions of assets, (vii) our maintenance of at least $3.0 million in a U.S. bank account, (viii) transactions with affiliates, (ix) changes to governing documents, (x) changes to certain agreements and leases and (xi) changes in control; however, certain of these restrictions contain exceptions which allow us to license, sell and monetize assets in our AAV-hAQP1 program in development to treat radiation-induced xerostomia, our AAV-GAD program in development to treat Parkinson's disease and our gene regulation platform technologies.

In connection with entering into the Financing Agreement, we granted warrants (the "Warrants") to Perceptive to purchase up to (i) 400,000 ordinary shares of the Company at an exercise price of $15.00 per share and (ii) 300,000 ordinary shares of the Company at an exercise price of $20.00 per share. The Warrants will expire on August 2, 2027.

Based on our current cash, cash equivalents, accounts receivable – related party, and tax incentive receivable at December 31, 2024, together with the proceeds from the anticipated closing of the strategic collaboration with Hologen Ltd, we estimate that we will be able to fund our operating expenses and capital expenditure requirements into 2027 and to repay our debt obligation of $75.0 million to Perceptive (due in August 2026). This estimate does not include the $285.0 million in milestones we are eligible to receive under the Asset Purchase Agreement upon first commercial sale of an RPGR Product in the United States and in at least one of the United Kingdom, France, Germany, Spain and Italy,

for completion of the transfer of certain manufacturing technology to Johnson & Johnson Innovative Medicine and upon regulatory approval of a Johnson & Johnson Innovative Medicine-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Cash Flows

We had $105.7 million and $130.6 million of cash, cash equivalents, and restricted cash as of December 31, 2024 and 2023, respectively.

The following table summarizes our sources and uses of cash for the period presented:

	For the Years Ended December 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (104,495)	$ (105,365)
Net cash provided by investing activities	23,479	34,034
Net cash provided by financing activities	54,534	84,023
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (26,482)	$ 12,692

Operating Activities

During the year ended December 31, 2024, our cash used in operating activities of $104.5 million was primarily due to our net loss of $147.8 million as we incurred expenses associated with research activities on our clinical programs, manufacturing of our clinical trial materials, preclinical research programs and general and administrative expenses. The net loss included net non-cash income and expense of $13.6 million, which consisted primarily of $25.2 million of share-based compensation, $12.8 million of depreciation and amortization, $2.9 million of a foreign currency loss and $1.3 million of non-cash interest, which was partially offset by $28.4 million of a gain on sale of nonfinancial assets and $0.2 million of a gain on termination of lease liabilities. Additionally, operating assets, consisting of accounts receivable – related party, contract assets – related party, prepaid expenses, tax incentive receivable, other current assets, inventory and other assets, net, decreased by $6.2 million and operating liabilities, consisting of accounts payable, accrued expenses, other current liabilities and deferred revenue – related party, increased by $23.5 million.

During the year ended December 31, 2023, our cash used in operating activities of $105.4 million was primarily due to our net loss of $84.0 million as we incurred expenses associated with research activities on our clinical programs, manufacturing of our clinical trial materials, preclinical research programs and general and administrative expenses. The net loss included net non-cash income and expense of $20.4 million, which consisted primarily of $27.7 million of share-based compensation, $13.7 million of depreciation and amortization, $1.3 million of non-cash interest and $1.1 million impairment related to acquired in-process research and development, which was partially offset by $54.2 million of a gain on sale of nonfinancial assets, $9.3 million of a foreign currency gain, $0.5 million of a fair value upward adjustment and $0.2 million of net change in right-of-use assets and liabilities. Additionally, operating assets, consisting of accounts receivable – related party, prepaid expenses, tax incentive receivable, other current assets and other assets, net, decreased by $6.0 million and operating liabilities, consisting of accounts payable, accrued expenses, other current liabilities and deferred revenue – related party, decreased by $6.9 million.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2024 of $23.5 million consisted of $28.4 million from proceeds from the sale of nonfinancial assets offset by $4.9 million of purchases of property and equipment for our manufacturing, laboratory and process development facilities.

Net cash provided by investing activities for the year ended December 31, 2023 of $34.0 million consisted of $54.2 million from proceeds from the sale of nonfinancial assets offset by $20.2 million of purchases of property and equipment for our manufacturing, laboratory and process development facilities.

Financing Activities

Net cash provided by financing activities was $54.5 million for the year ended December 31, 2024, which consisted primarily of $59.4 million from the issuance of ordinary shares, which was offset by $2.5 million of issuance costs and $2.3 million of payments for withholdings of shares for income taxes.

Net cash provided by financing activities was $84.0 million for the year ended December 31, 2023, which consisted primarily of $92.0 million from the issuance of ordinary shares, which was offset by $6.4 million of issuance costs and $1.5 million of payments for withholdings of shares for income taxes.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements under applicable SEC rules and do not have any holdings in variable interest entities.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are exposed to market risks in the ordinary course of our business. These risks primarily include foreign currency exchange rate sensitivities and interest rate risk.

Foreign Currency Exchange Risk

We currently operate in the United States, the United Kingdom and the European Union. Our activities in these jurisdictions expose us to currency exchange rate fluctuations primarily between the U.S. Dollar and the British pound sterling and euro. When the U.S. Dollar strengthens against these currencies, the U.S. Dollar value of non-U.S. Dollar based losses increases. To the extent that our international activities recorded in local currencies increase in the future, our exposure to fluctuations in currency exchange rates will correspondingly increase. As of December 31, 2024, we did not hold any foreign currency forward contracts. With respect to our foreign currency exposures as of December 31, 2024, we estimate a 10% unfavorable movement in foreign currency exchange rates would have the effect of creating an additional foreign currency loss of approximately $11.3 million within other non-operating income (expense) for the year ended December 31, 2024.

Interest Rate Risk

We are exposed to market risk as a result of changes in interest rates applicable to borrowings under our Notes Purchase Agreement. Borrowings under the Notes Purchase Agreement bear interest at a fluctuating rate per annum equal to 10.00% plus the secured overnight financing rate ("SOFR") administered by the Federal Reserve Bank of New York for a one-month tenor, subject to a 1.00% floor. See Note 13 to our consolidated financial statements included elsewhere in this Form 10-K. We may use interest rate cap derivatives, interest rate swaps or other interest rate hedging instruments to economically hedge and manage interest rate risk with respect to our variable floating rate debt. As of December 31, 2024, the annual interest rate was 14.85% and the outstanding balance of the Tranche 1 Notes was $75.0 million. Assuming no change in the outstanding borrowings under the Notes Purchase Agreement, we estimate that a hypothetical 1% increase in the SOFR would increase our annual interest expense by approximately $0.8 million for the year ended December 31, 2024.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm (PCAOB ID 42) F-2

Consolidated:

Balance Sheets F-4
Statements of Operations and Comprehensive Loss F-5
Statements of Shareholders' Equity F-6
Statements of Cash Flows F-6
Notes to Consolidated Financial Statements F-7

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of MeiraGTx Holdings plc and subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of MeiraGTx Holdings plc and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss**,** shareholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosures to which they relate.

Accrued Clinical Trial Costs

Description of the Matter	As discussed in Note 2 to the consolidated financial statements, the Company records costs for clinical trial activities based upon estimates of costs incurred through the balance sheet date that have yet to be invoiced by the contract research organizations and other vendors. Auditing the Company's accruals for clinical trial costs is challenging due to the fact that information necessary to estimate the accruals is accumulated from multiple sources. In addition, in certain circumstances, the estimate of services that have been incurred during the reporting period requires judgment because the timing and pattern of vendor invoicing does not correspond to the level of services provided and there may be delays in invoicing from clinical study sites and other vendors.
How We Addressed the Matter in Our Audit	To test the accrued clinical trial costs, our audit procedures included, among others, testing the completeness and accuracy of the underlying data used in the estimates and evaluating the significant assumptions including, but not limited to, patient enrollment and costs per patient, and rate of progress, which are used by management to estimate the recorded accruals. To assess the reasonableness of the significant assumptions, we corroborated the progress of clinical trials with the Company's clinical team and obtained information directly from third parties related to active patient progress and currently enrolled patients. We also tested subsequent invoices received from such third parties and inspected the Company's contracts with third parties and any pending change orders to assess the costs per patient and impact to the accrual through the balance sheet date.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.
Jericho, New York
March 13, 2025

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 103,659	$ 129,566
Accounts receivable - related party	707	10,138
Contract assets - related party	950	—
Inventory	385	—
Prepaid expenses	6,828	5,625
Tax incentive receivable	8,971	13,277
Other current assets	2,018	1,016
Total Current Assets	123,518	159,622
Property, plant and equipment, net	102,878	115,896
Intangible assets, net	821	1,118
Restricted cash	2,009	1,083
Other assets	1,002	1,917
Equity method and other investments	6,749	6,766
Right-of-use assets - operating leases, net	10,576	15,910
Right-of-use assets - finance leases, net	22,198	24,432
TOTAL ASSETS	$ 269,751	$ 326,744
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 23,586	$ 16,042
Accrued expenses	27,414	42,639
Lease obligations, current	4,053	4,193
Deferred revenue - related party, current	4,827	2,926
Other current liabilities	903	1,278
Total Current Liabilities	60,783	67,078
Deferred revenue - related party	57,576	34,017
Lease obligations	7,523	12,952
Asset retirement obligations	2,821	2,401
Note payable, net	73,221	72,119
TOTAL LIABILITIES	201,924	188,567
COMMITMENTS AND CONTINGENCIES (Note 14)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 78,397,380 and 63,601,015 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	3	2
Capital in excess of par value	773,565	693,841
Accumulated other comprehensive loss	(3,719)	(1,435)
Accumulated deficit	(702,022)	(554,231)
Total Shareholders' Equity	67,827	138,177
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 269,751	$ 326,744

See Notes to Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	For the Years Ended December 31,	
	2024	2023
Revenues:		
Service revenue - related party	$ 33,279	$ —
License revenue - related party	—	14,017
Total revenue	33,279	14,017
Operating expenses:		
Cost of service revenue - related party	23,791	—
General and administrative	54,216	47,293
Research and development	119,484	103,785
Total operating expenses	197,491	151,078
Loss from operations	(164,212)	(137,061)
Other non-operating income (expense):		
Foreign currency (loss) gain	(2,886)	9,300
Interest income	4,145	2,272
Interest expense	(13,272)	(13,245)
Gain on sale of nonfinancial assets	28,434	54,208
Fair value adjustment	—	499
Net loss	(147,791)	(84,027)
Other comprehensive loss:		
Foreign currency translation loss	(2,284)	(7,482)
Comprehensive loss	$ (150,075)	$ (91,509)
Net loss	$ (147,791)	$ (84,027)
Basic and diluted net loss per ordinary share	$ (2.12)	$ (1.49)
Weighted-average number of ordinary shares outstanding	69,822,353	56,486,525

See Notes to Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023
(in thousands, except share amounts)

	Ordinary Shares	Amount	Capital in Excess of Par Value	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
Balance at December 31, 2022	48,477,209	$ 2	$ 581,893	$ 6,047	$ (470,204)	$ 117,738
Share-based compensation activity	309,755	—	26,207	—	—	26,207
Issuance of shares in connection with asset acquisitions	40,138	—	209	—	—	209
Issuance of shares in connection with private placements	14,773,913	—	91,950	—	—	91,950
Issuance costs in connection with private placement	—	—	(6,418)	—	—	(6,418)
Other comprehensive loss	—	—	—	(7,482)	—	(7,482)
Net loss for the year ended December 31, 2023	—	—	—	—	(84,027)	(84,027)
Balance at December 31, 2023	63,601,015	2	693,841	(1,435)	(554,231)	138,177
Share-based compensation activity	537,848	—	22,851	—	—	22,851
Issuance of ordinary shares in at-the-market offering	1,508,517	—	8,390	—	—	8,390
Issuance costs in connection with ordinary shares	—	—	(657)	—	—	(657)
Issuance of shares in connection with registered offering	12,500,000	1	49,999	—	—	50,000
Issuance costs in connection with registered offering	—	—	(1,859)	—	—	(1,859)
Issuance of shares in connection with private placement	250,000	—	1,000	—	—	1,000
Other comprehensive loss	—	—	—	(2,284)	—	(2,284)
Net loss for the year ended December 31, 2024	—	—	—	—	(147,791)	(147,791)
Balance at December 31, 2024	78,397,380	$ 3	$ 773,565	$ (3,719)	$ (702,022)	$ 67,827

See Notes to Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (147,791)	$ (84,027)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	25,191	27,716
Foreign currency loss (gain)	2,886	(9,300)
Depreciation and amortization	12,828	13,730
Net change in right-of-use assets and liabilities	16	(222)
Gain on termination of lease liabilities	(172)	—
Loss on disposal of equipment, furniture and fixtures	9	13
Loss on equity method investment	17	6
Amortization of interest on asset retirement obligations	209	177
Amortization of debt discount	1,103	1,083
Fair value adjustment	—	(499)
Impairment of acquired in-process research and development and right-of-use assets	—	1,149
Gain on sale of nonfinancial assets	(28,434)	(54,208)
(Increase) decrease in operating assets:		
Accounts receivable - related party	6,325	9,975
Contract assets - related party	(954)	—
Inventory	(387)	—
Prepaid expenses	(1,328)	2,690
Tax incentive receivable	4,055	(5,148)
Other current assets	(2,302)	222
Other assets, net	759	(1,809)
Increase (decrease) in operating liabilities:		
Accounts payable	10,738	2,330
Accrued expenses	(13,959)	(382)
Other current liabilities	32	(1,355)
Deferred revenue - related party	26,664	(7,506)
Net cash used in operating activities	(104,495)	(105,365)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(4,955)	(20,174)
Proceeds from sale of nonfinancial assets	28,434	54,208
Net cash provided by investing activities	23,479	34,034
Cash flows from financing activities:		
Exercise of share options	—	10
Payments of withholdings on shares withheld for income taxes	(2,340)	(1,519)
Proceeds from the issuance of ordinary shares	59,390	91,950
Issuance costs in connection with ordinary shares	(2,516)	(6,418)
Net cash provided by financing activities	54,534	84,023
Net (decrease) increase in cash, cash equivalents and restricted cash	(26,482)	12,692
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1,501	2,441
Cash, cash equivalents and restricted cash at beginning of the year	130,649	115,516
Cash, cash equivalents and restricted cash at end of the year	$ 105,668	$ 130,649
Supplemental disclosure of non-cash transactions:		
Fixed asset acquisition included in accounts payable and accrued expenses	$ 851	$ 2,607
Change in estimate of asset retirement obligations	$ 345	—
Issuance of shares in connection with asset acquisition	$ —	$ 209
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 12,029	$ 13,054

See Notes to Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Principal Business Activity

The Company

MeiraGTx Holdings plc and subsidiaries (the "Company" or "Meira Holdings"), an exempted company incorporated under the laws of the Cayman Islands, is a vertically integrated, clinical-stage genetic medicines company with a broad pipeline of late-stage clinical programs, including Parkinson's disease, radiation-induced xerostomia and AIPL1-associated retinal dystrophy. MeiraGTx clinical programs use targeted local delivery of small doses of genetic medicines to treat both inherited and more common conditions with severe unmet need. The successful development of the clinical pipeline is supported by the Company's internal end-to-end manufacturing capabilities. The Company has two viral vector production facilities for good manufacturing practices ("GMP"), internal plasmid production for GMP, as well as an in-house Quality Control hub for stability and release, all fit for IND through commercial supply. In addition, the Company has developed a proprietary manufacturing platform with leading yield and quality aspects and commercial readiness. The Company's core capabilities in viral vector and capsid optimization allow increased potency, decreased dose and significantly reduced cost of goods for its genetic medicines. The Company has developed a potentially transformative gene regulation platform using bespoke synthetic riboswitch technology invented in-house that allows for the precise, dose-responsive expression of any transgene under the control of oral small molecules. The Company is focusing the riboswitch platform on *in vivo* delivery of biologic therapeutics such as the metabolic peptides GLP-1, GIP, glucagon, amylin, PYY and leptin via oral small molecules, as well as cell therapy for oncology and autoimmune diseases, and long-term intractable pain. The Company has developed unique comprehensive technology capabilities to apply genetic medicine to more common diseases, increasing efficacy, addressing novel targets, and expanding access in some of the largest disease areas where the unmet need remains high.

On January 30, 2019, the Company entered into a collaboration, option and license agreement with Janssen Pharmaceuticals, Inc. ("Janssen"), one of the Janssen Pharmaceuticals Companies of Johnson & Johnson (the "Collaboration Agreement"), for the research, development and commercialization of gene therapies for the treatment of inherited retinal diseases ("IRD"). Under the terms of the Collaboration Agreement, the Company received an upfront payment of $100.0 million in March 2019 and a $30.0 million milestone payment in December 2021. The Company also received funding for certain research, manufacturing, clinical development and commercialization costs, and had the potential to obtain additional milestone payments upon the achievement of such milestones and royalties on future net sales of products. On December 20, 2023, the Company entered into an Asset Purchase Agreement ("Asset Purchase Agreement") with Janssen pursuant to which the Company sold and assigned to Janssen, and Janssen purchased and assumed, that certain License Agreement, dated February 5, 2019, by and between UCL Business Plc (now UCL Business Ltd.) ("UCLB"), on the one hand, and MeiraGTx UK II Limited and MeiraGTx Limited, on the other hand (the "UCLB RPGR License Agreement"), relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the Asset Purchase Agreement. In connection with entering into the Asset Purchase Agreement, the Company entered into a Termination Agreement with Janssen terminating the Collaboration Agreement. The Company and Janssen also entered into a Supply Agreement on December 20, 2023 pursuant to which the Company agreed to manufacture and supply the RPGR Product for Janssen.

Under the Asset Purchase Agreement, Janssen paid the Company a non-refundable upfront cash payment of $65.0 million in December 2023. Additionally, pursuant to and subject to the terms and conditions set forth in the Asset Purchase Agreement, Janssen agreed to pay the Company future contingent consideration of up to an aggregate of $350.0 million, as follows: (i) a milestone payment of $50.0 million in connection with the achievement of the initiation of the extension study for the Phase 3 LUMEOS clinical trial for the RPGR Product; (ii) $10.0 million upon completion of certain specified development services for the drug substance for the RPGR Product; (iii) $5.0 million upon completion of certain specified development services for the drug product for the RPGR Product; (iv) $175.0 million upon the first commercial sale of an RPGR Product in the United States; (v) $75.0 million upon the first commercial sale of an RPGR Product in at least one of the United Kingdom, France, Germany, Spain and Italy;

(vi) $25.0 million upon completion of the transfer of certain manufacturing technology for drug substance and drug product from the Company to Janssen; and (vii) $10.0 million upon regulatory approval of a Janssen-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. As of December 31, 2024, we have received $60.0 million in milestone payments from Johnson & Johnson Innovative Medicine. Janssen is also responsible for any royalty or milestone amounts that become payable on the RPGR Product under the UCLB RPGR License Agreement.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Liquidity

The Company has not yet achieved profitable operations. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing, and commercialization of the Company's product candidates will require significant additional financing. The Company's accumulated deficit at December 31, 2024 totaled $702.0 million, and management expects to incur substantial losses in future periods. The success of the Company is subject to certain risks and uncertainties, including among others, uncertainty of product development; competition in the Company's field of use; uncertainty of capital availability; uncertainty in the Company's ability to enter into agreements with collaborative partners; expanding and protecting the Company's intellectual property portfolio; dependence on third parties; and dependence on key personnel. For the year ended December 31, 2024, the Company used $104.5 million in cash flows from operations and there are no assurances that the Company will generate positive cash flows in the future. Additionally, there are no assurances that the Company will be successful in obtaining an adequate level of financing for the development and commercialization of its product candidates.

As of December 31, 2024, the Company had cash, cash equivalents and restricted cash in the amount of $105.7 million, which consisted of depository and money market accounts held at large international banks. The Company estimates that its cash and cash equivalents on hand, accounts receivable – related party and tax incentive receivable at December 31, 2024 will be sufficient to cover its expenses for at least the next twelve months from the date of issuance of these consolidated financial statements.

Risks and Uncertainties

The Company operates in an industry that is subject to intense competition, government regulation and rapid technological change. The Company's operations are subject to significant risk and uncertainties including financial, operational, technological, regulatory and other risks, including the potential risk of business failure.

The Company's capital resources and operations to date have been funded primarily with the proceeds from the Collaboration Agreement, Asset Purchase Agreement and private and public equity offerings, as well as the proceeds from the debt financing described in Note 13. In the future, the Company may seek to raise additional capital through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable it to complete the development and potential commercialization of its product candidates.

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies

Consolidation

The accompanying consolidated financial statements include the accounts of Meira Holdings and its wholly owned subsidiaries:

MeiraGTx Limited, a limited company incorporated under the laws of England and Wales;
MeiraGTx, LLC, a Delaware limited liability company ("Meira LLC");
MeiraGTx UK II Limited, a limited company incorporated under the laws of England and Wales ("Meira UK II");
MeiraGTx Ireland DAC, a designated activity company incorporated under the laws of Ireland ("Meira Ireland");
MeiraGTx Netherlands B.V., a private company with limited liability incorporated under the laws of the Netherlands ("Meira Netherlands");
MeiraGTx Belgium, a private company with limited liability incorporated under the laws of Belgium ("Meira Belgium");
BRI-Alzan, Inc., a Delaware corporation;
MeiraGTx Bio Inc., a Delaware corporation;
MeiraGTx B.V., a private company with limited liability incorporated under the laws of the Netherlands ("Meira B.V.");
MeiraGTx Neurosciences, Inc., a Delaware corporation;
MeiraGTx Therapeutics, Inc., a Delaware corporation;
MeiraGTx UK Limited, a limited company incorporated under the laws of England and Wales;
MeiraGTx Neuro I, LLC, a Delaware limited liability company;
MeiraGTx Neuro II, LLC, a Delaware limited liability company;
MeiraGTx Manufacturing Limited, a limited company incorporated under the laws of England and Wales;
MeiraGTx Ocular UK Limited, a limited company incorporated under the laws of England and Wales;
MeiraGTx Gene Regulation Limited, a limited company incorporated under the laws of England and Wales; and
MeiraGTx Neuro UK Limited, a limited company incorporated under the laws of England and Wales.

All intercompany balances and transactions between the consolidated companies have been eliminated in consolidation.

Use of Estimates

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these consolidated financial statements, management used significant estimates in the following areas, among others: collaboration and service revenue, fair value of nonfinancial assets, stand-alone selling price and material rights in connection with the Asset Purchase and Supply Agreements, the accounting for research and development costs, share-based compensation, leases, asset retirement obligations, fair value of financial instruments and tax incentive receivable.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of checking and money market accounts held at large international banks that are readily convertible into cash.

Restricted Cash

Restricted cash represents a guarantee put in place as required by the terms of the research and innovation grant from IDA Ireland which offers financial assistance in establishing the Company's operations in Shannon, Ireland. The following table provides a reconciliation of the components of cash and cash equivalents and restricted cash reported in the Company's consolidated balance sheets to the total of the amount presented in the consolidated statements of cash flows (in thousands):

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 103,659	$ 129,566
Restricted cash	2,009	1,083
Total cash, cash equivalents and restricted cash in the condensed consolidated statement of cash flows	$ 105,668	$ 130,649

Inventory

The Company's inventory consists entirely of raw materials and is valued at the lower of cost or net realizable value. The Company regularly reviews its inventory quantities and, when appropriate, records a provision for obsolete and excess inventory to derive the new cost basis. The Company has not recognized a provision for obsolete and excess inventory as of December 31, 2024.

Financial Instruments

The carrying value of accounts receivable-related party, tax incentive receivable, other current assets, and accounts payable reported in the consolidated balance sheets equal or approximate fair value due to their short maturities.

Tax Incentive Receivable

Meira UK II is eligible to participate in United Kingdom ("UK") research and development tax incentive programs under which it is eligible to receive a cash refund from His Majesty's Revenue & Customs ("HMRC") for a percentage of the qualified research and development costs expended by Meira UK II under the small and medium sized enterprises ("SME") program and the research and development expenditures credit ("RDEC") program. The SME cash refund is available to companies with less than 500 employees and annual aggregate revenue of less than 100.0 million euros or total aggregate assets less than 86.0 million euros during the reimbursable period. The Company's estimate of the amount of cash refund it expects to receive related to the SME and RDEC programs is included in tax incentive receivable in the accompanying consolidated balance sheets and such amounts are recorded as a reduction of research and development expense in the statements of operations. During the years ended December 31, 2024 and 2023, the Company recorded reductions to research and development expenses of $5.5 million and $5.1 million, respectively.

In addition, the Company incurs Value Added Tax ("VAT") on services provided by UK and European Union vendors, which it is entitled to reclaim. The Company's estimate of the amount of cash refund it expects to receive

related to VAT was $2.0 million and $0.6 million as of December 31, 2024 and 2023, respectively, which is included in other current assets in the accompanying consolidated balance sheets.

Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid upon transfer of a liability in an orderly transaction between market participants at the measurement date and in the principal or most advantageous market for that asset or liability. The fair value should be calculated based on assumptions that market participants would use in pricing the asset or liability, not on assumptions specific to the entity. In addition, the fair value of liabilities should include consideration of non-performance risk including the Company's own credit risk.

The Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, for application to financial assets and liabilities. In addition to defining fair value, the standard expands the disclosure requirements around fair value and establishes a fair value hierarchy for valuation inputs. The hierarchy prioritizes the inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market. Each fair value measurement is reported in one of the three levels which are determined by the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1: Observable inputs such as quoted prices in active markets for identical assets the reporting entity has the ability to access as of the measurement date;
- Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The table below represents the values of the Company's financial assets and liabilities that are required to be measured at fair value on a recurring basis (in thousands):

		Fair Value Measurement Using:		
Description	December 31, 2024	Significant Observable Inputs (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable (Level 3)
Cash equivalents	$ 80,930	$ 80,930	$ —	$ —
Restricted cash	$ 2,009	$ 2,009	$ —	$ —

		Fair Value Measurement Using:		
Description	December 31, 2023	Significant Observable Inputs (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable (Level 3)
Cash equivalents	$ 46,868	$ 46,868	$ —	$ —
Restricted cash	$ 1,083	$ 1,083	$ —	$ —

At December 31, 2024, the Company believes the carrying value of the Tranche 1 Notes (as defined in Note 13) approximates fair value as the interest rate is reflective of the rate the Company could obtain on debt with similar terms and conditions.

Equity Method and Other Investments

The Company accounts for equity investments under the equity method of accounting when the requirements for consolidation are not met, and the Company has significant influence over the operations of the investee. Equity method investments are initially recorded at cost and subsequently adjusted for the Company's share of net income or loss and cash contributions and distributions and are included in equity method and other investments in the accompanying consolidated balance sheets. Equity investments that do not result in consolidation and are not accounted for under the equity method are measured at fair value, with any changes in fair value recognized in net income (loss). For any such investments that do not have readily determinable fair values, the Company elects the measurement alternative to measure the investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Equity method investments are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If it is determined that a loss in value of the equity method investment is other than temporary, an impairment loss is measured based on the excess of the carrying amount of an investment over its estimated fair value. Impairment analyses are based on current plans, intended holding periods, and available information at the time the analysis is prepared.

Concentrations of Credit Risk

The Company maintains its cash and cash equivalents primarily in depository and money market accounts within two large financial institutions in the United States and one large financial institution in the United Kingdom and Ireland. Cash balances deposited at these major financial banking institutions exceed the insured limits. The Company has not experienced any losses on its bank deposits and believes these deposits do not expose the Company to any significant credit risk.

Intangible Assets

Intangible assets consist of purchased rights to licensed technology as it relates to the Company's manufacturing processes and has future alternative use in the Company's operations. The licensed technology is being amortized on a straight-line basis over 7 years, which represents the estimated period of benefit and the expected pattern of consumption (see Note 6).

Property, Plant and Equipment, Net

Property, plant and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are depreciated over the lesser of their useful lives or the terms of the leases (see Note 5).

The estimated useful lives of the asset categories are as follows:

Asset Category	Useful Lives
Computer and office equipment	3 years
Laboratory equipment	5 years
Furniture and fixtures	5 years
Manufacturing equipment	7 years
Leasehold improvements	lesser of useful life or remaining term of lease

Expenditures for leasehold improvements are capitalized, and expenditures for maintenance and repairs are expensed to operations as incurred.

ASC Topic 360, *Property, Plant and Equipment*, addresses the financial accounting and reporting for impairment or disposal of long-lived assets. The Company reviews the recorded values of long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable. The Company did not record any material impairment charges in 2024 or 2023.

Leases

The Company accounts for leases in accordance with FASB Topic ASC 842, *Leases* ("ASC 842"). The Company determines if an arrangement is a lease at contract inception. A lease exists when a contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the Company has the right to control the use of the identified asset. The Company accounts for the lease and non-lease components as a single lease component.

From time to time the Company enters into direct financing lease arrangements that include a lessee obligation to purchase the leased asset at the end of the lease term, a bargain purchase option, or provides for minimum lease payments with a present value of 90% or more of the fair value of the leased asset at the date of lease inception.

Operating leases where the Company is the lessee are included in right-of-use ("ROU") assets – operating leases, net and lease obligations on the Company's consolidated balance sheets. The lease obligations are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date and subsequent reporting periods.

Finance leases where the Company is the lessee are included in ROU assets – finance leases, net and lease obligations on the Company's consolidated balance sheets. The lease obligations are initially measured in the same manner as for operating leases and are subsequently measured at amortized cost using the effective interest method.

Key estimates and judgments include how the Company determined (1) the discount rate used to discount the unpaid lease payments to present value, (2) lease term and (3) lease payments.

ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. As most of the Company's leases where it is the lessee do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. The Company uses the implicit rate when readily determinable.

The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a lessee option to extend (or not to terminate) the lease that is reasonably certain to be exercised, or an option to extend (or not to terminate) the lease controlled by the lessor.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date less any lease incentives received.

For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, minus any accrued lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

For finance leases, the ROU asset is subsequently amortized using the straight-line method from the lease commencement date to the earlier of the end of its useful life or the end of the lease term unless the lease transfers ownership of the underlying asset, or the Company is reasonably certain to exercise an option to purchase the

underlying asset. In those cases, the ROU asset is amortized over the useful life of the underlying asset. Amortization of the ROU asset is recognized and presented separately from interest expense on the lease liability.

The Company has elected not to recognize ROU assets and lease liabilities for all short-term leases that have lease terms of 12 months or less at lease commencement. Lease payments associated with short-term leases are recognized as an expense on a straight-line basis over the lease term.

Asset Retirement Obligations

Accounting for asset retirement obligations requires legal obligations associated with the retirement of long-lived assets to be recognized at fair value when incurred and capitalized as part of the related long-lived asset. In the absence of quoted market prices, the Company estimates the fair value of its asset retirement obligations using Level 3 present value techniques, in which estimates of future cash flows associated with retirement activities are discounted using a credit-adjusted risk-free rate. Asset retirement obligations currently reported on the Company's consolidated balance sheets were measured during a period of historically low interest rates. The impact on measurements of new asset retirement obligations using different rates in the future may be significant.

The Company uses estimates to determine the asset retirement obligations at the end of the lease term and discounts such asset retirement obligations using an estimated discount rate. Interest on the discounted asset retirement obligation is amortized over the term of the lease using the effective interest method and is recorded as interest expense in the consolidated statements of operations and comprehensive loss.

The change in asset retirement obligations is as follows (in thousands):

	For the Years Ended December 31,	
	2024	2023
Balance at beginning of period	$ 2,401	$ 2,179
Change in estimate	345	—
Assignment of leases to Johnson & Johnson Innovative Medicine	(115)	—
Amortization of interest	209	177
Effects of exchange rate changes	(19)	45
Balance at end of period	$ 2,821	$ 2,401

IDA Ireland Grant

In August 2021, Meira Ireland entered into an agreement pursuant to which it received a grant from IDA Ireland for financial assistance in establishing its operations in Shannon, Ireland. Under the terms of the grant, Meira Ireland is eligible to receive the lesser of €1.0 million or €10,000 for each job created (the "employment grant") and the lesser of €1.2 million or 4% of the actual expenditure on the provision of machinery and equipment (the "capital grant"). Meira Ireland may apply for a drawdown of the employment grant once a job has been created and the position has been held for a period of at least one month, and may apply for a drawdown of the capital grant once an eligible asset has been purchased and installed, conditioned on the creation of a cumulative number of jobs by the end of the immediately preceding year. An aggregate of 100 jobs must be created to receive the maximum benefit under the capital grant. An application for a drawdown must be accompanied by an audit certification for compliance with the terms of the grant. The Company has a guarantee in place with a bank in favor of IDA Ireland, pursuant to which it restricts cash in the amount of claims made under the grant such that the Company maintains the funds to cover any portion of the grant income that may become repayable in the future. This amount is presented as restricted cash in the accompanying consolidated balance sheet. All grant drawdowns were required to be completed by December 31, 2024, and the agreement terminates on the later of five years from the date of the last payment from the grant or five

years from completion of the capital investment, which is expenditure of at least €30.0 million on eligible machinery and equipment.

The Company recognizes grant income when there is reasonable assurance that the Company will comply with the conditions attached to the grant and that it will receive the grant. Grant income from the employment grant is recognized as a deduction from the amount of the related expense, and grant income from the capital grant is deducted from the carrying amount of the related asset and recognized in income over the asset's useful life in the form of a reduced depreciation charge. The Company received its first drawdown under the grant in 2023, which was comprised of $0.6 million for the employment grant and $0.4 million for the capital grant. The Company received its second drawdown under the grant in 2024, which was comprised of $0.5 million for the employment grant and $0.5 million for the capital grant. During the years ended December 31, 2024 and 2023, respectively, the Company recognized $0.6 and $1.0 million of grant income as a reduction of research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

During the five-year period ending on the termination of the grant agreement, Meira Ireland must maintain compliance with the terms of the grant. If the total number of jobs is less than 100 at the time of IDA Ireland's annual review, the Company may have to repay a portion of the capital grant, and if a job for which the Company received employment grant funding remains vacant for a period in excess of six calendar months, the Company may have to repay the employment grant received for that job.

Share-Based Compensation Expense

Options

The Company grants share options to employees, non-employee members of the Company's board of directors and non-employee consultants as compensation for services performed. Employee and non-employee members of the board of directors' awards of share-based compensation are accounted for in accordance with ASC 718, *Compensation – Stock Compensation,* or ASC 718. The Company accounts for forfeitures of stock option awards as they occur. ASC 718 requires all share-based payments to employees and non-employee directors, including grants of share options, to be recognized in the consolidated statement of operations and comprehensive loss based on their grant date fair values. The grant date fair value of share options is estimated using the Black-Scholes option valuation model.

Using this model, fair value is calculated based on assumptions with respect to (i) the fair value of the Company's ordinary shares on the grant date; (ii) expected volatility of the Company's ordinary share price, (iii) the periods of time over which the optionees are expected to hold their options prior to exercise (expected term), (iv) expected dividend yield on the Company's ordinary shares, and (v) risk-free interest rates.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if the Company had used different assumptions or estimates, the fair value of its ordinary shares and its share-based compensation expense could have been materially different.

The expected term of share options granted to the optionees is determined using the average of the vesting period and contractual life of the option, an accepted method for the Company's option grants under the Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 107 and No. 110, *Share-Based Payment.*

Expected volatility is based on an analysis of guideline companies and the Company's own volatility in accordance with ASC 718. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. Risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the option's expected term.

Restricted Share Units

The Company grants restricted share units ("RSUs") to employees, non-employee members of the Company's board of directors and non-employee consultants as compensation for services performed. Awards of RSUs are accounted for in accordance with ASC 718. ASC 718 requires all share-based payments to employees, non-employee members of the Company's board of directors and non-employee consultants, including grants of RSUs, to be recognized in the consolidated statement of operations and comprehensive loss based on their grant date fair values. The grant date fair value of RSUs is determined using the closing market price of the Company's ordinary shares on the date of grant.

Collaboration Arrangements

The Company evaluates its collaborative arrangements pursuant to ASC 808, *Collaborative Arrangements* ("ASC 808") and ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company considers the nature and contractual terms of collaborative arrangements and assesses whether the arrangement involves a joint operating activity pursuant to which the Company is an active participant and is exposed to significant risks and rewards with respect to the arrangement. If the Company is an active participant and is exposed to significant risks and rewards with respect to the arrangement, the Company accounts for the arrangement as a collaboration under ASC 808.

ASC 808 does not address recognition or measurement matters related to collaborative arrangements. Payments between participants pursuant to a collaborative arrangement that are within the scope of other authoritative accounting literature on income statement classification are accounted for using the relevant provisions of that literature. If the Company concludes that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, the Company recognizes its allocation of the shared costs incurred with respect to the jointly conducted activities pursuant to ASC 730, *Research and Development* ("ASC 730"). If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC 606. If the payments are not within the scope of other authoritative accounting literature, the income statement classification for the payments is based on an analogy to authoritative accounting literature or if there is no appropriate analogy, a reasonable, rational and consistently applied accounting policy election. Payments received from a collaboration partner to which this policy applies may include upfront payments in respect of a license of intellectual property, development and commercialization-based milestones, and royalties.

Refer to the discussion in Note 11 for further information related to the accounting for the Collaboration Agreement.

Revenue Recognition

The Company evaluates the promised goods or services to determine which promises, or group of promises, represent performance obligations. In contemplation of whether a promised good or service meets the criteria required of a performance obligation, the Company considers the stage of development of the underlying intellectual property, the capabilities and expertise of the customer relative to the underlying intellectual property, and whether the promised goods or services are integral to or dependent on other promises in the contract. When accounting for an arrangement that contains multiple performance obligations, the Company must develop judgmental assumptions, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success to determine the stand-alone selling price for each performance obligation identified in the contract.

When the Company concludes that a contract should be accounted for as a combined performance obligation and recognized over time, the Company must then determine the period over which revenue should be recognized and the method by which to measure revenue. The Company generally recognizes revenue using a cost-based input method.

At inception, the Company determines whether contracts are within the scope of ASC 606 or other topics. For contracts that are determined to be within the scope of ASC 606, the Company recognizes revenue when its customer or collaborator obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition the Company performs the following five steps:

i. identify the contract(s) with a customer;

ii. identify the performance obligations in the contract;

iii. determine the transaction price;

iv. allocate the transaction price to the performance obligations within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements typically consist of a license to the Company's intellectual property and research, development and manufacturing services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

If there are multiple performance obligations, the Company allocates the transaction price to each performance obligation based on their estimated standalone selling prices ("SSP"). The Company estimates the SSP for each

performance obligation by considering information such as market conditions, entity-specific factors, and information about its customer that is reasonably available. The Company considers estimation approaches that allow it to maximize the use of observable inputs. These estimation approaches may include the adjusted market assessment approach, the expected cost plus a margin approach or the residual approach. The Company also considers whether to use a different estimation approach or a combination of approaches to estimate the SSP for each performance obligation. Developing certain assumptions (e.g., treatable patient population, expected market share, probability of success and product profitability, and discount rate based on weighted-average cost of capital) to estimate the SSP of a performance obligation requires significant judgment.

The Company records amounts as contract assets when the right to consideration is deemed unconditional. Contract assets are reclassified as accounts receivable once billed. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's consolidated balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue – related party, current. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue – related party.

The Company's collaboration and revenue arrangements include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, the Company evaluates each milestone to determine when and how much of the milestone to include in the transaction price. The Company first estimates the amount of the milestone payment that the Company could receive using either the expected value or the most likely amount approach. The Company primarily uses the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, the Company considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty.) The Company updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

Research and Development Services: Under the Collaboration Agreement, the Company incurred research and development costs, with Johnson & Johnson Innovative Medicine responsible for up to 100% of the costs, depending on the type of research and development services being performed. The Company recorded costs associated with the development activities as research and development expenses in the consolidated statements of

operations and comprehensive loss consistent with ASC 730. The reimbursement of the research and development costs by Johnson & Johnson Innovative Medicine was representative of the joint risk sharing nature of the arrangement. The Company considered the guidance in ASC 808 and recognizes the payments received from Johnson & Johnson Innovative Medicine as a reduction to research and development expense when the related costs are incurred. Under the Asset Purchase Agreement, research and development services (PPQ services) are recorded as incurred under cost of service revenue – related party.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Customer Options: Customer options are evaluated at contract inception to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the standalone selling price. As a practical alternative to estimating the standalone selling price of a material right when the underlying goods or services are both (i) similar to the original goods or services in the contract and (ii) provided in accordance with the terms of the original contract, the Company allocates the total amount of consideration expected to be received from the customer to the total goods or services expected to be provided to the customer. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

Research and Development

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and travel of the Company's research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical and preclinical studies and for the drug product for the clinical studies and preclinical activities; facilities; supplies; rent, insurance, certain legal fees, share-based compensation, depreciation, other costs associated with clinical and preclinical activities and regulatory operations and acquisition of in process research and development write-offs. Research funding under collaboration agreements and refundable research and development credits / tax credits are recorded as an offset to these costs.

Costs for certain development activities, such as Company funded outside research programs, are recognized based on an evaluation of the progress to completion of specific tasks with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expenses, as the case may be.

Foreign Currencies

The Company's consolidated financial statements are presented in U.S. dollars, the reporting currency of the Company. The financial position and results of operations of our subsidiaries are measured using the foreign subsidiaries' local currency as the functional currency. These entities' cash accounts holding U.S. dollars and intercompany payables and receivables are remeasured based upon the exchange rate at the date of remeasurement with the resulting gain or loss included in the consolidated statements of operations and comprehensive loss. Expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Assets and liabilities have been translated at the rates of exchange on the consolidated balance sheet dates. The resulting translation gain and loss adjustments are recorded directly as a separate component of shareholders' equity and as other comprehensive loss on the consolidated statements of operations and comprehensive loss.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes*, or ASC 740, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Realization of net deferred tax assets is dependent on future taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. Realization of net deferred tax assets is dependent on future taxable income (see Note 10).

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2024 and 2023, the Company recorded unrecognized tax positions of $2.2 million and $2.0 million, respectively. No interest and penalties have been accrued relative to the unrecognized tax positions.

The Company is required to estimate income taxes in each of the jurisdictions in which it operates.

Net Loss per Ordinary Share

Basic net loss per ordinary share is computed by dividing net loss by the weighted average number of shares of the Company's ordinary shares assumed to be outstanding during the period of computation. Diluted net loss per ordinary share is computed similar to basic net loss per share except that the denominator is increased to include the number of additional ordinary shares that would have been outstanding if the potential ordinary share equivalents had been issued at the beginning of the year and if the additional ordinary shares were dilutive (treasury stock method) or the two-class method, whichever is more dilutive. For all periods presented, basic and diluted net loss per ordinary share are the same as any additional ordinary share equivalents would be anti-dilutive.

The following securities are considered to be ordinary share equivalents, but were not included in the computation of diluted net loss per ordinary share because to do so would have been anti-dilutive:

	December 31, 2024	December 31, 2023
Share options	8,232,587	8,226,707
Restricted share units	4,252,250	2,661,250
Deferred share units	—	185,000
Warrants	700,000	700,000
	13,184,837	11,772,957

Other Comprehensive Income (Loss)

Other comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The only component of other comprehensive income (loss) impacting the Company is foreign currency translation.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to

allocate resources in assessing performance. The Company has one reportable and operating segment, which is the development and manufacturing of genetic medicines, for purposes of reporting financial condition and results of operations. The Company's chief operating decision maker ("CODM") is the chief executive officer.

The accounting policies of its segment are the same as those described in the summary of significant accounting policies. The CODM allocates resources and assesses performance of the Company's single reportable segment by regularly reviewing the segment net loss that also is reported on the consolidated statement of operations and comprehensive loss as net loss.

The following table sets forth information about the Company's single reportable segment and the significant expenses reviewed by the CODM, including a reconciliation to net loss (in thousands):

	For the Years Ended December 31,	
	2024	2023
Service revenue - related party	$ 33,279	$ —
License revenue - related party	—	14,017
Operating expenses:		
Cost of service revenue - related party	23,791	—
General and administrative	39,389	31,522
Clinical programs:		
Botaretigene sparoparvovec	1,250	55,518
AAV-hAQP1	17,307	15,772
AAV-CNGB3 / AAV-CNGA3	(969)	2,184
AAV-GAD	6,411	7,598
Other ocular diseases	1,763	—
Manufacturing	53,445	50,221
Preclinical programs:		
Gene regulation	10,509	8,324
Neurodegenerative diseases	1,608	2,242
Preclinical ocular diseases	2,474	2,849
Other research and development[1]	2,494	3,831
Johnson & Johnson Innovative Medicine reimbursement	—	(70,429)
Share-based compensation	25,191	27,716
Depreciation and amortization	12,828	13,730
Total operating expenses	197,491	151,078
Other segment items[2]	16,421	53,034
Segment net loss	$ (147,791)	(84,027)
Adjustments or reconciling items	—	—
Net loss	$ (147,791)	$ (84,027)

[1] Other research and development is comprised of all other costs including payroll and payroll related costs, travel, rent and facilities costs and other non-program specific expenses.

[2] Other segment items is comprised of foreign currency (loss) gain, interest income, interest expense, gain on sale of nonfinancial assets and fair value adjustment.

The Company's service and license revenue, research funding and deferred revenue from the Collaboration Agreement and the Asset Purchase Agreement and related agreements were generated in the United Kingdom.

The following table summarizes long-lived assets by geographical area (in thousands):

	December 31, 2024	December 31, 2023
United States	$ 7,209	$ 11,071
United Kingdom	28,419	33,798
European Union	100,845	112,487
	$ 136,473	$ 157,356

Recent Accounting Pronouncements Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting - Improvements to Reportable Segment Disclosures*, which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. The Company adopted this standard on January 1, 2024 for the 2024 fiscal year, and for interim periods beginning January 1, 2025. The adoption of this standard did not have a material impact on the Company's consolidated financial statements. Refer to Segment Information within this footnote for additional information.

Recent Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. This update includes a number of amendments to clarify or improve disclosure and presentation requirements of a variety of topics in order to allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements and to align the requirements in the FASB accounting standard codification with the SEC's regulations. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is currently evaluating the impact of these amendments.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which requires that an entity disclose specific categories in the effective tax rate reconciliation as well as provide additional information for reconciling items that meet a quantitative threshold. Further, the ASU requires certain disclosures of state versus federal income tax expense and taxes paid. This ASU is effective for fiscal years beginning after December 15, 2024. The Company does not expect the adoption of this ASU to have a material impact on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement: Reporting Comprehensive Income: Expense Disaggregation Disclosures (Subtopic 220-40)*, which requires public business entities to disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. In January 2025, the FASB issued ASU No. 2025-01, *Clarifying the Effective Date*, which revised the effective date of ASU No. 2024-03 for interim periods. The guidance is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. The Company is currently assessing the impact of ASU 2024-03 and ASU 2025-01 on its consolidated financial statements.

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

3. Equity Method and Other Investments

The Company's investments consist of the following (in thousands):

		December 31, 2024		
Investee	Investment Type	Ownership Percentage	Carrying Value	Cost Basis
Visiogene LLC	Equity Method Investment	25 %	$ 5,133	$ 5,165
Other	Equity Investment	0.9 %	1,616	1,500
Total equity method and other investments			$ 6,749	$ 6,665

Visiogene LLC

On January 4, 2021, the Company and Visiogene LLC ("Visiogene") entered into a License and Investment Agreement ("Visiogene License Agreement") for an exclusive, worldwide license to certain of Visiogene's intellectual property relating to ocular gene therapy. Concurrently, the Company and Visiogene entered into a Preferred Unit Purchase Agreement ("Visiogene Unit Agreement") pursuant to which the Company purchased 3,000,000 Visiogene preferred units. In connection with the two Visiogene agreements, the Company paid $5.0 million in cash and issued to Visiogene 75,000 ordinary shares of the Company with a fair market value of $1.2 million based on the closing price of the Company's ordinary shares on the date of closing.

The Company accounted for the payments under the Visiogene License Agreement and Visiogene Unit Agreement as a basket transaction and allocated $1.0 million to the Visiogene License Agreement and the remaining $5.2 million was allocated to the Visiogene preferred units. The $1.0 million allocated to the Visiogene License Agreement was expensed as acquired in-process research and development as the Company determined there was no alternative future use. The Company accounts for this investment using the equity method of accounting.

During the years ended December 31, 2024 and 2023, the Company recorded de minimis research and development expenses related to the Company's share of Visiogene's losses.

4. Prepaid Expenses

Prepaid expenses at December 31, 2024 and 2023 consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Manufacturing costs	$ 1,826	38
Clinical trial costs	1,823	$ 1,530
Dues and license fees	1,253	1,439
Insurance	840	861
Facilities costs	657	630
Other	429	199
Research and development	—	685
Consulting	—	243
	$ 6,828	$ 5,625

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Property, Plant and Equipment, net

Property, plant and equipment, net at December 31, 2024 and 2023 consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Leasehold improvements	$ 99,371	$ 103,082
Manufacturing equipment	23,019	22,646
Laboratory equipment	14,741	15,389
Computer and office equipment	7,292	7,370
Furniture and fixtures	758	734
	145,181	149,221
Less: Accumulated depreciation and amortization	(42,303)	(33,325)
	$ 102,878	$ 115,896

In connection with certain operating leases, the Company has determined that it has asset retirement obligations in the aggregate amount of $5.4 million at the end of those leases. The Company discounted the initial asset retirement obligations using an 8% discount rate and during the year ended December 31, 2024, the Company recorded a change in estimate in connection with five leases using a 15% discount rate. The Company recorded an asset retirement obligation in the aggregate amount of $2.1 million, which is included in leasehold improvements and is being amortized over the term of the respective leases.

Depreciation and amortization expense related to property, plant and equipment was $11.4 million and $12.3 million for the years ended December 31, 2024 and 2023, respectively.

6. Intangible Assets

In November 2020, the Company entered into a non-exclusive, royalty-free technology license agreement that required the Company to pay an upfront payment to the licensor of $2.1 million. The Company accounted for the transaction as an asset acquisition and recorded an intangible asset as it was determined to have alternative future uses in connection with the Company's manufacturing capabilities.

The following table presents the details of the Company's intangible assets as of December 31, 2024 and 2023 (in thousands):

	December 31, 2024	December 31, 2023
Licensed Technology	$ 1,971	$ 2,000
Less: Accumulated amortization	(1,150)	(882)
	$ 821	$ 1,118

The intangible asset is being amortized over a period of seven years. Amortization expense of $0.3 million was recorded as a component of research and development expenses for each of the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, the expected amortization expense for the next three years is as follows (in thousands):

	Amortization Expense
2025	$ 281
2026	281
2027	259
Total amortization	$ 821

7. Accrued Expenses

Accrued expenses at December 31, 2024 and 2023 were comprised of the following (in thousands):

	December 31, 2024	December 31, 2023
Professional fees	$ 6,326	$ 6,499
Compensation and benefits	11,197	12,129
Clinical trial costs	3,864	8,713
Research and development	2,234	5,834
Manufacturing costs	1,540	2,634
Consulting	1,530	2,104
Fixed assets	326	1,472
Rent and facilities costs	257	142
Interest on Tranche 1 Notes	—	2,936
Other	140	176
	$ 27,414	$ 42,639

8. Share-Based Compensation

Equity Incentive Plans

The Company's 2018 Incentive Award Plan and 2016 Equity Incentive Plan (collectively, the "Plans"), were adopted by the Company's board of directors and shareholders. Under the Plans, the Company has granted share options and restricted share units ("RSUs") to selected officers, employees, non-employee members of the Company's board of directors and non-employee consultants. The Company's board of directors or a committee thereof administers the Plans. Upon the adoption of the 2018 Incentive Award Plan, the Company ceased issuing awards under the 2016 Equity Incentive Plan. The number of shares available for issuance under the 2018 Incentive Award Plan are increased on January 1 of each calendar year beginning in 2019 and ending in and including 2028, by an amount equal to the lesser of (A) 4% of the ordinary shares outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares determined by the Company's board of directors. Under the 2018 Incentive Award Plan the Company initially reserved up to 3,054,996 shares for issuance, which has been increased to 13,654,788 as of December 31, 2024. As of December 31, 2024, 300,888 shares remain available for future issuance. In January 2025, the number of shares available for issuance under the 2018 Incentive Award Plan increased by 3,135,895 shares.

Options

A summary of the Company's share option activity related to employees, non-employee members of the board of directors and non-employee consultants as of and for the years ended December 31, 2024 is as follows (in thousands, except share and per share amounts):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)
Outstanding at December 31, 2023	8,226,707	$ 12.96	6.35 years
Granted	365,100	$ 6.16	
Forfeited	(359,220)	$ 15.32	
Outstanding at December 31, 2024	8,232,587	$ 12.57	5.35 years
Options exercisable at December 31, 2024	6,874,024	$ 13.03	4.83 years
Options vested and expected to vest at December 31, 2024	8,232,587	$ 12.57	5.35 years
Aggregate intrinsic value of options outstanding as of December 31, 2024	$ 1,422		
Aggregate intrinsic value of options exercisable as of December 31, 2024	$ 1,422		

Options granted under the Plans have a maximum contractual term of ten years. Options granted generally vest 25% on the first anniversary of the date of grant and the balance ratably over the next 36 months. Options granted to directors when they join the board generally vest in 36 equal monthly installments following the date of grant, and annual options granted to directors generally vest on the earlier of the first anniversary of the date of grant or the day before the Company's next annual meeting of shareholders after the date of grant.

The Company recorded the following share-based compensation expense in connection with the options for the years ended December 31, 2024 and 2023 (in thousands):

	Years Ended December 31,	
	2024	2023
Research and development	$ 6,062	$ 8,577
General and administrative	3,892	5,054
Total share-based compensation	$ 9,954	$ 13,631

The total fair value of options vested during the years ended December 31, 2024 and 2023 was $12.1 million and $15.3 million, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2024 and 2023 was $3.91 per share and $5.67 per share, respectively. The grant date fair values of the share options granted were estimated using the Black-Scholes option valuation model with the following ranges of assumptions (see Note 2):

	2024	2023
Risk-free interest rate	4.04 - 4.17%	3.86 - 4.48%
Expected volatility	67%	72%
Expected dividend yield	0%	0%
Expected term (in years)	3.6 - 6.1	3.6 - 6.1

As of December 31, 2024, the total compensation expense relating to unvested options granted that had not yet been recognized was $8.5 million, which is expected to be recognized over a period of 3.2 years. The Company will issue shares upon exercise of options from ordinary shares reserved under the Plans.

Restricted Share Units

A summary of the Company's RSU activity related to employees, non-employee members of the board of directors and non-employee consultants for the year ended December 31, 2024 is as follows:

	Number of Restricted Share Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2023	2,661,250	$ 15.24
Granted	2,638,500	$ 5.97
Vested	(1,002,500)	$ 18.14
Forfeited	(45,000)	$ 4.87
Outstanding at December 31, 2024	4,252,250	$ 8.91

RSUs granted generally vest 50% on the second anniversary of the date of grant and 25% on the third and fourth anniversaries of the date of grant. Annual RSUs granted to directors generally vest in a single installment on the earliest to occur of the first anniversary of the grant date or the day immediately prior to the date of the next annual meeting of the Company's shareholders occurring after the date of grant. The RSUs granted to the directors in June 2021 will be paid on or within 30 days after the date a director ceases to serve on the board. For RSUs granted in future years, the directors may elect whether to defer the payment of their annual RSU awards under the Deferred Compensation Plan for Non-Employee Directors, which was adopted by the board on December 17, 2021. As of December 31, 2024, there were 272,500 vested shares that have been deferred. The related share-based compensation expense, which is recognized ratably over the requisite service period, is included in general and administrative and research and development expenses, as applicable, in the consolidated statements of operations and comprehensive loss.

The company recorded the following share-based compensation expense in connection with the RSUs for the years ended December 31, 2024 and 2023 (in thousands):

	Years Ended December 31,	
	2024	2023
Research and development	$ 5,070	$ 4,203
General and administrative	10,167	9,882
Total share-based compensation	$ 15,237	$ 14,085

As of December 31, 2024, the total compensation expense relating to unvested RSUs granted that had not yet been recognized was $21.9 million, which is expected to be recognized over a period of 3.3 years.

To satisfy employee minimum statutory tax withholding requirements for restricted share units that vest, the Company withholds a portion of the vesting ordinary shares. During the years ended December 31, 2024 and 2023, the Company withheld 377,152 and 237,859 ordinary shares with a total value of approximately $2.3 million and $1.5 million, respectively. These amounts are presented as a cash outflow from financing activities in the accompanying consolidated statement of cash flows.

During the years ended December 31, 2024 and 2023 the Company recognized total share-based compensation expense in the accompanying consolidated statements of operations and comprehensive loss as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Research and development	$ 11,132	$ 12,780
General and administrative	14,059	14,936
Total share-based compensation	$ 25,191	$ 27,716

The Company does not expect to realize any tax benefits from its share option activity or the recognition of share-based compensation expense because the Company currently has net operating losses and has a full valuation allowance against its deferred tax assets. Accordingly, no amounts related to excess tax benefits have been reported in cash flows from operations or cash flows from financing activities for the years ended December 31, 2024 and 2023.

9. Ordinary Shares

2024

At-the-Market

In December 2023, the Company entered into an “at-the-market” sales agreement with BofA Securities, Inc., or BofA, pursuant to which the Company may sell from time to time, ordinary shares having an aggregate offering price of up to $100.0 million through BofA, acting as the Company’s agent. During the year ended December 31, 2024, the Company raised gross proceeds of $8.4 million through the sale of 1,508,517 ordinary shares pursuant to an “at-the-market” equity offering program. Under the “at-the-market” equity program which is currently effective and may remain available for the Company to use in the future, the Company may sell an additional $91.6 million of ordinary shares. Whether the Company chooses to affect future sales under the “at-the-market” equity offering program will depend on a number of factors, including, among others, market conditions and the trading price of the Company’s ordinary shares relative to other sources of capital.

Equity Financing

On August 12, 2024, the Company entered into an underwriting agreement with BofA in connection with the issuance and sale by the Company in a public offering of 12,500,000 of the Company’s ordinary shares at a public offering price of $4.00 per share, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 (Registration No. 333-276183) and a related prospectus supplement filed with the SEC. The closing of the offering occurred on August 13, 2024. The Company received gross proceeds from the offering of $50.0 million and incurred underwriting discounts and commissions and estimated offering expenses of approximately $1.9 million.

On August 12, 2024, the Company agreed to sell shares to an accredited investor (the "Investor") through a private placement rather than through the public offering and as a result, on August 23, 2024, the Company entered into a securities purchase agreement with the Investor, pursuant to which the Company, in a private placement, agreed to issue and sell to the Investor 250,000 ordinary shares at a purchase price of $4.00 per share, for gross proceeds of $1.0 million (the "Private Placement"). The closing of the Private Placement occurred on August 29, 2024.

2023

May 2023 Private Placement

On May 3, 2023, the Company entered into a securities purchase agreement with certain accredited investors, pursuant to which the Company, in a private placement, agreed to issue and sell an aggregate of 10,773,913 ordinary shares at a purchase price of $5.75 per share, for gross proceeds of approximately $62.0 million and incurred issuance costs of approximately $4.1 million. The closing occurred on May 5, 2023.

Sanofi Private Placement

On October 30, 2023, the Company entered into an Investment Agreement with Sanofi Foreign Participations B.V., a wholly-owned subsidiary of Sanofi, and solely for the limited purposes set forth therein, Sanofi, pursuant to which, the Company, in a private placement, issued an aggregate of 4,000,000 ordinary shares, at a purchase price of $7.50 per share for gross proceeds of $30.0 million and incurred issuance costs of approximately $2.3 million.

10. Income Taxes

For the years ended December 31, 2024 and 2023, the Company recognized a tax benefit of $0.

As of December 31, 2024, the Company had U.S. federal and state net operating losses ("NOLs") and foreign carryforward tax losses which are available to reduce future taxable income of (in thousands):

	Federal	State/City
United Kingdom	$ 203,678	$ —
United States	$ 74,348	$ 19,285
Ireland	$ 78,309	$ —
Other	$ 29,987	$ —

All of the Company's carryforward tax losses will be indefinitely carried forward, with the exception of federal U.S. NOLs in the amount of $0.2 million as of December 31, 2024, which will begin to expire in 2037 and state NOLs in the amount of $19.0 million as of December 31, 2024, which will begin to expire in 2036. Also, as of December 31, 2024, the Company had orphan drug and research and development credits in the U.S. in the amount of $22.5 million which will begin to expire in 2035 and research and development credits of $1.9 million in the UK which can be carried forward indefinitely. The U.S. NOLs and UK carryforward tax losses may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders, as defined under Section 382 of the Internal Revenue Code, as well as UK tax rules. This could limit the amount of NOLs and carryforward tax losses that the Company can utilize annually to offset future taxable income or tax liabilities. As of August 2024, the Company had performed such an analysis and determined that there were no

limitations in the UK. However, for U.S. purposes, the Company determined that a change of ownership occurred in April 2016 and again in June 2018, but there was not a limit for utilizing these losses.

The Company's pre-tax income (loss) is as follows (in thousands):

	December 31, 2024	December 31, 2023
United Kingdom	$ (62,760)	$ 12,881
United States	(57,580)	(63,017)
Ireland	(25,762)	(29,965)
Other	(1,689)	(3,926)
	$ (147,791)	$ (84,027)

The Company is subject to the corporate tax rate in the UK as a limited UK corporation.

The following table summarizes a reconciliation of income tax benefit compared with the amounts at the UK statutory income tax rate (in thousands):

	December 31, 2024		December 31, 2023	
Statutory rate	(36,948)	25.00 %	(19,746)	23.50 %
Permanent differences - other	4,264	(2.88)%	2,391	(2.85)%
RTP and other adjustment	4,252	(2.88)%	(1,165)	1.39 %
State and local rate, net of federal tax	(634)	0.43 %	(698)	0.83 %
U.K. tax credit	6,476	(4.38)%	(4,028)	4.79 %
U.S. tax credit	(3,352)	2.27 %	(9,830)	11.70 %
Foreign tax rate differential	4,751	(3.21)%	4,558	(5.42)%
UK rate change	—	— %	239	(0.28)%
US state rate change	(309)	0.21 %	15,394	(18.32)%
Section 162(m) deferred adjustment	1,568	(1.06)%	2,728	(3.25)%
Disallowed interest	(4,106)	2.76 %	2,812	(3.35)%
Change in valuation allowance	24,038	(16.26)%	7,345	(8.74)%
Actual income tax benefit effective tax rate	—	— %	—	— %

The Expense/(Benefit) for income taxes from continuing operations consists of the following (in thousands):

	December 31, 2024	December 31, 2023
Current Tax Expense/(Benefit)		
United Kingdom	—	—
United States	—	—
Other	—	—
Total Current	—	—
Deferred Tax Expense/(Benefit)		
United Kingdom	(9,344)	2,393
United States	(11,405)	(6,251)
Ireland	(3,134)	(3,963)
Netherlands	(155)	(1,840)
Total Deferred	(24,038)	(9,661)
Change in Valuation Allowance	24,038	9,661
Total Income Tax Expense/(Benefit)	—	—

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Deferred Tax Assets/(Liabilities) (in thousands):

	December 31, 2024	December 31, 2023
Deferred Tax Assets:		
Net operating loss carryforwards	$ 85,308	$ 70,650
Interest expense	6,736	—
Capitalized research and development	26,312	19,606
Share-based compensation	11,921	14,290
R&D credit	22,160	21,687
Lease liability	2,767	4,070
Deferred tax assets	155,204	130,303
Less: valuation allowance	(149,382)	(125,884)
Deferred Tax Liabilities:		
Depreciation	(2,192)	(1,763)
Right of use assets	(2,099)	(3,777)
Other	(1,531)	1,121
Net deferred tax liability	$ —	$ —

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance, after consideration of the reversal of the deferred tax liabilities for the ROU assets and fixed assets, against its deferred tax assets at December 31, 2024 and 2023 because the Company's management has determined that it is more likely than not that these assets will not be fully realized.

As of December 31, 2024 and 2023, the Company recorded unrecognized tax positions of $2.2 million and $2.0 million, respectively. The unrecognized tax positions are netted with deferred tax assets above with a full valuation allowance. The changes to unrecognized tax positions for 2024 and 2023 were as follows (in thousands):

	December 31, 2024	December 31, 2023
Unrecognized tax benefits as of January 1	$ 2,029	$ 937
Gross increases/(decreases) related to current year	505	756
Gross increases/(decreases) related to prior years	(285)	336
Unrecognized tax positions as of December 31	$ 2,249	$ 2,029

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2024 and 2023, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations and comprehensive loss.

The Company files income tax returns in the United States, UK, various foreign jurisdictions and various U.S. state jurisdictions. In the U.S., all years remain subject to examination. The earliest year subject to examination in the UK is 2023.

MeiraGTx Holdings plc is a UK tax resident with no earnings in its foreign subsidiaries and the Company does not expect any temporary basis difference in its investment in these subsidiaries to reverse in the foreseeable future. Therefore, the Company has not recorded deferred taxes on the outside basis difference in its foreign subsidiaries. It is not probable to compute the amounts, if any.

11. Related Party Transactions

Relationship with Johnson & Johnson Innovative Medicine

Collaboration Agreement

On January 30, 2019, the Company entered into a Collaboration Agreement with Johnson & Johnson Innovative Medicine for the research, development and commercialization of gene therapies for the treatment of IRDs. Under the agreement, Johnson & Johnson Innovative Medicine paid the Company a non-refundable upfront fee of $100.0 million. Johnson & Johnson Innovative Medicine and the Company agreed to collaborate to develop the Company's clinical programs in retinitis pigmentosa and two genetic forms of achromatopsia and Johnson & Johnson Innovative Medicine had the exclusive right to commercialize these three product candidates ("Clinical IRD Product Candidates") globally.

Pursuant to the Collaboration Agreement, the Company and Johnson & Johnson Innovative Medicine also agreed on a research collaboration to develop a pipeline of preclinical inherited retinal disease gene therapy candidates ("Research IRD Product Candidates"). The parties agreed to select and prioritize the Research IRD Product Candidates and Johnson & Johnson Innovative Medicine had the right to opt-in for a fee for each of the specified targets (each an "Option Target") to obtain certain development, manufacturing and commercialization rights for the Research IRD Product Candidates.

Unless terminated earlier under certain termination clauses, the Collaboration Agreement was to continue in effect, on a product-by-product and country-by-country basis, until such time as the royalty terms expired in such country. The Company had determined enforceable rights existed in the Collaboration Agreement as the termination clauses were substantive termination penalties by way of the non-refundable upfront fee and the reversion of any licensed intellectual property granted to Johnson & Johnson Innovative Medicine upon the termination of the agreement.

Under the Collaboration Agreement, the Company and Johnson & Johnson Innovative Medicine were jointly developing Clinical IRD Product Candidates to permit Johnson & Johnson Innovative Medicine to commercialize such Clinical IRD Product Candidates under an exclusive license from the Company. In general, the Company had the primary responsibility to develop each Clinical IRD Product Candidate in accordance with the development plan for each Clinical IRD Product Candidate, including where applicable, conducting any necessary research in order to submit the applicable regulatory filings to regulatory authorities. The Company agreed to manufacture these products in its GMP manufacturing facilities for both clinical and commercial supply. Johnson & Johnson Innovative Medicine agreed to pay 100% of the clinical and commercialization costs of the products and the Company was eligible to receive untiered 20% royalties on net sales of products and additional development and commercialization milestones up to $340.0 million. The Company received a milestone payment of $30.0 million in December 2021. In connection with entering into the Asset Purchase Agreement, the Company entered into a Termination Agreement with Johnson & Johnson Innovative Medicine terminating the Collaboration Agreement.

Asset Purchase and Related Agreements

On December 20, 2023, the Company entered into the Asset Purchase Agreement with Johnson & Johnson Innovative Medicine pursuant to which the Company sold and assigned to Johnson & Johnson Innovative Medicine, and Johnson & Johnson Innovative Medicine purchased and assumed, the UCLB RPGR License Agreement relating to the research, development, manufacture and exploitation of the RPGR Product, and other related assets as described in the Asset Purchase Agreement. Simultaneously, the Company and Johnson & Johnson Innovative Medicine also entered into a Supply Agreement pursuant to which the Company agreed to manufacture and supply the RPGR Product for Johnson & Johnson Innovative Medicine. Under the Supply Agreement, MeiraGTx UK II, together with its affiliates, will manufacture commercial supply of the RPGR Product for Johnson & Johnson Innovative Medicine for an initial term of four years, with Johnson & Johnson Innovative Medicine having an

option to extend the Supply Agreement for a fifth year upon written notification. Johnson & Johnson Innovative Medicine may terminate the Supply Agreement for convenience upon 90 days' written notice with payment of a termination fee. Under the Asset Purchase Agreement, Johnson & Johnson Innovative Medicine paid the Company a non-refundable upfront fee of $65.0 million in December 2023 and the Company is eligible to receive fees from commercial supply of the RPGR Product and in addition, milestones of up to $350.0 million, as follows: (i) a milestone payment of $50.0 million in connection with the achievement of the initiation of the extension study for the Phase 3 LUMEOS clinical trial for the RPGR Product; (ii) $10.0 million upon completion of certain specified development services for the drug substance for the RPGR Product; (iii) $5.0 million upon completion of certain specified development services for the drug product for the RPGR Product; (iv) $175.0 million upon the first commercial sale of an RPGR Product in the United States; (v) $75.0 million upon the first commercial sale of an RPGR Product in at least one of the United Kingdom, France, Germany, Spain and Italy; (vi) $25.0 million upon completion of the transfer of certain manufacturing technology for drug substance and drug product from the Company to Johnson & Johnson Innovative Medicine; and (vii) $10.0 million upon regulatory approval of a Johnson & Johnson Innovative Medicine-selected manufacturing facility in each of the United States and European Union for commercial manufacture of the RPGR Product. As of December 31, 2024, we have received $60.0 million in milestone payments from Johnson & Johnson Innovative Medicine. Johnson & Johnson Innovative Medicine is also responsible for any royalty or milestone amounts that become payable on the RPGR Product under the UCLB RPGR License Agreement.

Revenue Recognition under the Johnson & Johnson Innovative Medicine Agreements

Collaboration Agreement

The Company evaluated the potential performance obligations in the Collaboration Agreement pursuant to ASC 606, which included the exclusive license to Clinical IRD Product Candidates, the research, development and manufacturing services ("the services"), and the participation in various joint committees and determined that none of the performance obligations by themselves were distinct. Goods and services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. The services, when combined with the licenses, represent a bundle and should be accounted for as a single performance obligation due to the relevance of the services to the value of the early-stage license and the potential for the intellectual property to be significantly modified during the services period. The Company also evaluated whether or not the right to purchase exclusive option rights for specified Research IRD Product Candidates represents future performance obligations and concluded that these represent a separate buyer decision at market rates, rather than a material right performance obligation. As such, these options were excluded from the initial allocation of transaction price and the Company would have accounted for these options as separate contracts when and if Johnson & Johnson Innovative Medicine had elected to exercise the options.

Under ASC 606, the Company recognized collaboration revenue using the cost-to-cost input method, which it believes best depicts the transfer of control to the customer. Under the cost-to-cost input method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the combined performance obligation by the potential product candidate. Under this method, revenue is being recorded as a percentage of the estimated transaction price based on the extent of progress towards completion. Under ASC 606, the estimated transaction price includes variable consideration subject to constraints. The Company does not include variable consideration to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will occur when any uncertainty associated with the variable consideration is resolved. The estimate of the Company's measure of progress and estimate of variable consideration included in the transaction price was updated at each reporting date as a change in estimate. The amount related to the unsatisfied portion was recognized as that portion was satisfied over time.

Under ASC 606 the Company accounts for (i) the licenses it conveyed with respect to the Clinical IRD Product Candidates and (ii) its obligations to perform services as a single performance obligation under the Collaboration Agreement with Johnson & Johnson Innovative Medicine on a product candidate basis. Johnson & Johnson

Innovative Medicine's right to purchase exclusive options to obtain certain development, manufacturing and commercialization rights were accounted for separately as they did not represent material rights, based on the criteria of ASC 606. Upon the exercise of any purchased option by Johnson & Johnson Innovative Medicine, the contract promises associated with an Option Target have used a separate cost-to-cost model for purposes of revenue recognition under ASC 606.

In 2019, the Company received a $100.0 million non-refundable upfront fee from Johnson & Johnson Innovative Medicine and during the year ended December 31, 2021, the Company received a $30.0 million milestone payment. The Company allocated these amounts plus other variable consideration not subject to constraint to each identified performance obligation using a combination of methods allowable under ASC 606. The Company applies the practical expedient in Topic 606 and does not include disclosures regarding amounts for variable consideration allocated to wholly-unsatisfied performance obligations or wholly-unsatisfied distinct goods that form part of a single performance obligation, if any. This variable consideration includes expected reimbursement of research and development costs.

Asset Purchase and Related Agreements

The agreements entered into in December 2023 were executed at the same time and were negotiated with a single commercial objective; therefore, the contracts were combined and accounted for as a single contract. These agreements were accounted for as a termination of the existing Collaboration Agreement and the creation of a new contract where the transaction price includes the remaining deferred revenue – related party from the terminated agreement of $30.6 million, the fixed upfront payment of $65.0 million under the Asset Purchase Agreement, and an aggregate of $1.8 million estimated variable consideration for transition services, offset by a credit of $5.1 million for pre-funded inventory, totaling $92.3 million. The transaction price was allocated to four performance obligations on a relative SSP basis, subject to certain exceptions for discounts and variable consideration. As the SSPs are not directly observable for any of the distinct goods and services, the SSPs were estimated based on a valuation. The total transaction price of $92.3 million was allocated to the performance obligations with respect to SSPs as follows: process performance qualification ("PPQ") services in the amount of $2.9 million, net of future billings, material rights representing the commercial supply of RPGR Product and an in-substance contract renewal option in the amount of $6.9 million, manufacturing technology transfer in the amount of $28.7 million, and the sale of nonfinancial assets representing the sale and transfer of all the Company's right, title, and interest in the intellectual property related to the RPGR Product and the assignment of the UCLB RPGR License Agreement to Johnson & Johnson Innovative Medicine in the amount of $53.8 million.

During the year ended December 31, 2024, the Company received a $50.0 million milestone payment in connection with the achievement of the initiation of the extension study for the Phase 3 LUMEOS clinical trial for the RPGR Product. The milestone payment was allocated to the four performance obligations on the same basis noted above increasing the value of each performance obligation as follows: PPQ services in the amount of $1.6 million, material rights representing the commercial supply of RPGR Product and an in-substance contract renewal option in the amount of $3.8 million, manufacturing technology transfer in the amount of $15.6 million, and the sale of nonfinancial assets representing the sale and transfer of all the Company's right, title, and interest in the intellectual property related to the RPGR Product and the assignment of the UCLB RPGR License Agreement to Johnson & Johnson Innovative Medicine in the amount of $29.0 million. Additionally, the Company received a $10.0 million milestone payment in connection with the completion of certain specified development services for the drug substance for the RPGR Product which was allocated to the PPQ services performance obligation. The Company also entered into additional agreements to provide additional services under the Asset Purchase Agreement and related agreements amounting to an aggregate of $5.7 million which was included in the transaction price and allocated to each of the respective performance obligations. Furthermore, the Company recorded certain changes in estimates related to the valuation of its performance obligations.

The transaction price allocated to PPQ services will be recognized over time using an inputs method measure of progress. The transaction price allocated to the material right for the commercial supply of RPGR Product will be

recorded as deferred revenue until Johnson & Johnson Innovative Medicine exercises its option to purchase supply and the Company transfers control of such supply to Johnson & Johnson Innovative Medicine. The transaction price allocated to the in-substance renewal option (material right) will be recorded as deferred revenue until Johnson & Johnson Innovative Medicine exercises the option and the Company transfers control of the underlying goods or services to Johnson & Johnson Innovative Medicine. The Company will account for the exercise of the in-substance renewal option (material right) as a continuation of the existing contract (i.e., a change in the transaction price). The transaction price allocated to the technology transfer will be recognized over time using an inputs method measure of progress. The Company will recognize a gain for the difference between the carrying amount of the nonfinancial assets and the consideration allocated to that unit of account when control of the nonfinancial assets transfers in accordance with ASC 610-20, *Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets*.

During the years ended December 31, 2024 and 2023, the Company recognized a gain of $28.4 and $54.2 million, respectively, related to the sale of nonfinancial assets which is included in other income in the consolidated statement of operations and comprehensive loss.

As of December 31, 2024, the aggregate transaction price allocated to unsatisfied performance obligations was $62.4 million which the Company expects to recognize over an estimated period of approximately 3.0 years.

A summary of the deferred revenue recognition is as follows (in thousands):

Deferred revenue at December 31, 2023	$	36,943
Milestone payment allocated to performance obligations		33,066
Other amounts collected or invoiced		7,809
Deferred revenue recognized as service revenue during the year ended December 31, 2024		(14,035)
Effects of exchange rate changes		(1,380)
Deferred revenue at December 31, 2024	$	62,403

During the year ended December 31, 2024, the Company recognized $14.0 million of deferred revenue – related party as service revenue in connection with PPQ services under the Asset Purchase Agreement and related agreements. During the year ended December 31, 2023, the Company recognized $14.0 million of deferred revenue – related party in connection with the Collaboration Agreement as license revenue.

During the year ended December 31, 2024, $33.3 million of service revenue, inclusive of the $14.0 million of deferred revenue – related party recognized as service revenue, was recognized based on cumulative progress of PPQ services under the Asset Purchase Agreement and related agreements. During the year ended December 31, 2023, the Company recognized $70.4 million related to the reimbursement of research and development expenses under the Collaboration Agreement, which were recorded as an offset to research and development expenses.

Debt Financing

On August 2, 2022 the Company, as borrower, and Meira UK II and Meira Ireland, as guarantors (the "Subsidiary Guarantors"), entered into a senior secured financing arrangement (the "Financing Agreement") by and among the Company, the Subsidiary Guarantors, the lenders and other parties from time to time party thereto and Perceptive Credit Holdings III, LP, as administrative agent and lender ("Perceptive"). On December 19, 2022, the Financing Agreement was converted to a notes purchase agreement and guaranty (the "Notes Purchase Agreement") between the same parties and under substantially the same terms and conditions as the Financing Agreement, subject to certain customary note constitution terms. Perceptive Advisors, LLC, an affiliate of Perceptive, is a 16.0% holder of the ordinary shares of the Company. Additionally, Ellen Hukkelhoven, Ph.D., a director of the Company, is an employee of Perceptive Advisors, LLC. Refer to the discussion in Note 13 for further information related to the accounting for the debt financing.

May 2023 Private Placement

On May 3, 2023, the Company issued 10,773,913 ordinary shares in a private placement for gross proceeds of $62.0 million, excluding offering costs of approximately $4.1 million. Perceptive Advisors, LLC and Adage Capital Partners, L.P. a greater than 5% holder of the ordinary shares of the Company, purchased 4,347,826 and 1,565,217 of the ordinary shares, respectively, issued on the same terms and conditions as the other investors in the offering.

12. Leases

The Company has commitments under operating leases for laboratory, warehouse, clinical trial sites and office space. The Company also has finance leases for manufacturing space and office equipment. The Company's leases have initial lease terms ranging from 3 years to 191 years. Certain lease agreements contain provisions for future rent increases. Payments due under the lease contracts include fixed payments.

Total rent expense recorded under these leases was $5.6 million and $5.5 million for the years ended December 31, 2024 and 2023, respectively.

Eight clinical trial site leases were assigned to Johnson & Johnson Innovative Medicine during the year ended December 31, 2024 in connection with the Asset Purchase Agreement and related agreements. There were no leases recognized during the years ended December 31, 2024 and 2023.

The components of lease cost for the years ended December 31, 2024 and 2023 are as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Finance lease cost		
Amortization of right-of-use assets	$ 981	$ 1,124
Total finance lease cost	981	1,124
Operating lease cost	5,630	5,473
Short-term lease cost	256	159
Total lease cost	$ 6,867	$ 6,756

Amounts reported in the consolidated balance sheets for leases where the Company is the lessee as of December 31, 2024 and 2023 were as follows (in thousands):

	December 31, 2024	December 31, 2023
Operating leases		
Right-of-use assets	$ 10,576	$ 15,910
Capitalized lease obligations	$ 11,576	$ 17,145
Finance leases		
Right-of-use assets	$ 22,198	$ 24,432
Weighted-average remaining lease term		
Operating leases	3.6 years	4.3 years
Finance leases	173.9 years	174.8 years
Weighted-average discount rate		
Operating leases	8.8 %	8.8 %
Finance leases	8.0 %	8.0 %

Other information related to leases as of the years ended December 31, 2024 and 2023 are as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 5,408	$ 5,662

Future minimum lease payments under non-cancellable leases as of December 31, 2024 are as follows (in thousands):

	Operating Leases
2025	$ 4,936
2026	5,078
2027	1,428
2028	1,238
2029	541
Total undiscounted lease payments	$ 13,221
Less: Imputed interest	(1,645)
Total lease liabilities	$ 11,576

13. Debt Financing

On August 2, 2022 the Company, and the Subsidiary Guarantors, entered into the Financing Agreement with Perceptive. On December 19, 2022, the Financing Agreement was converted to a Notes Purchase Agreement between the same parties and under substantially the same terms and conditions as the Financing Agreement, subject to certain customary note constitution terms. The Company and the Subsidiary Guarantors entered into a Consent and Amendment with Perceptive on August 10, 2023 (the "First Consent and Amendment), and the Company and the Subsidiary Guarantors entered into a second Consent and Amendment with Perceptive on December 20, 2023 (the "Second Consent and Amendment").

The Notes Purchase Agreement provides for an initial $75.0 million notes issuance (the "Tranche 1 Notes"). Pursuant to the First Consent and Amendment, the Company was able to request in its sole discretion, and Perceptive agreed to subscribe to purchase upon such request, an additional $25.0 million notes issuance (the "Tranche 2 Notes") at any time before August 2, 2024 subject to the terms of the Notes Purchase Agreement. Previously, the Company's request for issuance of the Tranche 2 Notes was to be determined at Perceptive's sole discretion. The Notes Purchase Agreement matures on August 2, 2026 and is interest-only during the term. The Company has the option to redeem outstanding principal notes at any time along with an applicable early redemption fee. Under each of the First Consent and Amendment and the Second Consent and Amendment, the Notes Purchase Agreement was amended to increase the applicable early redemption fee. Outstanding amounts under the Notes Purchase Agreement bear interest at a fluctuating rate per annum equal to 10.00% plus the secured overnight financing rate administered by the Federal Reserve Bank of New York for a one-month tenor, subject to a 1.00% floor. The annual interest rate was 14.85% at December 31, 2024. As of December 31, 2024, the outstanding balance of the Tranche 1 Notes was $75.0 million plus interest payable of $2.9 million. During the years ended December 31, 2024 and 2023, the Company recorded interest expense of $11.6 million and $11.3 million, respectively.

The Company's obligations under the Notes Purchase Agreement are secured by the Company's London, UK and Shannon, Ireland manufacturing facilities, $3.0 million of the Company's cash and the bank accounts of the Subsidiary Guarantors, and the issued and outstanding equity interests of the Subsidiary Guarantors.

The Notes Purchase Agreement imposes certain covenants and restrictions on the Company and the Subsidiary Guarantors, including restrictions pertaining to: (i) the incurrence of additional indebtedness, (ii) limitations on liens, (iii) limitations on certain investments, (iv) making distributions, dividends and other payments, (v) mergers, consolidations and acquisitions, (vi) dispositions of assets, (vii) the Company's maintenance of at least $3.0 million in a U.S. bank account, (viii) transactions with affiliates, (ix) changes to governing documents, (x) changes to certain agreements and leases and (xi) changes in control; however, certain of these restrictions contain exceptions which allow the Company to license, sell and monetize assets in its AAV-hAQP1 program in development to treat radiation-induced xerostomia, its AAV-GAD program in development to treat Parkinson's disease and its gene regulation platform technologies. As of December 31, 2024, the Company is in compliance with all covenants.

In connection with entering into the Financing Agreement, the Company granted warrants to Perceptive to purchase up to (i) 400,000 ordinary shares of the Company at an exercise price of $15.00 per share and (ii) 300,000 ordinary shares of the Company at an exercise price of $20.00 per share. The warrants are exercisable immediately and expire on August 2, 2027. The Company recorded a debt discount of $2.3 million for the allocated fair value of the warrants.

The Company also capitalized certain lender and legal costs associated with the Notes Purchase Agreement totaling $2.1 million, which were recorded as a discount to the loan. The aggregate discount of $4.4 million is being amortized to interest expense over the term of the Notes Purchase Agreement. The Company amortized $1.1 million of the discount to interest expense during each of the years ended December 31, 2024 and 2023. At December 31, 2024, the remaining unamortized discount was $1.8 million.

14. Commitments and Contingencies

There were no new material commitments or contingencies entered into during the year ended December 31, 2024.

15. Employee Benefit Plans

United States

On January 1, 2017, Meira LLC adopted a defined contribution retirement plan that complies with Section 401(k) of the Internal Revenue Code. All Meira LLC employees over the age of 21 are eligible to participate in the plan after three consecutive months of service. Employees are able to defer a portion of their pay into the plan on the first day of the month or after the day all age and service requirements have been met. The plan provides for a Company matching contribution. All eligible employees receive an employer matching contribution equal to the lesser of the amount the employee contributes to the plan or 6% of their salary up to the annual IRS limit.

United Kingdom

On August 1, 2016, Meira UK II adopted a defined contribution group personal pension plan that complies with HMRC for tax relief. All Meira UK II employees are eligible to participate in the plan upon joining the company and providing the required services. All eligible employees, if they elect to join the pension scheme, receive an employer pension contribution equal to 7.5% to 10.0% of their pensionable earnings. Currently, employees are required to contribute 0.5%, to meet minimum legal pension funding levels of 8%, but may make optional contributions up to the annual allowance HMRC limits.

Ireland

On November 20, 2020, MeiraGTx Ireland adopted a defined contribution pension plan. All MeiraGTx Ireland employees are eligible to participate in the plan upon joining the Company. All eligible employees, if they elect to join the pension scheme, receive an employer pension contribution. The Company's current contribution, exclusive of an employee match, is 4.5%, which exceeds Revenue Ireland requirements.

Belgium

Meira Belgium operates a defined contribution pension plan. All eligible employees receive an employer pension contribution of 8% of their annual salary. Employees do not make contributions to the plan.

During each of the years ended December 31, 2024 and 2023, employer contributions to all plans were $2.5 million.

16. Subsequent Event

Hologen Transactions

On March 9, 2025 (the "Signing Date"), the Company and its affiliates entered into a strategic collaboration with Hologen Limited, a non-cellular company limited by shares incorporated in Guernsey ("Hologen"), and its affiliates. Hologen is a leading developer of multi-modal generative AI foundation models of real-world clinical data for clinical medicine and pharmaceutical drug development. Hologen emerged as a spin-out from University College London and Kings College London. As part of the strategic collaboration, the Company and Hologen have entered into the Framework Agreements (as defined below), pursuant to which the Company and its affiliates will receive from Hologen an upfront cash payment of $200 million (the "Upfront Payment") on the Closing Date (as defined below), and Hologen will provide additional funding of up to an additional $230 million as further described below. As part of the strategic collaboration, the Company also received 250,000 Class A shares of Hologen at a nominal price. Furthermore, the Company has the option to receive up to an additional 500,000 Class A shares of Hologen at a nominal price if certain funding obligations as described herein are not met by Hologen. Each of Dr. Forbes and Mr. Giroux received a nominal equity interest in Hologen and are, respectively, members of Hologen's Scientific Advisory Board and Advisory Board.

The closing of the transactions contemplated by the Framework Agreements (the "Closing Date") is expected to occur in the second calendar quarter of 2025, subject to customary closing and funding conditions, including the receipt of the clearances and approvals applicable to the proposed transactions under the foreign direct investment laws of the United Kingdom and the satisfaction or waiver of certain other closing conditions.

Neuro Framework Agreement

On the Signing Date, the Company, MeiraGTx Neuro UK Limited, a private company limited by shares incorporated in England and a wholly-owned subsidiary of the Company ("MeiraGTx Neuro UK"), Hologen Neuro AI Limited, a non-cellular company limited by shares incorporated in Guernsey and an affiliate of Hologen ("Hologen Neuro"), and Hologen, entered into that certain Framework Agreement (the "Neuro Framework Agreement"), pursuant to which, on the Closing Date, the Company, MeiraGTx Neuro UK, MeiraGTx Neuro I, LLC, a Delaware limited liability company and a wholly-owned subsidiary of the Company ("MeiraGTx Neuro US"), Hologen, Hologen Neuro and Hologen Neuro AI UK Limited, a private company limited by shares incorporated in England and an affiliate of Hologen ("Hologen Neuro UK"), shall enter into a Collaboration and License Agreement (the "Collaboration Agreement") for the research, development, manufacture and commercialization of the Company's (i) AAV-GAD investigational gene therapy for the treatment of Parkinson's disease, AAV-BDNF investigational gene therapy for the treatment of genetic obesity disorders and other potential locally delivered genetic medicines to the central nervous system (the "Clinical Programs") and (ii) proprietary device designed to effect the local delivery of a gene therapy product into the central nervous system or any topographic or subcutaneous tissue modification on the face and scalp, of humans or animals (the "Delivery Device"), in each case, in accordance with the terms and conditions of the Collaboration Agreement.

On the Closing Date, under the Collaboration Agreement, MeiraGTx Neuro US will receive the applicable portion of the Upfront Payment in consideration for granting to Hologen Neuro and Hologen Neuro UK, as of the Closing Date and subject to the license granted by Hologen Neuro and Hologen Neuro UK back to MeiraGTx Neuro UK, exclusive, worldwide, royalty-free, fully paid-up licenses to certain of the Company's intellectual property rights for the research, development, manufacture and commercialization of the Clinical Programs and the Delivery Device. On the Closing Date, (a) MeiraGTx Neuro UK will receive Class A shares of Hologen Neuro representing a 30% ownership of the issued share capital of Hologen Neuro, in consideration for the provision of services to Hologen Neuro and Hologen Neuro UK as specified in the Collaboration Agreement, including services relating to the development of the Clinical Programs and the Delivery Device and certain other transition services, and (b) Hologen Guernsey will receive Class B shares of Hologen Neuro representing a 70% ownership of the issued share capital of Hologen Neuro, in consideration for paying the applicable portion of the Upfront Payment to MeiraGTx Neuro US, as well as a commitment to provide additional capital of up to $230 million to fund the development of the Clinical Programs and the Delivery Device. Additionally, Hologen will license to Hologen Neuro its proprietary multi-modal generative foundation models (LMMs), or large medicine models, pursuant to a license agreement mutually agreeable to the parties.

As of the Closing Date, Hologen Neuro shall be governed by a board of directors comprised of three representatives designated by Hologen and two representatives designated by MeiraGTx Neuro UK, and certain material business decisions (as further enumerated in the Neuro Framework Agreement) will require the approval of at least 70% of the directors then in office.

Following the Closing Date and in accordance with the terms of the Collaboration Agreement, the parties shall negotiate in good faith and enter into clinical and commercial supply agreements, pursuant to which MeiraGTx Neuro UK (directly, or through affiliates or subcontractors) shall manufacture and supply AAV-GAD, AAV-BDNF and other potential locally delivered genetic medicines to the central nervous system.

Manufacturing Framework Agreement

On the Signing Date, MeiraGTx Manufacturing Limited, a private company limited by shares incorporated in England and a wholly-owned subsidiary of the Company ("MeiraGTx Manufacturing"), MeiraGTx Limited, a private company limited by shares incorporated in England and a wholly-owned subsidiary of the Company ("MeiraGTx Limited"), and Hologen, entered into that certain Framework Agreement (the "Manufacturing Framework Agreement" and, together with the Neuro Framework Agreement, the "Framework Agreements"), pursuant to which, on the Closing Date and in exchange for the applicable portion of the Upfront Payment, Hologen will acquire a minority interest in MeiraGTx Manufacturing, an entity that will comprise the Company's flexible and scalable end-to-end genetic medicines manufacturing business, which is solely run by MeiraGTx Manufacturing and MeiraGTx Limited prior to the Closing Date. Hologen will also contribute a portion of the annual funding to MeiraGTx Manufacturing.

As of the Closing Date, MeiraGTx Manufacturing shall be governed by a board of directors comprised of three representatives designated by MeiraGTx Limited and two representatives designated by Hologen, and certain material business decisions (as further enumerated in the Manufacturing Framework Agreement) will require the approval of at least 70% of the directors then in office.

For a period of twelve months following the Closing Date, Hologen has an exclusive, irrevocable option to purchase additional shares in MeiraGTx Manufacturing at a specified price, such that following exercise of such option, Hologen shall own 40% of the issued share capital of MeiraGTx Manufacturing in the aggregate. In the event that Hologen does not exercise its option, MeiraGTx has an exclusive, irrevocable option to purchase all of the shares of MeiraGTx Manufacturing held by Hologen for the same price that Hologen paid for such shares. Such option shall be exercisable anytime beginning on the third anniversary of the Closing Date and ending three years thereafter.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), evaluated, as of the end of the period covered by this Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer) concluded that our disclosure controls and procedures were effective at the reasonable assurance level at the end of the period covered by this Form 10-K.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed under the supervision of our Chief Executive Officer and Chief Financial Officer, and affected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. GAAP and includes policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*. Based on its assessment and those criteria, management has concluded that we maintained effective internal control over financial reporting as of December 31, 2024.

Exemption from Attestation Report of the Registered Public Accounting Firm on Internal Control Over Financial Reporting

This Form 10-K does not include an attestation report on our internal control over financial reporting from our independent registered public accounting firm since we qualify as a "smaller reporting company" as defined under SEC rules.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2024, none of our directors or "officers" (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" and/or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

On March 13, 2025, our Board of Directors approved a waiver under the Company's Code of Business Conduct and Ethics for Alexandria Forbes, Ph.D., President and Chief Executive Officer, approving Dr. Forbes' participation on the Scientific Advisory Board of Hologen Limited and subscription of 100,000 shares of Hologen Limited for a nominal amount.

On March 13, 2025, our Board of Directors approved a waiver under the Company's Code of Business Conduct and Ethics for Richard Giroux, Chief Financial Officer and Chief Operating Officer, approving Mr. Giroux's participation on the Advisory Board of Hologen Limited and subscription of 50,000 shares of Hologen Limited for a nominal amount.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual shareholder meeting to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual shareholder meeting to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans (as of December 31, 2024)

The following table provides information as of December 31, 2024 regarding our ordinary shares that may be issued under the MeiraGTx Holdings plc 2016 Equity Incentive Plan, as amended (the "2016 Plan"), the MeiraGTx Holdings plc 2018 Incentive Award Plan (the "2018 Plan") and the MeiraGTx Holdings plc 2018 Employee Stock Purchase Plan (the "2018 ESPP").

Plan category:	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights (b)	Number of Securities Available for Future Issuance Under Equity Compensation Plans (excludes securities reflected in column(a)) (c)
Equity compensation plans approved by shareholders			
2016 Plan (1)	1,146,847	$ 5.26	—
2018 Plan (2) (3)	11,610,490	$ 13.76	300,888
2018 ESPP (4)	—	—	3,159,113
Equity compensation plans not approved by shareholders	—	—	—
Total	12,757,337	$ 12.57	3,460,001

(1) In connection with our IPO, we assumed the 2016 Plan. As the 2016 Plan was previously approved by our shareholders and, as we will not make future grants or awards under these plans, it is listed as "approved by shareholders." As such, the securities remaining available under the 2016 Plan have been excluded from the table above.

(2) Pursuant to the terms of the 2018 Plan, the number of ordinary shares available for issuance under the 2018 Plan automatically increases on each January 1, until and including January 1, 2028, by an amount equal to the lesser of: (a) 4% of the aggregate number of ordinary shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of ordinary shares as is determined by our board of directors.

(3) The weighted average exercise price of outstanding awards does not take into account the shares issuable upon vesting of outstanding restricted share units which have no exercise price. At December 31, 2024 there were a total of 4,252,250 shares subject to restricted share units included in the Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights. Deferred share units received by certain non-employee directors are fully vested and non-forfeitable and were not taken into account in the foregoing calculation.

(4) Pursuant to the terms of the 2018 ESPP, the number of ordinary shares available for issuance under the 2018 ESPP automatically increases on each January 1, until and including January 1, 2028, by an amount equal to the lesser of: (a) 1% of the aggregate number of ordinary shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of ordinary shares as is determined by our board of directors, subject to the limit set forth in the 2018 ESPP.

Other

The remaining information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual shareholder meeting to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual shareholder meeting to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2025 annual shareholder meeting to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Memorandum and Articles of Association of the Registrant.	10-Q	001-38520	3.1	8/7/19	
4.1	Specimen Share Certificate evidencing the ordinary shares of the Registrant.	S-1	333-224914	4.1	5/29/18	
4.2	Shareholder Agreement.	10-K	001-38520	4.2	3/11/20	
4.3	Description of Securities.	10-K	001-38520	4.3	3/11/20	
4.4	Form of Warrant Agreement, dated August 2, 2022, issued by MeiraGTx Holdings plc to certain warrant holders.	10-Q	001-38520	4.1	11/10/22	
10.1#	2016 Equity Incentive Plan, as amended, and form of option agreements thereunder.	S-1/A	333-224914	10.1	5/29/18	
10.2#	2018 Incentive Award Plan and forms of award agreements thereunder.	S-1/A	333-224914	10.2	5/29/18	
10.3#	Non-Employee Director Compensation Program.	10-Q	001-38520	10.1	08/12/24	
10.4#	Form of Indemnification Agreement for Directors and Officers.	S-1/A	333-224914	10.4	5/29/18	
10.5	License and Sub-Lease Agreement, dated May 31, 2019, between MeiraGTx LLC and Imclone Systems, LLC.	10-Q	001-38520	10.2	8/7/19	
10.6	Lease Agreement, effective February 2, 2016, among MeiraGTx Limited, Moorfields Eye Hospital NHS, Foundation Trust and Kadmon Corporation LLC.	S-1	333-224914	10.6	5/14/18	
10.7#	Employment Agreement, dated February 15, 2016, between MeiraGTx Limited and Alexandria Forbes, Ph.D., as amended.	S-1/A	333-224914	10.7	5/29/18	
10.8#	Employment Agreement, dated February 15, 2016 between MeiraGTx Limited and Richard Giroux, as amended.	S-1/A	333-224914	10.8	5/29/18	
10.9#	Employment Agreement, dated April 27, 2015, between MeiraGTx Limited and Stuart Naylor, Ph.D., as amended.	S-1/A	333-224914	10.9	5/29/18	
10.10†	Agreement and Plan of Merger, dated December 31, 2015, among MeiraGTx Acquisition Corporation, BRI-Alzan, Inc., F-Prime Inc., Gregory Petsko, Dagmar Ringe, Brandeis University and MeiraGTx Limited.	S-1/A	333-224914	10.14	5/29/18	
10.11#	2018 Employee Share Purchase Plan.	S-1/A	333-224914	10.15	5/29/18	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.12#	UK Sub-Plan Under the 2018 Incentive Award Plan.	10-K	001-38520	10.12	3/26/19	
10.13#	Form of Option Grant Notice and Option Agreement Under the UK Sub-Plan to the 2018 Incentive Award Plan.	10-K	001-38520	10.13	3/26/19	
10.14#	Form of Change in Control Agreement.	10-K	001-38520	10.14	3/11/21	
10.15	Lease agreement by and between Moorfields Eye Hospital NHS Foundation Trust and MeiraGTx UK II Limited, dated July 30, 2018.	10-Q	001-38520	10.4	8/8/18	
10.16	Lease agreement by and between Moorfields Eye Hospital NHS Foundation Trust and MeiraGTx UK II Limited, dated July 30, 2018.	10-Q	001-38520	10.5	8/8/18	
10.17	Transfer of Title, dated December 14, 2018, and Lease, dated October 12, 2001, relating to the Pharmacy Manufacturing Unit, Britannia Walk, London, England.	8-K	001-38520	10.1	12/14/18	
10.18	Overage Deed, dated December 14, 2018, between Moorfields Eye Hospital NHS Foundation Trust and MeiraGTx UK II Limited relating to the Pharmacy Manufacturing Unit, Britannia Walk, London, England.	8-K	001-38520	10.2	12/14/18	
10.19†	Consulting Agreement, dated October 5, 2018, between MeiraGTx Holdings plc, Vector Consulting LLC, Michael G. Kaplitt, Matthew During, and Stephen B. Kaplitt.	10-K	001-38520	10.19	3/26/19	
10.20†	License Agreement (RPE65), dated January 29, 2019, as amended and restated by and among UCL Business Plc, MeiraGTx UK II Limited and MeiraGTx Limited.	10-K	001-38520	10.20	3/26/19	
10.21†	License Agreement (CNGB3), dated January 29, 2019, as amended and restated by and among UCL Business Plc, MeiraGTx Holdings plc, MeiraGTx UK II Limited and MeiraGTx Limited.	10-K	001-38520	10.21	3/26/19	
10.22†	License Agreement (CNGA3), dated January 29, 2019, as amended and restated by and among UCL Business Plc, MeiraGTx UK II Limited and MeiraGTx Limited.	10-K	001-38520	10.22	3/26/19	
10.23†	Amendment No. 4 to Exclusive License Agreement, dated January 29, 2019, between UCLB and MeiraGTx Limited.	10-K	001-38520	10.24	3/26/19	
10.24††	Collaboration, Option and License Agreement, dated January 30, 2019, by and among Janssen Pharmaceuticals, Inc., MeiraGTx UK II Limited and MeiraGTx Holdings plc.					*
10.25††	First Amendment to Collaboration, Option and License Agreement, dated December 16, 2021.	10-K	001-3852	10.26	3/10/22	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.26	Registration Rights Agreement, dated February 26, 2019, by and among MeiraGTx Holdings plc and the investors named therein.	8-K	001-38520	10.2	2/26/19	
10.27	Agreement for Lease with Landlord's Refurbishment Works, dated May 29, 2019, between MeiraGTx UK II Limited and Provost 1 Limited and Provost 2 Limited, including agreed form of Lease between MeiraGTx UK II Limited and Provost 1 Limited and Provost 2 Limited.	10-Q	001-38520	10.3	8/7/19	
10.28#	Form of Restricted Share Unit Grant Notice and Restricted Share Unit Agreement Under the 2018 Incentive Award Plan.	10-K	001-38520	10.30	3/11/20	
10.29#	Form of Restricted Share Unit Grant Notice and Restricted Share Unit Agreement Under the UK Sub-Plan to the 2018 Incentive Award Plan.	10-K	001-38520	10.31	3/11/20	
10.30	Particulars and Conditions of Sale of Building 2, Block K, Shannon Free Zone, Shannon, County Clare, Ireland, dated as of August 4, 2020, by and between Shannon Commercial Enterprises DAC trading as Shannon Commercial Properties and MeiraGTx Ireland DAC, including agreed form of Lease between Shannon Commercial Enterprises DAC and MeiraGTx Ireland DAC.	10-Q	001-38520	10.1	11/5/20	
10.31	Particulars and Conditions of Sale of Building 3, Block K, Shannon Free Zone, Shannon, County Clare, Ireland, dated as of August 4, 2020, by and between Shannon Commercial Enterprises DAC trading as Shannon Commercial Properties and MeiraGTx Ireland DAC, including agreed form of Lease between Shannon Commercial Enterprises DAC and MeiraGTx Ireland DAC.	10-Q	001-38520	10.2	11/5/20	
10.32#	Deferred Compensation Plan for Non-Employee Directors.	10-K	001-38520	10.35	3/10/22	
10.33#	Form of Restricted Share Unit Grant Notice and Restricted Share Unit Agreement for Non-Employee Directors Under the 2018 Incentive Award Plan.	10-K	001-38520	10.36	3/10/22	
10.34††	Credit Agreement and Guaranty, dated August 2, 2022, by and among MeiraGTx Holdings plc, as borrower, MeiraGTx UK II Limited and MeiraGTx Ireland DAC, as guarantors, the lenders and other parties from time to time party thereto and Perceptive Credit Holdings III, LP, as administrative agent and lender.	10-Q	001-38520	10.1	11/10/22	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.35	Amendment No. 1 to Credit Agreement and Guaranty, dated December 19, 2022, by and among MeiraGTx Holdings plc, as borrower, certain subsidiary guarantors and lenders party thereto, and Perceptive Credit Holdings III, LP, as administrative agent.	10-K	001-38520	10.36	3/14/23	
10.36††	Amended and Restated Notes Purchase Agreement and Guaranty, dated December 19, 2022, by and among MeiraGTx Holdings plc, as issuer, the subsidiary guarantors and noteholders from time to time party thereto, and Perceptive Credit Holdings III, LP, as administrative agent.	10-K	001-38520	10.37	3/14/23	
10.37	Tranche 1 Note, dated December 19, 2022, by and among MeiraGTx Holdings plc, as issuer, the subsidiaries guarantors and noteholders from time to time party thereto, and Perceptive Credit Holdings III, LP, as administrative agent.	10-K	001-38520	10.38	3/14/23	
10.38	Consent and Amendment to Amended and Restated Notes Purchase Agreement and Guaranty, dated August 10, 2023, by and among MeiraGTx Holdings plc, as issuer, the subsidiary guarantors and noteholders from time to time party thereto, and Perceptive Credit Holdings III, LP, as administrative agent and noteholder.	8-K	001-38520	10.1	8/10/23	
10.39	Consent and Amendment to Amended and Restated Notes Purchase Agreement and Guaranty, dated December 20, 2023, by and among MeiraGTx Holdings plc, as issuer, the subsidiary guarantors and noteholders from time to time party thereto, and Perceptive Credit Holdings III, LP, as administrative agent and noteholder.	10-K	001-38520	10.39	3/15/24	
10.40	Securities Purchase Agreement, dated November 9, 2022, by and among MeiraGTx Holdings plc and Johnson & Johnson Innovation – JJDC, Inc.	10-K	001-38520	10.39	3/14/23	
10.41	Registration Rights Agreement, dated November 15, 2022, by and among MeiraGTx Holdings plc and Johnson & Johnson Innovation – JJDC, Inc.	10-K	001-38520	10.40	3/14/23	
10.42	First Amendment to Registration Rights Agreement, dated May 12, 2023, by and among MeiraGTx Holdings plc and Johnson & Johnson Innovation – JJDC, Inc.	10-Q	001-38520	10.3	8/10/23	
10.43	Securities Purchase Agreement, dated May 3, 2023, by and among MeiraGTx Holdings plc and the Investors named therein.	S-3	333-273672	10.1	8/3/23	
10.44	Registration Rights Agreement, dated May 5, 2023, by and among MeiraGTx Holdings plc and the Investors named therein.	S-3	333-273672	10.2	8/3/23	

Exhibit Number	Exhibit Description	Incorporated by Reference				
		Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.45	Investment Agreement, dated October 30, 2023, by and among MeiraGTx Holdings plc, Sanofi Foreign Participations B.V. and Sanofi.	8-K	001-38520	10.1	10/30/23	
10.46	Registration Rights Agreement, dated October 30, 2023, by and between MeiraGTx Holdings plc and Sanofi Foreign Participations B.V.	8-K	001-38520	10.2	10/30/23	
10.47††	Asset Purchase Agreement, dated December 20, 2023, by and among Janssen Pharmaceuticals, Inc., MeiraGTx UK II Limited and MeiraGTx Holdings plc.	10-K	001-38520	10.47	3/15/24	
10.48††	Termination Agreement, dated December 20, 2023, by and among Janssen Pharmaceuticals, Inc., MeiraGTx UK II Limited and MeiraGTx Holdings plc.	10-K	001-38520	10.48	3/15/24	
10.49††	Framework Agreement, dated March 9, 2025, by and among Hologen Limited, Hologen Neuro AI Limited, MeiraGTx Neuro UK Limited and MeiraGTx Holdings plc.					*
10.50††	Form of Collaboration and License Agreement by and among Hologen Neuro AI Ltd, Hologen Neuro AI UK Limited, Hologen Limited, MeiraGTx Holdings plc, MeiraGTx UK Neuro Limited and MeiraGTx Neuro I, LLC.					*
10.51††	Framework Agreement, dated March 9, 2025, by and among MeiraGTx Manufacturing Limited, MeiraGTx Limited and Hologen Limited.					*
19.1	MeiraGTx Holdings plc Insider Trading Compliance Policy.					*
21	List of Subsidiaries.					*
23.1	Consent of Ernst & Young LLP.					*
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended.					*
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended.					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**

Exhibit Number	Exhibit Description	Incorporated by Reference				
		Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
97.1	Policy for Recovery of Erroneously Awarded Compensation.	10-K	001-38520	97.1	3/15/24	
101.INS	Inline XBRL Instance Document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					*
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.					*
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					*

* Filed herewith
** Furnished herewith
# Management contract or compensation plan or arrangement
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended
†† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

Certain agreements filed as exhibits to this Form 10-K contain representations and warranties that the parties thereto made to each other. These representations and warranties have been made solely for the benefit of the other parties to such agreements and may have been qualified by certain information that has been disclosed to the other parties to such agreements and that may not be reflected in such agreements. In addition, these representations and warranties may be intended as a way of allocating risks among parties if the statements contained therein prove to be incorrect, rather than as actual statements of fact. Accordingly, there can be no reliance on any such representations and warranties as characterizations of the actual state of facts. Moreover, information concerning the subject matter of any such representations and warranties may have changed since the date of such agreements.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MeiraGTx Holdings plc (Registrant)

Date: March 13, 2025

By: /s/ Alexandria Forbes
Alexandria Forbes
President and Chief Executive Officer and
Director (Principal Executive Officer)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Alexandria Forbes, Ph.D. Alexandria Forbes, Ph.D.	President and Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2025
/s/ Richard Giroux Richard Giroux	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2025
/s/ Keith R. Harris, Ph.D. Keith R. Harris, Ph.D.	Chairman of the Board and Director	March 13, 2025
/s/ Ellen Hukkelhoven, Ph.D. Ellen Hukkelhoven, Ph.D.	Director	March 13, 2025
/s/ Lord Mendoza Lord Mendoza	Director	March 13, 2025
/s/ Nicole Seligman Nicole Seligman	Director	March 13, 2025
/s/ Thomas E. Shenk, Ph.D. Thomas E. Shenk, Ph.D.	Director	March 13, 2025
/s/ Debra Yu, M.D. Debra Yu, M.D.	Director	March 13, 2025

Exhibit 10.24

EXECUTION VERSION

Certain information marked as [***] has been excluded from this exhibit because it is both (i) not material and (ii) is the type that the registrant customarily and actually treats as private or confidential.

COLLABORATION, OPTION AND LICENSE AGREEMENT

BY AND BETWEEN

JANSSEN PHARMACEUTICALS, INC.,

MEIRAGTX UK II LIMITED

AND

MEIRAGTX HOLDINGS PLC

TABLE OF CONTENTS

1.	**DEFINITIONS**	1
2.	**OVERVIEW OF COLLABORATION**	26
	2.1. Overview of Clinical Development Plan Activities	26
	2.2. Overview of Research Plan Activities	28
	2.3. Overview of CMC Development Plan Activities and Other Manufacturing Activities	28
3.	**NON-CLINICAL RESEARCH**	28
	3.1. Research IRD Targets	29
	3.2. Research Plans	29
	3.3. Conduct of Research Activities	29
	3.4. Research Budget	29
	3.5. Research Records	30
	3.6. Audits	30
	3.7. Research Reports and Materials	31
	3.8. Research Costs	32
	3.9. Option	32
4.	**LICENSES**	33
	4.1. Licenses to Janssen	33
	4.2. Licenses to MeiraGTx	34
	4.3. Sublicense Rights	35
	4.4. Subcontractors	35
	4.5. Third Party Licenses	36
	4.6. Exclusivity	36
	4.7. No Other Rights	37
	4.8. MeiraGTx Know-How Transfer	37
5.	**GOVERNANCE**	38
	5.1. Alliance Managers	38
	5.2. Joint Steering Committee	38
	5.3. Joint Research Committee	39
	5.4. Joint Development Committee	39
	5.5. Joint Manufacturing Committee.	40
	5.6. Operational Teams	40
	5.7. Committee Representatives and Meetings	41

5.8. Resolution of Committee Disputes 42
6. DEVELOPMENT 42
6.1. Clinical IRD Products 42
6.2. Janssen Research IRD Products 46
7. REGULATORY 46
7.1. Clinical IRD Products 46
7.2. Research IRD Products 49
7.3. Pharmacovigilance 50
8. MANUFACTURING 50
8.1. Product Manufacturing outside Supply Agreements 50
8.2. Clinical Supply Agreement 51
8.3. Commercial Supply Agreement 51
8.4. Collaboration on CMC Development 51
8.5. [***] Manufacturing Services 54
9. COMMERCIALIZATION 54
10. FINANCIAL PROVISIONS 54
10.1. Upfront Payment 54
10.2. Research Costs 54
10.3. Clinical Development Costs 55
10.4. Clinical Development Manufacturing Costs 56
10.5. Process Development Costs 57
10.6. Development Milestone Payments 58
10.7. Commercial Milestone Payments 60
10.8. Royalties 61
10.9. Additional Royalty Provisions 61
10.10. Third Party Obligations 63
10.11. Reports and Royalty Payments 64
10.12. Disclaimer. 64
10.13. Payment Terms 64
10.14. Records and Audits 66
11. INTELLECTUAL PROPERTY RIGHTS 67
11.1. Ownership under the Clinical IRD Programs and Research IRD Programs 67
11.2. Ownership under the CMC Development Collaboration 67
11.3. Duties to the Other Party 67

11.4. Patent Prosecution and Maintenance 68
11.5. Third Party Infringement; Patent Actions 71
11.6. Product Infringement 74
11.7. Patents Licensed From Third Parties 74
11.8. Trademarks. 74
12. CONFIDENTIALITY 74
12.1. Duty of Confidence 74
12.2. Exceptions 75
12.3. Authorized Disclosures 75
12.4. Terms of this Agreement 76
12.5. Use of Residuals. 76
12.6. Data Privacy 76
13. PUBLICATIONS AND PUBLICITY 77
13.1. Use of Names 77
13.2. Press Releases and Publicity Related to this Agreement 77
13.3. Public Disclosures and Publications Related to the Programs or Products 77
13.4. Publications 78
13.5. Disclosures Required By Law 79
13.6. Publication 79
14. EFFECTIVENESS 79
14.1. Effective Date 79
14.2. Filings 80
14.3. Outside Date 80
15. TERM AND TERMINATION 80
15.1. Term 80
15.2. Termination 80
15.3. Rights in Insolvency 82
15.4. Effects of Expiration or Termination 83
15.5. Post-Termination Royalties to Janssen 86
15.6. Survival 86
15.7. Termination Not Sole Remedy 87
16. REPRESENTATIONS, WARRANTIES AND COVENANTS 87
16.1. Representations and Warranties by Each Party 87
16.2. Representations, Warranties and Covenants by MeiraGTx 88

16.3. Mutual Covenants 90
16.4. No Other Warranties 91
17. INDEMNIFICATION; LIABILITY; INSURANCE 91
17.1. Indemnification by MeiraGTx 91
17.2. Indemnification by Janssen 91
17.3. Indemnification Procedure 92
17.4. Mitigation of Loss 94
17.5. Limited Liability 94
17.6. Insurance Obligations 94
18. DISPUTE RESOLUTION 95
18.1. Dispute Resolution 95
18.2. Governing Law 97
18.3. Exclusions 97
18.4. Cumulative Remedies 98
18.5. Injunctive Relief 98
19. GENERAL PROVISIONS 98
19.1. Assignment 98
19.2. Extension to Affiliates 99
19.3. Severability 99
19.4. Force Majeure 99
19.5. Waivers and Amendments 99
19.6. Relationship of the Parties 100
19.7. Notices 100
19.8. Further Assurances 101
19.9. No Third Party Beneficiary Rights 101
19.10. English Language 101
19.11. Interpretation 101
19.12. Entire Agreement 102
19.13. Counterparts 103

Exhibits

Exhibit 1.34: Clinical Development Plans, Including Anticipated Costs and Timelines

Exhibit 1.34-1: Anticipated Costs and Timelines – CNGA3 Product

Exhibit 1.34-2: Anticipated Costs and Timelines – CNGB3 Product

Exhibit 1.34-3: Anticipated Costs and Timelines – RPGR Product

Exhibit 1.51: CMC Development Plans

Exhibit 1.103: Final Report Requirements

Exhibit 1.136: J&J Universal Calendar for 2019 and 2020

Exhibit 1.168: MeiraGTx Patents

Exhibit 1.221: IRD Genes

Exhibit 1.223: Research Plans

Exhibit 3.4: Research Budget Cap

Exhibit 3.5: Janssen Data Policies

Exhibit 4.4: MeiraGTx Subcontractors

Exhibit 8.2: Key Terms of Clinical Supply Agreement and Clinical Quality Assurance Agreement

Exhibit 8.3: Key Terms of Commercial Supply Agreement and Commercial Quality Assurance Agreement

Exhibit 8.4(a): CMC Development Plan Activities – Breakdown

Exhibit 16.2(b): Third Party Rights

Exhibit 16.2(g): MeiraGTx Existing Third Party Obligations

COLLABORATION, OPTION AND LICENSE AGREEMENT

This Collaboration, Option and License Agreement (this "**Agreement**") is made as of January 30, 2019 (the "**Execution Date**"), by and between Janssen Pharmaceuticals, Inc., a Pennsylvania corporation located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560, United States of America ("**Janssen**"), on the one hand, and MeiraGTx UK II Limited, a company organized and existing under the laws of England, located at 25 Provost Street, London N1 7NH, United Kingdom and MeiraGTx Holdings plc, a Cayman Islands corporation located at 430 East 29th Street, 10th Floor, New York, NY 10016, United States of America (MeiraGTx UK II Limited and MeiraGTx Holdings plc, individually or collectively, "**MeiraGTx**"), on the other hand. Janssen and MeiraGTx are each referred to individually as a "**Party**" and together as the "**Parties**."

RECITALS

WHEREAS, MeiraGTx has technology and expertise in gene therapy, including viral vector design and optimization and gene therapy manufacturing, and is applying such technology to develop therapeutic products, including the Clinical IRD Products (as defined below);

WHEREAS, Janssen, together with its Affiliates, is engaged in the Research, Development, and Commercialization of biopharmaceutical products globally;

WHEREAS, MeiraGTx and Janssen desire to enter into a collaboration to jointly Develop the Clinical IRD Products to permit Janssen to Commercialize such Clinical IRD Products under an exclusive license from MeiraGTx, all under the terms and conditions set forth herein;

WHEREAS, MeiraGTx and Janssen also desire to enter into a collaboration where Janssen would co-fund MeiraGTx's research on Research IRD Products (as defined below), and in return, MeiraGTx would grant Janssen an exclusive option to obtain an exclusive license to further Develop and Commercialize certain Research IRD Products, all under the terms and conditions set forth herein; and

WHEREAS, MeiraGTx and Janssen desire to collaborate on the Development of certain manufacturing and technical improvements and provide certain additional Manufacturing services, under the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the Parties agree as follows.

1. DEFINITIONS

Unless the context otherwise requires, the capitalized terms in this Agreement have the meanings set forth below or the meaning as designated in the indicated places throughout this Agreement.

1.1. "**Accounting Standards**" means GAAP, as generally and consistently applied throughout each Party's organization.

1.2. "**Acquired Party**" has the meaning set forth in Section 4.6(d).

1.3. "**Act**" means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. and the United States Public Health Service (PHS) Act, 42 U.S.C. §§ 201 et seq.

1.4. "**Advancement Criteria**" means the specific, objective criteria and standards that need to be fulfilled for a successful IND Submission in accordance with 21 C.F.R. §312 and any foreign counterpart to such regulation and any other requirements of any Regulatory Authority.

1.5. "**Adverse Event**" means (a) any untoward medical occurrence in a Clinical Study subject or in a patient who is administered a Product, whether or not considered related to such Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom, or disease associated with the use of a Product or (b) finding from any animal or in vitro testing or toxicology study, whether or not conducted by the sponsor, that suggests a significant risk in humans exposed to the drug.

1.6. "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, controls, is controlled by, or is under common control with that Party, for so long as such control exists. For the purpose of this definition, "control" means any of the following: (a) direct or indirect ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, (b) status as a general partner in any partnership, or (c) any other arrangement whereby the entity or person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity, whether through ownership of voting securities, by contract or otherwise. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and in such case, such lower percentage shall be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management and policies of such entity.

1.7. "**Affordable Basis**" means selling a Product for [***]. In determining Affordable Basis, the Parties recognize that, to the extent that a Party engages a Third Party in the Commercialization of a Product on an Affordable Basis, [***].

1.8. "**Agreement**" has the meaning set forth in the first paragraph of this Agreement.

1.9. "**Alliance Manager**" has the meaning set forth in Section 5.1.

1.10. "**Annual Net Sales**" means Net Sales of Product(s) in a Calendar Year.

1.11. "**Anti-Corruption Laws**" means all Applicable Laws and international financial institution rules regarding corruption, bribery, ethical business conduct, money laundering, political contributions, gifts and gratuities, or lawful expenses to public officials, healthcare professionals, and private persons, agency relationships, commissions, lobbying, books and records, and financial controls, including the FCPA.

1.12. "**Applicable Law**" means any applicable law, statute, code, ordinance, rule or regulation, enforceable guideline or other requirement, order, injunction, judgment, writ, stipulation, award, arbitration award, decree, other pronouncement having the effect of law, constitution or treaty enacted, promulgated, issued, enforced or entered by any Governmental Authority applicable to any Party or such Party's businesses, properties or assets, as may be amended from time to time.

1.13. "**Audited Party**" has the meaning set forth in Section 10.14(b).

1.14. "**Auditing Party**" has the meaning set forth in Section 10.14(b).

1.15. "**Auditor**" has the meaning set forth in Section 10.14(b).

1.16. "**Biosimilar Product**" means, in a particular country with respect to a particular Product, any biopharmaceutical product that: (a) has received all necessary approvals by the applicable Regulatory Authorities in such country to market and sell such product as a biopharmaceutical product; (b) is marketed or sold by a Third Party who is not a licensee or Sublicensee of Janssen or its Affiliates regarding such biopharmaceutical product; and (c) is approved as (i) a "biosimilar" (in the United States) of such Product, (ii) a "similar biological medicinal product" (in the EU) with respect to which such Product is the "reference medicinal product," or (iii) if not in the US or EU, the foreign equivalent of a "biosimilar" or "similar biological medicinal product" of such Product, in each case, for use in such country pursuant to a regulatory approval process governing approval of generic biologics based on the then-current standards for regulatory approval in such country (*e.g.,* the Biologics Price Competition and Innovation Act of 2009 or an equivalent under foreign law).

1.17. "**BLA**" means: (a) a Biologics License Application as defined in the Act and the regulations promulgated thereunder; (b) an MAA in the EU; or (c) any equivalent or comparable application, registration or certification in any other country or region.

1.18. "**Business Day**" means any day that is not a Saturday, Sunday, or other day on which commercial banks are authorized or required to be closed in New York, New York.

1.19. "**Calendar Quarter**" means a financial quarter based on the J&J Universal Calendar for that year that is used by Janssen and Affiliates for internal and external reporting purposes; *provided*, *however*, that the first Calendar Quarter of the Term extends from the Effective Date to the end of the then-current Calendar Quarter, and the last Calendar Quarter extends from the first day of such Calendar Quarter until the effective date of the termination or expiration of this Agreement.

1.20. "**Calendar Year**" means a year based on the J&J Universal Calendar for that year; *provided*, *however*, that the first Calendar Year of the Term extends from the Effective Date to the end of the then-current Calendar Year, and the last Calendar Year extends from the first day of such Calendar Year for the year during which termination or expiration of this Agreement will occur until the effective date of the termination or expiration of this Agreement.

1.21. "**CAPA**" has the meaning set forth in Section 3.6.

1.22. "**cGCP**" means the then-current ethical, scientific and quality standards, practices and procedures required by FDA for designing, conducting, recording and reporting trials that involve the participation of human subjects, as set forth in FDA regulations in 21 C.F.R. Parts 11, 50, 54, 56, and 312 and related FDA guidance documents, including the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline, or the equivalent Applicable Law of an applicable Regulatory Authority.

1.23. "**cGLP**" means the then-current good laboratory practice standards as required by the FDA under 21 C.F.R. Part 58 and all applicable FDA rules, regulations, orders and guidance, and the requirements with respect to current good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and the ICH Guidelines, or the equivalent Applicable Law of an applicable Regulatory Authority.

1.24. "**cGMP**" means the then-current good manufacturing practices as required by the FDA under provisions of 21 C.F.R. Parts 210 and 211 and all applicable FDA rules, regulations, orders and guidance, and the requirements with respect to current good manufacturing practices prescribed by the European Community under provisions of "The Rules Governing Medicinal Products in the European Community, Volume 4, Good Manufacturing Practices, Annex 13, Manufacture of Investigational Medicinal Products, July 2003," or the equivalent Applicable Law of an applicable Regulatory Authority.

1.25. "**Challenge**" or "**Challenging**" means, with respect to any MeiraGTx Patents, MeiraGTx Research Patents or Joint Patents, to contest the validity or enforceability of any such Patents, in whole or in part, in any court, arbitration proceeding or other tribunal, including the United States Patent and Trademark Office, the European Patent Office, and the United States International Trade Commission. As used in this term "Challenge", the term "**contest**" includes [***].

1.26. "**Challenged Patent**" has the meaning set forth in Section 15.2(c).

1.27. "**Change of Control**" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation; (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party; or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's assets or business to which the subject matter of this Agreement relates.

1.28. "**Claims**" means all Third Party demands, claims, actions, suits, causes of action and proceedings.

1.29. "**Clinical Development Budget**" has the meaning set forth in Section 6.1(d). Each Clinical Development Budget, upon approval in accordance with the terms and conditions herewith, will be automatically incorporated into this Agreement by reference and form a part of this Agreement.

1.30. "**Clinical Development Costs**" means, with respect to each Clinical IRD Product [***] all costs and expenses incurred on or after the Effective Date in connection with the performance of any Clinical Development Plan Activities for such Clinical IRD Product in accordance with the applicable Clinical Development Plan, including FTE Costs and fees charged by Third Party service providers, but excluding (a) overhead costs and capital expenditures and (b) all Clinical Development Manufacturing Costs.

1.31. "**Clinical Development Manufacturing Activities**" has the meaning set forth in Section 8.4(a).

1.32. "**Clinical Development Manufacturing Budget**" has the meaning set forth in Section 8.4(b). Each Clinical Development Manufacturing Budget, upon approval in accordance with the terms and conditions herewith, will be automatically incorporated into this Agreement by reference and form a part of this Agreement.

1.33. "**Clinical Development Manufacturing Costs**" means the fully-burdened cost incurred on or after the Effective Date (and, solely with respect to the Clinical Supply of the CNGA3 Product, such costs incurred prior to the Effective Date and as specified on Exhibit 1.34-1) by either Party or any of their respective Affiliates in connection with the performance of any Clinical Development Manufacturing Activities in accordance with this Agreement and consistent with (a) the applicable CMC Development Plan, (b) the Clinical Supply Agreement, and (c) all components defined in Commercial Manufacturing Costs, including in each case ((a)-(c)), all FTE Costs, Out-of-Pocket Costs, and depreciation of capital expenditures.

1.34. "**Clinical Development Plan**" means the strategic plan for Developing a Clinical IRD Product, as such plan may be agreed to, approved, amended or updated from time to time in accordance with Section 6.1(c). Each Clinical Development Plan will be automatically incorporated into this Agreement by reference and form a part of Exhibit 1.34 in accordance with Section 6.1(c). The anticipated costs and timelines for activities under the Clinical Development Plan for the CNGA3 Product are attached hereto as Exhibit 1.34-1. The anticipated costs and timelines for activities under the Clinical Development Plan for the CNGB3 Product are attached hereto as Exhibit 1.34-2. The anticipated costs and timelines for activities under the Clinical Development Plan for the RPGR Product are attached hereto as Exhibit 1.34-3.

1.35. "**Clinical Development Plan Activities**" has the meaning set forth in Section 6.1(c).

1.36. "**Clinical Development Plan Term**" means the term of a Clinical Development Plan, as set forth in such Clinical Development Plan, *provided* that in no event will the Clinical Development Plan Term exceed the Term.

1.37. "**Clinical Development Records**" has the meaning set forth in Section 6.1(g).

1.38. "**Clinical IRD Patents**" has the meaning set forth in Section 11.4(b).

1.39. "**Clinical IRD Products**" means: (a) the CNGB3 Product; (b) the CNGA3 Product; (c) the RPGR Product; and (d) [***].

1.40. "**Clinical IRD Target**" means: (a) the CNGB3 Target; (b) the CNGA3 Target; (c) the RPGR Target; and (d) [***].

1.41. "**Clinical IRD Target Indication**" means: (a) the CNGB3 Target Indication; (b) the CNGA3 Target Indication; (c) the RPGR Target Indication; and (d) [***].

1.42. "**Clinical Quality Assurance Agreement**" has the meaning set forth in Section 8.2.

1.43. "**Clinical Study**" means a (a) Phase 1 Study, (b) Phase 1/2 Study, (c) Phase 2 Study, (d) Phase 3 Study, (e) Pivotal Study or (f) other prospective study (including a non-interventional study or Natural History Study) or post-Regulatory Approval study, in each case of this subsection (f) in humans to obtain information regarding a disease state or product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of the product.

1.44. "**Clinical Supply**" means, with respect to a Clinical IRD Product or Janssen Research IRD Product, such Product Manufactured for use in a Clinical Study of such Product under this Agreement.

1.45. "**Clinical Supply Agreement**" has the meaning set forth in Section 8.2.

1.46. "**CMC**" means chemistry, manufacturing and controls.

1.47. "**CMC Development Collaboration**" has the meaning set forth in Section 8.4(a).

1.48. "**CMC Development Inventions**" means all Inventions, including CMC data, arising out of the CMC Development Collaboration, whether made solely by or on behalf of a Party or jointly with the other Party under this Agreement.

1.49. "**CMC Development Know-How**" means all Know-How, including CMC data, arising out of the CMC Development Collaboration, whether made solely by or on behalf of a Party or jointly with the other Party under this Agreement.

1.50. "**CMC Development Patents**" mean all Patents Covering patentable CMC Development Inventions or CMC Development Know-How.

1.51. "**CMC Development Plan**" means the strategic plan for the CMC Development Collaboration, as such plan may be agreed to, approved, amended or updated from time to time in accordance with Section 8.4(a). Each CMC Development Plan will be automatically incorporated into this Agreement by reference and form a part of Exhibit 1.51.

1.52. "**CMC Development Plan Activities**" has the meaning set forth in Section 8.4(a).

1.53. "**CMC Development Technology**" means the CMC Development Patents, CMC Development Inventions and CMC Development Know-How.

1.54. "**CMC Development Term**" has the meaning set forth in Section 2.3.

1.55. "**CMO**" means a Third Party contract Manufacturing organization.

1.56. "**CNGA3 Product**" means: (a) MeiraGTx's Gene Therapy Product [***] for the treatment of the CNGA3 Target Indication by expressing the CNGA3 Target; [***].

1.57. "**CNGA3 Target**" means the [***].

1.58. "**CNGA3 Target Indication**" means the inherited retinal disease resulting from the loss of function of the CNGA3 Target.

1.59. "**CNGB3 Product**" means: (a) MeiraGTx's Gene Therapy Product [***] for the treatment of the CNGB3 Target Indication by expressing the CNGB3 Target; [***].

1.60. "**CNGB3 Target**" means the [***].

1.61. "**CNGB3 Target Indication**" means the inherited retinal disease resulting from the loss of function of the CNGB3 Target.

1.62. "**Code**" means the United States Bankruptcy Code, 11 U.S.C. §§ 101 et seq.

1.63. "**Commercial Manufacturing Costs**" means [***].

1.64. "**Commercial Milestone Event**" has the meaning set forth in Section 10.7(a).

1.65. "**Commercial Milestone Payment**" has the meaning set forth in Section 10.7(a).

1.66. "**Commercial Quality Assurance Agreement**" has the meaning set forth in Section 8.3.

1.67. "**Commercial Supply**" means a Product Manufactured for Commercialization of such Product, including for Product launch.

1.68. "**Commercial Supply Agreement**" has the meaning set forth in Section 8.3.

1.69. "**Commercialize**" or "**Commercialization**" means to market, promote, detail, conduct Medical Affairs, distribute, import, export, offer to sell, use or sell biopharmaceutical products or conduct other commercialization activities, including activities directed to

obtaining Pricing Approvals, conducting pre- and post-Regulatory Approval activities and launching and promoting such biopharmaceutical products in each country, as applicable.

1.70. "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, those reasonable, good faith efforts normally used by such Party under similar circumstances for similar products or product candidates owned or controlled by such Party, or to which such Party has similar rights, which product or product candidate is of similar market potential in such country and is at a similar stage in its development or product life, taking into account all relevant scientific, technical, operational, commercial, economic and other factors that may affect the Development, Regulatory Approval, Manufacturing or Commercialization of a product, including (as applicable): actual and potential issues of safety, efficacy or stability; expected and actual product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected Development, Regulatory Approval, Manufacturing, and Commercialization costs, timelines and budgets; any issues regarding the ability to Manufacture or have Manufactured the product; the likelihood of obtaining Regulatory Approvals; the timing of such approvals; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the time of projected entry into the market, including the expected and actual competitiveness of alternative products; past performance of the product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; and expected and actual proprietary position, strength and duration of patent protection and anticipated regulatory or other exclusivity as such company would normally use to accomplish a similar objective under similar circumstances. With respect to a Party's obligations, Commercially Reasonable Efforts requires that the Party, to the extent doing so would be required by this Agreement and the definition of "Commercially Reasonable Efforts" to do so: [***]. To the extent that [***]. To the extent that [***].

1.71. "**Committee**" means the Joint Steering Committee, the Joint Research Committee, the Joint Development Committee, the Joint Manufacturing Committee or any other subcommittee established under Section 5.2(b), as applicable.

1.72. "**Competing Product**" means, with respect to any Product, any Gene Therapy Product that [***].

1.73. "**Completion Notice**" has the meaning set forth in Section 3.7(c).

1.74. "**Confidential Information**" means all confidential Know-How and other confidential information and data of a Party that is disclosed by or on behalf of a Party or any of its Affiliates or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement or of a financial, commercial, business, operational or technical nature. For clarity, the terms and conditions of this Agreement shall constitute the Confidential Information of both Parties and each Party will be deemed a Receiving Party with respect

thereto, and all research results shall constitute the Confidential Information of both Parties during the Term (subject to Section 15.4(b)).

1.75. "**Control**" or "**Controlled**" means, with respect to any Intellectual Property Rights, the legal authority or right (whether by ownership, license or otherwise, other than pursuant to this Agreement) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights to another Person, or to otherwise disclose such Intellectual Property Rights to another Person, without violating any Applicable Law, breaching the terms of any agreement with a Third Party or misappropriating the proprietary or trade secret information of a Third Party, and, subject to Section 10.10, without incurring payment obligations by reason of licensing, sublicensing, or providing access to the other Party with respect thereto (unless such other Party agrees in writing to bear all such costs arising from the license, sublicense, or access to such item by such other Party). Notwithstanding anything to the contrary in this Agreement, in the event of a Change of Control of a Party, (a) any Intellectual Property Rights Controlled by any acquiring entity (and not Controlled by such Party or its Affiliates) immediately prior to the effective date of such Change of Control and (b) any Intellectual Property Rights independently developed or acquired by or on behalf of any acquiring entity without access to or use of any Intellectual Property Rights used or made available under this Agreement or pre-acquisition employees of such Party or its pre-acquisition Affiliates, in each case ((a) and (b)) shall not be deemed to be Controlled by such Party or its Affiliates after the effective date of such Change of Control for purposes of this Agreement.

1.76. "**Controlling Party**" has the meaning set forth in Section 11.5(d).

1.77. "**Cover**" or "**Covered**" means that, but for a license granted to a Person under a Valid Claim of a Patent, the act of Developing, Manufacturing, or Commercializing by such Person would infringe, or contribute to or induce the infringement of, such Valid Claim.

1.78. "**CPR Mediation Procedure**" has the meaning set forth in Section 18.1(b).

1.79. "**CPR Rules**" has the meaning set forth in Section 18.1(c)(i).

1.80. "**Damages**" means all losses, liabilities, damages, taxes, costs and expenses of every kind and nature (including reasonable attorneys' fees).

1.81. "**Data Exclusivity Right**" means any data exclusivity rights or exclusive marketing rights conferred by any Regulatory Authority with respect to a Product (other than Patents), including orphan drug exclusivity, market exclusivity, data exclusivity, or pediatric exclusivity.

1.82. "**Debarred Person**" means a Person that is: (a) debarred from or disqualified under the Act or any other governmental program; (b) on any of the FDA clinical investigator enforcement lists (including, the (i) Disqualified/Totally Restricted List, (ii) Restricted List and (iii) Adequate Assurances List); (c) excluded from participation in any governmental healthcare program or other federal or state program, convicted of an offense under 42 U.S.C. § 1320a-7, or otherwise deemed ineligible for participation in health care or federal

or state programs; or (d) is the subject of a conviction described in 21 U.S.C. 335a or is subject to any similar sanction.

1.83. "**Deemed Sublicensee Distributor**" means any Third Party appointed by Janssen or any of its Affiliates or its or their sublicensees to distribute, market, and sell Product, with or without packaging rights, in one or more countries in the Territory, in circumstances where: (a) the Third Party purchases Product from Janssen or its Affiliates or its or their sublicensees and otherwise makes an upfront, royalty or other payment (separate from a payment for supply of Product) to Janssen or its Affiliates or its or their sublicensees with respect to Product; or (b) the Third Party engages in material promotional activity under a co-promotion agreement with Janssen with respect to Product. For clarity, a Deemed Sublicensee Distributor shall be deemed a Sublicensee for the purpose of Net Sales and corresponding Royalty calculations.

1.84. "**Develop**" or "**Development**" means any and all drug development activities, other than Research activities, conducted before or after obtaining Regulatory Approval that are reasonably related to or leading to the development, preparation and submission of data and information to a Regulatory Authority for the purpose of obtaining, supporting or expanding Regulatory Approval or to the appropriate body for obtaining, supporting or expanding Pricing Approval, including all activities related to pharmacokinetic profiling, design and conduct of Clinical Studies, regulatory affairs, regulatory strategy, safety matters, statistical analysis, report writing, and Regulatory Filing creation and submission (including the services of outside advisors and consultants in connection therewith).

1.85. "**Development Milestone Event**" has the meaning set forth in Section 10.6.

1.86. "**Development Milestone Payment**" has the meaning set forth in Section 10.6.

1.87. "**Disclosing Party**" has the meaning set forth in Section 12.1.

1.88. "**Dispute**" has the meaning set forth in Section 18.1(a).

1.89. "**Distributor**" means any Third Party appointed by Janssen or any of its Affiliates or its or their sublicensees to distribute, market, and sell Product, with or without packaging rights, in one or more countries in the Territory, in circumstances where: (a) the Third Party purchases Product from Janssen or its Affiliates or its or their sublicensees, but does not otherwise make any upfront, royalty or other payment (separate from a payment for supply of Product) to Janssen or its Affiliates or its or their sublicensees with respect to Product; and (b) the Third Party does not engage in any material promotional activity under a co-promotion agreement with Janssen with respect to Product.

1.90. "**Dollar**" or "**Dollars**" or "**$**" means the legal tender of the United States of America.

1.91. "**Drug Master File**" means, for each Product, the drug master file that includes detailed information about such Product, processes, facilities, articles or Materials used in the Manufacture of such Product, which is or is intended to be submitted to a Regulatory Authority, including "Drug Master Files" as defined in 21 C.F.R. § 314.420, any non-

United States equivalents and any equivalent information applicable for a Gene Therapy Product.

1.92. "**Effective Date**" has the meaning set forth in Section 14.1

1.93. "**EMA**" means the European Medicines Agency or any successor entity thereto.

1.94. "**End-of-Phase 2 Meeting**" means any "End-of-Phase 2 Meeting" as described in 21 CFR 312.47, or, with respect to the EU, a similar meeting with the EMA.

1.95. "**EU**" means the European Union, as its membership may be constituted from time to time, and any successor thereto; *except* that, for purposes of this Agreement, the EU will be deemed to include [***].

1.96. "**European Commission**" means the executive of the EU that promotes its general interest.

1.97. "**Execution Date**" has the meaning set forth in the first paragraph of this Agreement.

1.98. "**Executive Officers**" means the Chief Executive Officer of MeiraGTx and the Global Head of Janssen Research and Development of Janssen.

1.99. "**Existing Third Party Obligations**" has the meaning set forth in Section 10.10(a).

1.100. "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1, et seq.).

1.101. "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.102. "**Field**" means the diagnosis, prevention or treatment of diseases and other conditions in all Indications in humans.

1.103. "**Final Report**" means, with respect to each Research Plan, a final report containing, at a minimum, the contents of Exhibit 1.103, including [***]. A Final Report must contain the results of Research Plan Activities that [***].

1.104. "**Final Report Delivery Date**" has the meaning set forth in Section 3.7(c).

1.105. "**First Commercial Sale**" means, with respect to any Product, and on a country-by-country basis, the first commercial sale in an arm's length transaction of such Product to a Third Party by Janssen, its Affiliates or Sublicensees in such country following receipt of applicable Regulatory Approval and Pricing Approval of such Product in such country. For clarity, the First Commercial Sale of a Product shall not include: (a) any distribution or other sale solely where the Product is supplied without charge or at the actual Manufacturing cost thereof (without allocation of indirect costs or any markup); (b) any sale by Janssen to its Affiliates or Sublicensees for further re-sale by such Affiliate or Sublicensee; or (c) sales for clinical trial purposes, early access or compassionate use programs.

1.106. [***]

1.107. "**Force Majeure**" has the meaning set forth in Section 19.4.

1.108. "**FTE**" means a full-time person, or more than one person working the equivalent of a full-time person, working directly on performing Research Plan Activities, Clinical Development Plan Activities or CMC Development Plan Activities, where "full-time" is considered [***] per Calendar Year. For clarity, indirect personnel (including support functions such as managerial, financial, legal or business development) shall not constitute FTEs.

1.109. "**FTE Costs**" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.

1.110. "**FTE Rate**" means [***] The FTE Rate shall be adjusted annually in proportion to the Consumer Price Index for all Urban Consumers for [***] to [***], as published by the U.S. Department of Labor, Bureau of Statistics (national CPI-U; Base Period: 1982-84=100; available at http://www.bls.gov/cpi/home.htm). Rate changes shall be effective as of the first (1st) day of the first (1st) Calendar Quarter of the Calendar Year. Notwithstanding the foregoing, for any time period during the Term that is less than a full Calendar Year, the above referenced rate will be proportionately reduced to reflect such portion of FTEs for such full Calendar Year.

1.111. "**Future Third Party Obligations**" means any Intellectual Property Rights of a Third Party that Cover the composition of matter, use or Manufacture of, or are necessary or useful to use or make, a Product, excluding any Intellectual Property Rights under any Existing Third Party Obligation.

1.112. "**GAAP**" means accounting principles generally accepted in the United States of America, as in effect from time to time, consistently applied.

1.113. "**Gene Therapy Product**" means any [***] product that delivers [***] for purposes of [***].

1.114. "**Governing Law**" has the meaning set forth in Section 18.2.

1.115. "**Governmental Authority***"* means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of: (a) any government of any country or territory; (b) any nation, state, province, county, city or other political subdivision thereof; (c) any supranational body; or (d) any arbitrator with binding authority.

1.116. "**HSR Act**" means the Hart-Scott-Rodino Act of 1976.

1.117. "**HSR Clearance Date**" means the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated under this Agreement have expired or have been terminated.

1.118. "**HSR Filing**" means filings by Janssen and MeiraGTx with the United States Federal Trade Commission and the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto, or any foreign form substantially equivalent thereto.

1.119. "**Improved Clinical IRD Product**" means, for any Clinical IRD Product, any Gene Therapy Product that: (a) contains [***]; and (b) [***].

1.120. "**Improved Janssen Research IRD Product**" means, for any Janssen Research IRD Product, any Gene Therapy Product that: (a) contains [***]; and (b) [***].

1.121. "**IND**" means an Investigational New Drug Application (including any amendments thereto) filed with the FDA pursuant to 21 CFR Part 312 before the commencement of a clinical trial of a Product, or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application or a clinical trial exemption, or any other equivalent or related regulatory submission, license or authorization.

1.122. "**IND Submission**" means the submission of an IND to a Regulatory Authority in a Major Market Country.

1.123. "**Indemnification Claim Notice**" has the meaning set forth in Section 17.3(b).

1.124. "**Indemnified Party**" has the meaning set forth in Section 17.3(b).

1.125. "**Indemnifying Party**" has the meaning set forth in Section 17.3(b).

1.126. "**Indemnitee**" means a MeiraGTx Indemnitee or a Janssen Indemnitee, as the context requires.

1.127. "**Indication**" means (a) any disease, condition or syndrome, or (b) any sign or symptom of or associated with a disease, condition or syndrome.

1.128. "**Initial Research Plan Term**" has the meaning set forth in Section 2.2(b).

1.129. "**Insolvency Event**" means, in relation to either Party, any one of the following: (a) that Party becomes insolvent according to Applicable Law; (b) that Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings, which are dismissed within [***]; (c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator, or similar officer is appointed in respect of that Party; (d) a notice shall have been issued to convene a meeting for the purpose of passing a resolution to wind up that Party, or such a resolution shall have been passed other than a resolution for the solvent reconstruction or reorganization of that Party; (e) a resolution shall have been passed by that Party or that Party's directors to make an application for an administration order or to appoint an administrator; or (f) that Party proposes or makes any general assignment, composition, or arrangement with or for the benefit of all or some of that Party's creditors

or makes or suspends or threatens to suspend making payments to all or some of that Party's creditors.

1.130. "**Intellectual Property Rights**" means any Know-How, Inventions, Patents, and copyrights.

1.131. "**Interest Rate**" has the meaning set forth in Section 10.13(f).

1.132. "**Interim Report**" has the meaning set forth in Section 3.7(b).

1.133. "**Internal Research**" means non-commercial research activities conducted by Janssen.

1.134. "**Invention**" means any process, method, composition of matter, article of manufacture, discovery, improvement, or finding, including Know-How, patentable or otherwise, that is first developed, generated, conceived or reduced to practice as a result of a Party (acting solely or jointly with the other Party) exercising its rights or carrying out its obligations in accordance with this Agreement, whether directly or via its Affiliates, employees, agents or independent contractors, including all rights, title and interests in and to the intellectual property rights in and to any of the foregoing.

1.135. "**IRD Gene**" means a gene whose loss of function is responsible for an inherited retinal disease.

1.136. "**J&J Universal Calendar**" means the Johnson & Johnson universal calendar for a given year. The J&J Universal Calendar for 2019 and 2020 is set forth on Exhibit 1.136 attached hereto, and the J&J Universal Calendar for subsequent years will be provided to MeiraGTx by Janssen upon MeiraGTx's request in writing from time to time.

1.137. "**Janssen**" has the meaning set forth in the first paragraph of this Agreement.

1.138. "**Janssen Indemnitees**" has the meaning set forth in Section 17.1.

1.139. "**Janssen Quality Requirements**" means, with respect to (a) MeiraGTx's Manufacturing or supply obligations for any Products under this Agreement and (b) the Clinical Studies to be conducted pursuant to this Agreement, in each case ((a) and (b)) the standards and requirements that meet Janssen's or any Regulatory Authorities' quality requirements.

1.140. "**Janssen Research IRD Patents**" has the meaning set forth in Section 11.4(d)(ii).

1.141. "**Janssen Research IRD Product**" means (a) any Research IRD Product for which Janssen has exercised the applicable Option in accordance with Section 3.9(b), and (b) any Improved Janssen Research IRD Product.

1.142. "**Janssen Technology**" means all Patents, Inventions and Know-How Controlled by Janssen or its Affiliates during the Term that are necessary to conduct the Research Plan Activities for a Research IRD Product in accordance with the respective Research Plan, conduct the Clinical Development Plan Activities for a Clinical IRD Product in accordance with the respective Clinical Development Plan or conduct the CMC Development Plan

Activities in accordance with the respective CMC Development Plan, in each case of the foregoing to the extent the results of such activities are or will be incorporated into, with Janssen's prior written permission, any Clinical IRD Product, Research IRD Product or Manufacturing process therefor.

1.143. "**Joint Development Committee**" or "**JDC**" means the committee established as set forth in Section 5.4(a).

1.144. "**Joint Inventions**" has the meaning set forth in Section 11.1(c).

1.145. "**Joint Manufacturing Committee**" or "**JMC**" means the committee established as set forth in Section 5.5(a).

1.146. "**Joint Patents**" has the meaning set forth in Section 11.1(c).

1.147. "**Joint Product Patents**" mean all Joint Patents that Cover (a) one or more components of a Product; or (b) any approved use of a Product; [***].

1.148. "**Joint Research Committee**" or "**JRC**" means the committee established as set forth in Section 5.3(a).

1.149. "**Joint Steering Committee**" or "**JSC**" means the committee established as set forth in Section 5.2(a).

1.150. "**Joint Technology**" means Joint Patents and Joint Inventions.

1.151. "**JRD**" has the meaning set forth in Section 10.13(g).

1.152. "**Know-How**" means any non-public or proprietary information and all other proprietary rights (including technical and scientific information) that may exist or be created under the laws of any jurisdiction in the world, including technical information, know-how, data (including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, Manufacturing data and descriptions, market data, financial data or descriptions), Materials, research results, inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, expertise, other technology applicable to compounds, formulations, compositions or products, to their Manufacture, Development, registration, use or Commercialization, methods of assaying or testing them or processes for their Manufacture, formulations containment, compositions incorporating or comprising them, including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, Manufacturing, preclinical and clinical data, Regulatory Filings or Regulatory Materials and copies thereof, relevant to the Development, Manufacture, use or Commercialization of or which may be useful in studying, testing, development, production or formulation of products, or intermediates for the synthesis thereof, but excluding Patents.

1.153. "**Licensed Patent Action**" has the meaning set forth in Section 11.5(a).

1.154. "**Loss of Market Exclusivity Due to a Biosimilar Product**" means, with respect to any Product in any country, that both of the following events have occurred: (a) [***] and (b) one or more Biosimilar Product(s) of such Product are marketed or sold by one or more Third Parties who are not licensees or Sublicensees of Janssen or its Affiliates in such country.

1.155. "**Loss of Market Exclusivity Due to a Competing Product**" means, with respect to any [***] in any country, that all of the following events have occurred: (a) one or more Competing Product(s) of such [***] (other than a Biosimilar Product of such [***]) are marketed or sold by one or more Third Parties who are not licensees or Sublicensees of Janssen or its Affiliates in such country; [***]

1.156. "**MAA**" means an application for the authorization or approval to market Product(s) in any country or group of countries outside the United States, as defined by Applicable Law and filed with the Regulatory Authority of a given country or group of countries.

1.157. "**Major European Countries**" means [***].

1.158. "**Major Market Countries**" means the [***].

1.159. "**Manufacture**" or "**Manufacturing**" means activities directed to producing, manufacturing, processing, sourcing of materials, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.160. "**Manufacturing Costs**" means Clinical Development Manufacturing Costs or Commercial Manufacturing Costs, as applicable to the Product. For clarity, in no event shall [***].

1.161. "**Manufacturing Services Agreement**" has the meaning set forth in Section 8.5.

1.162. "**Materials**" means any tangible compositions of matter, articles of manufacture, assays, chemical, biological or physical materials, and other similar materials, including media composition.

1.163. "**Medical Affairs**" means activities conducted by a Party's or its Affiliate's medical affairs department, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of Products and are not conducted by a Party's medical affairs department.

1.164. "**MeiraGTx**" has the meaning set forth in the first paragraph of this Agreement.

1.165. "**MeiraGTx Facility**" means the Manufacturing facility operated by MeiraGTx or its Affiliate located at 92 Britannia Walk, London, N1 7NQ, United Kingdom, or such other

Manufacturing facility operated by MeiraGTx or one of its Affiliates as mutually agreed by the Parties in writing.

1.166. "**MeiraGTx Indemnitees**" has the meaning set forth in Section 17.2.

1.167. "**MeiraGTx Know-How**" means any Know-How or Inventions Controlled by MeiraGTx or any of its Affiliates as of the Execution Date or thereafter until this Agreement expires or terminates, which are: (a) used in or otherwise relating to any Clinical IRD Product; or (b) otherwise used by MeiraGTx in the Development, Manufacture, or Commercialization of any Clinical IRD Product in the Field. The MeiraGTx Know-How excludes (y) any Know-How or Inventions embodied solely in the MeiraGTx [***] Technology and (z) any Joint Inventions.

1.168. "**MeiraGTx Patents**" means any Patents Controlled by MeiraGTx or any of its Affiliates as of the Execution Date or thereafter until this Agreement expires or terminates, which Cover any Clinical IRD Products, Clinical IRD Targets, MeiraGTx Know-How in the Field or Clinical Development Plan Activities, including such Patents set forth on Exhibit 1.168. The MeiraGTx Patents exclude (a) any Patents that solely Cover the MeiraGTx [***] Technology and (b) any Joint Patents.

1.169. "**MeiraGTx Research Know-How**" means any Know-How or Inventions Controlled by MeiraGTx or any of its Affiliates as of the Execution Date or thereafter until this Agreement expires or terminates that are used in or otherwise relating to any Research IRD Product (including any Janssen Research IRD Product). The MeiraGTx Research Know-How excludes (a) any Know-How or Inventions embodied solely in the MeiraGTx [***] Technology and (b) any Joint Inventions.

1.170. "**MeiraGTx Research Patents**" means any Patents Controlled by MeiraGTx or any of its Affiliates as of the Execution Date or thereafter until this Agreement expires or terminates that claim or otherwise Cover any Research IRD Products (including any Janssen Research IRD Products), Research IRD Targets or MeiraGTx Research Know-How in the Field or otherwise Cover any Research Plan Activities. The MeiraGTx Research Patents exclude (a) any Patents that solely Cover the MeiraGTx [***] Technology and (b) any Joint Patents.

1.171. "**MeiraGTx Research Technology**" means the MeiraGTx Research Know-How and the MeiraGTx Research Patents.

1.172. "**MeiraGTx [***] Technology**" means MeiraGTx's [***] technology, which directly relates to [***].

1.173. "**MeiraGTx Technology**" means the MeiraGTx Know-How and the MeiraGTx Patents.

1.174. "**Missing Information Notice**" has the meaning set forth in Section 3.7(c).

1.175. "**Natural History Study**" means a human clinical study that follows a group of people over time who have, or are at risk of developing, a specific medical condition or disease.

1.176. "**Net Sales**" means the gross amounts invoiced on sales of a Product by Janssen, or any of its Affiliates or Sublicensees, to a Third Party purchaser in an arms-length transaction, less the following customary and commercially reasonable deductions, determined in accordance with Janssen's Accounting Standards and internal policies and actually taken, paid, accrued, allocated or allowed based on good faith estimates:

(a) trade, cash or quantity discounts, allowances and credits, excluding commissions for commercialization;

(b) excise taxes, use taxes, tariffs, sales taxes and customs duties, or other government charges imposed on the sale of Product (including value added tax, but only to the extent that such value added taxes are not reimbursable or refundable), and specifically excluding, for clarity, any income taxes assessed against the income arising from such sale;

(c) compulsory or negotiated payments and cash rebates or other expenditures to governmental authorities (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs; including pay-for-performance agreements, risk sharing agreements and government levied fees as a result of the Affordable Care Act;

(d) rebates, chargebacks, administrative fees and discounts (or equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy benefit managers (or equivalent thereof), specialty pharmacy providers, governmental authorities or their agencies or purchasers, reimbursers or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of Product;

(e) outbound freight, shipment and insurance costs to the extent included in the price and separately itemized on the invoice price;

(f) retroactive price reductions, credits or allowances actually granted upon claims, rejections or returns of Product, including for recalls or damaged or expired goods, billing errors and reserves for returns;

(g) any invoiced amounts which are not collected by the selling Party or its Affiliates or Sublicensees, including bad debts; and

(h) any deductions in the context of payments that are due or collected significantly after invoice issuance.

All aforementioned deductions shall only be allowable to the extent they are commercially reasonable by Janssen and shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount verifiable based on Janssen's and its Affiliates' reporting system. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to Product and other products of Janssen and its Affiliates and Sublicensees such that Product does not bear a disproportionate portion of such deductions.

The following shall be excluded from Net Sales calculations for all purposes: (a) sales of Product for the use in conducting Clinical Studies or other scientific testing of Product in a country, (b) compassionate and named patient sales or sales on an Affordable Basis and (c) any disposition of Product as free samples, donations, patient assistance, test marketing programs or other similar programs or studies.

1.177. "**Non-Withholding Party**" has the meaning set forth in Section 10.13(d).

1.178. "**Operational Team**" has the meaning set forth in Section 5.6.

1.179. "**Option**" has the meaning set forth in Section 3.9(b).

1.180. "**Option Election Date**" has the meaning set forth in Section 3.9(b).

1.181. "**Option Exercise Notice**" has the meaning set forth in Section 3.9(b).

1.182. "**Option Fee**" has the meaning set forth in Section 3.9(b).

1.183. "**Option Opt-Out**" has the meaning set forth in Section 3.9(b).

1.184. "**Option Opt-Out Date**" has the meaning set forth in Section 3.9(b).

1.185. "**Option Period**" means, for a given Research IRD Product, the period (a) beginning on the date that the Parties finalize a Research Plan for such Research IRD Target associated with such Research IRD Product and (b) expiring on (i) such date that is [***] after the Final Report Delivery Date with respect to such Research IRD Target associated with such Research IRD Product or (ii) such date that the Parties otherwise mutually agree to in writing.

1.186. "**Out-of-Pocket Costs**" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties for services or materials specifically identifiable and incurred to conduct such activities for such Product in the Territory, including payments to contract personnel (including contractors, consultants and subcontractors) in each case, pursuant to the applicable Clinical Development Plan, Research Plan or CMC Development Plan, and provided that such expenses shall have been recorded as income statement items in accordance with such Party's Accounting Standards and shall not include any pre-paid amounts, capital expenditures, or items intended to be covered by the FTE Rate.

1.187. "**Party**" or "**Parties**" has the meaning set forth in the first paragraph of this Agreement.

1.188. "**Patents**" means any and all (a) patents, (b) pending patent applications, including all provisionals applications, divisionals, continuations, substitutions, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) any other form of government-issued right substantially

similar to any of the foregoing, and (f) all United States and foreign counterparts of any of the foregoing.

1.189. "**Person**" means any individual, limited liability or general partnership, limited liability company, joint venture, firm, corporation, association, trust, unincorporated organization or other entity or body, including a Governmental Authority.

1.190. "**Phase 1 Study**" means a clinical study of an investigational product in patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies. The investigational product can be administered to patients as a single agent or in combination with other investigational or marketed agents and shall be deemed commenced when the first patient in such study has received his or her initial dose of a product. A "Phase 1 Study" shall include any clinical trial that would satisfy the requirements of 21 C.F.R. § 312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.

1.191. "**Phase 1/2 Study**" means a combined Phase 1 Study and Phase 2 Study.

1.192. "**Phase 2 Study**" means a clinical study of an investigational product in patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information. The investigational product can be administered to patients as a single agent or in combination with other investigational or marketed agents and shall be deemed commenced when the first patient in such study has received his or her initial dose of a product. A "Phase 2 Study" shall include any clinical trial that would satisfy the requirements of 21 C.F.R. § 312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.

1.193. "**Phase 3 Study**" means a clinical study of an investigational product in patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. § 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. The investigational product can be administered to patients as a single agent or in combination with other investigational or marketed agents and shall be deemed commenced when the first patient in such study has received his or her initial dose of a product. For clarity, Phase 3 Studies include clinical studies of approved products for unapproved Indications.

1.194. "**Pivotal Study**" means a human clinical study in any country that is prospectively designed to generate data intended to satisfy the requirements of 21 C.F.R. § 312.21(c) in the U.S. or a similar clinical study prescribed by a Regulatory Authority from another country, from time to time, pursuant to Applicable Law. For clarity, a Pivotal Study may be a Phase 2 Study, a Phase 1/2 Study, or a Phase 3 Study.

1.195. "**PO**" has the meaning set forth in Section 10.13(c).

1.196. [***]

1.197. "**Pricing Approval**" means, with respect to a product and any country or regulatory jurisdiction, any pricing and reimbursement approvals that are commercially necessary to conduct a launch of such product in such country or regulatory jurisdiction (even if such approvals are not legally required to launch such product in such country or regulatory jurisdiction). For purposes of illustration, with respect to the Major European Countries, the following pricing and reimbursement approvals are examples of those that are currently necessary to conduct a launch of a drug or biological product: in France, publication of the reimbursed price level in the official journal and registration on a reimbursement list by or on behalf of Comité Economique des Produits de Santé or Haute Autorité de Santé (or a successor agency); in Italy, publication of reimbursement in the Government's Official Gazette (by Agenzia Italiana del Farmaco or a successor agency); in Germany, execution of contract with the head association of sick funds (GKV-Spitzenverband, Gesetzlichen Krankenversicherung, or a successor agency); in Spain, authorization by La Comisión Interministerial de Precios de los Medicamentos or La Comisión Nacional para el Uso Racional de los Medicamentos (or a successor agency) for national patient access to reimbursement by or on behalf of a Governmental Authority; and in the United Kingdom, a recommendation by the National Institute for Health and Care Excellence (or a successor agency) to obtain mandatory funding to enable broad market access.

1.198. "**Prior CDA**" means that certain Confidential Disclosure Agreement, dated [***].

1.199. "**Priority Review Voucher**" means a priority review voucher issued by the United States Department of Health and Human Services that entitles the holder of such voucher to Priority Review of a single human drug application submitted under Section 505(b)(1) of the Act or Section 351(a) of the United States Public Health Service Act, as further defined in Section 529(a)(2) of the Act (21 U.S.C. § 360ff(a)(2)).

1.200. "**Privacy and Data Security Laws**" means all applicable privacy, security and data protection laws, rules, regulations, and guidelines with respect to privacy, security and data protection including the collection, processing, storage, protection and disclosure of Sensitive Information.

1.201. "**Process Development Activities**" has the meaning set forth in Section 8.4(a).

1.202. "**Process Development Budget**" has the meaning set forth in Section 8.4(c). Each Process Development Budget, upon approval in accordance with the terms and conditions herewith, will be automatically incorporated into this Agreement by reference and form a part of this Agreement.

1.203. "**Process Development Costs**" means the fully-burdened cost incurred on or after the Effective Date by either Party or any of their respective Affiliates in connection with the performance of any Process Development Activities in accordance with this Agreement and consistent with the applicable CMC Development Plan, including all FTE Costs, Out-of-Pocket Costs, and depreciation of capital expenditures.

1.204. "**Product**" means, as applicable, any Clinical IRD Product or Janssen Research IRD Product.

1.205. "**Product Infringement**" has the meaning set forth in Section 11.6.

1.206. "**Product Marks**" has the meaning set forth in Section 11.8.

1.207. "**Qualified Change of Control**" means, with respect to MeiraGTx, a Change of Control in which the acquiring Person, as of the time of such Change of Control, (a) [***] or (b) [***].

1.208. "**Quality Agreement**" means, as applicable, the Clinical Quality Assurance Agreement or the Commercial Quality Assurance Agreement.

1.209. "**Receiving Party**" has the meaning set forth in Section 12.1.

1.210. "**Regulatory Approval**" means, with respect to each product in any country or jurisdiction, the approval of the applicable Regulatory Authority necessary for the marketing and sale of such product in such country or jurisdiction by the relevant Regulatory Authority, excluding separate pricing or reimbursement approvals that may be required, as it may be amended or updated from time to time.

1.211. "**Regulatory Authority**" means any Governmental Authority responsible for granting Regulatory Approvals for Products, including the FDA, EMA, European Commission and any corresponding national or regional regulatory authorities.

1.212. "**Regulatory Filings**" means, with respect to any product, any application or submission to a Regulatory Authority of any appropriate regulatory application, and shall include any submission to a regulatory advisory board, MAA, and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings shall include any BLA or the corresponding application in any other country or group of countries.

1.213. "**Regulatory Lead Party**" means, on a Clinical IRD Product-by-Clinical IRD Product basis, the Party allocated primary responsibility for all regulatory matters relating to such Clinical IRD Product including all Regulatory Filings and related Regulatory Materials in accordance with Section 7.1(a).

1.214. "**Regulatory Materials**" means any notifications, communication, correspondence, registrations, approvals, or other filings made to, received from or otherwise conducted with a Regulatory Authority related to Developing, Manufacturing, or otherwise Commercializing a biopharmaceutical product in a particular country or jurisdiction, other than Regulatory Filings.

1.215. "**Research**" or "**Researching**" means activities, other than Development, Manufacturing and Commercialization, related to the advance, design, delivery, discovery, generation, identification, optimization, profiling, characterization, production, process development, cell line development, pre-clinical development or non-clinical or pre-clinical studies of drug candidates and products, including such non-clinical studies and other material Development activities to be undertaken to generate data sufficient to enable the filing of an IND.

1.216. "**Research Budget**" has the meaning set forth in Section 3.4. Each Research Budget, upon approval in accordance with the terms and conditions herewith, will be automatically incorporated into this Agreement by reference and form a part of this Agreement.

1.217. "**Research Budget Cap**" has the meaning set forth in Section 3.4.

1.218. "**Research Costs**" has the meaning set forth in Section 3.8.

1.219. "**Research IRD Patents**" has the meaning set forth in Section 11.4(d)(i).

1.220. "**Research IRD Product**" has the meaning set forth in Section 3.2.

1.221. "**Research IRD Target**" means any IRD Gene nominated and approved by the JRC in accordance with Section 3.1.

1.222. "**Research IRD Target Indication**" means, with respect to any Research IRD Target, the inherited retinal disease resulting from the loss of function of such Research IRD Target, as specified in a Research Plan.

1.223. "**Research Plan**" means the strategic plan for Researching a Research IRD Product, as such plan may be agreed to, approved, amended or updated from time to time in accordance with Section 3.2. Each Research Plan, upon approval in accordance with the terms and conditions herewith, will be automatically incorporated into this Agreement by reference and form a part of Exhibit 1.223. In addition, each initial Research Plan will be attached hereto as a sequentially numbered part of Exhibit 1.223 upon approval in accordance with this Agreement (*e.g.*, Exhibit 1.223-1, Exhibit 1.223-2).

1.224. "**Research Plan Activities**" has the meaning set forth in Section 3.2.

1.225. "**Research Plan Term**" means, subject to Section 2.2(b), the Initial Research Plan Term, together with if applicable, the Research Tail Period.

1.226. "**Research Records**" has the meaning set forth in Section 3.5.

1.227. "**Research Results**" mean all tangible Materials, and copies of all material data, results, and research records relating to a Research IRD Product generated in connection with a Research Plan.

1.228. "**Research Tail Notice**" has the meaning set forth in Section 2.2(b).

1.229. "**Research Tail Period**" has the meaning set forth in Section 2.2(b).

1.230. "**Residuals**" means [***] hereunder.

1.231. "**Review Period**" has the meaning set forth in Section 13.4(a).

1.232. "**Right of Reference**" means the "right of reference or use" as that term is defined in 21 C.F.R. § 314.3(b) and any foreign counterpart to such regulation.

1.233. "**Royalty**" or "**Royalties**" has the meaning set forth in Section 10.8.

1.234. "**Royalty Term**" has the meaning set forth in Section 10.9(a).

1.235. "[***] **Product**" means: (a) MeiraGTx's Gene Therapy Product [***] for the treatment of the [***] Target Indication by expressing the [***] Target; [***].

1.236. "[***] **Product Opt-In Date**" has the meaning set forth in Section 2.1(b)(iii).

1.237. "[***] **Target**" means the [***].

1.238. "[***] **Target Indication"** means the inherited retinal disease resulting from the loss of function of the [***] Target.

1.239. "**RPGR Product**" means: (a) MeiraGTx's Gene Therapy Product [***] for the treatment of the RPGR Target Indication by expressing the RPGR Target; [***].

1.240. "**RPGR Target**" means the [***].

1.241. "**RPGR Target Indication**" means the inherited retinal disease resulting from the loss of function of the RPGR Target.

1.242. "**Sales & Royalty Report**" means a written report or reports showing each of: (a) the Net Sales of each Product in the Territory, on a US and ex-US basis, during the reporting period by Janssen and its Affiliates and Sublicensees; and (b) the Royalties payable, in United States Dollars, which shall have accrued hereunder with respect to such Net Sales.

1.243. [***]

1.244. "**Senior Officers**" means, for Janssen, the Therapeutic Area Head for Cardio Vascular and Metabolism or another senior executive designee with responsibilities and seniority comparable thereto, and for MeiraGTx, the Chief Executive Officer of MeiraGTx.

1.245. "**Sensitive Information**" means personally identifiable information, which information may include names, address, other contact information, social security number, date of birth, passwords, protected health information, biometrics, personal identification numbers and codes or other information or data that is protected by Applicable Laws or can be used for identity theft.

1.246. "**Sole Inventions**" has the meaning set forth in Section 11.1(b).

1.247. "**Sponsorship Transfer Date**" means, on a Clinical IRD Product-by-Clinical IRD Product basis and country-by-country basis, the date, [***], on which Janssen shall become the sponsor of the IND for such Clinical IRD Product.

1.248. "**Sublicensee**" means any Person, other than an Affiliate or a Distributor (but not a Deemed Sublicensee Distributor), to which a Party grants a sublicense of any right granted to such Party hereunder in accordance with the terms of this Agreement.

1.249. "**Supply Agreement**" means, as applicable, the Clinical Supply Agreement or the Commercial Supply Agreement.

1.250. "**Target**" means, as applicable, any Clinical IRD Target or Research IRD Target.

1.251. "**Target Indication**" means, with respect to any IRD Gene, the inherited retinal disease resulting from the loss of function of such IRD Gene.

1.252. "**Technology**" means Patents and Know-How.

1.253. "**Term**" has the meaning set forth in Section 15.1.

1.254. "**Terminated Product**" means any Product pursuant to which this Agreement is expired or terminated in accordance with the terms and conditions herein.

1.255. "**Territory**" means all countries and territories of the world.

1.256. "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.257. "**Third Party Infringement**" has the meaning set forth in Section 11.5(a).

1.258. "**Third Party License**" means a written agreement between a Party or its Affiliates and a Third Party to license or acquire Third Party Intellectual Property Rights, including any such agreement entered into as a result of settlement of any claims for infringement of Third Party Intellectual Property Rights.

1.259. "[***] **Clinical Development Budget Period**" has the meaning set forth in Section 6.1(d).

1.260. "[***] **Clinical Development Manufacturing Budget Period**" has the meaning set forth in Section 8.4(b).

1.261. "[***] **Process Development Budget Period**" has the meaning set forth in Section 8.4(c).

1.262. "[***] **Research Budget Period**" has the meaning set forth in Section 3.4.

1.263. "**Trade Control Laws**" mean all applicable statutory and regulatory requirements related to export controls, economic sanctions, trade embargoes, imports of goods and payment of custom duties.

1.264. "**Trademarks**" mean all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, symbols, designs, and all other indicia of ownership, and combinations thereof.

1.265. "[***]" means [***].

1.266. "**United States**" or "**U.S.**" means the United States of America, its territories and possessions.

1.267. "**U.S. Export Control Laws**" means all applicable U.S. laws and regulations relating to the export or re-export of commodities, technologies or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et seq., the Arms Export Control Act, 22 U.S.C. §§ 2778-2779, the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, the U.S. Department of Commerce's Export Administration Regulations, the U.S. Department of State's International Traffic in Arms Regulations, and the economic sanctions programs administered by the U.S. Department of Treasury's Office of Foreign Asset Controls.

1.268. "**Valid Claim**" means: (a) a claim of any issued and unexpired Patent that (i) has not been dedicated to the public, disclaimed, revoked or held unenforceable or invalid by a decision of a Governmental Authority of competent jurisdiction from which no appeal can be taken, or a decision of a Governmental Authority of competent jurisdiction that can be appealed, but with respect to which an appeal has not been taken within the time allowed for appeal, and (ii) has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a claim of any pending patent application that (i) has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction, (ii) has not been finally rejected by an administrative agency or other governmental action from which no appeal can be taken and (iii) has not been pending or filed more than [***] from the earliest possible priority date for such patent application; *provided* that if such claim is later issued, it shall from the issuance date forward be deemed to be a Valid Claim.

1.269. "**Withholding Party**" has the meaning set forth in Section 10.13(d).

2. OVERVIEW OF COLLABORATION

2.1. Overview of Clinical Development Plan Activities.

(a) General Scope. The Parties will jointly Develop Clinical IRD Products through seeking Regulatory Approval for each of the Clinical IRD Products in accordance with the terms and conditions of this Agreement. MeiraGTx will have the primary responsibility to Develop each Clinical IRD Product in accordance with the Clinical Development Plan for each such Clinical IRD Product, including where applicable, conducting any necessary Development in order to submit the applicable Regulatory Filings to Regulatory Authorities. With respect to any Clinical IRD Product, following Regulatory Approval of such Clinical IRD Product in a country, Janssen will be responsible for conducting, at its cost and expense, Commercialization and post-approval Development of such Clinical IRD Product in such country. This Section 2.1(a) is qualified in its entirety by the more detailed provisions of this Agreement set forth below (including Section 2.1(b) and Section 6.1).

(b) [***] Product.

(i) [***] *Meetings*. As of the Execution Date, (A) the [***] Product is deemed not to be a Clinical IRD Product or Research IRD Product under this Agreement, (B) the [***]

Target is deemed not to be a Clinical IRD Target or a Research IRD Target under this Agreement and (C) the [***] Target Indication is deemed not to be a Clinical IRD Target Indication under this Agreement. To the extent not prohibited by Applicable Law, Janssen shall have the right to participate in any [***] in each case relating to the [***] Product, and MeiraGTx shall provide the [***] to Janssen. Prior to any [***], MeiraGTx shall also provide Janssen for review and comment at least [***] in advance of any deadline for comments [***] copies [***] by or on behalf of MeiraGTx prior to the relevant submission with respect to the [***] Product to Janssen, and incorporate reasonable comments thereto provided by Janssen.

(ii) *Meeting Between Parties*. Within [***] following the date that MeiraGTx provides to Janssen [***] with respect to the [***] Product, the Parties shall meet to discuss MeiraGTx's plans for Developing the [***] Product. At or prior to such meeting between the Parties, MeiraGTx shall provide to Janssen all information in MeiraGTx's possession or control reasonably necessary for Janssen to evaluate whether to make the [***] Product a Clinical IRD Product hereunder, including MeiraGTx's [***] with respect to the [***] Product, information regarding [***] of the [***] Product, profile and full statistical analyses of the efficacy and safety of the [***] Product [***], MeiraGTx's good faith forecasts of all future Clinical Development Costs of the [***] Product (including a proposed Clinical Development Plan and proposed Clinical Development Budget for the [***] Product as contemplated in Section 6.1(c) and Section 6.1(d)) and [***].

(iii) *Opt-In Process*. Within [***] following the date that the Parties meet to discuss MeiraGTx's plans for Developing the [***] Product pursuant to Section 2.1(b)(ii), Janssen will notify MeiraGTx in writing whether Janssen will make the [***] Product a Clinical IRD Product hereunder. If Janssen notifies MeiraGTx that Janssen elects to make the [***] Product a Clinical IRD Product hereunder (such date, the "[***] **Product Opt-In Date**"), then (A) the [***] Product will automatically become a Clinical IRD Product, (B) the [***] Target will automatically become a Clinical IRD Target, (C) the [***] Target Indication will automatically become a Clinical IRD Target Indication, (D) the Development, Manufacturing and Commercialization terms applicable to Clinical IRD Products shall immediately go into effect in accordance herewith with respect to the [***] Product and (E) Janssen shall [***].

(iv) *Declining to Opt-In*. If Janssen notifies MeiraGTx in writing that Janssen will not elect to make the[***] Product a Clinical IRD Product hereunder, or if Janssen fails to notify MeiraGTx during such [***] period set forth in Section 2.1(b)(iii) that Janssen will elect to make the [***] Product a Clinical IRD Product hereunder, then, as of such date of notice or as of the end of such [***] period, as applicable: (A) the [***] Product will not become a Clinical IRD Product or Research IRD Product under this Agreement, the [***] Target will not become a Clinical IRD Target or Research IRD Target under this Agreement, and the [***] Target Indication will not become a Clinical IRD Target Indication or a Research IRD Target Indication under this Agreement; (B) MeiraGTx will retain its rights with regard to the Research, Development, Manufacture or Commercialization of the [***] Product and [***] Target; (C) MeiraGTx may continue the Research, Development, Manufacture and Commercialization of the [***] Product and [***] Target outside of this Agreement, [***]; (D) Janssen shall have [***]; (E) Janssen shall have no obligation to Develop, Manufacture or Commercialize the [***] Product; (F) Janssen shall have [***]; and (G) each of MeiraGTx and Janssen shall not be subject to the exclusivity obligations set forth in Section 4.6 with respect to the [***] Target.

2.2. Overview of Research Plan Activities.

(a) General Scope. During the applicable Research Plan Term, and in accordance with the terms and conditions of this Agreement, MeiraGTx will conduct Research on each Research IRD Target and design, synthesize, test and optimize Research IRD Products designed to treat the Research IRD Target Indication associated with such Research IRD Target in accordance with the applicable Research Plan and Janssen's feedback, with the aim of achieving IND Submission for each of the Research IRD Products. As part of any Research Plan, upon the Parties' mutual agreement, MeiraGTx may initiate Natural History Studies prior to any IND Submission with respect to the applicable Research IRD Target Indication associated with such Research IRD Target. Each Research IRD Target will be Researched according to a separate Research Plan, and Janssen will have an exclusive Option to select Research IRD Products arising out of any Research Plan Activities to advance such Research IRD Products, at Janssen's sole cost and expense, into Development and Commercialization in accordance with Section 3.9(b). This Section 2.2(a) is qualified in its entirety by the more detailed provisions of this Agreement set forth below (including Article 3).

(b) Research Plan Term. With respect to each Research Plan, MeiraGTx will begin the respective Research Plan Activities on or [***] by the JSC pursuant to Section 3.2. MeiraGTx will continue such Research Plan Activities for [***] thereafter (the "**Initial Research Plan Term**"). Subject to all the other terms and conditions of this Agreement, Janssen may elect, at the end of the Initial Research Plan Term, to continue funding any ongoing and previously approved Research Plan Activities in accordance with the previously approved Research Budget and Section 3.8, until the respective Final Report Delivery Date or such other reasonable date mutually agreed by the Parties, by so notifying MeiraGTx in writing at least [***] before the end of the Initial Research Plan Term (such additional period, the "**Research Tail Period**," and such notice, the "**Research Tail Notice**"). Any changes during the Research Tail Period to the respective ongoing and previously approved Research Plan and Research Plan Activities from the end of the Initial Research Plan Term shall require the Parties' mutual written agreement. If MeiraGTx does not receive the Research Tail Notice from Janssen at least [***] before the end of the Initial Research Plan Term, then the Research Plan Activities shall cease [***] after the date that such Research Plan is first approved by the JSC. Notwithstanding the foregoing, nothing shall obligate MeiraGTx to conduct any further Research Plan Activities as of (a) the Final Report Delivery Date with respect to such Research Plan or (b) such date that this Agreement terminates with respect to such Research Plan.

2.3. Overview of CMC Development Plan Activities and Other Manufacturing Activities.

During the Term, and in accordance with the terms and conditions of this Agreement and the applicable Supply Agreements: (a) MeiraGTx will Manufacture certain Products for Janssen; and (b) [***] Beginning on such date that the Parties finalize a CMC Development Plan and for [***] thereafter ("**CMC Development Term**"), the Parties will collaborate together to Develop the Manufacturing process used for each clinical program undertaken hereunder in connection with each Clinical IRD Product and Research IRD Product. This Section 2.3 is qualified in its entirety by the more detailed provisions of this Agreement set forth below (including Article 8).

3. NON-CLINICAL RESEARCH

3.1. Research IRD Targets.

During the [***] period beginning on the Effective Date (or, if Janssen provides written notice to MeiraGTx at least [***] prior to the expiration of such [***] period of Janssen's election to extend such period by another [***], during the [***] period beginning on the Effective Date), the JRC will nominate and approve IRD Genes (including, at the JRC's discretion, any IRD Gene set forth in Exhibit 1.221) as Research IRD Targets. Subject to Section 3.2, any IRD Gene approved by the JRC as a Research IRD Target will become the subject of a Research Plan. During the applicable Research Plan Term or as otherwise mutually agreed by the Parties, MeiraGTx will conduct Research on each such Research IRD Target, subject to the terms and conditions herein.

3.2. Research Plans.

[***], the Parties will, through the JRC, jointly create a Research Plan for each Research IRD Target. Each Research Plan will set forth for such Research IRD Target: [***] The JRC shall develop and submit each initial Research Plan to the JSC for its review and approval, [***] in accordance herewith, and each initial Research Plan will be automatically attached hereto and form a part of Exhibit 1.223. From time to time, and at least on an annual basis, the JRC will develop, review, and approve amendments or updates to each Research Plan, subject to the terms and conditions of this Agreement. Each such amended or updated Research Plan will be deemed to be automatically replacing the respective Research Plan previously in effect, and will be automatically incorporated into this Agreement by reference and form a part of this Agreement. Each Research Plan shall also be consistent with the terms of this Agreement.

3.3. Conduct of Research Activities.

Following approval of each Research Plan as set forth in Section 3.2, with respect to each Research Plan, MeiraGTx will use Commercially Reasonable Efforts to perform (itself or through its Affiliates or subject to Section 4.4, permitted subcontractors) the Research Plan Activities associated with such Research Plan in accordance with the applicable Research Plan (including the timelines set forth therein) for the duration of the Research Plan Term. In performing its respective Research Plan Activities, MeiraGTx: (a) will conduct such activities in a good scientific manner and in compliance with all Applicable Laws in all material respects, including, where applicable, cGMP, cGLP, cGCP, good pharmacovigilance practices and current international regulatory standards; (b) will not employ or use any Debarred Person; and (c) will not use any MeiraGTx [***] Technology during the course of performing Research Plan Activities or incorporate any MeiraGTx [***] Technology into any Research IRD Product [***].

3.4. Research Budget.

Each Research Plan will be subject to a rolling budget covering Research Costs associated with the anticipated Research Plan Activities under such Research Plan to be performed during the [***] (such [***] period, the "[***] **Research Budget Period**"), in each case broken down by Calendar Quarter and broken out on a line item basis to show Out-of-Pocket Costs (including for Manufacturing related activities) and FTE Costs of FTEs directly engaged to perform each such Research Plan Activity (each, as agreed to, approved, amended or updated from time to time in accordance with this Section 3.4, a "**Research Budget**"). No Research Budget for any Calendar

Year shall exceed in any event the applicable Calendar Year cap provided in Exhibit 3.4 attached hereto without the prior written consent of both Parties (such cap, as may be amended by the Parties in writing, the "**Research Budget Cap**"). [***], the JRC shall develop and submit to the JSC for its review and approval, a Research Budget for each Research Plan, and upon the JSC's approval, such Research Budget will be automatically incorporated into this Agreement by reference and form a part of this Agreement. Each Research Budget will be reviewed by the JRC and approved by the JSC (a) [***] based on: (i) the Parties' good faith estimation of the anticipated Research Plan Activities to be conducted during the relevant [***] Research Budget Period; and (ii) information prepared by the Parties in good faith for their own internal planning processes relating to anticipated Research Plan Activities for such Research IRD Product; or (b) whenever the total Research Costs for any given Calendar Quarter are reasonably expected to be at least [***] percent ([***]%) higher than the Research Budget for such Calendar Quarter, whether as a result of any amendments to the Research Plan or increases in costs for the Research Plan Activities already planned for such Calendar Quarter. Each such amended or updated Research Budget will automatically replace the respective Research Budget previously in effect, and will be automatically incorporated into this Agreement by reference and form a part of this Agreement. With respect to any Calendar Quarter, in no event will a Party be responsible for any Research Costs that exceed the respective portion of the then-current Research Budget recommended and proposed by the JRC and approved by the JSC, except as otherwise provided in Section 10.2(b) or mutually agreed by the Parties in writing.

3.5. Research Records.

MeiraGTx will prepare and maintain, and cause its Affiliates and their respective employees and permitted subcontractors to prepare and maintain, records, accounts, notes, reports, data and laboratory notebooks with respect to the Research Plan Activities hereunder ("**Research Records**"), in sufficient detail and in a good scientific manner appropriate for scientific, regulatory and intellectual property protection purposes and in compliance with Applicable Law, which Research Records shall: (a) be segregated from other research activities not performed under this Agreement; and (b) be complete and accurate, and fully and accurately reflect all work done, data and developments made, and results achieved in the performance of the Research Plan Activities. MeiraGTx shall retain, and cause its Affiliates and their respective employees and permitted subcontractors to retain, Research Records for at least [***] or such longer period as may be required by Applicable Law. MeiraGTx shall comply with Janssen's data policies set forth on Exhibit 3.5 attached hereto with regard to Research Records.

3.6. Audits.

With respect to any facility or site at which MeiraGTx conducts any Research Plan Activities, Janssen shall have the right, [***] upon reasonable written notice by Janssen, and during normal business hours, to inspect such site and facility of MeiraGTx or to accompany MeiraGTx to inspect any subcontractor site once per year and also for cause, to verify MeiraGTx's compliance with Applicable Law in carrying out its obligations under this Agreement, including those relating to cGMP, cGLP, cGCP and good pharmacovigilance practices. In the event that any such facility or site is found to be non-compliant with cGMP, cGLP, cGCP or good pharmacovigilance practices during such an audit, and such non-compliance relates to or impacts any Research Plan Activities hereunder, MeiraGTx shall submit to Janssen proposed Corrective and Preventative Actions

("**CAPA**") within [***] after Janssen provides notice of such non-compliance. Janssen shall have the right to review and comment on such CAPA, which comments MeiraGTx shall consider in good faith. MeiraGTx shall use Commercially Reasonable Efforts to implement such CAPA [***] after review and comment by Janssen. Except as may otherwise be provided in a Supply Agreement, if any Regulatory Authority or any other Governmental Authority conducts or gives notice of its intent to conduct any audit or inspection at any offices or facilities (including Research facilities) of MeiraGTx or any applicable permitted subcontractor where such audit or inspection relates to any Research IRD Product, then MeiraGTx will [***] notify Janssen and, to the extent such audit or inspection relates to a Research IRD Product and to the extent practicable and not prohibited by Applicable Law, secure for Janssen the right to participate in any such audit or inspection.

3.7. Research Reports and Materials.

(a) General. MeiraGTx will keep Janssen reasonably informed regarding the status, progress, and results of its Research Plan Activities under each Research Plan, including a review of results (including Manufacturing related campaign reports) and progress against timelines in such Research Plan through regularly scheduled JRC (and, if applicable, Operational Team) meetings. Through the course of such discussions, and notwithstanding anything herein to the contrary, with respect to each Research Plan, the Parties will mutually agree on the lead Research IRD Product to treat the Research IRD Target Indication with respect to any Research IRD Target (and on the plan for pre-IND Manufacturing of such lead Research IRD Product for the respective IND).

(b) Interim Reports. On [***], with respect to each Research Plan, MeiraGTx shall create and submit to the JRC (and, if applicable, the Operational Team) for its review and discussion, a written report (such report, an "**Interim Report**") that includes: (i) a summary of the Research Plan Activities completed during the most recently completed [***] under such Research Plan; (ii) a copy of all results and data generated during such period related to such Research Plan; (iii) progress against the timeline set forth in such Research Plan, with appropriate documentation to substantiate all such activities and results; and (iv) Research Costs incurred in the most recently completed [***] under such Research Plan. MeiraGTx shall also make its employees and consultants available for an in-person or telephonic meeting with Janssen at least [***] every [***] to discuss MeiraGTx's progress with respect to the conduct of Research Plan Activities.

(c) Final Report. MeiraGTx shall provide Janssen with a written Final Report within [***] after the completion or earlier termination of each Research Plan. Janssen shall have [***] following receipt of the Final Report to notify MeiraGTx in writing if Janssen in good faith believes that any information is missing from the Final Report (a "**Missing Information Notice**"), which Missing Information Notice shall identify with reasonable detail such required information that Janssen believes is missing. If Janssen delivers a Missing Information Notice to MeiraGTx, MeiraGTx shall deliver the missing required information identified in such Missing Information Notice as soon as practicable to Janssen, and Janssen will [***] notify MeiraGTx in writing upon Janssen's confirmation that MeiraGTx has provided to Janssen all such missing required information that MeiraGTx must provide (a "**Completion Notice**"). The Final Report will be deemed complete on the date on which MeiraGTx receives the Completion Notice. If Janssen does not deliver a timely Missing Information Notice to MeiraGTx within the [***] period described

above in this Section 3.7(c), the initial Final Report will be deemed complete on the date such [***] period lapses. For purposes of this Agreement, "**Final Report Delivery Date**" means the date upon which Janssen has received a complete Final Report in accordance with this Section 3.7(c). During the [***] period following the Final Report Delivery Date, MeiraGTx shall: (i) promptly update the Final Report if any new data relating to any Research IRD Product or Research IRD Target becomes available; and (ii) upon Janssen's reasonable request, provide to Janssen and its representatives reasonable access during normal business hours to MeiraGTx's personnel to discuss such updated Final Report.

3.8. Research Costs.

Subject to Section 10.2, the Parties will be responsible for the documented FTE Costs and Out-of-Pocket Costs, in each case, incurred by or on behalf of MeiraGTx during the Research Plan Term in accordance with the then-current Research Plan, including the cost of any Natural History Studies that are part of such Research Plan (collectively, the "**Research Costs**") as follows: Janssen will be responsible for [***] percent ([***]%) of all Research Costs under each Research Plan, and MeiraGTx will be responsible for [***] percent ([***]%) of all Research Costs under each Research Plan, in each case to the extent that such Research Costs are incurred [***]. All Research Costs will be reconciled and paid in accordance with the procedure described in Section 10.2. Notwithstanding anything herein to the contrary, Janssen will [***].

3.9. Option.

(a) Provision of Information. During the applicable Research Plan Term, Janssen and the JRC and JSC will assess the results provided in each Interim Report provided under a Research Plan, and the JSC will review and determine whether the Advancement Criteria for the respective Research IRD Product have been met. Janssen will determine (based on the Interim Reports or the Final Report for a given Research IRD Product) whether it wishes to further Develop any such Research IRD Product by exercising the Option as set forth in Section 3.9(b).

(b) Exercise of Option. Subject to the terms and conditions of this Agreement, with respect to each Research IRD Target, MeiraGTx hereby grants to Janssen an exclusive (even as to MeiraGTx) option (each, an "**Option**"), exercisable during the applicable Option Period, to obtain, on a Research IRD Target-by-Research IRD Target basis, the exclusive license (as set forth in Section 4.1(b)(ii)) to each Research IRD Product that treats the Research IRD Target Indication resulting from the loss of function of such Research IRD Target. With respect to each Research IRD Target, during the applicable Option Period, Janssen may exercise the applicable Option for such Research IRD Target by delivering a notice of Janssen's exercise of such Option to MeiraGTx (each, an "**Option Exercise Notice**") and paying MeiraGTx [***], which fee shall be non-creditable and non-refundable (each, an "**Option Fee**," and such date of receipt of notice, the "**Option Election Date**"). After receipt of such Option Exercise Notice, MeiraGTx shall submit an invoice to Janssen for such Option Fee, and Janssen shall make such Option Fee payment to MeiraGTx within [***] after Janssen's receipt of such invoice. For clarity, the [***]. As of such Option Election Date, each such Research IRD Product for which Janssen has exercised an Option will become a Janssen Research IRD Product, the exclusive license granted to Janssen in Section 4.1(b)(ii) for such Janssen Research IRD Product will become effective, and Janssen shall assume all responsibility, at Janssen's sole cost and expense, for the further Development, Manufacture,

and Commercialization of such Research IRD Product in accordance with this Agreement. In addition, with respect to any Option, and on a Research IRD Target-by-Research IRD Target basis, Janssen may deliver a written notice to MeiraGTx of its intention not to exercise such Option. If with respect to any given Option Janssen fails to provide an Option Exercise Notice before the expiration of the applicable Option Period, or if Janssen provides written notice to MeiraGTx that Janssen does not wish to exercise the applicable Option, then such Option will expire on a Research IRD Target-by-Research IRD Target basis (each, an "**Option Opt-Out**," and each of such dates, an "**Option Opt-Out Date**"), and: (i) the exclusivity obligations applicable to MeiraGTx under Section 4.6(c) shall expire, and the exclusivity obligations applicable to Janssen under 4.6(b) shall not take effect, in each case with respect to each Research IRD Product that treats the Research IRD Target Indication resulting from the loss of function of such Research IRD Target; (ii) MeiraGTx may freely Develop, Manufacture and Commercialize, or grant to any Third Party rights to Develop, Manufacture and Commercialize, at MeiraGTx's sole cost and expense, each such Research IRD Product without further obligation to Janssen; (iii) the non-exclusive license granted from MeiraGTx to Janssen in Section 4.1(b)(i) will terminate with respect to the Research Plan Activities applicable to each such Research IRD Product; (iv) Janssen shall have [***] except as otherwise expressly provided herein; (v) Janssen shall have no obligation to Develop or Commercialize any such Research IRD Product; and (vi) Janssen shall have [***].

4. LICENSES

4.1. Licenses to Janssen.

(a) Clinical IRD Products. Subject to the terms and conditions of this Agreement and each Supply Agreement, MeiraGTx hereby grants, on behalf of itself and its Affiliates, to Janssen an exclusive (even as to MeiraGTx), royalty-bearing, sublicensable (through multiple tiers, solely as provided in Section 4.3), transferable (in accordance with Section 19.1) license under the MeiraGTx Technology and MeiraGTx's interest in the Joint Technology during the Term, to Develop, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, and otherwise exploit, Manufacture and Commercialize Clinical IRD Products in the Field in the Territory. For clarity, Janssen may not exercise its rights to make, have made (except by MeiraGTx or its Affiliates or permitted CMOs) or Manufacture Clinical IRD Products in the Field in the Territory except as expressly permitted in a Supply Agreement.

(b) Research IRD Products.

(i) *Non-Exclusive License to Perform Obligations*. Subject to the terms and conditions of this Agreement, MeiraGTx hereby grants, on behalf of itself and its Affiliates, to Janssen a non-exclusive, sublicensable (through multiple tiers, solely as provided in Section 4.3), transferable (in accordance with Section 19.1) license under the MeiraGTx Research Technology and MeiraGTx's interest in the Joint Technology during the Term, for purposes of Janssen conducting its obligations under this Agreement, including any Research Plan Activities assigned to Janssen in the respective Research Plan.

(ii) *Exclusive License Following Option Exercise*. Subject to the terms and conditions of this Agreement and each Supply Agreement, with respect to each Janssen Research IRD Product, MeiraGTx hereby grants, on behalf of itself and its Affiliates, to Janssen an exclusive

(even as to MeiraGTx), royalty-bearing, sublicensable (through multiple tiers, solely as provided in Section 4.3), transferable (in accordance with Section 19.1) license, under the MeiraGTx Research Technology and MeiraGTx's interest in the Joint Technology during the Term, to Research, Develop, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, and otherwise exploit, Manufacture and Commercialize such Janssen Research IRD Product in the Field in the Territory. For clarity, Janssen may not exercise its rights to make, have made (except by MeiraGTx or its Affiliates or permitted CMOs) or Manufacture Janssen Research IRD Products in the Field in the Territory except as expressly permitted in a Supply Agreement.

(c) Internal Research License. Subject to the terms and conditions of this Agreement, MeiraGTx hereby grants, on behalf of itself and its Affiliates, to Janssen a non-exclusive, royalty-free, sublicensable (but only to its Affiliates) license, under the MeiraGTx Technology, MeiraGTx Research Technology and MeiraGTx's interest in the Joint Technology to conduct Internal Research in the Field in the Territory. The license granted under this Section 4.1(c) shall be perpetual and survive any expiration of this Agreement and any termination of this Agreement by Janssen under Section 15.2(a)(i) for MeiraGTx's uncured material breach or under Section 15.2(b) for a MeiraGTx Insolvency Event. In addition, upon an Option Opt-Out for a Research IRD Product pursuant to Section 3.9(b), the license granted under this Section 4.1(c) shall be perpetual and survive with respect to such Research IRD Product, except as otherwise expressly provided in this Section 4.1(c). [***]

4.2. Licenses to MeiraGTx.

(a) Clinical IRD Products.

(i) *License Back for Performance of Obligations and Manufacture.* Subject to the terms and conditions of this Agreement, with respect to each Clinical IRD Product, Janssen hereby grants, on behalf of itself and its Affiliates, to MeiraGTx a non-exclusive, royalty-free, sublicensable (solely as provided in Section 4.3), transferable (in accordance with Section 19.1) license, under the MeiraGTx Technology and both Parties' interest in the Joint Technology to: (A) perform MeiraGTx's obligations under this Agreement with respect to such Clinical IRD Product; and (B) make, have made and otherwise Manufacture such Clinical IRD Product in accordance with the terms herewith.

(ii) *Non-exclusive License to Janssen Technology.* Subject to the terms and conditions of this Agreement, with respect to each Clinical IRD Product, Janssen hereby grants, on behalf of itself and its Affiliates, to MeiraGTx, a non-exclusive, royalty-free, sublicensable (solely as provided in Section 4.3), transferable (in accordance with Section 19.1) license under the Janssen Technology during the Term, for purposes of MeiraGTx conducting its obligations under this Agreement, including any Clinical Development Plan Activities assigned to MeiraGTx in the respective Clinical Development Plan or the Manufacture of any Clinical IRD Products in accordance with the terms herewith.

(b) Research IRD Products.

(i) *Non-Exclusive License Back for Manufacture.* Subject to the terms and conditions of this Agreement, with respect to each Janssen Research IRD Product, Janssen hereby grants, on behalf of itself and its Affiliates, to MeiraGTx a non-exclusive, royalty-free, sublicensable (solely as provided in Section 4.3), transferable (in accordance with Section 19.1) license, under the MeiraGTx Research Technology and Janssen's interest in the Joint Technology to make, have made and otherwise Manufacture such Janssen Research IRD Product in accordance with the terms herewith.

(ii) *Non-Exclusive License to Janssen Technology.* Subject to the terms and conditions of this Agreement, with respect to each Research IRD Product (including any Janssen Research IRD Product), Janssen hereby grants, on behalf of itself and its Affiliates, to MeiraGTx, a non-exclusive, royalty-free, sublicensable (solely as provided in Section 4.3), transferable (in accordance with Section 19.1) license under the Janssen Technology during the Term, for purposes of MeiraGTx conducting its obligations under this Agreement, including any Research Plan Activities assigned to MeiraGTx in the respective Research Plan or the Manufacture of any Research IRD Products in accordance with the terms herewith.

4.3. Sublicense Rights.

Janssen may sublicense through multiple tiers the rights granted to it by MeiraGTx under Section 4.1(a) and Section 4.1(b) at any time [***]; *provided* that: (a) each such sublicense shall be consistent with the terms and conditions of this Agreement (including Section 4.1 and Article 12) and shall be subject to any Third Party License requirements with respect to any Technology in-licensed by MeiraGTx and (b) each sublicense to a Third Party collaborator shall be in writing and shall contain terms prohibiting the Third Party collaborator from using any MeiraGTx Confidential Information, MeiraGTx Know-How or MeiraGTx Research Know-How for any purpose inconsistent with this Agreement. In the case of any sublicense by Janssen, Janssen shall remain primarily responsible for, and directly liable to MeiraGTx for, the payment of all royalties payable based on Net Sales of Product by any Janssen Sublicensee and the payment of all Development Milestone Payments and Commercial Milestone Payments even if a Sublicensee is responsible for the achievement of any such milestone with respect to any Product. Either Party may exercise its rights and perform its rights and obligations under this Agreement itself or through any of its Affiliates. Except for MeiraGTx sublicensing to an Affiliate or as permitted under Section 4.4, MeiraGTx may not sublicense the rights granted to it by Janssen under this Agreement without first obtaining, in each case, Janssen's prior written consent (which shall not be unreasonably withheld, delayed, or conditioned), and any such sublicense must be consistent with the terms of this Agreement (including Section 4.2 and Article 12).

4.4. Subcontractors.

Each Party may engage subcontractors to perform any obligations assigned to it under this Agreement, except that: (a) [***]; (b) prior to [***]; (c) prior to [***]; (d) the subcontracting Party shall remain fully responsible for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself; (e) each contract between a Party and a subcontractor shall be consistent with the provisions of this Agreement, including (i) obligations of confidentiality and non-use applicable to Confidential Information that are at least as stringent as those set forth in Article 12 and (ii) obligations of assignment of all Inventions and other

Intellectual Property Rights developed in the course of performing any such work under this Agreement to the subcontracting Party and obligations of cooperation to execute any documents to confirm or perfect such assignment; and (f) the subcontracting Party shall remain at all times fully liable for all acts or omissions of such subcontractor. Any reference to a Party's performance hereunder shall include references to any performance by its subcontractors permitted in accordance with this Section 4.4.

4.5. Third Party Licenses.

All rights licensed to a Party from a Third Party and sublicensed to the other Party under this Agreement will be subject to and subordinate to the terms of the applicable Third Party License to the extent such terms apply to a sublicensee of such Third Party Intellectual Property Rights, except that no Party shall be obligated to comply with any such Third Party License until such Third Party License has been disclosed to such Party.

4.6. Exclusivity.

(a) Janssen Exclusivity for Clinical IRD Targets. On a Clinical IRD Target-by-Clinical IRD Target basis, beginning on (i) the Effective Date with respect to the CNGA3 Target, CNGB3 Target and RPGR Target and (ii) the [***] Product Opt-In Date with respect to the [***] Target, and ending on the earlier of (A) [***] of the Effective Date or (B) the expiration or termination of this Agreement with respect to the Clinical IRD Product associated with such Clinical IRD Target, [***] other than Researching, Developing, Manufacturing, and Commercializing Clinical IRD Products in accordance with the terms and conditions of this Agreement. In addition, on a Clinical IRD Product-by-Clinical IRD Product basis, beginning on [***] and for [***] thereafter, [***]

(b) Janssen Exclusivity for Research IRD Targets. On a Research IRD Target-by-Research IRD Target basis, beginning on the Option Election Date associated with the Janssen Research IRD Product intended to treat the Research IRD Target Indication resulting from the loss of function of such Research IRD Target and ending on the earlier of (i) the [***] of the Option Election Date associated with the Janssen Research IRD Product intended to treat such Research IRD Target Indication resulting from the loss of function of such Research IRD Target or (ii) the expiration or termination of this Agreement with respect to the Janssen Research IRD Product intended to treat such Research IRD Target Indication resulting from the loss of function of such Research IRD Target, [***] other than Researching, Developing, Manufacturing, and Commercializing Janssen Research IRD Products in accordance with the terms and conditions of this Agreement.

(c) MeiraGTx Exclusivity Obligations. Beginning on the Effective Date, [***] other than Researching, Developing, Manufacturing and Commercializing Gene Therapy Products in accordance with the terms and conditions of this Agreement. The prohibition contained in the immediately preceding sentence shall end:

[***]

provided, *however*, that if both subsections (ii) and (iii) above apply to any one particular case, the longer period described in subsection (ii) or (iii) shall apply thereto.

(d) Mergers and Acquisitions Involving Competing Products. Subject to Section 4.6(e), in the event that a Third Party merges with a Party or becomes an Affiliate of a Party or assets of a Third Party are combined with a Party or an Affiliate of a Party ("**Acquired Party**") during the Term through merger, acquisition, consolidation or other similar transaction, and as of the closing date of such merger, acquisition, consolidation or other similar transaction, such Third Party is engaged in the Research, Development, Manufacture or Commercialization of a Competing Product, then, unless the Parties mutually agree otherwise, the Acquired Party or its new Affiliate (as applicable) shall have [***] from the closing date of such transaction to wind down or complete the Divestiture of such Competing Product, and its new Affiliate's conduct of the Research, Development, Manufacture and Commercialization of such Competing Product during such [***] period shall not be deemed a breach of the Acquired Party's exclusivity obligations set forth in this Section 4.6; *provided* that such new Affiliate conducts the Research, Development, Manufacture and Commercialization of such Competing Product during such [***] period independently of the activities of this Agreement and does not use any of the other Party's Intellectual Property Rights or Confidential Information (except as may be separately licensed by such other Party to such new Affiliate) in such conduct. "**Divestiture**", as used in this Section 4.6(d), means the sale or transfer of rights to the Research, Development, Manufacture and Commercialization of a Competing Product to a Third Party without receiving a continuing share of profit, royalty payment or other economic interest in the success of such Competing Product.

(e) Qualified Change of Control. In the event of a Qualified Change of Control involving MeiraGTx, Janssen shall have the right to terminate [***], by providing MeiraGTx with written notice at least [***] after the announcement of such Qualified Change of Control, with such termination to be effective within [***] of such notice; *provided* that all other obligations under this Agreement, including under Section 4.1 and Article 10, shall remain in full force and effect. For clarity, upon Janssen's termination notice to MeiraGTx in accordance with the preceding sentence, (i) all Committees shall be disbanded and Janssen shall have sole and exclusive control with respect to any activities previously conducted pursuant to this Agreement and (ii) Janssen shall not have any further obligations to share any information, updates or reports with MeiraGTx with respect to any activities previously conducted pursuant to this Agreement, *except* with respect to Section 10.6, Section 10.7, Section 10.8, Section 10.9, Section 10.11 (including Sales & Royalty Reports) and any other applicable payment obligations. In the event that Janssen elects to not exercise its rights under this Section 4.6(e), the terms of Section 4.6(d) shall apply.

4.7. No Other Rights.

Each Party expressly reserves and retains all Patents, Know-How, and other intellectual property rights not expressly granted herein, and no right or license under any Intellectual Property Rights of either Party is granted or shall be granted by implication, estoppel or otherwise. Each licensee Party covenants to the licensor Party that the licensee Party shall not (and shall require that any of its Affiliates or Sublicensees shall not) use any of the licensor Party's Intellectual Property Rights licensed under this Agreement for any purpose other than as expressly provided under this Agreement for such licensee Party.

4.8. MeiraGTx Know-How Transfer.

(a) Clinical IRD Products. Within [***] following the Effective Date, MeiraGTx will deliver to Janssen all copies of: (i) MeiraGTx Know-How reasonably necessary or useful for the Development or Commercialization of the Clinical IRD Products; and (ii) documents and files related to the MeiraGTx Patents Covering the Clinical IRD Products. Thereafter, on a [***] basis during the Term or as otherwise mutually agreed by the Parties, MeiraGTx shall [***] disclose to Janssen (through the JSC, JDC, or JRC, as applicable) any additional MeiraGTx Know-How reasonably necessary or useful for the Development or Commercialization of any Clinical IRD Product that came into existence after the prior disclosure, will provide reasonable assistance to Janssen in connection with understanding and using all such MeiraGTx Know-How for purposes consistent with the licenses and rights granted to Janssen under Section 4.1 and will provide any new documents or files related to the MeiraGTx Patents Covering the Clinical IRD Products that came into MeiraGTx's possession or control after the prior disclosure. All costs of the transfer set forth in this Section 4.8(a) shall be deemed Clinical Development Costs hereunder and paid in accordance with the terms and conditions set forth in Section 6.1(f).

(b) Research IRD Products. With respect to any Janssen Research IRD Product, within [***] after Janssen's exercise of the respective Option, MeiraGTx will deliver to Janssen all copies of: (i) MeiraGTx Research Know-How reasonably necessary or useful for the Development or Commercialization of the applicable Janssen Research IRD Product; and (ii) documents and files related to the MeiraGTx Research Patents Covering the Janssen Research IRD Product. Thereafter, on a [***] basis during the Term or as otherwise mutually agreed by the Parties, MeiraGTx shall [***] disclose to Janssen (through the JSC, JDC, or JRC, as applicable) any additional MeiraGTx Research Know-How reasonably necessary or useful for the Development or Commercialization of any Janssen Research IRD Product that came into existence after the prior disclosure, will provide reasonable assistance to Janssen in connection with understanding and using all such MeiraGTx Research Know-How for purposes consistent with the licenses and rights granted to Janssen under Section 4.1 and will [***]. All costs of the transfer set forth in this Section 4.8(b) shall be [***].

5. GOVERNANCE

5.1. Alliance Managers.

Within [***] following the Effective Date, each Party shall designate an individual employee to facilitate communication and coordination of the Parties' activities under this Agreement and to provide support and guidance to the JSC (each, an "**Alliance Manager**"). Each Alliance Manager may not serve as a representative of its respective Party on any Committee.

5.2. Joint Steering Committee.

(a) Purpose; Formation. Within [***] following the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**" or "**Joint Steering Committee**"). The JSC shall monitor, make certain decisions, and provide strategic oversight of the activities under this Agreement and facilitate communications between the Parties with respect to the Research, Development, Manufacturing, and Commercialization of the Products.

(b) Specific Responsibilities. In addition to providing general oversight of all activities hereunder, the JSC shall in particular have the following responsibilities, in each case to the extent the applicable decisions are not made at the level of another Committee: (i) reviewing and approving each initial Clinical Development Plan; (ii) reviewing and approving the overall regulatory strategy for the Clinical IRD Products; (iii) approving all material Regulatory Filings and Regulatory Materials as necessary, subject to Section 7.1(c); (iv) reviewing and approving each initial Research Plan for a Research IRD Target; (v) reviewing and approving each initial CMC Development Plan; (vi) approving, upon recommendation and proposal by the applicable Committee, Research Budgets, Clinical Development Budgets, Clinical Development Manufacturing Budgets and Process Development Budgets as provided herein (*provided* that no Research Budget for a Calendar Year shall exceed the respective Research Budget Cap for such Calendar Year); (vii) facilitating the flow of information with respect to the Development and Commercialization of the Products; (viii) receiving and discussing reports from the other Committees; (ix) providing guidance to the other Committees on all significant strategic issues that fall within the scope of such Committees; (x) establishing such additional joint subcommittees as it deems necessary to achieve the objectives and intent of this Agreement; (xi)facilitating the prosecution and maintenance with respect to Patents pursuant to Section 11.4 and resolving disputes with respect to such Patents; (xii) resolving disputes for which it is responsible as provided in this Agreement; and (xiii) performing such other functions as expressly provided in this Agreement.

5.3. Joint Research Committee.

(a) Purpose; Formation. Within [***] following the Effective Date, the Parties shall establish a committee to oversee the Research Plan Activities and otherwise facilitate the flow of information between the Parties with respect to, and provide a forum to discuss, Research Plan Activities (the "**JRC**" or "**Joint Research Committee**").

(b) Specific Responsibilities. The JRC shall be responsible for: (i) nominating and approving IRD Genes to become Research IRD Targets; (ii) discussing, preparing, and recommending for submission to the JSC for approval, each initial Research Plan and discussing and approving as applicable amendments thereto; (iii) discussing, preparing, and recommending for submission to the JSC for approval, each Research Budget; (iv) overseeing and directing the Research Plan Activities, including Natural History Studies; (v) reviewing and discussing all reports describing the Research Plan Activities and the Research Results (including Interim Reports and Final Reports); (vi) performing such other functions as may be delegated to it by the JSC; and (vii) performing such other functions expressly delegated to it in this Agreement.

5.4. Joint Development Committee.

(a) Purpose; Formation. Within [***] following the Effective Date, the Parties shall establish a committee to oversee the Clinical Development Plan Activities of the Parties with respect to each Clinical IRD Product and otherwise facilitate the flow of information between the Parties with respect to, and provide a forum to discuss, the Development of Products (the "**JDC**" or "**Joint Development Committee**").

(b) Specific Responsibilities. The JDC shall in particular have the following responsibilities: (i) reviewing, amending, and recommending for approval by the JSC, each initial Clinical Development Plan and discussing and approving as applicable amendments thereto; (ii) discussing, preparing, and recommending for submission to the JSC for approval, each Clinical Development Budget; (iii) reviewing and monitoring the Parties' Clinical Development Plan Activities and progress against each Clinical Development Plan, including facilitating discussions between the Parties regarding the Development of each Clinical IRD Product; (iv) reviewing and recommending to the JSC for approval all material Regulatory Filings and all Regulatory Materials as necessary or as requested by the JSC, subject to Section 7.1(c); (v) discussing and recommending to the JSC for approval the overall regulatory strategy for each Clinical IRD Product; (vi) discussing the Development reports; (vii) determining the timing of the transition between the Parties with respect to regulatory matters pursuant to Section 7.1(a)(iii); (viii) reviewing and monitoring the Parties' Development activities with respect to safety matters; (ix) developing and reviewing the overall publication strategy for the Parties in connection with this Agreement, subject to Section 13.4; (x) performing such other functions as may be delegated to it by the JSC; and (xi) performing such other functions expressly delegated to it in this Agreement.

5.5. Joint Manufacturing Committee.

(a) Purpose; Formation. Within [***] following the Effective Date, the Parties shall establish a committee to oversee and coordinate the Manufacturing activities of the Parties with respect to each Clinical IRD Product or Research IRD Product and otherwise facilitate the flow of information between the Parties with respect to, and provide a forum to discuss, the Manufacturing of Products and the CMC Development Collaboration (the "**JMC**" or "**Joint Manufacturing Committee**").

(b) Specific Responsibilities. The JMC shall in particular have the following responsibilities: (i) reviewing, amending, and recommending for approval by the JSC initial Manufacturing plans, initial CMC Development Plans and discussing and approving as applicable amendments thereto, including with respect to capacity; (ii) discussing, preparing, and recommending for submission to the JSC for approval each Clinical Development Manufacturing Budget and Process Development Budget; (iii) overseeing the Manufacturing of Products used in Development activities, including discussing any potential supply issues, interruptions, the outcome of any Regulatory Authority inspection of Manufacturing facilities used by or on behalf of MeiraGTx, and any remedial actions required, if applicable, as a result of such inspection; (iv) overseeing the CMC Development Plan Activities for all Clinical IRD Products, Research IRD Products, and Janssen Research IRD Products; (v) collaborating on the creation of the Manufacturing-related Regulatory Filings and all Regulatory Materials for any Clinical IRD Product and any Research IRD Product being Manufactured by or on behalf of MeiraGTx; (vi) overseeing the Know-How transfer of Manufacturing technology to Janssen in accordance with any Supply Agreement; (vii) reviewing and approving specifications for Clinical IRD Products and Research IRD Products; (viii) performing such other functions as may be delegated to it by the JSC; and (ix) performing such other functions expressly delegated to it in this Agreement.

5.6. Operational Teams.

From time-to-time, each of the JSC, JRC, JDC or JMC may establish and delegate specific matters or duties within its responsibilities to directed teams (each, an "**Operational Team**"), the composition, operation, and responsibilities of which will be determined by the applicable establishing Committee. Operational Teams may be established on an *ad hoc* basis for purposes of a specific activity or on such other basis as the applicable establishing Committee may determine. Each Operational Team will report to, and its activities will be subject to the oversight of, the applicable establishing Committee and the JSC, and no Operational Team's authority may exceed that specified for the applicable establishing Committee. Any disagreement between the representatives of the Parties on any Operational Teams will be referred to the applicable establishing Committee for resolution in accordance with Section 5.8.

5.7. Committee Representatives and Meetings.

(a) Committee Representatives. Each Party shall initially appoint [***], and no more than [***] representatives to each Committee, with the exception of the JSC, which shall have [***] representatives from each Party. Each Committee representative shall have appropriate knowledge and expertise within the applicable Party to make decisions or recommendations arising within the scope of the applicable Committee's responsibilities. Each Party may replace its representatives on any Committee upon written notice to the other Party. Each Party shall appoint [***] of its representatives on each Committee to act as a co-chairperson of such Committee. The responsibility for running each meeting of each Committee shall alternate between the co-chairpersons of such Committee from meeting-to-meeting, with Janssen's co-chairperson running the first meeting of each Committee. The co-chairpersons of each Committee shall jointly prepare and circulate agendas to such Committee's representatives before each such Committee meeting and shall direct the preparation of reasonably detailed documentation for each such Committee meeting, which shall be approved by the Committee's co-chairpersons and circulated to Committee representatives within [***] of such meeting. Unless mutually agreed upon by the Parties, any member of one Committee shall not be a member of another Committee under this Agreement, and Alliance Managers and Senior Officers may not serve on any Committee.

(b) Non-Committee Representatives. Each Party may [***] invite [***], in addition to its representatives, to attend Committee meetings in a non-voting capacity; *provided* that if either Party intends to have any Third Party attend such a meeting, such Party shall obtain the other Party's prior written consent for such Third Party to attend such meeting, which consent shall not be unreasonably withheld, conditioned, or delayed; and *provided further* that each Party's co-chairperson of the JMC may attend any JDC meeting in a non-voting capacity and each Party's co-chairperson of the JDC may attend any JMC meeting in a non-voting capacity, in each case without the consent of the other Party. Each Party shall be responsible for ensuring that each Committee member that it appoints and each Third Party that it invites to a Committee meeting complies with the confidentiality and non-use obligations set forth in this Agreement.

(c) Meetings. Each Committee shall hold meetings at such times as it elects to do so, but at least [***] in the case of the JRC, the JDC and the JMC, and at least [***] in the case of the JSC; *provided* that the JSC shall hold its first meeting no later than [***] from the Effective Date. Meetings of any Committee may be held in person or by audio or video teleconference; *provided* that unless otherwise agreed by the Parties, at least [***] meeting per [***] for each Committee

shall be held in person. Notwithstanding Section 5.7(a), upon the Parties' mutual agreement, any meeting of a Committee may be combined with any meeting of another Committee. Each Party shall be responsible for all of its own costs and expenses of participating in any Committee meetings. No action taken at any meeting of a Committee shall be effective unless at least [***] Committee representative of each Party is participating in such meeting.

(d) Dissolution. Each Committee will continue to exist until the earlier of completion of such Committee's obligations under this Agreement or mutual agreement of the Parties to disband such Committee; *provided* that following the dissolution of the JSC, the JSC may, upon the Parties' agreement, continue to meet on a [***] basis (or more or less frequently, if mutually agreed by the Parties) solely to serve as a forum for sharing and discussing information.

5.8. Resolution of Committee Disputes.

(a) Votes. All decisions of each Committee shall be made by [***] vote, with each Party's representatives on the respective Committee collectively having [***] vote.

(b) Disputes. If, after reasonable discussion and good-faith consideration of each Party's view on a particular matter before any Committee other than the JSC and within the scope of its authority, the representatives of the Parties on such Committee cannot reach an agreement as to such matter within [***] after such matter was brought to such Committee for resolution, such disagreement shall be referred to the JSC for resolution. If, after reasonable discussion and good-faith consideration of each Party's view on a particular matter before the JSC and within the scope of its authority, the representatives of the Parties on the JSC cannot reach an agreement as to such matter within [***] after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC from another Committee, such disagreement shall be referred to the Senior Officers for resolution.

(c) Final Decision-Making Authority. If the Senior Officers cannot in good faith resolve a particular matter within [***] after such matter has been referred to them, then: [***]

(d) No Other Powers. Notwithstanding anything herein to the contrary, each Committee shall have only the powers assigned expressly to it in this Article 5 and elsewhere in this Agreement, and no Committee shall have any power to amend, modify or waive compliance with this Agreement, or to impose additional obligations on a Party beyond those provided in this Agreement.

6. DEVELOPMENT

6.1. Clinical IRD Products.

(a) Clinical IRD Products. Subject to the terms and conditions of this Agreement (including Section 2.1(b)), the Parties will collaborate with one another to Develop the Clinical IRD Products.

(b) Responsibility. Subject to the oversight of the JSC and JDC, the Parties will jointly collaborate with one another on the Development of each Clinical IRD Product in accordance with this Agreement and the applicable Clinical Development Plan for such Clinical IRD Product,

including conducting any necessary Research to support BLA approval for such Clinical IRD Product.

(c) Clinical Development Plans. The anticipated costs and timelines for activities under the Clinical Development Plans for the CNGA3 Product, the CNGB3 Product and the RPGR Product are attached hereto as parts of Exhibit 1.34. [***] with respect to the CNGA3 Product, CNGB3 Product and RPGR Product, the JDC shall develop and submit to the JSC for its review and approval, a Clinical Development Plan for each such Clinical IRD Product, and upon the JSC's approval, each such initial Clinical Development Plan will be attached hereto and form a part of Exhibit 1.34. If Janssen elects to make the [***] Product a Clinical IRD Product in accordance with Section 2.1(b), no later than [***] following the [***] Product Opt-In Date, the JDC shall develop and submit to the JSC for its review and approval, a Clinical Development Plan for the [***] Product, and upon the JSC's approval, such initial Clinical Development Plan shall be attached hereto and form a part of Exhibit 1.34. In the event that any Clinical Development Plan for a Clinical IRD Product conflicts with the anticipated costs and timelines set forth in Exhibit 1.34 for such Clinical IRD Product, the Clinical Development Plan shall control. Each Clinical Development Plan will set forth in reasonable detail at all times (i) all activities that are necessary or useful to be undertaken to achieve and maintain Regulatory Approval in the relevant Major Market Country for such Clinical IRD Product (the "**Clinical Development Plan Activities**"), (ii) an estimated timeline for completing such activities and the respective Clinical Development Plan Term, (iii) the respective deliverables for such activities and (iv) the allocation of responsibilities between the Parties for performance of each such activity. The terms of, and Clinical Development Plan Activities set forth in, each Clinical Development Plan will at all times be designed to expedite Regulatory Approval, reimbursement and Commercialization of the Clinical IRD Product that is the subject of such Clinical Development Plan, and to be in compliance with all Applicable Laws and in accordance with professional and ethical standards customary in the biopharmaceutical industry. From time to time, and at least on an annual basis, the JDC will develop, review and approve amendments or updates to each Clinical Development Plan for a Clinical IRD Product, subject to the remaining terms and conditions of this Agreement. Each such amended or updated Clinical Development Plan will automatically replace the respective Clinical Development Plan previously in effect, and will be automatically incorporated into this Agreement by reference and form a part of this Agreement. Each Clinical Development Plan shall also be consistent with the terms of this Agreement.

(d) Clinical Development Budgets. Each Clinical Development Plan, when approved by the Parties in accordance with Section 6.1(c), will be subject to a rolling budget covering Clinical Development Costs associated with the anticipated Clinical Development Plan Activities for such Clinical IRD Product to be performed during the [***] (such [***] period, the "[***] **Clinical Development Budget Period**"), in each case broken down by Calendar Quarter and broken out on a line item basis to show Out-of-Pocket Costs and FTE Costs of FTEs directly engaged to perform each such Development activity including for each Development activity with respect to each Clinical Study conducted thereunder (each, as agreed to, approved, amended or updated from time to time in accordance with this Section 6.1(d), a "**Clinical Development Budget**"). [***] with respect to the CNGA3 Product, CNGB3 Product and RPGR Product, and [***] in the event that Janssen elects to make the [***] Product a Clinical IRD Product in accordance with Section 2.1(b), the JDC shall develop and submit to the JSC for its review and approval, a Clinical Development Budget for the respective Clinical IRD Product, and upon the

JSC's approval, each such Clinical Development Budget will be automatically incorporated into this Agreement by reference and form a part of this Agreement. Each Clinical Development Budget will be reviewed by the JDC and approved by the JSC (i) at least [***] (and [***] of the applicable [***] Clinical Development Budget Period) based on: (A) the Parties' good faith estimation of the anticipated Clinical Development Plan Activities to be conducted during the relevant [***] Clinical Development Budget Period; and (B) information prepared by the Parties in good faith for their own internal planning processes relating to anticipated Clinical Development Plan Activities for such Clinical IRD Product; or (ii) whenever the total Clinical Development Costs for any given Calendar Quarter are reasonably expected to be at least [***] percent ([***]%) higher than the Clinical Development Budget for such Calendar Quarter, whether as a result of any amendments to the Clinical Development Plan or increases in costs for the Clinical Development Plan Activities already planned for such Calendar Quarter (*provided*, *however*, that following the beginning of a Calendar Year, the JSC may not increase the Clinical Development Budget for such Calendar Year by more than [***] percent ([***]%) without the Parties' prior written approval). Each such amended or updated Clinical Development Budget will automatically replace the respective Clinical Development Budget previously in effect, and will be automatically incorporated into this Agreement by reference and form a part of this Agreement. With respect to any Calendar Quarter, in no event will a Party be responsible for any Clinical Development Costs that exceed the respective portion of the then-current Clinical Development Budget recommended and proposed by the JDC and approved by the JSC, except as otherwise provided in Section 10.3(b).

(e) Conduct of Clinical Development Activities. On a Clinical IRD Product-by-Clinical IRD Product basis, Janssen and MeiraGTx will each use Commercially Reasonable Efforts to perform their respective Clinical Development Plan Activities in accordance with each Clinical Development Plan (including the timelines set forth therein). In performing its respective Clinical Development Plan Activities, each Party: (i) will conduct such activities in good scientific manner and in compliance with all Applicable Laws in all material respects, including, where applicable, those relating to cGMP, cGLP, cGCP, good pharmacovigilance practices and requirements for protection of human subjects; (ii) will not employ or use any Debarred Person; and (iii) in the case of MeiraGTx, will not use any MeiraGTx [***] Technology during the course of performing any Clinical Development Plan Activities or incorporate any MeiraGTx [***] Technology into any Clinical IRD Product unless otherwise mutually agreed to by the Parties.

(f) Clinical Development Costs. Janssen will be responsible for one hundred percent (100%) of all Clinical Development Costs for each Clinical IRD Product; *provided*, *however*, that in no event will any Clinical Development Costs for any Calendar Quarter exceed the applicable Clinical Development Budget for such Calendar Quarter, except as otherwise provided in Section 10.3(b). Notwithstanding anything herein to the contrary, in no event [***].

(g) Clinical Development Records. Each Party will prepare and maintain, and cause its Affiliates and their respective employees and permitted subcontractors to prepare and maintain, records, accounts, notes, reports and data with respect to the Clinical Development Plan Activities hereunder ("**Clinical Development Records**"), in sufficient detail and in a good scientific manner appropriate for scientific, regulatory, and intellectual property protection purposes and in compliance with Applicable Law and such Party's standard practices (including cGLP with respect to activities that require cGLP compliance to be submitted in Regulatory Filings including INDs

and BLAs), which Clinical Development Records will: (i) be segregated from other development activities not performed under this Agreement; and (ii) be complete and accurate, and fully and accurately reflect all work done, data and developments made, and results achieved in the performance of the Clinical Development Plan Activities. Each Party shall retain, and cause its Affiliates and their respective and permitted subcontractors to retain, Clinical Development Records for at least [***] or such longer period as may be required by Applicable Law. Each Party shall comply with Janssen's data policies set forth on Exhibit 3.5 attached hereto with regard to Clinical Development Records.

(h) Audits. With respect to any facility or site at which a Party conducts any Clinical Development Plan Activities, and subject to the terms of any agreement between such Party and any applicable permitted subcontractor with respect to any facility or site of such subcontractor, the other Party shall have the right, at its own expense, upon reasonable written notice by such other Party, and during normal business hours, to inspect such site and facility of such Party or to accompany such Party to inspect any subcontractor site once per year and also for cause, to verify such Party's compliance with Applicable Law in carrying out its obligations under this Agreement, including those relating to cGMP, cGLP, cGCP, good pharmacovigilance practices and requirements for protection of human subjects. In the event that any such facility or site is found to be non-compliant with cGMP, cGLP, cGCP, good pharmacovigilance practices and requirements for protection of human subjects during such an audit, and such non-compliance relates to or impacts any Clinical Development Plan Activities hereunder, the audited Party shall submit to the auditing Party proposed CAPA within [***] after the auditing Party provides notice of such non-compliance. The auditing Party shall have the right to review and comment on such CAPA, which comments the audited Party shall consider in good faith. The audited Party shall use Commercially Reasonable Efforts to implement such CAPA [***] after review and comment by the auditing Party. Except as may otherwise be provided in a Supply Agreement, if any Regulatory Authority or any other Governmental Authority conducts or gives notice of its intent to conduct any audit or inspection at any offices or facilities (including Development facilities) of MeiraGTx or any applicable permitted subcontractor where such audit or inspection relates to any Clinical IRD Product, then MeiraGTx will [***] notify Janssen and, to the extent such audit or inspection relates to a Clinical IRD Product and to the extent practicable and not prohibited by Applicable Law, secure for Janssen the right to participate in any such audit or inspection.

(i) Reports. Each Party will: (i) provide to the JDC, on a [***], or [***] by the JDC, an update regarding any Clinical Development Plan Activities conducted by or on behalf of such Party hereunder; and (ii) promptly (and where safety is concerned, immediately within [***]) share with the other Party all material developments and information that it comes to possess relating to the Development of each Clinical IRD Product, including: (A) safety concerns (including Adverse Events and any planned or actual inspection of any MeiraGTx facility by a Regulatory Authority or audit of any subcontractor providing material services to MeiraGTx by MeiraGTx or any Regulatory Authority); (B) study reports and data generated from Clinical Studies and (C) any significant Clinical Development Costs incurred by MeiraGTx. Each Party shall also make its employees and consultants available for an in-person or telephonic meeting with the other Party at least once every Calendar Quarter to discuss such Party's progress with respect to the conduct of the Clinical Development Plan Activities hereunder.

(j) Improved Clinical IRD Products. The Parties will only Develop an Improved Clinical IRD Product in accordance with the terms herewith with the written consent of both Parties; *provided*, *however*, that [***], then [***].

6.2. Janssen Research IRD Products.

(a) Responsibility and Costs. Janssen will be solely responsible for conducting, at its sole cost and expense, Development of each Janssen Research IRD Product, except that Janssen will use Commercially Reasonable Efforts to Develop [***].

(b) Reports. Janssen will provide to the JDC, on a [***] basis for its review and discussion, a high-level report summarizing: (i) any material Development and regulatory activities for each Janssen Research IRD Product under Development by or on behalf of Janssen over the prior Calendar Quarter; and (ii) any planned future Development and regulatory activities for each Janssen Research IRD Product (if any), including those activities it anticipates to initiate or has initiated for the following Calendar Year.

(c) Additional Support for Janssen Research IRD Products. On a Janssen Research IRD Product-by-Janssen Research IRD Product basis, Janssen may request that MeiraGTx assist in subsequent Development of such Janssen Research IRD Product. At MeiraGTx's sole discretion, it may elect to provide such assistance, in which case it will so notify Janssen in writing and thereafter MeiraGTx's costs of Developing such Janssen Research IRD Product shall be [***].

(d) Improved Janssen Research IRD Products. The Parties will only Research or Develop an Improved Janssen Research IRD Product in accordance with the terms herewith with the written consent of both Parties, *provided*, *however*, that [***], then [***].

7. REGULATORY

7.1. Clinical IRD Products.

(a) Responsibility for Regulatory Matters.

(i) *Regulatory Lead Party*. Subject to the review and approval of the JDC and JSC, on a Clinical IRD Product-by-Clinical IRD Product and country-by-country basis, (A) MeiraGTx will be the Regulatory Lead Party prior to [***]; and (B) Janssen will be the Regulatory Lead Party on and after [***]. On and after [***] for a Clinical IRD Product, Janssen will have responsibility for all regulatory matters relating to such Clinical IRD Product, including with respect to Regulatory Filings and meetings with Regulatory Authorities; *provided* that MeiraGTx will reasonably cooperate with Janssen to provide any reasonable additional assistance or materials reasonably requested by Janssen.

(ii) *General*. Subject to the review and approval of the JDC and this Section 7.1, on a Clinical IRD Product-by-Clinical IRD Product and country-by-country basis, until [***], MeiraGTx as the Regulatory Lead Party for such Clinical IRD Product shall be responsible for (A) overseeing, monitoring and coordinating all regulatory actions, communications, and filings with, and submissions to, each Regulatory Authority with respect thereto, (B) interfacing,

corresponding and meeting with each Regulatory Authority with respect thereto and (C) seeking and maintaining all Regulatory Filings with respect to such Clinical IRD Product.

(iii) *Transition*. With respect to each Clinical IRD Product, within a reasonable period following the Effective Date as determined by the JDC, MeiraGTx shall take all actions required by the FDA (and, where relevant, other Regulatory Authorities) to designate Janssen as the express and authorized regulatory agent of record for MeiraGTx in the United States (and, as applicable, other countries) for the purposes of Development and regulatory activities for such Clinical IRD Product in the United States (and, as applicable, such other countries). On a Clinical IRD Product-by-Clinical IRD Product basis and country-by-country basis, upon a date prior to the applicable Sponsorship Transfer Date as reasonably determined by the JDC, MeiraGTx will [***] assign and transfer to Janssen or its designee all existing Regulatory Filings and other Regulatory Materials with respect to such Clinical IRD Product, including all Drug Master Files and all written correspondence, minutes of meetings and memoranda of oral communications with any Regulatory Authority, on electronic media (including rendered source documents when available), to the extent not already provided to Janssen previously; *provided*, *however*, that Regulatory Filings and other Regulatory Materials with respect to such Clinical IRD Product generated on or after the Effective Date shall be provided in accordance with Janssen's instructions (including Janssen's formatting and Electronic Common Technical Document (eCTD) requirements). Each Party will submit to the applicable Regulatory Authority all filings, letters and other documentation necessary to effect such assignment and transfer as soon as practicable, in an efficient and seamless manner for such Clinical IRD Product. Each Party shall provide to the other Party a copy of any and all notices received by such Party from such Regulatory Authority confirming such assignment and transfer.

(iv) *Right of Reference*. For each Clinical IRD Product, each Party hereby grants and will cause its Affiliates, licensees, and Sublicensees to grant to the other Party, a Right of Reference to, and a right to access, copy and use, all information and data (including all CMC information) included in or used in support of any Drug Master File maintained by or on behalf of such Party that relates to such Clinical IRD Product to the extent necessary for the other Party to Develop or Manufacture such Clinical IRD Product in accordance with the applicable Clinical Development Plan or CMC Development Plan. From and after the Sponsorship Transfer Date, MeiraGTx hereby grants and will cause its Affiliates, licensees, and Sublicensees to grant to Janssen, a Right of Reference to, and a right to copy, access, and otherwise use, all information and data (including all CMC information) included in or used in support of any Drug Master File maintained by or on behalf of MeiraGTx that relates to such Clinical IRD Product to the extent not transferred to Janssen pursuant to Section 7.1(a)(iii). Notwithstanding anything to the contrary in this Agreement, MeiraGTx will not, and will cause its Affiliates, licensees, and Sublicensees not to, withdraw or inactivate any Regulatory Filing that Janssen, its Affiliates or Sublicensees reference or otherwise use pursuant to this Section 7.1(a)(iv). In addition, Janssen hereby grants and will cause its Affiliates, licensees, and Sublicensees to grant to MeiraGTx a Right of Reference to, and a right to access, copy and use, all information and data (including CMC information) included in or used in support of any Drug Master File maintained by or on behalf of Janssen that relate to the RPGR Product to the extent necessary to Research, Develop, Manufacture or Commercialize the [***] Product, solely in the event that Janssen elects to not make the [***] Product a Clinical IRD Product in accordance with Section 2.1(b). [***]

(b) Regulatory Meetings. Until the Sponsorship Transfer Date for any Clinical IRD Product, MeiraGTx will: (i) provide Janssen with reasonable advance notice of all substantive meetings, conferences, and discussions (whether in person or by telephonic or video conference) with any Regulatory Authorities pertaining to such Clinical IRD Product; (ii) provide Janssen with draft briefing materials and meeting presentations for review reasonably in advance and consider in the preparation of such meetings, conferences or discussions any reasonable input timely provided by Janssen; and (iii) to the extent not prohibited by Applicable Law, grant Janssen the right to participate in any such meetings, conferences or discussions and facilitate such participation (such number of representatives to attend to be determined by Janssen). If Janssen elects not to participate in such meetings, conferences or discussions, MeiraGTx shall provide Janssen, upon Janssen's request, with written summaries of such meetings, conferences or discussions in English after the conclusion thereof.

(c) Regulatory Filings. Until the Sponsorship Transfer Date of any Clinical IRD Product, MeiraGTx will: (i) provide to Janssen for review and comment in accordance with such timeframes specified by the JDC (such timeframe to be no less than [***] in advance of any regulatory deadline, or if any Regulatory Authority deadline is sooner, as reasonably in advance as possible), copies in English of all Regulatory Filings and Regulatory Materials to be submitted (other than routine correspondence and administrative documents and documents related to Pricing Approval) by or on behalf of MeiraGTx prior to the relevant submission with respect to such Clinical IRD Product; (ii) incorporate reasonable comments thereto provided by Janssen; and (iii) [***] notify and provide Janssen any Regulatory Materials (other than routine correspondence and administrative documents and documents related to Pricing Approval) received from any Regulatory Authority with respect to such Clinical IRD Product.

(d) Regulatory Vouchers. If a Priority Review Voucher is issued to MeiraGTx for any Clinical IRD Product, then MeiraGTx will transfer such Priority Review Voucher to Janssen. If Janssen elects to transfer to a Third Party or otherwise monetize such Priority Review Voucher, the proceeds thereof will be allocated [***], with [***] percent ([***]%) to Janssen and [***] percent ([***]%) to MeiraGTx. If Janssen uses such Priority Review Voucher for one of its programs or for the programs of one of its Affiliates, then: (i) the value of such Priority Review Voucher will be determined by: (A) taking the values of the [***] most recent publicly disclosed sales or transfers of a Priority Review Voucher as of the time that the Party was granted such Priority Review Voucher; (B) removing the highest and lowest of such [***] publicly disclosed values; and (C) averaging the values of the remaining [***] publicly disclosed values; and (ii) the determined value of such Priority Review Voucher will be allocated [***], with [***] percent ([***]%) to Janssen and [***] percent ([***]%) to MeiraGTx.

(e) [***] Product. In the event that Janssen notifies MeiraGTx that Janssen does not elect to make the [***] Product a Clinical IRD Product or that Janssen fails to notify MeiraGTx that Janssen will make the [***] Product a Clinical IRD Product, in each case as set forth in Section 2.1(b), then MeiraGTx shall [***] notify Janssen of [***] that directly relates to or impacts any Clinical IRD Product or Janssen Research IRD Product. In addition, if Janssen becomes aware of [***], MeiraGTx shall [***] provide any [***].

7.2. Research IRD Products.

(a) Responsibility and Costs for Regulatory Matters. For each Janssen Research IRD Product, Janssen will be solely responsible, [***] for determining the regulatory plans and strategies and other regulatory matters relating to such Janssen Research IRD Product, including: (i) overseeing, monitoring and coordinating all regulatory actions, communications and filings with, and submissions to, each Regulatory Authority with respect to such Janssen Research IRD Product; and (ii) interfacing, corresponding, and meeting with each Regulatory Authority. Janssen shall invite MeiraGTx to attend, in an observational role or, to the extent permitted by Applicable Law, in a participatory role, material meetings and telephone conferences with regulators regarding such Janssen Research IRD Product. MeiraGTx will cooperate with and provide reasonable assistance to Janssen and its designees upon Janssen's request in connection with filings to any Regulatory Authority relating to such Janssen Research IRD Product, including by executing any required documents, providing access to personnel and providing Janssen with copies of all reasonably required documentation (such documents to be generated and provided to Janssen in accordance with Janssen's formatting requirements and Electronic Common Technical Document (eCTD) requirements, to the extent that such documents are generated on or after the Effective Date).

(b) Ownership of Regulatory Filings. For each Janssen Research IRD Product, Janssen or its designee will own all Regulatory Filings and related Regulatory Materials with respect to each such Janssen Research IRD Product, including any Drug Master Files maintained by or on behalf of MeiraGTx primarily related to and reasonably necessary for the Development of such Janssen Research IRD Product. At Janssen's request, MeiraGTx will [***] assign and transfer to Janssen, all Regulatory Filings and related Regulatory Materials with respect to such Janssen Research IRD Product that is in the possession or control of MeiraGTx and exclusively related to such Janssen Research IRD Product (such Regulatory Materials to be generated and provided to Janssen in rendered source document format when available and in accordance with Janssen's formatting requirements and Electronic Common Technical Document (eCTD) requirements, to the extent that such documents are generated on or after the Effective Date), and each Party will submit all filings, letters and other documentation necessary to effect such assignment and transfer to the applicable Regulatory Authority as soon as reasonably practicable, but no later than [***] after such request for such Janssen Research IRD Product. Each Party shall provide to the other Party a copy of any and all notices received by such Party from such Regulatory Authority confirming such assignment and transfer.

(c) Right of Reference. MeiraGTx hereby grants, and will cause its Affiliates, licensees, and Sublicensees to grant, to Janssen, at the request of Janssen or its Affiliates or Sublicensees, a Right of Reference to, and a right to copy, access, and otherwise use, all information and data (including all CMC information) included in or used in support of any Drug Master File maintained by or on behalf of MeiraGTx that relates to a Janssen Research IRD Product to the extent necessary to Research, Develop, Manufacture or Commercialize such Janssen Research IRD Product, in each case, not transferred to Janssen pursuant to Section 7.2(b). Notwithstanding anything to the contrary in this Agreement, MeiraGTx will not, and will cause its Affiliates, licensees, and Sublicensees not to, withdraw or inactivate any Regulatory Filing that Janssen, its Affiliates or Sublicensees reference or otherwise use pursuant to this Section 7.2(c). [***]

(d) Regulatory Vouchers. Janssen shall have the sole right to apply for any Priority Review Voucher for any Janssen Research IRD Product. [***].

7.3. Pharmacovigilance.

On a Product-by-Product basis, the Parties shall negotiate in good faith and mutually agree upon a written pharmacovigilance agreement for each Product no later than the earliest of (a) close of the Phase 3 Study for such Product, (b) the Sponsorship Transfer Date for such Product, or (c) engagement in Commercialization for such Product. Each such written pharmacovigilance agreement shall contain provisions to ensure that the safety data exchange and other pharmacovigilance responsibilities of both Parties with respect to regulatory reporting requirements are fulfilled in accordance with Applicable Laws with respect to such Product. Janssen will take the lead for safety and hold the global safety database on behalf of both Parties for all Clinical IRD Products no later than [***], Janssen will take the lead for safety and hold the global safety database on behalf of both Parties for all Janssen Research IRD Products as of such date determined by the JDC, and the respective pharmacovigilance agreement shall contain safety lead and global safety database provisions consistent with the foregoing.

7.4. Clinical Study Quality Agreement.

The Parties shall use good faith efforts to negotiate and execute [***] following the Effective Date an agreement to govern the conduct and quality of Clinical Studies, consistent with good pharmacovigilance practices and Janssen Quality Requirements.

8. MANUFACTURING

8.1. Product Manufacturing outside Supply Agreements.

(a) For Research. Subject to the terms and conditions of this Agreement and the oversight of the JSC and JMC, MeiraGTx will Manufacture (i) Clinical IRD Products required for Research under Section 6.1(b) in accordance with the applicable CMC Development Plans and (ii) Research IRD Products for Research in accordance with the applicable CMC Development Plans, in each case ((i) and (ii)) in accordance with Janssen Quality Requirements.

(b) For Development. Subject to the terms and conditions of this Agreement and the oversight of the JSC and JMC, MeiraGTx will Manufacture Clinical IRD Products for use in respective Clinical Studies in accordance with Janssen Quality Requirements.

(c) MeiraGTx Facility. All Products to be Manufactured by MeiraGTx as set forth in this Section 8.1 will be Manufactured at the MeiraGTx Facility. If MeiraGTx wishes to use a CMO to Manufacture any Product, MeiraGTx shall first offer such Manufacturing opportunity to Janssen, and Janssen shall have [***] to respond regarding whether it wishes to be engaged as a CMO of such Product for MeiraGTx. If Janssen responds to MeiraGTx within such [***] period that Janssen wishes to be engaged as a CMO, then the Parties will [***] negotiate in good faith and agree upon the terms of such Manufacturing. If Janssen responds to MeiraGTx within such [***] period that Janssen does not wish to be engaged as a CMO, or if Janssen fails to respond within such [***] period, then MeiraGTx may use a Third Party as its CMO, *provided* that

MeiraGTx obtains Janssen's prior written consent thereto (not to be unreasonably withheld, conditioned or delayed) prior to engaging such CMO for such services.

(d) Price for Supply of Products. The costs for Manufacturing Products in accordance with Section 8.1(a) shall be set forth in the Clinical Development Manufacturing Budget. The Manufacturing of Clinical IRD Products in accordance with Section 8.1(b) shall be [***]. Janssen shall [***].

8.2. Clinical Supply Agreement.

At such time as directed by the JSC and subject to the oversight of the JMC, the Parties will [***] negotiate in good faith a definitive clinical supply agreement for MeiraGTx to Manufacture and supply Janssen Research IRD Products for use in respective Clinical Studies ("**Clinical Supply Agreement**"), along with the associated quality agreement for such Janssen Research IRD Products ("**Clinical Quality Assurance Agreement**"). The Clinical Supply Agreement and the Clinical Quality Assurance Agreement will contain such terms provided in Exhibit 8.2 attached hereto. The Clinical Supply Agreement and Clinical Quality Assurance Agreement will each also be consistent with the terms and conditions of this Agreement and contain other terms and conditions customary for agreements of such nature. The Clinical Supply Agreement and the Clinical Quality Assurance Agreement will each be executed prior to the initiation of any Clinical Study applicable to the Products supplied thereunder.

8.3. Commercial Supply Agreement.

At such time as directed by the JSC and subject to the oversight of the JMC, the Parties will [***] negotiate in good faith a definitive commercial supply agreement for MeiraGTx to Manufacture and supply Clinical IRD Products for Commercial Supply ("**Commercial Supply Agreement**"), along with the associated quality agreement for such Clinical IRD Products ("**Commercial Quality Assurance Agreement**"). The Commercial Supply Agreement and Commercial Quality Assurance Agreement will contain such terms provided in Exhibit 8.3 attached hereto. The Commercial Supply Agreement and Commercial Quality Assurance Agreement will each also be consistent with the terms and conditions of this Agreement and contain other terms and conditions customary for agreements of such nature. The Commercial Supply Agreement and Commercial Quality Assurance Agreement will each be executed by the Parties at least [***] prior to the reasonably anticipated date of the First Commercial Sale of any Clinical IRD Product.

8.4. Collaboration on CMC Development.

(a) CMC Development Plan. Subject to the oversight of the JMC and JSC, during the CMC Development Term, Janssen and MeiraGTx will each collaborate with one another to Develop the Manufacturing process used for each clinical program undertaken hereunder in connection with any Clinical IRD Product or Research IRD Product, to identify certain technical Manufacturing process improvements and efficiencies and to share data packages necessary for regulatory filings in connection therewith ("**CMC Development Collaboration**"). The Parties will undertake the CMC Development Collaboration in accordance with this Agreement and one or more CMC Development Plans, which plan will set forth (i) all activities that are necessary or useful to be undertaken by each Party in connection with such CMC Development Collaboration

(the "**CMC Development Plan Activities**"), (ii) an estimated timeline for completing such activities, (iii) the respective deliverables for such activities and (iv) the allocation of responsibilities between the Parties for performance of each such activity. In addition, the CMC Development Plan Activities will comprise of: (x) those specific activities listed under "Clinical Development Manufacturing Activities" in Exhibit 8.4(a) attached hereto ("**Clinical Development Manufacturing Activities**") and (y) those specific activities listed under "Process Development Activities" in Exhibit 8.4(a) attached hereto ("**Process Development Activities**"). In the event that any CMC Development Plan Activity does not fall under one of the specific activities listed in Exhibit 8.4(a), the JMC shall discuss and determine whether such CMC Development Plan Activity should be (1) treated as a Clinical Development Manufacturing Activity hereunder and subject to the cost provisions set forth in Section 8.4(d) or (2) treated as a Process Development Activity hereunder and subject to the cost provisions set forth in Section 8.4(e). The JMC shall develop and submit an initial CMC Development Plan to the JSC for its review and approval,[***], and upon the JSC's approval, such initial CMC Development Plan will be automatically attached hereto and form a part of Exhibit 1.51. From time to time, and at least on an annual basis, the JMC shall propose, review and approve amendments or updates to each CMC Development Plan, subject to the remaining terms and conditions of this Agreement. Each such amended or updated CMC Development Plan will automatically replace the respective CMC Development Plan previously in effect, and will be automatically incorporated into this Agreement by reference and form a part of this Agreement. Each CMC Development Plan shall also be consistent with the terms of this Agreement. The Parties will use Commercially Reasonable Efforts to carry out their respective obligations under each CMC Development Plan.

(b) Clinical Development Manufacturing Budget. The CMC Development Collaboration will be subject to a rolling budget covering Clinical Development Manufacturing Costs associated with the anticipated Clinical Development Manufacturing Activities to be performed during the [***] (such [***] period, the "[***] **Clinical Development Manufacturing Budget Period**"), in each case broken down by Calendar Quarter and broken out on a line item basis to show Out-of-Pocket Costs and FTE Costs of FTEs directly engaged to perform each such Clinical Development Manufacturing Activity and further broken down by Party (the "**Clinical Development Manufacturing Budget**"). [***] after the Effective Date, the Clinical Development Manufacturing Budget will be developed by the JMC, and recommended and proposed to the JSC for review and approval, and upon approval by the JSC, each such Clinical Development Manufacturing Budget will be automatically incorporated into this Agreement by reference and form a part of this Agreement. The Clinical Development Manufacturing Budget will be reviewed by the JMC and approved by the JSC (i) at least [***] (and [***] for the first Calendar Year of the applicable [***] Clinical Development Manufacturing Budget Period) based on: (A) the Parties' good faith estimation of the anticipated Clinical Development Manufacturing Activities to be conducted during the relevant [***] Clinical Development Manufacturing Budget Period; and (B) information prepared by the Parties in good faith for their own internal planning processes relating to anticipated Clinical Development Manufacturing Activities; or (ii) whenever the total Clinical Development Manufacturing Costs for any given Calendar Quarter are reasonably expected to be at least [***] percent ([***]%) higher than the Clinical Development Manufacturing Budget for such Calendar Quarter, whether as a result of any amendments to the CMC Development Plan or increases in costs for the Clinical Development Manufacturing Activities already planned for such Calendar Quarter (*provided*, *however*, that following the beginning of a Calendar Year, the JSC may not increase the Clinical Development Manufacturing

Budget for such Calendar Year by more than [***] percent ([***]%) without the Parties' prior written approval). Each such amended or updated Clinical Development Manufacturing Budget will automatically replace the respective Clinical Development Manufacturing Budget previously in effect, and will be automatically incorporated into this Agreement by reference and form a part of this Agreement. With respect to any Calendar Quarter, in no event will a Party be responsible for any Clinical Development Manufacturing Costs that exceed the respective portion of the then-current Clinical Development Manufacturing Budget recommended and proposed by the JMC and approved by the JSC, except as otherwise provided in Section 10.4(b).

(c) Process Development Budget. The CMC Development Collaboration will be subject to a rolling budget covering Process Development Costs associated with the anticipated Process Development Activities to be performed during the [***] (such [***] period, the "[***] **Process Development Budget Period**"), in each case broken down by Calendar Quarter and broken out on a line item basis to show Out-of-Pocket Costs and FTE Costs of FTEs directly engaged to perform each such Process Development Activity and further broken down by Party (the "**Process Development Budget**"). [***] following the Effective Date, the Process Development Budget will be developed by the JMC, and recommended and proposed to the JSC for review and approval, and upon approval by the JSC, each such Process Development Budget will be automatically incorporated into this Agreement by reference and form a part of this Agreement. The Process Development Budget will be reviewed by the JMC and approved by the JSC (i) at least [***] (and [***] for the first Calendar Year of the applicable [***] Process Development Budget Period) based on: (A) the Parties' good faith estimation of the anticipated Process Development Activities to be conducted during the relevant [***] Process Development Budget Period; and (B) information prepared by the Parties in good faith for their own internal planning processes relating to anticipated Process Development Activities; or (ii) whenever the total Process Development Costs for any given Calendar Quarter are reasonably expected to be at least [***] percent ([***]%) higher than the Process Development Budget for such Calendar Quarter, whether as a result of any amendments to the CMC Development Plan or increases in costs for the Process Development Activities already planned for such Calendar Quarter (*provided*, *however*, that following the beginning of a Calendar Year, the JSC may not increase the Process Development Budget for such Calendar Year by more than [***] percent ([***]%) without the Parties' prior written approval). Each such amended or updated Process Development Budget will automatically replace the respective Process Development Budget previously in effect, and will be automatically incorporated into this Agreement by reference and form a part of this Agreement. With respect to any Calendar Quarter, in no event will a Party be responsible for any Process Development Costs that exceed the respective portion of the then-current Process Development Budget recommended and proposed by the JMC and approved by the JSC, except as otherwise provided in Section 10.5(b).

(d) Clinical Development Manufacturing Costs. Janssen will be responsible for [***] of the documented Clinical Development Manufacturing Costs; *provided*, *however*, that in no event will any Clinical Development Manufacturing Costs for any Calendar Quarter exceed the applicable Clinical Development Manufacturing Budget for such Calendar Quarter, except as otherwise provided in Section 10.4(b). All Clinical Development Manufacturing Costs shall be reconciled and paid in accordance with the procedure described in Section 10.4. Notwithstanding anything herein to the contrary, [***].

(e) Process Development Costs. Janssen and MeiraGTx will each be responsible for [***] of the documented Process Development Costs; *provided*, *however*, that in no event will a Party's portion of any Process Development Costs for any Calendar Quarter exceed its portion of the applicable Process Development Budget for such Calendar Quarter, except as otherwise provided in Section 10.5(b). All Process Development Costs shall be reconciled and paid in accordance with the procedure described in Section 10.5. Notwithstanding anything herein to the contrary, in no event will [***] of any Process Development Costs [***].

8.5. [***] Manufacturing Services.

During the [***] after the Effective Date, if MeiraGTx intends to grant any Third Party the right to reserve for such Third Party one (1) vector Manufacturing suite at the MeiraGTx Facility for Manufacturing of any product other than a Product, then MeiraGTx shall [***]. If Janssen notifies MeiraGTx in writing within [***] of receipt of MeiraGTx's notice that Janssen desires to [***], then the Parties [***] (the "**Manufacturing Services Agreement**"), which agreement will contain customary terms and conditions, including [***], *except* that, if Janssen [***] for Manufacturing. If Janssen either responds to MeiraGTx that [***].

9. COMMERCIALIZATION

Janssen will be solely responsible, at its sole cost and expense, for all aspects of Commercialization in the Territory of each Clinical IRD Product and each Janssen Research IRD Product, including planning and implementation, distribution, booking of sales, pricing and reimbursement, *except* that Janssen shall use Commercially Reasonable Efforts, at its expense, to Commercialize (a) for each Clinical IRD Target, [***] and (b) for each Research IRD Target for which Janssen has exercised an Option, [***], in each case ((a) and (b)) following the obtaining of Regulatory Approval for such Clinical IRD Product or Janssen Research IRD Product (as applicable) and [***] such Regulatory Approval has been obtained.

10. FINANCIAL PROVISIONS

10.1. Upfront Payment.

Provided that this Agreement is not terminated in accordance with Section 14.3, Janssen shall pay to MeiraGTx within [***], a one-time, non-refundable, non-creditable payment of One Hundred Million Dollars ($100,000,000) in partial consideration of the collaborations, options, licenses and rights granted by MeiraGTx to Janssen under this Agreement ("**Upfront Payment**"). For clarity, Janssen shall have no obligation to pay the Upfront Payment in the event that this Agreement is terminated in accordance with Section 14.3.

10.2. Research Costs.

(a) Invoices. For each Research Plan, commencing upon the first Calendar Quarter immediately following the date that such Research Plan is first approved by the JSC pursuant to Section 3.2 and continuing thereafter during the applicable Research Plan Term so long as MeiraGTx incurs Research Costs under this Agreement, MeiraGTx will submit to Janssen within [***] after the conclusion of each Calendar Quarter an invoice setting forth the Research Costs that MeiraGTx incurred in performing its Research Plan Activities under such Research Plan in

such Calendar Quarter. Each invoice shall include the nature and amount of Research services rendered or deliverables provided, and each invoice shall provide proper support for expenses included on the invoice. Reasonable support documents for Out-of-Pocket Costs include invoices or pro forma invoices from Third Party vendors. For FTE reimbursement, proper support includes an FTE time report break down by function.

(b) Research Costs. Within [***] after receipt of such invoice, Janssen shall make a reconciliation payment to MeiraGTx equal to [***] percent ([***]%) of all Research Costs incurred during such Calendar Quarter; *provided*, *however*, that if the total Research Costs for such Calendar Quarter exceeds the Research Budget for such Calendar Quarter, then MeiraGTx will provide written notice to Janssen as far in advance as reasonably possible of such cost overrun along with a reasonably detailed explanation of such cost overrun. Janssen shall pay for such excess only if: (i) the JSC approves of such excess; or (ii) such excess exceeds the Research Budget for such Calendar Quarter by [***] percent ([***]%) or less and is attributable to a change in Applicable Law; *provided*, *however*, that in no event will any total Research Costs for a Calendar Year exceed the Research Budget Cap for such Calendar Year, which excess may only be approved by the Parties in writing. Janssen shall not be obligated to pay for any Research Costs in excess of the Research Budget except as otherwise set forth in this Section 10.2(b) or with the Parties' written approval therefor. All such reconciliation payments shall be non-creditable and non-refundable. In addition, subject to the terms and conditions herein, if any Research Plan Activities will exceed the respective portion of the applicable Research Budget or extend beyond the applicable Research Plan Term, then (1) MeiraGTx shall provide written notice to Janssen, as far in advance as reasonably possible, that MeiraGTx intends to not perform such Research Plan Activities (with reasonable detail regarding such Research Plan Activities and Research Costs), (2) MeiraGTx shall afford the JSC or the Parties, as applicable, a reasonable opportunity to approve additional funding or reimburse such Research Plan Activities as permitted in this Section 10.2(b), and (3) MeiraGTx shall not be obligated to undertake such Research Plan Activities unless the JSC or the Parties, as applicable, agree to provide such additional funding as permitted in this Section 10.2(b).

10.3. Clinical Development Costs.

(a) Invoices. For each Clinical IRD Product (and any Janssen Research IRD Product subject to Section 6.2(c)), commencing upon the first Calendar Quarter immediately following the Effective Date and continuing thereafter so long as MeiraGTx incurs Clinical Development Costs under this Agreement, MeiraGTx will submit to Janssen within [***] after the conclusion of such Calendar Quarter an invoice setting forth the Clinical Development Costs MeiraGTx incurred in such Calendar Quarter. Each invoice shall include the nature and amount of Development services rendered or deliverables provided, and each invoice shall provide proper support for expenses included on the invoice. Reasonable support documents for Out-of-Pocket Costs include invoices or pro forma invoices from Third Party vendors. For FTE reimbursement, proper support includes an FTE time report break down by function.

(b) Clinical Development Costs. Within [***] after receipt of such invoice and report, Janssen will pay to MeiraGTx all the Clinical Development Costs set forth in each such invoice; *provided*, *however*, that if the total Clinical Development Costs for such Calendar Quarter exceeds the Clinical Development Budget for such Calendar Quarter, then MeiraGTx will provide written

notice to Janssen as far in advance as reasonably possible of such cost overrun along with a reasonably detailed explanation of such cost overrun. Janssen shall pay for such excess only if: (i) the JSC approves of such excess; or (ii) such excess exceeds the Clinical Development Budget for such Calendar Quarter by [***] percent ([***]%) or less and is attributable to (A) a change in Applicable Law, (B) a variation in actual patient enrollment from projected patient enrollment or (C) a change to a clinical trial protocol required or requested by any Regulatory Authority; *provided*, *however*, that in no event will total Clinical Development Costs in any given Calendar Year exceed the Clinical Development Budget for such Calendar Year by more than [***] percent ([***]%), which excess may only be approved by the Parties in writing. Janssen shall not be obligated to pay for any Clinical Development Costs in excess of the Clinical Development Budget except as otherwise set forth in this Section 10.3(b). All such payments of MeiraGTx's Clinical Development Costs shall be non-creditable and non-refundable. In addition, subject to the terms and conditions herein, if any Clinical Development Plan Activities will exceed the respective portion of the applicable Clinical Development Budget or extend beyond the applicable Clinical Development Plan Term, then (x) MeiraGTx shall provide written notice to Janssen, as far in advance as reasonably possible, that MeiraGTx intends to not perform such Clinical Development Plan Activities (with reasonable detail regarding such Clinical Development Plan Activities and Clinical Development Costs), (y) MeiraGTx shall afford the JSC or the Parties, as applicable, a reasonable opportunity to approve additional funding or reimburse such Clinical Development Plan Activities as permitted in this Section 10.3(b), and (z) MeiraGTx shall not be obligated to undertake such Clinical Development Plan Activities unless the JSC or the Parties, as applicable, agree to provide such additional funding as permitted in this Section 10.3(b).

10.4. Clinical Development Manufacturing Costs.

(a) Invoices. For each Clinical IRD Product (and any Janssen Research IRD Product subject to Section 6.2(c)), commencing upon the [***] following the Effective Date and continuing thereafter so long as MeiraGTx incurs Clinical Development Manufacturing Costs under this Agreement, MeiraGTx will submit to Janssen within [***] after the conclusion of such Calendar Quarter an invoice setting forth the Clinical Development Manufacturing Costs MeiraGTx incurred in such Calendar Quarter. Each invoice shall include the nature and amount of services rendered or deliverables provided in connection with Clinical Development Manufacturing Activities, and each invoice shall provide proper support for expenses included on the invoice. Reasonable support documents for Out-of-Pocket Costs include invoices or pro forma invoices from Third Party vendors. For FTE reimbursement, proper support includes an FTE time report break down by function.

(b) Clinical Development Manufacturing Costs. Within [***] after receipt of such invoice and report, Janssen will pay to MeiraGTx [***] the Clinical Development Manufacturing Costs set forth in each such invoice; *provided*, *however*, that if the total Clinical Development Manufacturing Costs for such Calendar Quarter exceeds the Clinical Development Manufacturing Budget for such Calendar Quarter, then MeiraGTx will provide written notice to Janssen as far in advance as reasonably possible of such cost overrun along with a reasonably detailed explanation of such cost overrun. Janssen shall pay for such excess only if: (i) the JSC approves of such excess; or (ii) such excess exceeds the Clinical Development Manufacturing Budget for such Calendar Quarter by [***] percent ([***]%) or less and is attributable to (A) a change in Applicable Law, (B) a variation in actual patient enrollment from projected patient enrollment or (C) a change to a

clinical trial protocol required or requested by any Regulatory Authority; *provided*, *however*, that in no event will total Clinical Development Manufacturing Costs in any given Calendar Year exceed the Clinical Development Manufacturing Budget for such Calendar Year by more than [***] percent ([***]%), which excess may only be approved by the Parties in writing. Janssen shall not be obligated to pay for any Clinical Development Manufacturing Costs in excess of the Clinical Development Manufacturing Budget except as otherwise set forth in this Section 10.4(b). All such payments of MeiraGTx's Clinical Development Manufacturing Costs shall be non-creditable and non-refundable. In addition, subject to the terms and conditions herein, if any Clinical Development Manufacturing Activities will exceed the respective portion of the applicable Clinical Development Manufacturing Budget or extend beyond the applicable CMC Development Term, then (x) MeiraGTx shall provide written notice to Janssen, as far in advance as reasonably possible, that MeiraGTx intends to not perform such Clinical Development Manufacturing Activities (with reasonable detail regarding such Clinical Development Manufacturing Activities and Clinical Development Manufacturing Costs), (y) MeiraGTx shall afford the JSC or the Parties, as applicable, a reasonable opportunity to approve additional funding or reimburse such Clinical Development Manufacturing Activities as permitted in this Section 10.4(b), and (z) MeiraGTx shall not be obligated to undertake such Clinical Development Manufacturing Activities unless the JSC or the Parties, as applicable, agree to provide such additional funding as permitted in this Section 10.4(b).

10.5. Process Development Costs.

(a) Invoices. Within [***] after the conclusion of each Calendar Quarter, MeiraGTx and Janssen each will submit to the other Party an invoice setting forth the Process Development Costs it incurred in such Calendar Quarter under the CMC Development Plan. Each invoice shall include the nature and amount of services rendered or deliverables provided in connection with Process Development Activities, and each invoice shall provide proper support for expenses included on the invoice. Reasonable support documents for Out-of-Pocket Costs include invoices or pro forma invoices from Third Party vendors. For FTE reimbursement, proper support includes an FTE time report break down by function.

(b) Process Development Costs. Within [***] after receipt of such invoices, the Parties will confer and agree in writing on whether a reconciliation payment is due from MeiraGTx to Janssen or Janssen to MeiraGTx, and if so, the amount of such reconciliation payment, so that [***] Process Development Costs; *provided*, *however*, that if the Process Development Costs incurred by a Party for such Calendar Quarter exceeds such Party's Process Development Budget for such Calendar Quarter, then such Party will provide written notice to the other Party as far in advance as reasonably possible of such cost overrun along with a reasonably detailed explanation of such cost overrun. The other Party shall pay for its portion of such excess only if: (i) the JSC approves of such excess; or (ii) such excess exceeds the Process Development Budget for such Calendar Quarter by [***] percent ([***]%) or less and is attributable to a change in Applicable Law; *provided*, *however*, that in no event will total Process Development Costs in any given Calendar Year exceed the Process Development Budget for such Calendar Year by more than [***] percent ([***]%), which excess may only be approved by the Parties in writing. The Party owed a reconciliation in connection with any Process Development Costs shall provide an invoice for the amount of such reconciliation payment to the paying Party, and such paying Party will make such reconciliation payment to the other Party, within [***] following receipt of the other

Party's invoice for such amount. Janssen shall not be obligated to pay for any portion of Process Development Costs in excess of the applicable portion of the applicable Process Development Budget except as otherwise set forth in this Section 10.5(b). All such payments shall be non-creditable and non-refundable. In addition, subject to the terms and conditions herein, if any Process Development Activities will exceed the respective portion of the applicable Process Development Budget or extend beyond the applicable CMC Development Term, then (x) MeiraGTx shall provide written notice to Janssen, as far in advance as reasonably possible, that MeiraGTx intends not to perform such Process Development Activities (with reasonable detail regarding such Process Development Activities and Process Development Costs), (y) MeiraGTx shall afford the JSC or the Parties, as applicable, a reasonable opportunity to approve additional funding or reimburse such Process Development Activities as permitted in this Section 10.5(b), and (z) MeiraGTx shall not be obligated to undertake such Process Development Activities unless the JSC or the Parties, as applicable, agree to provide such additional funding as permitted in this Section 10.5(b).

10.6. Development Milestone Payments.

In partial consideration of the cooperation of MeiraGTx in conducting the Clinical Development Plan Activities hereunder, and subject to Section 10.10(b), on a Product-by-Product basis, Janssen shall make milestone payments to MeiraGTx (each, a "**Development Milestone Payment**") upon the first (1st) achievement of each milestone event set forth in this Section 10.6 (each, a "**Development Milestone Event**") as set forth in the applicable tables below. Each Development Milestone Payment shall be non-refundable and non-creditable.

(a) Clinical IRD Products. Subject to the terms and conditions of this Section 10.6, on a Clinical IRD Product-by-Clinical IRD Product basis, Janssen shall make the Development Milestone Payments provided below to MeiraGTx upon the first (1st) achievement of the corresponding Development Milestone Event for the applicable Clinical IRD Product. Each Development Milestone Payment for a Clinical IRD Product will be payable only once with respect to the respective Clinical IRD Product, even if the corresponding Development Milestone Event occurs: (i) more than once; (ii) with respect to more than one (1) Gene Therapy Product that treats the same Clinical IRD Target Indication as such Clinical IRD Product, including if such Clinical IRD Product [***]; or (iii) for Development Milestone Events set forth in the tables below, with respect to more than one (1) Indication. The aggregate total of all Development Milestone Payments made with respect to each Clinical IRD Product shall not exceed the amount identified as the Development Milestone Cap for such Clinical IRD Product in the applicable table below.

(i) *RPGR Product*

Development Milestone Event	**Development Milestone Payment (USD)**
[***]	[***]
[***]	[***]

[***]	[***]
[***]	**[***]**

(ii) *CNGB3 Product*

Development Milestone Event	**Development Milestone Payment (USD)**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	**[***]**

(iii) *CNGA3 Product*

Development Milestone Event	**Development Milestone Payment (USD)**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	**[***]**

(iv) *[***] Product (subject to Section 2.1(b))*

Development Milestone Event	**Development Milestone Payment (USD)**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	**[***]**

(b) Research IRD Products. Subject to the terms and conditions of this Section 10.6, on a Janssen Research IRD Product-by-Janssen Research IRD Product basis, Janssen shall make the Development Milestone Payments provided below to MeiraGTx upon the first (1st) achievement of the corresponding Development Milestone Event for each Janssen Research IRD Product. Each Development Milestone Payment for a Janssen Research IRD Product will be payable only once, even if the corresponding Development Milestone Event occurs: (i) more than once; (ii) with respect to more than one (1) Gene Therapy Product that treats the same Research IRD Target Indication as such Janssen Research IRD Product, including if such Janssen Research IRD Product [***]; or (iii) for Development Milestone Events set forth in the table below, with respect to more than one Indication. The aggregate total of all Development Milestone Payments made with respect to each Janssen Research IRD Product shall not exceed the amount identified as the Development Milestone Cap for such Janssen Research IRD Product in the table below.

(i) *Each Janssen Research IRD Product*

Development Milestone Event	**Development Milestone Payment (USD)**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	**[***]**

(c) Payment Terms for Development Milestone Payments. Janssen shall provide MeiraGTx with written notice of the achievement of each Development Milestone Event for which payment is due hereunder within [***] after the Calendar Quarter in which such Development Milestone Event has been achieved. After receipt of such notice, MeiraGTx shall submit an invoice to Janssen for the corresponding Development Milestone Payment, and Janssen shall make the corresponding Development Milestone Payment to MeiraGTx within [***] after Janssen's receipt of such invoice.

10.7. Commercial Milestone Payments.

(a) Commercial Milestone Payments and Events for Clinical IRD Products. In partial consideration of the cooperation provided by MeiraGTx to Janssen under this Agreement, and subject to Section 10.10(b), on a Clinical IRD Product-by-Clinical IRD Product basis, Janssen shall make one (1)-time payments of each of the sales milestone payments indicated below (each, a "**Commercial Milestone Payment**") to MeiraGTx when the worldwide, aggregate (*i.e.*, cumulative since First Commercial Sale) Net Sales of a Clinical IRD Product first achieves the Dollar thresholds indicated in the table below (each, a "**Commercial Milestone Event**"). Each Commercial Milestone Payment will be payable only once with respect to a Clinical IRD Product,

notwithstanding the number of times a Dollar threshold indicated in the table below is reached. Each Commercial Milestone Payment shall be non-refundable and non-creditable.

Commercial Milestone Event	Commercial Milestone Payment (USD)
[***]	[***]
[***]	[***]
[***]	[***]

(b) Payment Terms for Commercial Milestone Payments. Janssen shall provide MeiraGTx with written notice of the achievement of each Commercial Milestone Event within [***] after the Calendar Quarter in which such Commercial Milestone Event is achieved. Janssen shall make the corresponding Commercial Milestone Payment to MeiraGTx within [***] following the end of the Calendar Quarter in which such Commercial Milestone Event was achieved.

(c) Commercial Milestone Terms for Janssen Research IRD Products. For the avoidance of doubt, Janssen does not owe MeiraGTx any commercial milestone payments for Research IRD Products.

10.8. Royalties.

In partial consideration of the collaborations, options, licenses and rights granted by MeiraGTx to Janssen under this Agreement, Janssen shall make royalty payments to MeiraGTx, on a Product-by-Product basis, based on Annual Net Sales of the applicable Product within the Field in the Territory, as reported by Janssen or its Affiliates or Sublicensees for each Calendar Quarter, at the applicable rates set forth below during the applicable Royalty Term and subject to Section 10.9, Section 10.10, and where applicable, Section 15.2(a)(ii) (such payments, "**Royalties**").

(a) Clinical IRD Products. Janssen shall pay to MeiraGTx Royalties, on a Clinical IRD Product-by-Clinical IRD Product basis, on Annual Net Sales for each Clinical IRD Product within the Field in the Territory equal to twenty percent (20%) of Annual Net Sales of such Clinical IRD Product in the Territory.

(b) Janssen Research IRD Products. Janssen shall pay to MeiraGTx Royalties, on a Janssen Research IRD Product-by-Janssen Research IRD Product basis, on Annual Net Sales for each such Janssen Research IRD Product within the Field in the Territory equal to [***] percent ([***]%) of Annual Net Sales of such Janssen Research IRD Product in the Territory.

10.9. Additional Royalty Provisions.

(a) Royalty Term. Subject to this Section 10.9, on a Product-by-Product and country-by-country basis, the Royalties due under Section 10.8 shall be payable on Annual Net Sales commencing from the First Commercial Sale of such Product in a country until the later of: (i) expiration of the last Valid Claim of: [***] in each case ((A)-(D)) in such country; (ii) ten (10) years from the date of the First Commercial Sale of such Product in such country; or (iii)

expiration of the last Data Exclusivity Right applicable to such Product in such country (the "**Royalty Term**").

(b) Royalty Step-Down. For each Product and for any period during the Royalty Term in which the sale of such Product in a given country is neither: (i) Covered by any Valid Claim described in Section 10.9(a)(i); nor (ii) protected by any Data Exclusivity Right applicable to such Product in such country, then the Royalty rate applicable to Net Sales of such Product in such country during such period shall be equal to [***] percent ([***]%) of the applicable Royalty rate set forth in Section 10.8 on Net Sales (*i.e.*, [***] percent ([***]%) for Clinical IRD Products and [***] percent ([***]%) for Janssen Research IRD Products).

(c) Loss of Market Exclusivity of a Product Due to a Biosimilar Product. On a country-by-country basis, if a Loss of Market Exclusivity Due to a Biosimilar Product occurs with respect to a Product in a country, the Royalty rate applicable to Net Sales of such Product in such country shall be equal to [***] percent ([***]%) of the applicable Royalty rate set forth in Section 10.8 on Net Sales from the date such Loss of Market Exclusivity Due to a Biosimilar Product occurs until the end of the Royalty Term (*i.e.*, [***] percent ([***]%) for Clinical IRD Products and [***] percent ([***]%) for Janssen Research IRD Products).

(d) Loss of Market Exclusivity of a Clinical IRD Product Due to a Competing Product. On a country-by-country basis, if a Loss of Market Exclusivity Due to a Competing Product occurs with respect to a Clinical IRD Product in a country, the Royalty rate applicable to Net Sales of such Clinical IRD Product in such country shall be equal to [***] percent ([***]%) of the applicable Royalty rate set forth in Section 10.8 on Net Sales from [***] until [***] (*i.e.*, [***]% for Clinical IRD Products).

(e) Single Royalty. Only a single Royalty shall be due under this Agreement: (i) with respect to the sale of the same unit of Product; and (ii) on the sale of a Product even if the Manufacture or Commercialization of such Product Covered more than one (1) Valid Claim described in Section 10.9(a)(i).

(f) Royalty Minimum. Notwithstanding anything to the contrary in this Agreement, in no event will the applicable Royalty otherwise due to MeiraGTx in a Calendar Quarter be reduced by more than [***] due to the deductions contemplated in this Agreement (*i.e.*, not below [***] for Clinical IRD Products and [***] percent ([***]%) for Janssen Research IRD Products); *provided*, *however*, that [***].

(g) Compulsory Licenses and Other Step-In Rights. If Janssen, its Affiliates or any of its Sublicensees are required to grant any licenses or other rights to a Third Party (including any Governmental Authority) to Develop, Manufacture, or Commercialize a Product because of the actions of any Governmental Authority, then the Royalty rates set forth in Section 10.8 shall not apply, and instead, [***] for each such Product reflecting the applicable market for such Product in such country, subject to [***].

(h) Combination Products. In the event that a Party reasonably determines that any Product will be incorporated into any other product sold by Janssen or its Affiliates or Sublicensees and such Product will not be priced separately from such other product sold by Janssen or its

Affiliates, such Party shall [***] provide written notice thereof to the other Party. Upon receipt of such notice, the Parties shall [***] enter into good faith discussions to determine the reasonable Net Sales value with respect to such Product, which shall be [***].

10.10. Third Party Obligations.

(a) Existing Third Party Obligations. [***] shall remain responsible for the payment of royalty, milestone, and other payment obligations, if any, due to Third Parties in connection with any Third Party License that exists as of the Effective Date and under which MeiraGTx Technology or MeiraGTx Research Technology has been licensed to MeiraGTx and is sublicensed to Janssen under Section 4.1 for Clinical IRD Products and Janssen Research IRD Products (the "**Existing Third Party Obligations**"). All such payments in respect of the Existing Third Party Obligations shall be made [***] in accordance with the terms of its agreements with the applicable Third Party License.

(b) Future Third Party Obligations. If either Party reasonably determines that licensing Future Third Party Obligations would be necessary or useful to Develop, Manufacture, or Commercialize any Product in the Field in the Territory under this Agreement, then MeiraGTx shall have the first right to negotiate and acquire (subject to Janssen's approval; and, for clarity, if MeiraGTx declines to exercise its first right to negotiate and acquire such Future Third Party Obligations or otherwise fails to do so within [***] of any request therefor by Janssen, Janssen shall have the right to do so) a Third Party License to such Future Third Party Obligations. If either Party negotiates and acquires a Third Party License to such Future Third Party Obligations, then: (i) [***]; (ii) [***]; *provided*, *however*, that Janssen shall have the right to [***] for such Product [***] percent ([***]%) of the [***] paid to such Third Party under such Third Party License, and to the extent that Janssen cannot [***] paid to such Third Party exceed any [***] owed to MeiraGTx for such Product at the time of payment to such Third Party, then Janssen may [***] payable for such Product; and (iii) Janssen thereafter shall have the right to [***] up to [***] percent ([***]%) of the [***] subject to the following conditions: (A) Janssen may [***] and [***]; (B) such [***]; (C) if any such Third Party License either: (1) includes additional Intellectual Property Rights other than Intellectual Property Rights that are Controlled by a Third Party and that are necessary or useful to Develop, Manufacture, or Commercialize any Product in the Field in the Territory; or (2) Covers products other than such Product, then any such [***] would be equitably allocated by Janssen in good faith among all products and programs to which such Third Party License applies; and (D) to the extent that Janssen cannot [***], then Janssen may [***].

(c) Breaches, Amendments and Terminations. Neither MeiraGTx nor its Affiliates will breach or default under any Existing Third Party Obligation or any Third Party License for a Future Third Party Obligation. Neither MeiraGTx nor its Affiliates will terminate any such Third Party License in a manner that would terminate any rights that are licensed to Janssen hereunder or otherwise diminish the scope or exclusivity of such Intellectual Property Rights licensed to Janssen hereunder. In the event that MeiraGTx or one of its Affiliates receives notice of a potential dispute in connection with or an alleged breach by MeiraGTx or one of its Affiliates under any such Third Party License, where termination of such Third Party License or any diminishment of the scope or exclusivity of such Intellectual Property Rights licensed to Janssen hereunder is or could be sought by the counterparty, then MeiraGTx will [***], but in no event less than [***] thereafter, provide

written notice thereof to Janssen and grant Janssen the right (but not the obligation) to cure such alleged breach, to the extent not prohibited by such Third Party License. In the event that MeiraGTx receives a notice of termination of such a Third Party License by a counterparty, MeiraGTx will [***], but in any event within [***] following receipt of such notice, notify Janssen of such termination in writing. In the event that MeiraGTx or one of its Affiliates intends to materially amend such a Third Party License, then MeiraGTx will [***], but in no event less than [***] before, provide written notice thereof to Janssen. Janssen will have the right (but not the obligation), acting reasonably, to reject any amendment that would increase Janssen's obligations under this Agreement (including any financial obligations) or diminish the licenses or rights granted to Janssen under this Agreement and in the event of any such rejection, neither MeiraGTx nor its Affiliates will enter into any such amendment unless and until Janssen approves such amendment.

10.11. Reports and Royalty Payments.

For as long as Royalties are due under Section 10.8, Janssen shall furnish to MeiraGTx a draft Sales & Royalty Report, within [***] after the end of each Calendar Quarter, showing the estimated amount of Annual Net Sales of Products and Royalties due for such Calendar Quarter. Janssen shall furnish to MeiraGTx a final Sales & Royalty Report and pay such Royalties contained in such final Sales & Royalty Report within [***] following the end of the applicable Calendar Quarter.

10.12. Disclaimer.

MeiraGTx expressly acknowledges and agrees that, despite the efforts and obligations required by this Agreement which may result in the achievement of a Development Milestone Event, Commercial Milestone Event or Net Sales of Product, such event or Net Sales of Product may not be achieved and MeiraGTx, in that case, would not be entitled to receive such further payments hereunder (the Development Milestone Payment, Commercial Milestone Payment or Royalties, as the case may be), other than (i) the Upfront Payment, (ii) Research Costs to be paid as set forth in Section 10.2, (iii) Clinical Development Costs to be paid as set forth in Section 10.3, (iv) Clinical Development Manufacturing Costs to be paid as set forth in Section 10.4, (v) Process Development Costs to be paid as set forth in Section 10.5, (vi) any Option Fee (if and when the respective Option is exercised as set forth in Section 3.9(b)), (vii) such portion of the proceeds of Priority Review Vouchers to be paid to MeiraGTx as set forth in Section 7.1(d) and (viii) such other costs to be paid by Janssen for Manufacturing of Products as set forth in Section 8.1(d). Any Development Milestone Payment, Commercial Milestone Payment or Royalties are contingent upon satisfaction of the conditions provided for herein which may not be satisfied. Except as otherwise expressly provided herein (but without waiving the implied covenant of good faith and fair dealing), Janssen will be under no obligation to use its Commercially Reasonable Efforts, best efforts or any other standard of diligence with respect to satisfying the conditions to any payment hereunder.

10.13. Payment Terms.

(a) Manner of Payment. All payments to be made by a Party hereunder will be made in Dollars by wire transfer to such bank account as the other Party may timely designate to the other in writing. Any payment which falls due on a date which is not a Business Day in the location

from which the payment will be made may be made on the next succeeding Business Day in such location. For the avoidance of doubt, no payment obligations shall be incurred by either Party under or in connection with this Agreement unless and until the Effective Date.

(b) Currency Exchange. With respect to Annual Net Sales invoiced in Dollars, the Annual Net Sales and the amounts due to MeiraGTx under this Agreement shall be expressed in Dollars. When the conversion of payments from any foreign currency is required to be undertaken by Janssen, the Dollar equivalent shall be calculated using Janssen's then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into Dollars.

(c) Invoices. All invoices hereunder to be paid by a Party must reference a valid purchase order ("**PO**") number which the other Party shall provide to such Party within [***] after the Effective Date and invoices shall include the nature and amount of services rendered or deliverables provided and such other terms and conditions specified herein. Invoices to Janssen must be sent to the Johnson & Johnson Accounts Payable Department via [***] if MeiraGTx establishes a web invoice account or sent by postal mail to the address indicated on the PO. Invoices to MeiraGTx must be sent to [***], with a cc to [***]. The other Party reserves the right to return to such Party unprocessed and unpaid those invoices that do not reference the applicable PO number. For clarity, no invoices shall be required with respect to any Royalties due under Section 10.8.

(d) Withholding Taxes. Either Party (the "**Withholding Party**") may withhold from payments due to the other Party (the "**Non-Withholding Party**") amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments, which shall be remitted in accordance with Applicable Law. Any such tax required to be withheld will be an expense of and borne by the Non-Withholding Party. If any such tax is assessed against and paid by the Withholding Party, then the Non-Withholding Party will indemnify and hold harmless the Withholding Party from and against such tax, including interest. The Withholding Party shall provide to the Non-Withholding Party all relevant documentation and correspondence, and shall also provide to the Non-Withholding Party any other cooperation or assistance on a reasonable basis as may be necessary to enable the Non-Withholding Party to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. The Withholding Party shall give proper evidence from time to time as to the payment of any such tax. The Parties shall cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include the Withholding Party making payments from a single source, where possible.

(e) Tax Forms. On the date of execution of this Agreement, MeiraGTx will deliver to Janssen an accurate and complete Internal Revenue Service Form W-8BEN-E certifying that MeiraGTx is entitled to the applicable benefits under the Income Tax Treaty between the United Kingdom and the United States.

(f) Late Payments. Any undisputed payments or portions thereof due hereunder which are not paid when due will bear interest at the rate per annum equal to the lesser of: [***] or (ii) the

highest rate permitted by Applicable Law, calculated on the number of days such payment is paid after the date such payment is due, and compounded monthly (the "**Interest Rate**").

(g) Janssen Entities. [***] acting as paying agent for Janssen, may make certain payments due under this Agreement, and Janssen shall reimburse [***] for all such payments.

10.14. Records and Audits.

(a) Records. Each Party shall keep complete, true, and accurate books and records in accordance with its Accounting Standards in relation to this Agreement, including with respect to Research Costs, Clinical Development Costs, Clinical Development Manufacturing Costs, Process Development Costs, Manufacturing Costs, Net Sales, and such other information contained in Sales & Royalty Reports. Each Party shall keep such books and records for at least [***] following the Calendar Year to which they pertain.

(b) Audits. Each Party (the "**Auditing Party**") may, upon written request, cause an internationally-recognized independent accounting firm (the "**Auditor**"), which is reasonably acceptable to the other Party (the "**Audited Party**"), to inspect the relevant records of such Audited Party and its Affiliates to verify the payments made and amounts reported by the Audited Party and the related reports, statements, and books of accounts, as applicable. Such audit shall be limited to a period of time no more than [***] immediately preceding the year in which the audit is requested, and an audit of the records relating to a particular Calendar Year may be conducted once and not more than once. Before beginning its audit, the Auditor shall execute a written undertaking acceptable to the Audited Party by which the Auditor shall agree to keep confidential all information made available to the Auditor during the audit. Each Party and its Affiliates shall make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from the Auditing Party. The records shall be reviewed to verify the accuracy of the Audited Party's Sales & Royalty Report and other payment obligations and compliance with the financial terms of this Agreement. Such inspection right shall not be exercised more than [***], unless the audit reveals a non-compliance by the Audited Party with the terms of this Agreement in which case the audit may be repeated within [***] to confirm compliance. The Auditing Party agrees to hold in confidence all information received and learned in the course of any audit in accordance with Article 12. The Auditor shall provide a draft audit report and basis for any determination to the Audited Party prior to distributing the final report so that the Audited Party can provide comment on the draft report. The final audit report will be provided to the Audited Party at the time such report is provided to the Auditing Party.

(c) Overpayments and Underpayments. If the final result of the inspection reveals an underpayment or an overpayment by either Party, the underpaid or overpaid amount shall be settled within [***] of the Audited Party's receipt of the final report. The Auditing Party shall pay for any audit, as well as its expenses associated with enforcing its rights with respect to any payments under this Agreement, except that, if an underpayment of amounts due by the Audited Party of more than [***] percent ([***]%) of the total payments due under this Agreement for the applicable year is discovered, reasonable and necessary fees and expenses charged by the Auditor shall be paid by the Audited Party, subject to reasonable substantiation thereof.

11. INTELLECTUAL PROPERTY RIGHTS

11.1. Ownership under the Clinical IRD Programs and Research IRD Programs.

(a) Ownership. As between the Parties, and subject to the licenses granted under this Agreement, each Party retains all rights, title, and interests in and to all Intellectual Property Rights that such Party owns or Controls as of the Effective Date or that it develops or otherwise acquires after the Effective Date outside the performance of the activities under this Agreement.

(b) Sole Inventions. Each Party shall solely own any and all Inventions and Know-How developed, conceived, generated or reduced to practice solely by it, its Affiliates or its or their employees, agents or independent contractors in the course of performing activities under any Research Plan or Clinical Development Plan hereunder during the Term ("**Sole Inventions**"). Inventorship shall be determined in accordance with U.S. patent laws.

(c) Joint Inventions. Except as set forth in Section 11.2, the Parties shall jointly own any and all Inventions and Know-How developed, conceived, generated or reduced to practice jointly by a Party, its Affiliates or its or their employees, agents or independent contractors together with another Party, its Affiliates or its or their employees, agents or independent contractors in the course of performing activities under this Agreement during the Term ("**Joint Inventions**"). All Patents Covering Joint Inventions shall be referred to herein as "**Joint Patents**". Except to the extent a Party is expressly limited by the terms of this Agreement, including via exclusive license to the other Party, each Party shall be entitled to practice, license (through multiple tiers), assign (their respective interest only) and otherwise exploit the Joint Inventions and Joint Patents in all countries and jurisdictions without the duty of accounting or seeking consent from the other Party. Upon the reasonable request of either Party, the other Party shall execute documents that evidence or confirm the requesting Party's right to engage in such activities. Inventorship shall be determined in accordance with U.S. patent laws.

11.2. Ownership under the CMC Development Collaboration.

The Parties shall jointly own any and all CMC Development Inventions, CMC Development Know-How and CMC Development Patents regardless of inventorship. Except to the extent a Party is expressly limited by the terms of this Agreement, including by exclusive license to the other Party, each Party shall be entitled to practice, license (through multiple tiers), assign (their respective interest only) and otherwise exploit the CMC Development Inventions, CMC Development Know-How and CMC Development Patents in all countries and jurisdictions without the duty of accounting or seeking consent from the other Party. Upon the reasonable request of either Party, the other Party shall execute documents that evidence or confirm the requesting Party's right to engage in such activities.

11.3. Duties to the Other Party.

(a) Assignment. Each Party hereby assigns to the other Party, one-half of its interest in and to any CMC Development Inventions, CMC Development Know-How and CMC Development Patents, including all rights of action and claims for damages and benefits arising due to past and present infringement of said rights, such that each Party owns an undivided joint interest in and to such CMC Development Inventions, CMC Development Know-How and CMC

Development Patents. Each Party shall and shall cause its Affiliates and contractors to, execute and take such further actions reasonably necessary to effectuate such joint ownership in and to such CMC Development Inventions, CMC Development Know-How and CMC Development Patents.

(b) Disclosure. Each Party shall [***] disclose to the JSC all Inventions made by or on behalf of such Party and its Affiliates and subcontractors in the course of performing activities under this Agreement during the Term, including all invention disclosures or other similar documents submitted to such Party by it, its Affiliates or its or their employees, agents or contractors relating to such Invention, and shall also respond to reasonable requests from the other Party for additional information relating to any such Inventions.

(c) Personnel Obligations. Each Party shall cause each employee, agent or contractor of such Party to, and shall cause each of its respective Affiliates or Sublicensees performing work under this Agreement to, prior to commencing such work, be bound by invention assignment obligations, including: (i) [***] reporting any Intellectual Property Right arising from such work; (ii) presently assigning to the applicable Party all of his, her or its rights, title and interests in and to any Intellectual Property Right arising from such work (excluding any agreements with academic universities or other governmental entities, for which a non-exclusive license, or an option for an exclusive license may be obtained); (iii) reasonably cooperating in the preparation, filing, prosecution, maintenance, defense, and enforcement of any Patent; and (iv) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement.

(d) Common Ownership under Joint Research Agreements. Notwithstanding anything to the contrary in this Agreement, neither Party will have the right to invoke Common Ownership under a Joint Research Agreement pursuant to 35 U.S.C. § 102(c) (AIA) when exercising its rights under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed. If a Party is permitted to invoke the 35 U.S.C. § 102(c) (AIA) as required by the preceding sentence, the Parties will reasonably cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. § 102(c) (AIA).

(e) Updated Exhibit. On each anniversary of the Effective Date during the Term, MeiraGTx shall provide to the JSC an updated copy of Exhibit 1.168, setting forth a true, complete and accurate list of all Patents Controlled by MeiraGTx or any of its Affiliates as of such date, which claim or otherwise Cover any Clinical IRD Products, Clinical IRD Targets or MeiraGTx Know-How in the Field.

11.4. Patent Prosecution and Maintenance.

(a) Sole Patents. Each Party shall have the sole and exclusive right to prosecute and maintain all Patents Covering each Party's Sole Inventions [***], except to the extent the prosecution of such Patents is otherwise covered by another provision of this Section 11.4.

(b) Clinical IRD Product Patents. Subject to the terms of this Section 11.4, the Parties shall jointly prosecute and maintain (i) the MeiraGTx Patents in MeiraGTx's name and (ii) the Joint Patents Covering Clinical IRD Products in both Parties' names (collectively, (i) and (ii), "**Clinical IRD Patents**"). The Parties shall [***]. The Parties shall [***]. Each Party shall be reasonably informed of the status of the Clinical IRD Patents, shall be provided with all material correspondences received from any patent authorities in connection therewith and shall be entitled to consultation and reasonable input with respect to proposed filings and correspondence. In addition, the Parties shall [***] to consult with and consider the reasonable input of [***] with respect to those MeiraGTx Patents licensed from [***] to MeiraGTx. In the event of a dispute, the Parties shall follow the process of Section 5.8.

(c) CMC Development Patents. Subject to the terms of this Section 11.4, as between the Parties, Janssen shall have the first right, but not the obligation, to prosecute and maintain all CMC Development Patents in both Parties' names, subject to consultation and reasonable input from MeiraGTx. The Parties shall [***] and will be joint owners of the CMC Development Patents. The Parties shall [***]. Janssen shall keep MeiraGTx reasonably informed of the status of the CMC Development Patents, shall provide MeiraGTx with all material correspondences received from any patent authorities in connection therewith and shall in good faith consult with and consider reasonable input from MeiraGTx with respect to proposed filings and correspondence. If Janssen decides not to prosecute or maintain any CMC Development Patent, Janssen shall notify MeiraGTx thereof in writing, and MeiraGTx shall thereupon have the right, but not the obligation, to assume the prosecution and maintenance thereof in both Parties' names, [***], and [***]. In the event of a dispute, the Parties shall follow the process of Section 5.8.

(d) Research IRD Product Patents.

(i) *Prior to the Receipt of the Applicable Option Exercise Notice*. Prior to MeiraGTx's receipt of an applicable Option Exercise Notice with respect to a Research IRD Product, subject to the terms of this Section 11.4, as between the Parties, MeiraGTx shall have the first right, but not the obligation, to prosecute and maintain (A) the MeiraGTx Research Patents in MeiraGTx's name and (B) Joint Patents Covering such Research IRD Product in both Parties' names (collectively, (A) and (B), "**Research IRD Patents**"), [***], subject to consultation and reasonable input from Janssen. MeiraGTx shall keep Janssen reasonably informed of the status of the Research IRD Patents and shall provide Janssen with all material correspondences received from any patent authorities in connection therewith. If MeiraGTx decides not to prosecute or maintain any Research IRD Patent, MeiraGTx shall notify Janssen thereof in writing, and Janssen shall thereupon have the right, but not the obligation, to assume the prosecution and maintenance of such Research IRD Patent [***] (with such MeiraGTx Patents in MeiraGTx's name and such Joint Patents in both Parties' names).

(ii) *After Exercise of the Applicable Option*. On or after Janssen's exercise of an Option with respect to a Research IRD Product, subject to the terms of this Section 11.4, as between the Parties, Janssen shall have the first right, but not the obligation, to prosecute and maintain (A) the MeiraGTx Research Patents Covering such Janssen Research IRD Product in MeiraGTx's name and (B) the Joint Patents Covering such Janssen Research IRD Product in both Parties' names (collectively, (A) and (B), "**Janssen Research IRD Patents**"), subject to consultation and reasonable input from MeiraGTx. [***] shall [***] the cost of and expenses

thereof. The Parties shall [***] to facilitate the prosecution and maintenance of such Janssen Research IRD Patents. Janssen shall keep MeiraGTx reasonably informed of the status of the Janssen Research IRD Patents, shall provide MeiraGTx with all material correspondences received from any patent authorities in connection therewith and shall in good faith consult with and consider reasonable input from MeiraGTx with respect to proposed filings and correspondence. If Janssen decides not to prosecute or maintain any Janssen Research IRD Patent, Janssen shall notify MeiraGTx thereof in writing, and MeiraGTx shall thereupon have the right, but not the obligation, to assume the prosecution and maintenance thereof (in MeiraGTx's name with respect to any MeiraGTx Research Patent and both Parties' names with respect to any Joint Patent Covering Janssen Research IRD Products)] [***], and [***] shall [***] the costs and expenses thereof. In addition, each Party shall [***] to consult with and consider the reasonable input of [***] with respect to those MeiraGTx Research Patents licensed from [***] to MeiraGTx and Covering such Janssen Research IRD Product. In the event of a dispute, the Parties shall follow the process of Section 5.8.

(e) Cooperation. Upon a Party's request, the other Party shall provide the prosecuting and maintaining Party with all reasonable assistance and cooperation in connection with its prosecution and maintenance of the applicable Patents, including by providing access to relevant persons and executing all documentation reasonably requested by the prosecuting and maintaining Party.

(f) Patent Term Extension. The Parties shall cooperate with one another in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to the Clinical IRD Patents, CMC Development Patents, Research IRD Patents and Janssen Research IRD Patents. [***] shall have [***] to obtain patent term extensions or supplemental protection certificates or their equivalents with respect to such Patents that Cover Products and shall report to [***] on the status thereof.

(g) Recordation. To the extent permitted by Applicable Law, if MeiraGTx is responsible for prosecuting any Clinical IRD Patent, CMC Development Patent, Research IRD Patent or Janssen Research IRD Patent, as applicable, under this Section 11.4, then (i) [***] following the Effective Date, MeiraGTx shall record with each Governmental Authority (where such right is available with such Governmental Authority and such Governmental Authority permits the filing of a form of short notice of license) the licenses granted in Section 4.1 against each such Clinical IRD Patent, CMC Development Patent, Research IRD Patent or Janssen Research IRD Patent then issued by or filed with such Governmental Authority and being prosecuted by MeiraGTx, as applicable, and (ii) thereafter on a reasonably regular basis as determined by the JSC or upon Janssen's reasonable written request, MeiraGTx shall record with each Governmental Authority (where such right is available with such Governmental Authority and such Governmental Authority permits the filing of a form of short notice of license) the licenses granted in Section 4.1 against each Clinical IRD Patent, CMC Development Patent, Research IRD Patent or Janssen Research IRD Patent newly filed with such Governmental Authority and being prosecuted by MeiraGTx, as applicable, in each case ((i)-(ii)) by using a form of short notice of license mutually agreed to by the Parties (but shall not, for the avoidance of doubt, file or publicly disclose this Agreement itself for such purposes). To the extent permitted by Applicable Law, if Janssen is responsible for prosecuting any Clinical IRD Patent, CMC

Development Patent, Research IRD Patent or Janssen Research IRD Patent, as applicable, under this Section 11.4, then Janssen shall have the right to record with a Governmental Authority (where such right is available with such Governmental Authority and such Governmental Authority permits the filing of a form of short notice of license) the licenses granted in Section 4.1 against any such Clinical IRD Patent, CMC Development Patent, Research IRD Patent or Janssen Research IRD Patent then issued by or filed with such Governmental Authority and prosecuted by Janssen, as applicable, by using a form of short notice of license mutually agreed by the Parties (but shall not, for the avoidance of doubt, file or publicly disclose this Agreement itself for such purposes). For clarity, for purposes of this Section 11.4(g), a form of short notice of license may include a short notice form provided by a Governmental Authority or, where permitted by such Governmental Authority, any other short notice of license drafted by the Parties (*e.g.*, a custom short statement that the Parties confirm that certain scheduled Patents are subject to a license grant).

11.5. Third Party Infringement; Patent Actions.

(a) Notice. If either Party becomes aware of: (i) existing or threatened infringement, misappropriation or other violation by a Third Party of any of the MeiraGTx Technology, MeiraGTx Research Technology, Janssen Technology, CMC Development Technology or any Joint Patents ("**Third Party Infringement**"); (ii) request for declaratory judgment, opposition, nullity action, interference, inter partes reexamination, inter partes review, post-grant review, derivation proceeding or similar action alleging the invalidity, unenforceability or non-infringement of any of the MeiraGTx Patents, MeiraGTx Research Patents, Janssen Technology, CMC Development Patents or any Joint Patents (each, a "**Licensed Patent Action**"); or (iii) a BLA for a Biosimilar Product referencing a Product submitted to a Party or a Regulatory Authority, it shall [***] notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken.

(b) Enforcement Rights for MeiraGTx Know-How, CMC Development Technology and Clinical IRD Patents.

(i) *Janssen's First Right of Enforcement*. Janssen shall have the first right, but not the obligation, in the case of the MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents to bring and control an appropriate suit or other action or defend against any Third Party Infringement or Licensed Patent Action with respect to any MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents. MeiraGTx shall provide reasonable assistance to Janssen in such enforcement or defense, at Janssen's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by Applicable Laws to pursue such action or if requested by Janssen. Janssen shall consult with MeiraGTx and keep MeiraGTx reasonably informed of the status of the enforcement or defense of such MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents. Janssen shall consider MeiraGTx's comments with respect to the enforcement or defense of such MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, as applicable, in good faith. Prior to settling any such suit or action, Janssen shall notify MeiraGTx in writing as to the terms of such proposed settlement to the extent relating to MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents and shall not execute such settlement without MeiraGTx's written consent if MeiraGTx identifies to Janssen in reasonable detail a material risk of a material

negative impact on the MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, taking into account the potential impact on the value of the Products worldwide as a result of such settlement. If Janssen recovers monetary damages in such claim, suit or action with respect to the MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, after Janssen recoups its costs and expenses associated with such litigation, with respect to any portion of such recovery remaining, [***].

(ii) *MeiraGTx's Back-Up Right of Enforcement*. If Janssen does not, within the earlier of [***] after learning about a Third Party Infringement or Licensed Patent Action or [***] before the expiration date for filing an appropriate suit or responding to or taking any action (as applicable), initiate and prosecute any legal action to enforce or defend the MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, as applicable, then MeiraGTx shall have the right, but not the obligation, to commence such a suit or take such an action to enforce or defend the applicable MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, as applicable. In such event, Janssen shall take appropriate actions in order to enable MeiraGTx to commence a suit or take the actions set forth in the preceding sentence. Prior to settling any such suit or action, MeiraGTx shall notify Janssen in writing as to the terms of such proposed settlement and shall not execute such settlement without Janssen's written consent if Janssen identifies to MeiraGTx in reasonable detail a material risk of a material negative impact on the MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, taking into account the potential impact on the value of the Products worldwide as a result of such settlement. Prior to MeiraGTx commencing such a suit or action, MeiraGTx shall consider in good faith any reasonable Janssen business concerns. If Janssen identifies to MeiraGTx in reasonable detail a material risk of a material negative impact on the MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents resulting directly from such a suit or action, taking into account the potential impact on the value of the Products worldwide, then MeiraGTx shall not commence any such suit or action. If MeiraGTx recovers monetary damages in such claim, suit or action with respect to the MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, any portion of such recovery remaining after MeiraGTx recoups its costs and expenses associated with such litigation, shall be [***].

(c) Enforcement Rights for MeiraGTx Research Know-How and Research IRD Patents.

(i) *Parties' First Right of Enforcement*. Prior to Janssen's exercise of the applicable Option, MeiraGTx shall have the sole right to bring and control an appropriate suit or other action against any Third Party Infringement or Licensed Patent Action with respect to the MeiraGTx Research Know-How or Research IRD Patents; *provided*, *however*, that in the event that any such Third Party Infringement or Licensed Patent Action also affects MeiraGTx Know-How, CMC Development Technology or Clinical IRD Patents, Janssen shall have the first right, but not the obligation, to bring and control such suit or other action pursuant to Section 11.5(b)(i). On or after Janssen's exercise of the applicable Option, Janssen shall have the first right, but not the obligation, in the case of the applicable MeiraGTx Research Know-How and Research IRD Patents to bring and control an appropriate suit or other action against any Third Party Infringement or Licensed Patent Action with respect to such MeiraGTx Research Know-How or Research IRD Patents. MeiraGTx shall provide reasonable assistance to Janssen in such enforcement or defense, at Janssen's request and expense, including joining such action as a party plaintiff to ensure legal

standing if required by Applicable Laws to pursue such action or if requested by Janssen. Janssen shall consult with MeiraGTx and keep MeiraGTx reasonably informed of the status of the enforcement or defense of such MeiraGTx Research Know-How and Research IRD Patents. Janssen shall consider MeiraGTx's comments with respect to the enforcement or defense of such MeiraGTx Research Know-How or Research IRD Patents in good faith. Prior to settling any such suit or action, Janssen shall notify MeiraGTx in writing as to the terms of such proposed settlement to the extent relating to MeiraGTx Research Know-How and Research IRD Patents and shall not execute such settlement without MeiraGTx's written consent if MeiraGTx identifies to Janssen in reasonable detail a material risk of a material negative impact on the MeiraGTx Research Know-How or Research IRD Patents, taking into account the potential impact on the value of the Products worldwide as a result of such settlement. If Janssen recovers monetary damages in such claim, suit or action with respect to the MeiraGTx Research Know-How or Research IRD Patents, after Janssen recoups its costs and expenses associated with such litigation, with respect to any portion of such recovery remaining, [***].

(ii) *MeiraGTx's Back-Up Right of Enforcement*. If Janssen does not, within [***] after learning about a Third Party Infringement or Licensed Patent Action or [***] before the expiration date for filing an appropriate suit or responding to or taking any action (as applicable), initiate and prosecute any legal action to enforce or defend the MeiraGTx Research Know-How or Research IRD Patents, as applicable, then MeiraGTx shall have the right, but not the obligation, to commence such a suit or take such an action to enforce the applicable MeiraGTx Research Know-How or Research IRD Patents. In such event, Janssen shall take appropriate actions in order to enable MeiraGTx to commence a suit or take the actions set forth in the preceding sentence. Prior to settling any such suit or action, MeiraGTx shall notify Janssen in writing as to the terms of such proposed settlement and shall not execute such settlement without Janssen's written consent if Janssen identifies to MeiraGTx in reasonable detail a material risk of a material negative impact on the MeiraGTx Research Know-How or Research IRD Patents, taking into account the potential impact on the value of the Products worldwide as a result of such settlement. Prior to MeiraGTx commencing such a suit or action, MeiraGTx shall consider in good faith any reasonable Janssen business concerns. If Janssen identifies to MeiraGTx in reasonable detail a material risk or a material negative impact on the MeiraGTx Research Know-How or Research IRD Patents resulting directly from such a suit or action, taking into account the potential impact on the value of the Research IRD Products worldwide, then MeiraGTx shall not commence any such suit or action. If MeiraGTx recovers monetary damages in such claim, suit or action with respect to the MeiraGTx Research Know-How or Research IRD Patents, any portion of such recovery remaining after MeiraGTx recoups its costs and expenses associated with such litigation shall be [***].

(d) Cooperation. At the request of the Party bringing and controlling any Third Party Infringement or defending any Licensed Patent Action, as applicable ("**Controlling Party**"), the other Party shall provide reasonable assistance in connection with such action, including by executing reasonably appropriate documents, providing access to such Party's premises and employees, cooperating reasonably in discovery, and joining as a party to the action if requested by the Controlling Party. The Controlling Party will keep the other Party reasonably informed of all material developments in connection with any such suit, and the other Party shall have the right to consult with the Controlling Party and to participate in and, if appropriate, be represented by

independent but mutually agreed upon counsel in such litigation at such other Party's own cost and expense.

11.6. Product Infringement.

If a Party becomes aware of any actual or potential Claim alleging that the Research, Development, Manufacture, or Commercialization of any Products under this Agreement infringes, misappropriates, or otherwise violates any Intellectual Property Rights of a Third Party (or would if carried out) ("**Product Infringement**"), then such Party will notify the other Party [***] following the receipt of service of process in such action, suit, or proceeding, or the date on which such Party becomes aware that such action, suit, or proceeding has been instituted, and the Parties will meet as soon as possible to discuss the overall strategy for defense of such matter. Janssen shall have the first right (but not the obligation) to defend any Claims of Product Infringement. If Janssen does not intend to defend such Product Infringement or determines to cease defending any such Product Infringement and informs MeiraGTx that it wishes for MeiraGTx to defend such Product Infringement, then MeiraGTx will have the right, but not the obligation, upon written notice to Janssen, to defend such Product Infringement or take over defense of the Product Infringement from Janssen, as applicable. Notwithstanding anything to the contrary, if either Party has an obligation to indemnify the other Party with respect to such Claim of Product Infringement, then the provisions of Article 17 will apply with respect thereto.

11.7. Patents Licensed From Third Parties.

Each Party's rights under this Article 11 with respect to the prosecution and maintenance, enforcement, and defense of any Patent that is licensed from a Third Party shall be subject to the rights retained by such Third Party with respect to such Patent.

11.8. Trademarks.

Janssen shall have the right to brand any and all Product(s) using Janssen related Trademarks it determines appropriate for such Product(s), which may vary by country or within a country ("**Product Marks**"). Subject to Section 15.4(c)(iii), Janssen shall own all rights in Product Marks and shall have the sole right to register and maintain Product Marks in the countries and regions it determines reasonably necessary, and Janssen shall have the sole right, in its discretion and at its expense, to defend and enforce such Product Marks.

12. CONFIDENTIALITY

12.1. Duty of Confidence.

Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for [***] after the expiration or earlier termination of this Agreement, subject to the other provisions of this Article 12, each Party will, as a receiving Party (the "**Receiving Party**"), and will cause its Affiliates to, maintain in confidence, not publish or otherwise disclose and otherwise safeguard, any and all Confidential Information disclosed by or on behalf of the other Party (the "**Disclosing Party**") or its Affiliates under this Agreement to it, using such degree of care that such Party uses with respect to its own confidential information (which shall in no event be less than a reasonable degree of care). During

the Term and for [***] after the expiration or earlier termination of this Agreement, subject to the other provisions of this Article 12, the Receiving Party may only use such Confidential Information for the purposes of this Agreement and in connection with the performance of its obligations or exercise of rights granted or reserved in this Agreement.

12.2. Exceptions.

The obligations under this Article 12 shall not apply to any information to the extent that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Receiving Party or its Affiliates;

(b) was known to, or was otherwise in the possession of, the Receiving Party or its Affiliates, as evidenced by written records of the Receiving Party and its Affiliates kept in the ordinary course of business, prior to the time of disclosure by the Disclosing Party or any of its Affiliates;

(c) is disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party or any of its Affiliates; or

(d) is independently developed by or on behalf of the Receiving Party or its Affiliates outside of its performance under this Agreement, as evidenced by written records of the Receiving Party and its Affiliates kept in the ordinary course of business, without the use of the Confidential Information disclosed by the Disclosing Party or its Affiliates to the Receiving Party or its Affiliates under this Agreement.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party, unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

12.3. Authorized Disclosures.

(a) Disclosures. Except as expressly permitted by this Agreement, in addition to disclosures allowed under Section 12.2 or Section 12.4, the Receiving Party and its Affiliates may only disclose to Third Parties the Disclosing Party's Confidential Information to the extent such disclosure is necessary in the following instances: (i) in connection with the performance of its obligations or exercise of rights granted or reserved in this Agreement, under non-disclosure and non-use provisions no less restrictive than those in this Agreement; (ii) in connection with the prosecution and maintenance of Patents as permitted by this Agreement; (iii) in connection with Regulatory Filings or audits by Regulatory Authorities for any Product; (iv) in connection with

prosecuting or defending litigation as permitted by this Agreement; (v) in complying with applicable court orders or governmental regulations (including securities regulations); (vi) in the case of any Party, in communication with its employees, directors, officers, agents, contractors, consultants, and professional advisers; Affiliates; potential or actual collaborators, partners, and licensees (including potential co-marketing and co-promotion contractors); and potential or actual investment bankers, acquirers, lenders or investors, each of the foregoing whom, on a need-to-know basis and prior to disclosure, must be bound by similar obligations of confidentiality and non-use no less restrictive than those contained in this Article 12; (vii) as permitted in accordance with Article 13; or (viii) as mutually agreed to in writing by the Parties.

(b) Disclosures pursuant to Applicable Law. If the Receiving Party is required to disclose Confidential Information of the Disclosing Party pursuant to Applicable Law (including the rules of the Securities and Exchange Commission or any stock exchange) or in connection with any bona fide legal process, including disclosures of the type contemplated by Section 12.3(a), such disclosure to the extent reasonably necessary shall not be deemed a breach of this Agreement; *provided*, *however*, that the Receiving Party, except where reasonably impracticable or legally impermissible, will: (i) inform the Disclosing Party as soon as reasonably practicable following it becoming aware of the required disclosure; (ii) limit the disclosure to the required purpose; and (iii) at the Disclosing Party's request and reasonable expense, assist in attempting to object to, limit or seek to secure confidential treatment of the required disclosure.

12.4. Terms of this Agreement.

The Parties acknowledge and agree that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of each Party, subject to Section 13.5.

12.5. Use of Residuals.

Residuals shall not be considered Confidential Information of MeiraGTx and the restrictions set forth in this Article 12 shall not apply to the use of Residuals.

12.6. Data Privacy.

(a) Privacy and Data Security Laws. Without limiting a Party's other obligations under this Agreement, each Party shall, and shall cause its Affiliates and permitted subcontractors to, implement and maintain reasonable security procedures and practices appropriate to the nature of Sensitive Information such Party is processing and take such other actions as are reasonably necessary to protect the security and confidentiality of such Sensitive Information against any threats or hazards to the security or integrity of such Sensitive Information in accordance with Privacy and Data Security Laws.

(b) Data Breaches. If a Party learns of any security breach involving Sensitive Information of the other Party collected, prepared or developed in connection with this Agreement, such Party shall immediately notify the owning Party of the same, and shall, at the owning Party's expense, reasonably cooperate with the owning Party in investigating and responding to the foregoing. The Party whose Sensitive Information has been breached (or allegedly breached) shall have the sole right to determine the content, timing and other details of any notices to affected individuals or Governmental Authorities in connection with such breach.

13. PUBLICATIONS AND PUBLICITY

13.1. Use of Names.

Except as otherwise expressly permitted herein or to the extent required pursuant to Section 13.5, neither Party may use the names or Trademarks of the other Party or its Affiliates for any purpose, including in any press release, publication, or other form of public disclosure, without first obtaining, in each case, the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned, or delayed), except for those disclosures for which consent has already been obtained or which are required by Applicable Law. Notwithstanding the foregoing, Janssen shall be entitled to use the name of MeiraGTx and its Affiliates to the extent necessary under Applicable Law in connection with the Development or Commercialization of any Product.

13.2. Press Releases and Publicity Related to this Agreement.

The Parties shall agree on a form of a press release that may be issued by each, if desired, on or shortly following the Execution Date. Thereafter, except to the extent required to comply with Applicable Law or otherwise pursuant to Section 13.5, neither Party shall issue any press releases or other public statements, whether oral or written, disclosing the existence of this Agreement, or the terms hereof, without first obtaining, in each case, the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed. Notwithstanding the foregoing, to the extent information in connection with this Agreement has already been publicly disclosed in accordance with this Agreement, either Party (or its Affiliates) may subsequently disclose the same information to the public without the consent of the other Party.

13.3. Public Disclosures and Publications Related to the Programs or Products.

Except to the extent required pursuant to Section 13.5, and subject to this Section 13.3, each Party shall not issue any press releases or other public statements, whether oral or written, regarding the Research Plan Activities, Research IRD Targets, Research IRD Products, CMC Development Plan Activities, Clinical Development Plan Activities, Clinical IRD Products and Clinical IRD Targets, without first obtaining, in each case, the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed. MeiraGTx shall be permitted to provide public statements with respect to certain Clinical IRD Products pursuant to obligations incurred prior to the Execution Date; *provided* that Janssen has actual knowledge as of the Execution Date of such obligations; and *provided further* that such public statements shall be approved by Janssen prior to their release (such approval not to be unreasonably withheld, conditioned, or delayed). In addition, and notwithstanding the foregoing, on or after the respective Sponsorship Transfer Date with respect to any Clinical IRD Product and on or after the respective Option Election Date with respect to any Janssen Research IRD Product, Janssen may publish a press release or other public statement about such Clinical IRD Product or Janssen Research IRD Product, as applicable; *provided* that Janssen shall provide MeiraGTx with a copy of any such press release or public statement reasonably in advance of such publication and consider in good faith any comments timely provided by MeiraGTx to Janssen with respect to such press release or public statement, as applicable.

13.4. Publications.

(a) Review Process. The Parties may wish to publish or present the results of the programs or Products hereunder. Either Party may publish the results or observations of its work on a program or Product hereunder after providing the other Party [***] to review the proposed publication, abstract or presentation ("**Review Period**") to determine whether the proposed publication, abstract or presentation contains any Confidential Information of the non-submitting Party. If within the Review Period, the non-submitting Party determines that the proposed publication, abstract or presentation contains any such Confidential Information, the non-submitting Party will notify the submitting Party in writing of the presence of the Confidential Information in the proposed publication, abstract or presentation and the submitting Party will delete such Confidential Information from the proposed publication, abstract or presentation. If, within the Review Period, the non-submitting Party identifies material in such publication, abstract or presentation which, if published, would disclose an Invention of the non-submitting Party that has not yet been protected through the filing of a Patent or would adversely affect the Intellectual Property Rights owned by the non-submitting Party, then at the non-submitting Party's election, (i) the submitting Party will delay submission of its publication, abstract or presentation for an additional period, not to exceed [***] or such other period mutually agreed to by the Parties, in order to allow for the filing of a Patent or other appropriate Intellectual Property Rights protection for such material or (ii) the submitting Party will remove the identified material prior to publication.

(b) Acknowledgments. Proper acknowledgement will be made for contributions, if any, of each Party to the results or other information and material disclosed in any publication, abstract or presentation under this Section 13.4. Authorship of scientific publications will be determined in accordance with customary academic and industry policies and procedures, the scientific contribution, and the standards of the applicable journal.

13.5. Disclosures Required By Law.

Notwithstanding Section 13.1, Section 13.2, and Section 13.3, each Party may make any disclosures required to comply with any duty of disclosure it may have pursuant to Applicable Law or the requirements of any Governmental Authority or Regulatory Authority or pursuant to the rules of any recognized stock exchange (including the rules of the Securities and Exchange Commission). If a disclosure required by Applicable Law, the requirements of any Governmental Authority or Regulatory Authority, or the rules of any recognized stock exchange arises, the Parties shall coordinate with each other with respect to the timing, form, and content of such required disclosure. If so requested by the other Party, except where impracticable or not legally permitted, the Party subject to such obligation shall use commercially reasonable efforts to obtain an order protecting the confidentiality of such provisions of this Agreement, as determined by the Disclosing Party in consultation with its legal counsel. Without limiting the foregoing, MeiraGTx shall use commercially reasonable efforts to provide Janssen with each proposed filing by MeiraGTx with the United States Securities and Exchange Commission (or any recognized stock exchange, including Nasdaq, or any similar regulatory agency in any country other than the United States) describing the terms of this Agreement (including any filings of this Agreement) at least [***] prior to submission of such filing, and shall seek confidential treatment of portions of this Agreement or such terms or information as may be reasonably requested by Janssen in a timely manner.

13.6. Publication and Transparency of Clinical Research Results.

All research results of clinical trials hereunder will be posted on clinicalstudyresults.org and on any other registry with requirements consistent with the registration and publication guidelines of the International Committee of Medical Journal Editors, to the extent required. All data and information posted on clinicaltrial.gov, clinicalstudyresults.org or any other registry will be subject to prior review by the other Party pursuant to Section 13.4(a). All research results generated from clinical trials hereunder may be made available to Third Parties pursuant to data transparency policies and mechanisms of Janssen or its Affiliates then in effect.

14. EFFECTIVENESS

14.1. Effective Date.

Except for the Parties' obligations under Article 12, Article 13 and this Article 14, which shall be effective as of the Execution Date, this Agreement shall not become effective until the first date (the "**Effective Date**") on which (a) expiration or early termination of all applicable waiting periods under the HSR Act has occurred, (b) each of the representations of MeiraGTx set forth in Section 16 are true and correct in all material respects, (c) an officer of MeiraGTx has delivered a written certificate with respect to (b) to Janssen, (d) an updated copy of Exhibit 1.168, setting forth a true, complete and accurate list of all Patents Controlled by MeiraGTx or any of its Affiliates as of the Effective Date, which claim or otherwise Cover any Clinical IRD Products, Clinical IRD Targets or MeiraGTx Know-How in the Field, has been delivered to Janssen and (e) [***] has entered into a binding commitment with MeiraGTx to provide to Janssen the right to undertake a

back-up license under [***]'s license grant to MeiraGTx; *provided*, *however*, that Janssen may waive the conditions described in clause (b), (c), (d) or (e) above.

14.2. Filings.

The Parties shall cooperate with one another in the preparation and execution of all documents that are required to be filed pursuant to the HSR Act. Each Party shall, within [***] following the Execution Date (or such later time as may be agreed to in writing by the Parties), file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, and/or with equivalent foreign authorities, any HSR Filing required of it in the reasonable opinion of either Party with respect to the transactions contemplated hereby. Neither Party shall seek expedited treatment of any HSR Filing without the other Party's prior written consent. Each Party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, [***] take all actions necessary to make the filings required of such Party or its Affiliates under the HSR Act. The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; *provided*, *however*, that Janssen shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of MeiraGTx) required to be paid to any Governmental Authority in connection with making any such HSR Filing.

14.3. Outside Date.

This Agreement shall terminate (a) at the election of either Party, immediately upon written notice to the other Party, if the U.S. Federal Trade Commission or the U.S. Department of Justice, or an equivalent authority in the European Union, seeks a preliminary injunction under applicable antitrust and non-competition laws against Janssen and MeiraGTx to enjoin the transactions contemplated by this Agreement; or (b) at the election of either Party, immediately upon written notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to one hundred eighty (180) days after the effective date of the HSR Filing. In the event of such termination, this Agreement shall be of no further force and effect.

15. TERM AND TERMINATION

15.1. Term.

The term of this Agreement shall commence upon the Effective Date and, unless terminated pursuant to Section 15.2, shall continue in full force and effect, on a Product-by-Product and country-by-country basis, until such time as the Royalty Term expires in such country (the "**Term**"). On a Product-by-Product and country-by-country basis, effective upon the expiration of the Royalty Term for such Product in such country (but not for any termination of this Agreement), the licenses granted to Janssen will each become fully paid-up, royalty-free, irrevocable, and perpetual in such country with respect to such Product.

15.2. Termination.

This Agreement may be terminated as follows:

(a) Termination for Breach.

(i) *General*. Subject to Section 15.2(a)(ii), if either Janssen or MeiraGTx is in material breach of this Agreement, the non-breaching Party must give written notice to the breaching Party within [***] following the alleged breach specifying the claimed particulars of such breach in sufficient detail to put the allegedly breaching party on reasonable notice of the nature of the alleged breach, and in the event such material breach is not cured within [***] after such notice (or in the case of any undisputed payment obligations, [***] after such notice), the non-breaching Party shall have the right thereafter to terminate this Agreement immediately, in whole or with respect to the applicable Product (except with respect to a material breach by Janssen arising under Section 6.1(e), Section 6.2(a), Section 8.4(a), Article 9 and Section 19.4, which must be terminated on a Product-by-Product basis), by giving written notice to the breaching Party to such effect; *provided*, *however*, that if such breach is capable of being cured but cannot be cured within the period referenced above and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable under the circumstances to cure such breach; it being understood that no such extension shall apply with respect to any undisputed payment obligations. If arbitration is commenced with respect to any alleged breach hereunder pursuant to Section 18.1, no purported termination of this Agreement pursuant to this Section 15.2(a)(i) shall take effect until: (A) a final resolution of such arbitration; and (B) the losing Party in such arbitration fails to satisfy the arbitration award within the cure time frames referenced above.

(ii) *Janssen Special Remedy*. If Janssen would have the right to terminate this Agreement under Section 15.2(a)(i), in whole or in part, for an uncured material breach by MeiraGTx in connection with a Product, then Janssen may, in its sole discretion, elect: (A) to either exercise such termination right or (B) in lieu of exercising such termination right, and without limiting Janssen's rights otherwise set under this Agreement, subsequently reduce any payment amounts due to MeiraGTx under [***] for such Product by [***] percent ([***]%) as a result of this Section 15.2(a)(ii).

(b) Termination for Insolvency. This Agreement may be immediately terminated in its entirety by a Party by providing written notice of termination to the other Party in the event of an Insolvency Event of the other Party.

(c) Termination for Patent Challenge. To the extent permitted by Applicable Law, if Janssen or any of its Affiliates Challenges any Patent included in the MeiraGTx Patents, MeiraGTx Research Patents or Joint Patents in any country in the Territory (such Patent, a "**Challenged Patent**"), then MeiraGTx may, following written notice to Janssen and *provided that* Janssen or its Affiliate does not withdraw such Challenge within [***] after receipt of such notice, terminate this Agreement in its entirety by providing written notice of termination to Janssen; *provided that* this Section 15.2(c) will not apply to, and MeiraGTx may not terminate this Agreement with respect to (i) any claim or proceeding that would otherwise be a Challenge hereunder to the extent commenced by a Third Party that after the Effective Date acquires or is acquired by Janssen or its Affiliates or its or their business or assets, whether by stock purchase, merger, asset purchase, or otherwise; *provided that* such proceeding commenced prior to the closing of such acquisition; (ii) any claim or proceeding by a licensor of a product licensed by Janssen for which the licensor has an existing challenge, whether in a court or administrative proceeding, against any MeiraGTx

Patent, MeiraGTx Research Patent or Joint Patent; (iii) any Challenge required to be commenced pursuant to an order of a Governmental Authority or Applicable Law; (iv) any Challenge that is commenced by a Sublicensee; *provided that* Janssen demands that such Sublicensee withdraw such Challenge [***] after Janssen becomes aware of such Challenge and terminates the sublicense agreement with the applicable Sublicensee if such Sublicensee does not withdraw such Challenge within [***] after receipt of such demand from Janssen; (v) any proceeding not initiated, directed or controlled by or on behalf of Janssen or one of its Affiliates, for which Janssen or the Affiliate, as the case may be, opposes, or assists any Third Party to oppose, the grant of a MeiraGTx Patent, MeiraGTx Research Patent or Joint Patent pursuant to any application in relation thereto in an administrative proceeding, such as a patent re-examination, *inter partes* review, or other post grant proceeding or opposition; (vi) challenges by an open forum entity or other industry group in which Janssen or its Affiliates or Sublicensees do not direct or control the action of such entity; (vii) general activities not specifically directed to a particular Patent, such as amicus briefs on cases not involving any MeiraGTx Patent, MeiraGTx Research Patent or Joint Patent; (viii) lobbying or other efforts directed to patent issues generally and not to any specific Patent; (ix) any affirmative defense or other validity, enforceability, or non-infringement challenge, whether in the same action or in any other agency or forum of competent jurisdiction, advanced by Janssen, any of its Affiliates or Sublicensees in response to any claim or action brought in the first instance by, or on behalf of, MeiraGTx or any Third Party; (x) providing documents or testimony in response to any discovery requests or court order in a valid legal process not directed to Challenging any Challenged Patent; or (xi) any Challenge related to any Clinical IRD Patent, CMC Development Patent, Research IRD Patent or Janssen Research IRD Patent for which Janssen's reasonable input with respect to such Patent's prosecution, maintenance or enforcement pursuant to Section 11.4 or Section 11.5 was not included in any filings or correspondence with patent authorities or otherwise accepted or pursued by MeiraGTx (as applicable).

(d) Termination by Janssen At Will. Beginning on [***], Janssen may terminate this Agreement at will in its entirety or on a Product-by-Product basis at any time on: (i) [***] prior written notice to MeiraGTx, if prior to the First Commercial Sale of such Product; and (ii) on [***] prior written notice to MeiraGTx, if following the First Commercial Sale of such Product.

15.3. Rights in Insolvency.

The Parties agree that this Agreement constitutes an executory contract under Section 365 of the Code for the license of "intellectual property" as defined under Section 101 of the Code and constitutes a license of "intellectual property" for purposes of any similar laws in any other country in the Territory. The Parties further agree that Janssen, as licensee of such rights under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Code, including under Section 365(n) of the Code, and any similar laws in any other country in the Territory and that Janssen cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of Janssen's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Janssen. The Parties further agree that, in the event of an Insolvency Event by or against MeiraGTx under the Code and any similar laws in any other country in the Territory, Janssen may be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property (including Materials and Research Results), and the same, if not already in its

possession, will be [***] delivered to it: (a) upon any such commencement of an Insolvency Event upon its written request therefor, unless MeiraGTx elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of MeiraGTx upon written request therefor by Janssen. Whenever MeiraGTx or any of its successors or assigns provides to Janssen any of the intellectual property licensed hereunder (or any embodiment thereof including Materials and Research Results) pursuant to this Section 15.3, Janssen shall have the right to perform MeiraGTx's obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by Janssen shall release MeiraGTx from liability resulting from rejection of the license or the failure to perform such obligations. MeiraGTx and Janssen each acknowledges and agrees that Option Fees, Development Milestone Payments, Commercial Milestone Payments and Royalties constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code.

All rights, powers and remedies of Janssen provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to MeiraGTx. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

(i) the right of access to any intellectual property rights (including all embodiments thereof) of MeiraGTx licensed to Janssen hereunder, or any Third Party with whom MeiraGTx contracts to perform an obligation of MeiraGTx under this Agreement, and, in the case of the Third Party, which is necessary for the Manufacture, use, sale, import or export of Products; and

(ii) the right to contract directly with any Third Party to complete the contracted work.

15.4. Effects of Expiration or Termination.

(a) Licenses. Upon any expiration or termination of this Agreement after the Effective Date, in whole or in part, any licenses granted by a Party under Section 4.1 with respect to a Terminated Product will terminate, except to the extent necessary for Janssen to perform any of its obligations that survive such termination, to conduct wind-down activities in compliance with applicable legal and ethical obligations, or to the extent set forth in Section 4.1(c) or Section 15.1, and each of the Parties' respective obligations with respect to such Terminated Product shall terminate, except as set forth in Section 15.1, Section 15.4, Section 15.5 and Section 15.6. For clarity, upon any termination in part of this Agreement, the licenses granted under Article 4 shall survive with respect to the Products not affected by such partial termination.

(b) Confidential Information. Upon any expiration or termination of this Agreement, in whole or in part, each Party will destroy all written, electronic, or other materials containing Confidential Information of the other Party, including all copies thereof relating to such Terminated Product within [***] of such termination and provide certification of such destruction to the owning Party; *provided*, that: (i) a Party may retain one (1) copy of any materials containing Confidential Information of the other Party in its archives solely for the purpose of monitoring its

ongoing confidentiality obligations hereunder; and (ii) a Party will not be obligated to destroy such materials containing Confidential Information of the other Party that are necessary for the Party to exercise any other license or right of such Party that survives such termination of this Agreement; *provided*, *however*, that the receiving Party's use of such Confidential Information will continue to be subject to the requirements and restrictions set forth in Article 12.

(c) Wind-Down Activities. Upon any termination of this Agreement, in whole or in part, by MeiraGTx for Janssen's uncured material breach under Section 15.2(a), by MeiraGTx under Section 15.2(b) or Section 15.2(c), or by Janssen under Section 15.2(d), then the following shall occur:

(i) Janssen hereby grants to MeiraGTx, with respect to the Terminated Product(s), a non-exclusive, perpetual and irrevocable right and license, with the right to grant sublicenses (through multiple tiers), under Janssen's Sole Inventions as necessary to Develop, Manufacture and Commercialize such Terminated Product(s) in the Field in the Territory;

(ii) Effective as of such termination date, Janssen hereby assigns, and shall [***] transfer (at MeiraGTx's reasonable expense, unless MeiraGTx terminated this Agreement, in whole or in part, for Janssen's uncured material breach under Section 15.2(a), in which case such transfer shall be at Janssen's reasonable expense) on an as-is, where-is basis, to MeiraGTx or MeiraGTx's designee possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including all Regulatory Approvals and Pricing Approvals), and global safety database, in each case relating to the Development, Manufacture or Commercialization of the Terminated Product(s) and to the extent permitted under Applicable Law, and Janssen shall reasonably cooperate, at no additional out-of-pocket cost to Janssen, with requests by MeiraGTx for assistance necessary to facilitate MeiraGTx's assumption of regulatory responsibilities for the Terminated Product(s) in the applicable countries in which direct transfer is not permitted during the [***] following such termination date;

(iii) Effective as of such termination date, Janssen hereby assigns (and shall ensure that its Affiliates or Sublicensees hereby assign) to MeiraGTx all Trademarks used solely with respect to the Terminated Product(s) in the Territory (together with the goodwill associated with the foregoing); and

(iv) Effective as of such termination date, Janssen shall [***] provide MeiraGTx with a summary of all Third Party agreements relating to the Development, Manufacture or Commercialization of the Terminated Product(s) to which Janssen is a party (other than those to be assigned to MeiraGTx) and shall assign to MeiraGTx any Third Party agreements solely relating to the Development, Manufacture or Commercialization of the Terminated Product(s), and MeiraGTx shall accept such assignment, including responsibility for all liabilities and obligations accruing under such agreements from and after the date of termination, in each case to the extent permitted thereunder. With respect to each agreement relating to the Development, Manufacture or Commercialization of Terminated Product(s) that is not transferred to MeiraGTx, at MeiraGTx's request, Janssen shall use reasonable efforts to facilitate a direct introduction between MeiraGTx and the Third Party counterparty to such agreement.

(d) Clinical Studies. If Janssen is conducting any Clinical Study on the date of notice of termination for any reason under this Agreement, then MeiraGTx shall notify Janssen within [***] after the notice of termination with regard to any Clinical Study, whether MeiraGTx elects to have Janssen (i) complete such Clinical Study on behalf of MeiraGTx (unless Janssen reasonably believes there is a material safety issue that should prevent the continuation of such Clinical Study), (ii) wind down such Clinical Study as soon as practicable, subject to compliance with ethical and legal requirements, or (iii) transfer such Clinical Study to MeiraGTx as soon as practicable. Notwithstanding the foregoing, if Janssen terminates this Agreement pursuant to Section 15.2(a) or 15.2(b), then this Section 15.4(d) shall not apply and Janssen, at its sole discretion, shall determine whether to continue or wind down any ongoing Clinical Study, subject to compliance with ethical and legal requirements; and each Party shall bear its own expenses incurred pursuant to such wind down. In addition, and subject to the foregoing:

(i) If MeiraGTx notifies Janssen of its election to have Janssen complete a Clinical Study on behalf of MeiraGTx, Janssen and MeiraGTx will, as necessary, negotiate in good faith a separate agreement pursuant to which Janssen would complete such Clinical Study. If the Parties fail to reach agreement within [***] after MeiraGTx makes such election, Janssen may wind down such Clinical Study, subject to compliance with ethical and legal requirements or, if requested by MeiraGTx, transfer such Clinical Study to MeiraGTx.

(ii) If MeiraGTx notifies Janssen of its election to have Janssen wind down such Clinical Study (or fails to provide notice within such [***] period), then Janssen shall wind-down such Clinical Study as soon as practicable, subject to compliance with ethical and legal requirements.

(iii) If MeiraGTx notifies Janssen of its election to have Janssen transfer such Clinical Study to MeiraGTx, then Janssen shall use commercially reasonable efforts to transfer, and MeiraGTx shall use commercially reasonable efforts to assume, such Clinical Study as [***] as practicable (and, in any event, within [***]) after the effective date of termination.

(iv) The costs of ongoing Clinical Studies under this Section 15.4(d) shall be borne as follows:

(A) By [***] after the effective date of termination, if [***]. [***] shall reimburse [***] for any such costs incurred by [***] after the effective date of termination.

(B) By [***] after the effective date of termination, if [***]. [***] shall reimburse [***] after the effective date of termination.

(C) By [***] as follows after the effective date of termination, if [***]: (x) by [***] until the earlier of (i) completion of such wind-down or (ii) [***] after the effective date of termination for such Clinical Study for such Clinical IRD Product; and (y) by [***] until the completion of such wind-down; *provided* that both Parties shall cooperate to wind-down such Clinical Study for such Clinical IRD Product as soon as reasonably practicable, including through discussions with the applicable Regulatory Authorities to minimize the compliance and legal requirement period for such wind-down.

(D) By [***] after the effective date of termination, if [***] until the completion of such wind-down.

(e) Further Actions. Janssen shall take all such further actions within the [***] following such termination of this Agreement, in whole or in part, as may be reasonably requested by MeiraGTx in order to give effect to the foregoing clauses in this Section 15.4, [***].

(f) Rights Terminated. Except as set forth in Section 15.1, Section 15.4, Section 15.5 and Section 15.6, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination of this Agreement, in whole or in part, with respect to the Terminated Product(s). For clarity, termination of this Agreement, in whole or part, will not affect a Party's rights to freely exploit CMC Development Inventions or CMC Development Patents in accordance with Article 11. In addition, upon any expiration or termination of this Agreement after the Effective Date, in whole or in part, each Party shall not undertake any further actions under this Agreement following such expiration or termination except in accordance with this Section 15.4. Subject to Section 15.2(a)(ii), Section 15.4(d) and Section 15.5, in the event of any expiration or termination of this Agreement, in whole or in part, (i) Janssen will pay all amounts then due and owing to MeiraGTx in accordance with Article 10 as of the effective date of such expiration or termination; (ii) each Party will use reasonable efforts to mitigate and avoid any costs incurred by or on behalf of such Party on or after such date of expiration and termination, to the extent to be reimbursed by the other Party in accordance with the express terms herewith (including under Section 15.4(d)(iv)(C)); and (iii) no further payment amounts shall be due to MeiraGTx with respect to the Terminated Product(s) after the effective date of such expiration or termination.

15.5. Post-Termination Royalties to Janssen.

Following termination of this Agreement, in whole or in part, with respect to a Product, MeiraGTx shall be obligated to pay Janssen a royalty on Net Sales of such Product in the amount of: (a) [***] percent ([***]%) of Net Sales if a Phase 2 Study has not been initiated for such Product as of the effective date of termination; (b) [***] percent ([***]%) of Net Sales if a Phase 2 Study has been initiated as of the effective date of termination but a Pivotal Study has not been initiated for such Product as of the effective date of termination; (c) [***] percent ([***]%) of Net Sales if a Pivotal Study has been initiated for such Product as of the effective date of termination but Pricing Approval in at least one (1) country has not been obtained for such Product as of the effective date of termination; or (d) [***] percent ([***]%) of Net Sales if Pricing Approval in at least one (1) country has been obtained for such Product as of the effective date of termination. The royalty reporting, payment, record-keeping, audit and withholding tax provisions set forth in Sections 10.8, 10.9, 10.11, 10.13(d) and 10.14 and "Royalty Term" definition set forth in Section 10.9(a) shall apply *mutatis mutandis* to royalties payable pursuant to this Section 15.5. For purposes of this Section 15.5, "Net Sales" shall have the meaning given to it in Section 1.176, as if the references to Janssen in such definition were to MeiraGTx.

15.6. Survival.

Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Subject to the other terms and conditions regarding the termination and survival of obligations under this Agreement in the event of expiration or

termination of this Agreement, upon expiration or termination of this Agreement, all provisions of this Agreement will cease to have any effect, except that the following provisions will survive any such expiration or termination for any reason for the period of time specified therein, or if not specified, then they will survive indefinitely: Article 1 (Definitions), Section 3.5 (Research Records), Section, 3.7(c) (Final Report), Section 4.1(c) (Internal Research License), Section 4.7 (No Other Rights), Section 6.1(g) (Clinical Development Records), Section 10.1 (Upfront Payment) (only with respect to the last sentence), Section 10.11 (Reports and Royalty Payments), Section 10.12 (Disclaimer), Section 10.13 (Payment Terms), Section 10.14 (Records and Audits), Section 11.1 (Ownership under the Clinical IRD Programs and Research IRD Programs), Section 11.2 (Ownership under the CMC Development Collaboration), Section 11.3 (Duties to the Other Party), Section 11.8 (Trademarks) (only with respect to the second sentence), Article 12 (Confidentiality), Section 13.1 (Use of Names), Section 13.2 (Press Releases and Publicity Related to this Agreement), Section 13.4 (Publications) (*provided*, *however*, that Section 13.4 shall not survive in the event of any expiration or termination of this Agreement in its entirety), Section 13.5 (Publications Required by Law), Section 14.3 (Outside Date), Section 15.1 (Term), Section 15.3 (Rights in Insolvency), Section 15.4 (Effects of Expiration or Termination), Section 15.5 (Post-Termination Royalties to Janssen), Section 15.6 (Survival), Section 15.7 (Termination Not Sole Remedy), Article 17 (Indemnification; Liability; Insurance), Article 18 (Dispute Resolution) and Article 19 (General Provisions).

15.7. Termination Not Sole Remedy.

Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein, and except that termination shall be MeiraGTx's sole remedy with respect to any failure by Janssen to discharge its obligations under Section 6.1(e), Section 6.2(a), Section 8.4(a) and Article 9.

16. REPRESENTATIONS, WARRANTIES AND COVENANTS

16.1. Representations and Warranties by Each Party.

Each Party hereby represents and warrants to the other Party, that as of the Execution Date and the Effective Date:

(a) such Party is a company duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation or incorporation;

(b) such Party has full power and authority to execute, deliver, and perform this Agreement, and has taken all action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement by such Party and the performance of all obligations of such Party as contemplated by this Agreement;

(c) this Agreement constitutes a legal, valid, and binding agreement enforceable against such Party in accordance with its terms;

(d) the person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;

(e) all consents, approvals and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with entering into this Agreement have been obtained, except in the case of the Execution Date as required pursuant to the HSR Act; and

(f) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, the performance of such Party's obligations hereunder and the licenses, options, rights of negotiation and other rights to be granted by such Party pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents; (ii) conflict with, violate, result in a breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Execution Date or Effective Date, including with respect to applicable Third Party Licenses; or (iii) conflict with or violate any requirements of Applicable Laws existing as of the Execution Date or Effective Date and applicable to such Party.

16.2. Representations, Warranties and Covenants by MeiraGTx.

In addition to the representations and warranties made by MeiraGTx in Section 16.1 above and Section 16.3 below, MeiraGTx hereby represents, warrants and covenants to Janssen that, (1) as of the Execution Date, (2) except as otherwise expressly provided, the Effective Date, and (3) solely with respect to Sections 16.2(a), (b), (d), (f), (g), (i), (k), (l), and (m), and solely with respect to the [***] Product as a Research IRD Product, as of the Option Election Date:

(a) MeiraGTx has, and will have during the Term of this Agreement, the full right, power and authority to grant the licenses, exclusivity, options, right of first negotiation and other rights granted to Janssen hereunder, including under (i) the MeiraGTx Patents and MeiraGTx Know-How; and (ii) to MeiraGTx's knowledge, the MeiraGTx Research Patents and MeiraGTx Research Know-How that each Cover Research IRD Products;

(b) MeiraGTx has not entered, and during the Term, will not enter, into any written agreement that grants or would grant to any Affiliate or Third Party, including any academic organization or agency or other Person, any rights to (i) any Clinical IRD Target or Clinical IRD Product; or (ii) to MeiraGTx's knowledge, any Research IRD Product or related Research IRD Target, or that otherwise conflicts or would conflict with the rights granted to Janssen hereunder or MeiraGTx's ability to fully perform its obligations hereunder, apart from those rights set forth in Exhibit 16.2(b);

(c) Exhibit 1.168 sets forth a true, complete and accurate list of all Patents Controlled by MeiraGTx or any of its Affiliates as of the Execution Date, which claim or otherwise Cover any Clinical IRD Products, Clinical IRD Targets or MeiraGTx Know-How in the Field, and each such updated copy of Exhibit 1.168 provided by MeiraGTx to Janssen as of the Effective Date and to the JSC on each anniversary of the Effective Date thereafter sets forth a true, complete and accurate list of all Patents Controlled by MeiraGTx or any of its Affiliates as of such respective dates, which claim or otherwise Cover any Clinical IRD Products, Clinical IRD Targets or MeiraGTx Know-How in the Field.

(d) the MeiraGTx Technology comprises all of the Intellectual Property Rights used by MeiraGTx and its Affiliates and consultants in the Research, Development and Manufacturing of the Clinical IRD Products prior to the Execution Date, and no MeiraGTx [***] Technology is used by MeiraGTx or its Affiliates or consultants, or is otherwise necessary, for the Research, Development, Manufacture or Commercialization of Clinical IRD Products;

(e) to MeiraGTx's knowledge, (i) the MeiraGTx Research Technology comprises all of the Intellectual Property Rights used by MeiraGTx and its Affiliates and consultants in the Research, Development and Manufacturing of Research IRD Products prior to the Execution Date, and (ii) no MeiraGTx [***] Technology is used by MeiraGTx or its Affiliates or consultants, or is otherwise necessary, for the Research, Development, Manufacture or Commercialization of Research IRD Products;

(f) neither MeiraGTx nor its Affiliates is or was engaged in the Commercialization of any Clinical IRD Product or Research IRD Product on or prior to the Execution Date;

(g) Exhibit 16.2(g) sets forth a complete and accurate list of all Existing Third Party Obligations as of the Execution Date, and besides Existing Third Party Obligations as set forth in Exhibit 16.2(g), neither MeiraGTx nor any of its Affiliates is subject to any royalty, milestone or other payment obligation to any Third Party in connection with the practice, or the grant of rights to Janssen to practice, (i) any of the MeiraGTx Technology, including with respect to the Commercialization of Clinical IRD Products under this Agreement and (ii) to MeiraGTx's knowledge, any of the MeiraGTx Research Technology, including with respect to the Commercialization of Research IRD Products;

(h) MeiraGTx has provided Janssen with complete, true and accurate copies of all agreements in effect between MeiraGTx and [***] relating to this Agreement;

(i) MeiraGTx has not materially breached, or received any notice of breach or default under, any Existing Third Party Obligation, and each Existing Third Party Obligation is valid, binding and in full force and effect;

(j) Exhibit 4.4 sets forth a complete and accurate list of all subcontractors that MeiraGTx has existing relationships with as of the Execution Date, such subcontractors' activities or obligations in connection with this Agreement and if applicable, any MeiraGTx commitments specifically requiring either of the Parties to engage any such subcontractors in connection with any Clinical Development Plan Activities or Research Plan Activities on or after the Effective Date;

(k) to MeiraGTx's knowledge, the Research, Development, Manufacture and Commercialization of the Products, do not, or will not, infringe or misappropriate the Intellectual Property Rights of any Third Party, and MeiraGTx or any of its Affiliates or licensees or Sublicensees of any MeiraGTx Technology or MeiraGTx Research Technology Covering Research IRD Products have not received any written notice alleging such infringement or misappropriation, except that [***];

(l) there are no claims, judgments, orders, decrees, or settlements against or owed by MeiraGTx or any of its Affiliates, and there is no written action or proceeding of any nature, civil,

criminal, regulatory or otherwise, pending or, to the knowledge of MeiraGTx, threatened against MeiraGTx or any of its Affiliates, in each case that would prevent MeiraGTx from performing its obligations under this Agreement or from granting the licenses and other rights set forth hereunder;

(m) none of MeiraGTx, its Affiliates, or licensees or Sublicensees of any MeiraGTx Technology, have initiated or been involved in any proceeding or other Claims in which it alleges that any Third Party is or was infringing or misappropriating any (i) MeiraGTx Technology or (ii) to MeiraGTx's knowledge, MeiraGTx Research Technology Covering Research IRD Products, nor have any such proceedings been threatened by MeiraGTx, its Affiliates, or licensees or Sublicensees, nor does MeiraGTx or its Affiliates know of any valid basis for any such proceedings; and

(n) MeiraGTx has provided Janssen with true, accurate and complete copies of all agreements listed in Exhibit 16.2(b) and Exhibit 16.2(g) attached hereto (including amendments and addendums to such agreements).

16.3. Mutual Covenants.

(a) Compliance. Each Party shall comply, and shall cause its Affiliates, subcontractors and Sublicensees to comply, in all material respects with all Applicable Laws applicable to the Development, Manufacture and Commercialization of Products and performance of its obligations under this Agreement, including, to the extent applicable, the statutes, regulations and written directives of the FDA (including cGCP, cGLP, and cGMP), the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. § 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), Anti-Corruption Laws, Privacy and Data Security Laws, Trade Control Laws and U.S. Export Control Laws.

(b) No Debarred Person. In the course of the Research, Development, Manufacture and Commercialization of the Products, neither Party nor its Affiliates, Sublicensees or subcontractors shall use any employee, officer, director, agent or consultant who is or has been a Debarred Person, or, to such Party's or its Affiliate's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party [***] in writing upon becoming aware that any person performing services under this Agreement has become a Debarred Person or is the subject of debarment proceedings or pending or threatened debarment proceedings by any Regulatory Authority.

(c) Know-How and IP Protection. All of a Party's employees and other Persons acting on such Party's behalf, in each case with access to Know-How and Inventions as contemplated herein, are obligated to maintain the confidentiality of such Know-How and Inventions and not use such Know-How or Inventions for any purpose inconsistent with the terms and conditions of this Agreement. All of a Party's employees and other Persons performing activities hereunder on behalf of such Party in accordance herewith will be obligated to assign all rights, title and interests in and to any Inventions developed by them in connection with such activities, whether or not patentable, to such Party.

16.4. No Other Warranties.

EXCEPT AS EXPRESSLY STATED HEREIN, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF JANSSEN OR MEIRAGTX; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

17. INDEMNIFICATION; LIABILITY; INSURANCE

17.1. Indemnification by MeiraGTx.

MeiraGTx shall indemnify, defend and hold Janssen, its Affiliates and Sublicensees, and their respective officers, directors, employees and agents ("**Janssen Indemnitees**") harmless from and against any Damages arising out of or resulting from any Claims of Third Parties against them to the extent arising or resulting from:

(a) the negligence, gross negligence or willful misconduct of any MeiraGTx Indemnitee or contractor in connection with this Agreement;

(b) the breach of any of the covenants, agreements, warranties or representations made by MeiraGTx to Janssen under this Agreement;

(c) MeiraGTx's Research activities with respect to any Research IRD Products prior to the respective Option Election Date, including pursuant to Section 2.2(a) and Section 3.3;

(d) MeiraGTx's Research or Development activities with respect to the [***] Product unless and until Janssen elects to make the [***] Product a Clinical IRD Product pursuant to Section 2.1(b);

(e) MeiraGTx's Research or Development activities with respect to any Clinical IRD Product, including its Clinical Development Plan Activities pursuant to Section 6.1(c) and Section 6.1(e), and, prior to the Sponsorship Transfer Date, regulatory activities pursuant to Section 7.1(a); or

(f) MeiraGTx's Manufacturing activities with respect to any Product, including Manufacturing Products pursuant to Section 8.1, any Supply Agreement or any Quality Agreement, and conducting CMC Development Plan Activities pursuant to Section 8.4(a);

except that MeiraGTx shall not be obliged to so indemnify the Janssen Indemnitees for any Claim to the extent that Janssen has an obligation to indemnify MeiraGTx Indemnitees pursuant to Section 17.2 for such Claim.

17.2. Indemnification by Janssen.

Janssen shall indemnify, defend and hold MeiraGTx, its Affiliates and Sublicensees, and their respective officers, directors, employees and agents ("**MeiraGTx Indemnitees**") harmless from and against any Damages arising out of or resulting from any Claims of Third Parties against them to the extent arising or resulting from:

(a) the negligence, gross negligence or willful misconduct of any Janssen Indemnitee or contractor in connection with this Agreement;

(b) the breach of any of the covenants, agreements, warranties or representations made by Janssen to MeiraGTx under this Agreement;

(c) Janssen's Research, Development or Commercialization activities with respect to any Janssen Research IRD Product pursuant to Section 2.2(a), Section 6.2(a), Section 7.2(a) or Article 9;

(d) Janssen's Development or Commercialization activities with respect to any Clinical IRD Product, including conducting its Clinical Development Plan Activities pursuant to Section 6.1(c) and Section 6.1(e), regulatory activities after [***] pursuant to Section 7.1(a) and Commercialization activities pursuant to Article 9; or

(e) Janssen's Manufacturing activities with respect to any Product, including Manufacturing Products pursuant to the applicable Supply Agreements and conducting its CMC Development Plan Activities pursuant to Section 8.4(a);

except that Janssen shall not be obliged to so indemnify the MeiraGTx Indemnitees for any Claim to the extent that MeiraGTx has an obligation to indemnify Janssen Indemnitees pursuant to Section 17.1 for such Claim.

17.3. Indemnification Procedure.

(a) For the avoidance of doubt, all indemnification claims in respect of a Janssen Indemnitee or MeiraGTx Indemnitee shall be made solely by Janssen or MeiraGTx, respectively.

(b) A Party seeking indemnification hereunder (the "**Indemnified Party**") shall notify the other Party (the "**Indemnifying Party**") in writing reasonably [***] after the assertion against the Indemnified Party of any Claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder (an "**Indemnification Claim Notice**"); *provided*, that the failure or delay to so notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected thereby. The Indemnification Claim Notice shall contain a description of the Claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party shall furnish [***] to the Indemnifying Party copies of all correspondence, communications, and official documents (including court documents) received or sent in respect of such Claim.

(c) Subject to Section 17.3(d) and Section 17.3(e), the Indemnifying Party shall have the right, upon written notice given to the Indemnified Party, to assume the defense and handling

of such Claim, at the Indemnifying Party's sole expense, in which case Section 17.3(d) shall govern. The assumption of the defense of a Claim by the Indemnifying Party shall be construed as acknowledgement that the Indemnifying Party is liable to indemnify any Indemnitee with respect to the Claim, and shall constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. Until the Indemnifying Party gives such written notice to the Indemnified Party, Section 17.3(e) shall govern. An Indemnifying Party will not have the right to conduct the defense of any Claim (a) brought by a Governmental Authority, (b) where such Claim involves injunctive relief (which cannot reasonably be severed from the proceeding for damages) or (c) where the Indemnified Party reasonably believes that the Indemnifying Party does not have the financial resources to discharge its indemnification obligation in full, unless the Indemnifying Party posts a bond to cover such potential indemnification obligations.

(d) Upon assumption of the defense of a Claim by the Indemnifying Party: (i) the Indemnifying Party shall have the right to and shall assume sole control and responsibility for defending and handling the Claim; (ii) the Indemnifying Party may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Claim any law firm or counsel selected by the Indemnifying Party which is reasonably acceptable to the Indemnified Party; (iii) the Indemnifying Party shall keep the Indemnified Party informed of the status of such Claim; and (iv) the Indemnifying Party shall have the right to settle such Claim on any terms the Indemnifying Party chooses; *provided*, *however*, that it shall not, without the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, conditioned, or delayed), agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification under this Agreement or which admits any wrongdoing or responsibility for the Claim on behalf of the Indemnified Party or which involves a conduct restriction or obligation of any kind. The Indemnified Party shall cooperate with the Indemnifying Party and shall be entitled to participate in, but not control, the defense of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party shall furnish such records, information, and testimony, provide witnesses, and attend such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, the Indemnitees, and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided.

(e) If the Indemnifying Party does not assume the defense of the Indemnified Party in accordance with Section 17.3(c), the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party shall keep the Indemnifying Party reasonably informed of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned, or delayed. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no

expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

(f) Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

17.4. Mitigation of Loss.

Each Indemnified Party will take and will procure that the other Janssen Indemnitees (where Janssen is the Indemnified Party) or the MeiraGTx Indemnitees (where MeiraGTx is the Indemnified Party) take all such reasonable steps and actions in order to mitigate any potential Damages under this Article 17.

17.5. Limited Liability.

NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECULATIVE OR PUNITIVE DAMAGES OF ANY KIND ARISING FROM OR RELATING TO THIS AGREEMENT, THE NEGOTIATION OF THIS AGREEMENT OR THE ACTIVITIES CONDUCTED HEREUNDER, OR ANY OTHER DAMAGES NOT REASONABLY FORESEEABLE AS A PROXIMATE RESULT OF THE BREACH OF A PARTY OF THIS AGREEMENT, ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE), REGARDLESS OF ANY NOTICE, AWARENESS OR ADVICE OF THE LIKELIHOOD OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 17.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT INDEMNIFICATION FOR DAMAGES OF THE NATURE DESCRIBED ABOVE THAT ARE PAYABLE TO A THIRD PARTY FOLLOWING A FINAL ADJUDICATION OF THE MATTER IN QUESTION OR A SETTLEMENT EFFECTED IN ACCORDANCE WITH THIS AGREEMENT.

17.6. Insurance Obligations

Each Party, at its own expense, shall procure and maintain during the Term and for a period of [***] thereafter product liability insurance adequate to cover the activities to be conducted by such Party and its obligations under this Agreement that are consistent with normal business practices of prudent companies similarly situated; *provided*, *however*, that in no event shall such product liability insurance be written in amounts less than [***] per claim or per occurrence and annual aggregate. All such insurance shall include worldwide coverage. Prior to the initiation of any Clinical Study of a Product, the Party responsible for such Clinical Study shall secure, and maintain in full force and effect, clinical trial insurance as required by Applicable Law in those territories where such Clinical Study shall be conducted. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Section 17.1 and Section 17.2. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] prior to the cancellation, non-renewal or material change of such insurance that could materially adversely affect the rights of such other Party hereunder. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance shall not relieve that Party of its

obligations set forth in this Agreement. The Parties acknowledge and agree that Janssen may meet its obligations under this Section 17.6 through self-insurance consistent with the levels set forth herein with prior written notice to MeiraGTx. In such event, Janssen shall provide a written certification of such self-insurance to MeiraGTx upon request.

18. DISPUTE RESOLUTION

18.1. Dispute Resolution.

(a) Escalation; Decision-Making Authority. In the case of any dispute, claim or controversy between the Parties arising from or related to this Agreement, or the interpretation, application, breach, termination or validity of this Agreement and which are not subject to Section 5.8(c) (a "**Dispute**"), the Parties will discuss and negotiate in good faith a solution acceptable to the Parties and in the spirit of this Agreement. If, after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement within [***] (or such longer period as agreed in writing by the Parties), then the Dispute may be referred to the Executive Officers for resolution at the request of either Party. If, after negotiating in good faith, the Executive Officers fail to reach agreement within [***] of submission to the Executive Officers (or such longer period as agreed in writing by the Parties), then either Party may upon written notice to the other submit the Dispute to non-binding mediation pursuant to Section 18.1(b).

(b) Mediation.

(i) If the Parties fail to resolve the Dispute pursuant to Section 18.1(a), the Parties shall attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then-current Mediation Procedure of the International Institute for Conflict Prevention and Resolution ("**CPR Mediation Procedure**") (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York.

(ii) Either Party may initiate mediation by written notice to the other Party of the existence of a Dispute. The Parties agree to select a mediator within [***] of the notice and the mediation will begin [***] after the selection. The mediation will continue until the mediator, or either Party, declares in writing, no sooner than after the conclusion of [***] of a substantive mediation conference attended on behalf of each Party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than [***] from the initial notice by a Party to initiate meditation unless the Parties agree in writing to extend that period.

(iii) Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until [***] after the conclusion of the mediation.

(c) Arbitration. If the Parties fail to resolve the Dispute pursuant to Section 18.1(a) or Section 18.1(b), and a Party desires to pursue resolution of the Dispute, subject to Section 18.5, the Dispute shall be resolved by final and binding arbitration as follows:

(i) The Dispute shall be finally resolved by arbitration in accordance with the then-current CPR Rules for Non-Administered Arbitration Rules ("**CPR Rules**") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The place of arbitration shall be New York, New York. All aspects of the arbitration shall be treated as confidential.

(ii) Whenever a Party decides to institute such arbitration proceedings, such Party shall as [***] as practicable, give written notice to that effect to the other Party. The law of this arbitration clause shall be the law of New York, USA, the seat and venue of the arbitration shall be New York, USA, and the arbitration proceedings shall be conducted in the English language. The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by both Parties. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. There shall be three (3) arbitrators for the Dispute, selected as follows: each Party shall select an arbitrator in accordance with the "screened" appointment procedure provided in CPR Rule 5.4, and the chair will be chosen in accordance with CPR Rule 6.4. If, however, the aggregate award sought by the Parties is less than [***] and equitable relief is not sought, a single arbitrator shall be appointed in accordance with the CPR Rules. Candidates for the arbitrator position(s) may be interviewed by representatives of the Parties in advance of their selection, *provided* that all Parties are represented.

(iii) The hearing on the merits shall be concluded within [***] after the initial prehearing conference and the award shall be rendered within [***] of the conclusion of the hearing, or of any post-hearing briefing, which briefing shall be completed by both sides within [***] after the conclusion of the hearing, unless the arbitrator(s) determine(s), in a reasoned decision, that the interest of justice or the complexity of the case requires that the time limit for concluding the hearing on the merits or rendering the award be extended. In the event the Parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical.

(iv) The hearing on the merits will be concluded in [***] or less, unless the arbitrator(s) determine(s), in a reasoned decision, that the interest of justice or the complexity of the case requires that the time limit for concluding the hearing on the merits or rendering the award be extended. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A transcript of the testimony adduced at the hearing shall be made and shall be made available to each Party.

(v) The Parties shall allow and participate in discovery in accordance with the United States Federal Rules of Civil Procedure. Unresolved discovery disputes shall be submitted to the arbitrator(s).

(vi) The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "*amiable compositeur*" or "*natural justice and equity*."

(vii) The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs.

(viii) The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the entry of judgment on any award rendered hereunder. Judgment on the award may be entered in any court of competent jurisdiction.

(ix) The award of the arbitral tribunal shall be final and binding upon the Parties, and the prevailing Party may apply to a court of competent jurisdiction for enforcement of such award. When any Dispute occurs and when any Dispute is under arbitration, except for the matters in Dispute, the Parties shall continue to fulfill their respective obligations and shall be entitled to exercise their rights under this Agreement. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Applicable Law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties. Notwithstanding anything to the contrary contained in this Agreement, each Party to the Dispute shall be entitled to seek provisional remedies, interim measures of protection and emergency relief, if possible, such as attachment, preliminary injunction, replevin or other equitable relief, from the arbitral tribunal or any court of competent jurisdiction in accordance with the Applicable Laws of that jurisdiction in order to avoid irreparable harm, maintain the status quo, preserve its status and priority as a creditor or preserve the subject matter of the Dispute.

(d) Waivers. EACH PARTY HERETO WAIVES: (I) ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY AND (II) ANY CLAIM FOR ATTORNEY FEES, COSTS AND PREJUDGMENT INTEREST; *PROVIDED*, *HOWEVER*, THAT THE FOREGOING WILL NOT LIMIT A PARTY'S OBLIGATIONS IN RESPECT OF DAMAGES CLAIMED BY A THIRD PARTY.

18.2. Governing Law.

This Agreement shall be governed by and construed under the laws of the State of New York, without giving effect to the conflicts or choice of laws provision thereof ("**Governing Law**"). The United Nations Convention on Contracts for the International Sale of Goods (1980) shall not apply to the interpretation of this Agreement.

18.3. Exclusions.

Nothing in this Article 18 shall preclude a Party from: (a) seeking and obtaining in any competent court injunctive or equitable relief to preserve the status quo or prevent immediate harm to the Party; or (b) submitting any dispute, controversy or Claim relating to the scope, validity, enforceability or infringement of any Patents or Trademarks to adjudication in accordance with the Applicable Laws of the country or jurisdiction in which the relevant patent is pending or has been issued, including before any patent or trademark administrative body in the country in which such Patent or Trademark was granted or arose. The Parties agree that the venue of any such adjudication involving a patent pending in or issued by the United States will be a U.S. federal district court sitting in New York, New York or an appellate body of such court, and for a patent

pending in or issued by any other country, any competent court having jurisdiction over the subject of the Patent controversy or Claim sitting in the capital of such country (or if there is not any such competent court in the capital, a location reasonably proximate to the capital), and each Party hereby irrevocably submits to the jurisdiction of such courts or administrative bodies.

18.4. Cumulative Remedies.

Unless expressly stated otherwise in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to, and not in lieu of, any other remedy referred to in this Agreement or otherwise available to either Party under Applicable Law.

18.5. Injunctive Relief.

Notwithstanding anything to the contrary set forth in this Agreement, the Parties each stipulate and agree that given the nature of the Confidential Information and Intellectual Property Rights and the competitive damage and irreparable harm that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information or Intellectual Property Rights to any Third Party, monetary damages may not be a sufficient remedy for any breach of Section 4.4, Article 11, Article 12 or Article 13 by a Party. In the case of any such breach or threatened breach, in addition to all other remedies, the non-breaching Party will be entitled to seek equitable relief (including temporary or permanent restraining orders, specific performance or other injunctive relief) for any such breach or threatened breach from any court of competent jurisdiction without first submitting to the dispute resolution procedures set forth in Section 18.1.

19. GENERAL PROVISIONS

19.1. Assignment.

Subject to Section 4.6(d) and Section 4.6(e), neither Party may assign its rights or obligations under this Agreement, in whole or in part, without the other Party's prior written consent, except that either Party may assign this Agreement, in whole or in part, without the other Party's consent to: (a) an Affiliate of the assigning Party; or (b) any Third Party successor or purchaser of all or substantially all of its business or assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other similar transaction. In addition, Janssen may, without the prior written consent of MeiraGTx, assign its rights and obligations, in whole or in part, under this Agreement to a Third Party, where Janssen or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest any Products in order to comply with Applicable Law or the order of any Governmental Authority as a result of a merger or acquisition or similar transaction. In any such case, Janssen shall provide MeiraGTx with advance notice of any such assignment. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). For clarity: (i) an assignment to an Affiliate will terminate, and all rights so assigned will revert to the assigning Party, if and when such Affiliate ceases to be an Affiliate of the assigning Party; and (ii) sublicensing of any licenses granted under this Agreement will be governed by Section 4.1(c) and Section 4.3. Any attempted assignment in contravention of the foregoing will be null and void.

Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

19.2. Extension to Affiliates.

Each Party may discharge any obligations and exercise any rights under this Agreement through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party. Any reference to performance by a Party hereunder includes any performance by its Affiliates.

19.3. Severability.

If any of the provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement shall be construed as if such provision were not contained herein, the remainder of this Agreement shall be in full force and effect, and the Parties will negotiate in good faith to substitute any invalid or unenforceable provision with a valid and enforceable provision such that this Agreement conforms as nearly as possible with the original intent of the Parties.

19.4. Force Majeure.

If either Party is prevented from performing its obligations under this Agreement due to any contingency beyond its reasonable control ("**Force Majeure**"), including acts of Governmental Authorities, any war, terrorism, hostilities between nations, civil commotions, riots, national industry strikes, sabotage, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, the Party so affected shall not be responsible to the other Party for any delay or failure of performance of its obligations hereunder, for so long as and to the extent that such Force Majeure prevents such performance. If a Force Majeure arises, the Party immediately affected thereby shall give prompt written notice to the other Party specifying the Force Majeure event complained of, and shall use Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence to resume performance of its obligations with reasonable dispatch.

19.5. Waivers and Amendments.

The delay or failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right, term or condition or excuse a similar subsequent failure to perform any such term or condition by the other Party, and no waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, in any one (1) or more instances, will be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

19.6. Relationship of the Parties.

Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between MeiraGTx and Janssen or their respective Affiliates, or to constitute one as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

19.7. Notices.

All notices, consents, waivers, and other communications under this Agreement must be in writing, in the English language, and will be deemed to have been duly given when: (a) delivered by hand; (b) when sent by an internationally recognized overnight delivery service (receipt requested); or (c) when sent by confirmed email, in each case, to the appropriate addresses set forth below (or to such other addresses as a Party may designate by notice in accordance with this Section 19.7):

If to MeiraGTx:

MeiraGTx UK II Limited
25 Provost Street
London N1 7NH
Email: [***]
Attn: Chief Operating Officer

with a copy to:

MeiraGTx – US
430 East 29th Street, 10th Floor
New York, NY 10016
Attn: Chief Operating Officer

If to Janssen:

Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Road
Titusville, NJ 08560
Attention: President

with a copy to:

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
Attn: General Counsel, Pharmaceuticals

Any such notice shall be deemed to have been given on the date delivered. A Party may add, delete (so long as at least one (1) person is remaining) or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 19.7.

19.8. Further Assurances.

Janssen and MeiraGTx hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver, and to cause to be executed, acknowledged, and delivered, any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

19.9. No Third Party Beneficiary Rights.

The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights to any Third Party (including any third party beneficiary rights), except with respect to certain Janssen Indemnitees and certain MeiraGTx Indemnitees, who are Third Parties, solely with respect to Article 17.

19.10. English Language.

This Agreement was prepared and executed in the English language, which language shall govern the interpretation of, and any disputes regarding, the terms of this Agreement. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

19.11. Interpretation.

Unless the context of this Agreement otherwise requires:

(a) references to an Article, Section or Exhibit means an Article or Section of, or Exhibit to, this Agreement, unless another agreement is specified;

(b) the term "including" (in its various forms) means "including without limitation";

(c) a particular statute or statutory instrument, regulation or any of their provisions shall include all rules and regulations thereunder and shall be construed as a reference to that statute or statutory instrument, regulation or such provision as the same may have been or may from time to time hereafter be modified, amended or re-enacted;

(d) words denoting the singular shall include the plural and vice versa, and words denoting any gender shall include all genders;

(e) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement;

(f) the Exhibits and other attachments form part of the operative provisions of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits and attachments;

(g) the headings in this Agreement, in any Exhibit to this Agreement and in the table of contents to this Agreement are for information and convenience only and shall not in any way affect the construction of or be considered in the interpretation of this Agreement;

(h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement;

(i) the word "or" will be interpreted in the inclusive sense commonly associated with the term "and/or";

(j) "days" refers to calendar days;

(k) the terms "hereof", "herein", "hereby", and derivative or similar words refer to this entire Agreement;

(l) general words shall not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things;

(m) the words "shall" and "will" have the same meaning; and

(n) the Parties agree that each Party has been represented by legal counsel in connection with this Agreement, the terms and conditions of this Agreement are the result of negotiations between the Parties, each Party has participated in the drafting hereof, and the terms and provisions of this Agreement shall not be construed and applied in favor of or against any Party by reason of the extent to which any Party participated in the preparation of this Agreement.

19.12. Entire Agreement.

This Agreement, together with its Exhibits, which are incorporated by reference herein, sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and supersedes all prior discussions, representations, understandings, agreements, proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter; *provided*, *however*, that the Prior CDA shall survive in accordance with its terms, except that any Information (as defined in the Prior CDA) that was disclosed by MeiraGTx LLC under the Prior CDA and that relates to the subject matter of this Agreement will be deemed Confidential Information of MeiraGTx under this Agreement and treated in accordance with the terms and conditions of Article 12 and Article 13. If any conflict between a substantive provision of this Agreement and any Exhibit hereto arises, the substantive provisions of this Agreement shall prevail.

19.13. Counterparts.

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which taken together shall be deemed to constitute one and the same single instrument. Signature pages of this Agreement exchanged by facsimile or other electronic transmission will be deemed to be as effective as an original executed signature page.

[*Signature Pages Follow*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

MEIRAGTX UK II LTD

By: /s/ Alexandria Forbes
Name: Alexandria Forbes
Title: Chief Executive Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

MEIRAGTX HOLDINGS PLC

By: /s/ Alexandria Forbes
Name: Alexandria Forbes
Title: Chief Executive Officer

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

JANSSEN PHARMACEUTICALS, INC.

By: /s/ Jeffrey N. Smith
Name: Jeffrey N. Smith
Title: Vice President

Exhibit 1.34

Clinical Development Plans, Including Anticipated Costs and Timelines

See attached for anticipated costs and timelines.

Initial Clinical Development Plans to be attached upon approval as Exhibits 1.34-4, -5, -6 and (as applicable) -7 in accordance with Section 6.1(c).

Exhibit 1.34-1

Anticipated Costs and Timelines – CNGA3 Product

[***]

Exhibit 1.34-2

Anticipated Costs and Timelines – CNGB3 Product

[***]

Exhibit 1.34-3

Anticipated Costs and Timelines – RPGR Product

[***]

Exhibit 1.51

CMC Development Plans

To be attached upon approval.

Exhibit 1.103

Final Report Requirements

Required

[***]

Exhibit 1.136

J&J Universal Calendar for 2019 and 2020

[***]

Exhibit 1.168

MeiraGTx Patents

[***]

Exhibit 1.221

IRD Genes

[***]

Exhibit 1.223

Research Plans

To be attached upon approval.

Exhibit 3.4

Research Budget Cap

Calendar Year	2019	2020	2021
Research Budget Cap*	[***]	[***]	[***]

* Total budget to be [***] in accordance with Section 3.8. Includes all pre-clinical work required to [***].

Exhibit 3.5

Janssen Data Policies

JANSSEN DATA GENERATION, PROCESSING AND STORAGE POLICIES

[***]

Exhibit 4.4

MeiraGTx Subcontractors

Subcontractor	**Activities**
[***]	

MeiraGTx Commitments to Engage Scheduled Subcontractors: [***]

Exhibit 8.2

Key Terms of Clinical Supply Agreement and Clinical Quality Assurance Agreement

The Clinical Supply Agreement will substantially contain the following provisions:

[***]

Exhibit 8.3

Key Terms of Commercial Supply Agreement and Commercial Quality Assurance Agreement

The Commercial Supply Agreement will substantially contain the following provisions:

[***]

Exhibit 8.4(a)

CMC Development Plan Activities – Breakdown

[***]

Exhibit 16.2(b)

Third Party Rights

[***]

Exhibit 16.2(g)

MeiraGTx Existing Third Party Obligations

[***]

Exhibit 10.49

EXECUTION VERSION

Certain information marked as [***] has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

HOLOGEN NEURO AI LIMITED

FRAMEWORK AGREEMENT

Dated as of March 9, 2025

TABLE OF CONTENTS

		Page
1.	DEFINITIONS.	7
2.	INCORPORATION MATTERS.	15
	2.1 Incorporation	15
	2.2 Name	15
	2.3 Registered Office	15
	2.4 Term	15
	2.5 Purpose and Powers	15
	2.6 Limited Liability	15
	2.7 Principal Office	16
3.	RELATIONSHIP BETWEEN THIS AGREEMENT AND THE ARTICLES.	16
	3.1 No Amendment of the Articles	16
	3.2 Conflict	16
	3.3 Compliance with the Articles	16
4.	CONDITIONS TO COMPLETION.	16
	4.1 Completion Conditions	16
	4.2 Efforts to Satisfy the Foreign Investment Clearances Condition	16
	4.3 No Obligation to Disclose Sensitive Information	17
	4.4 Non-Satisfaction of Conditions	17
	4.5 Notification of Satisfaction of Completion Condition	18
	4.6 Conduct of Business Prior to Completion	18
5.	POST COMPLETION MATTERS.	18
	5.1 Effect from Completion	18
6.	COMPLETION.	18
	6.1 Completion	18
	6.2 Completion Actions	18
	6.3 Failure to Comply with Obligation	18
	6.4 Right to Defer Completion	19
7.	FUNDING	19
	7.1 Hologen Commitment	19

TABLE OF CONTENTS
(continued)

		Page
8.	MEMBERSHIP AND SHARES.	19
	8.1 Members	19
	8.2 Shares	19
	8.3 Voting	19
	8.4 Specific Limitations	19
	8.5 Additional Members and Shares	19
	8.6 Certification	19
9.	DISTRIBUTIONS.	19
	9.1 Determination	19
	9.2 Distributions.	20
	9.3 No Violation	21
10.	STATUS, RIGHTS AND POWERS OF MEMBERS.	21
	10.1 No Management or Control	21
	10.2 Member Duties	21
11.	BOARD OF DIRECTORS AND INVESTOR RIGHTS.	22
	11.1 Board of Directors.	22
	11.2 Authority of Board of Directors	24
	11.3 Actions Requiring Director Supermajority	25
12.	KEY MANAGEMENT PERSONNEL.	25
	12.1 Management Team	25
	12.2 Key Management Personnel	25
13.	BOOKS, RECORDS, ACCOUNTING AND REPORTS.	25
	13.1 Books and Records	25
	13.2 Inspection	25
	13.3 Filings	26
	13.4 Non-Disclosure.	26
	13.5 Information Rights	27
14.	TAX MATTERS.	28
	14.1 ECI	28

TABLE OF CONTENTS
(continued)

		Page
	14.2 Tax Residence	28
	14.3 Listed Transactions	29
	14.4 Tax Information	29
15.	TRANSFER OF SHARES.	29
	15.1 Restricted Transfer.	29
	15.2 Permitted Transferees	29
	15.3 Transfer Requirements	29
	15.4 Admission as a Member	30
	15.5 Withdrawal of Member	30
	15.6 Additional Transfer Restrictions	30
16.	RIGHT OF FIRST REFUSAL; RIGHT OF CO-SALE; PREEMPTIVE RIGHTS; AND DRAG-ALONG RIGHTS.	30
	16.1 Right of First Refusal.	30
	16.2 Right of Co-Sale.	32
	16.3 Effect of Failure to Comply with Right of First Refusal and Right of Co-Sale.	33
	16.4 Preemptive Rights	34
	16.5 Drag-Along Right.	35
17.	DISSOLUTION OF COMPANY.	37
	17.1 Termination of Membership	37
	17.2 Events of Dissolution	38
	17.3 Liquidation	38
	17.4 No Action for Dissolution	38
	17.5 No Further Claim	38
18.	INDEMNIFICATION.	38
	18.1 General Indemnification Rights	38
	18.2 Indemnification for Claims Brought by Indemnified Person	39
	18.3 Advancement of Defense Costs	39
	18.4 Company as Primary Indemnitor	39
	18.5 Persons Entitled to Indemnity	39

TABLE OF CONTENTS
(continued)

			Page
	18.6	Obligation to Indemnify is Non-Recourse	40
	18.7	Procedure Agreements	40
	18.8	Reliance, etc.	40
	18.9	Directors' and Officers' Insurance	40
	18.10	Limitations	40
	18.11	Period	40
19.	WARRANTIES BY THE MEMBERS.		40
	19.1	Financial Capability	40
	19.2	Compliance with Anti-Bribery Laws and Anti-Money Laundering Laws	40
	19.3	Beneficial Ownership	41
	19.4	Compliance with Sanctions Laws	41
	19.5	Competing Product	41
	19.6	Purchase for Own Account	42
	19.7	Duly Formed	42
	19.8	Knowledge and Experience	42
	19.9	Economic Risk	42
	19.10	Solvency	42
	19.11	Binding Agreement	42
	19.12	No Breach	42
	19.13	Disputes	42
	19.14	Consents	43
	19.15	Company Covenants	43
20.	COMPANY WARRANTIES.		43
	20.1	Duly Formed	43
	20.2	Activities in Other Jurisdictions	43
21.	ADDITIONAL COVENANTS.		43
	21.1	Non-Competition; Non-Solicitation	43
	21.2	Change of Control Notice	45
	21.3	Licenses and Permits	45

TABLE OF CONTENTS
(continued)

		Page
	21.4 Compliance with Laws	45
	21.5 Unrelated Business Taxable Income	45
	21.6 United States Trade or Business	45
	21.7 PFIC/CFC	45
	21.8 Notice of Noncompliance	45
22.	AMENDMENTS TO AGREEMENT.	46
	22.1 Amendments	46
	22.2 Binding Effect	46
23.	GENERAL	46
	23.1 Successors; Governing Law	46
	23.2 Notices	46
	23.3 Severability	47
	23.4 Construction	47
	23.5 Table of Contents, Headings	47
	23.6 No Third Party Rights	47
	23.7 Entire Agreement	47
	23.8 Effect of Waiver or Consent	48
	23.9 Counterparts and Electronic Delivery	48
	23.10 Jurisdiction and Venue	48
	23.11 Business Days	48
	23.12 Survival	48
	23.13 Gender	48
	23.14 Currency	49
SCHEDULE 6.2 COMPLETION DELIVERIES		50
SCHEDULE 6.2 – ANNEX A COLLABORATION AND LICENSE AGREEMENT		52
SCHEDULE 8.5 DEED OF ADHERENCE		53

HOLOGEN NEURO AI LIMITED

FRAMEWORK AGREEMENT

This Framework Agreement (as may be amended from time to time, this "Agreement"), dated as of March 9, 2025 (the "Effective Date"), is made as a DEED by and among:

(1) Hologen Limited, a non-cellular company limited by shares incorporated in Guernsey with company number 74905 whose registered office is at c/o Elysium Fund Management, 1st Floor, Royal Chambers, St. Julian's Avenue, St. Peter Port, GY1 3JX, Guernsey ("Hologen");

(2) Hologen Neuro AI Limited, a non-cellular company limited by shares incorporated in Guernsey with company number 74942 whose registered office is at c/o Elysium Fund Management, 1st Floor, Royal Chambers, St Julian's Avenue, St Peter Port, GY1 3JX, Guernsey (the "Company");

(3) MeiraGTx Neuro UK Limited, a private company limited by shares incorporated in England with company number 16108121 and having a place of business at 92 Britannia Walk, London N1 7NQ UK ("MeiraGTx");

(4) MeiraGTx Holdings plc, a Cayman Islands exempted company having a place of business at 450 East 29th Street, 14th Floor, New York, NY 10016, USA ("MeiraGTx Holdings," and together with Hologen, the Company and MeiraGTx, the "Parties," and each a "Party");

and each other Person who at any time after the Effective Date becomes a Party to this Agreement in accordance with the terms of this Agreement and the Act.

RECITALS

WHEREAS, the Parties hereto wish to cooperate and leverage their respective experiences, knowledge and expertise in order to explore and expand the business opportunities of the Parties and their respective Affiliates under the terms set out in this Agreement;

WHEREAS, the Company has been incorporated in Guernsey, as a non-cellular company limited by shares on December 30, 2024;

WHEREAS, at Completion, the Company shall enter into that certain Subscription Agreement with MeiraGTx and Hologen (the "Subscription Agreement"), pursuant to which (i) the Company shall issue to MeiraGTx, and MeiraGTx shall subscribe for, Class A Shares representing thirty percent (30%) of the entire issued share capital of the Company in exchange for the collaboration services MeiraGTx will provide under the Collaboration Agreement (as defined below) (the "MeiraGTx Subscription") and (ii) the Company shall issue to Hologen, and Hologen shall subscribe for, Class B Shares representing seventy percent (70%) of the entire issued share capital of the Company (the "Hologen Subscription"); and

WHEREAS, the Company and the Members desire to enter into this Agreement to provide for, among other things, the management of the business and affairs of the Company, the distribution policy, the respective rights and obligations of the Members to each other and to the Company and certain other matters as described herein.

NOW, THEREFORE, in consideration of the mutual covenants expressed herein, the Parties hereby agree as follows:

AGREEMENT

1. DEFINITIONS.

For purposes of this Agreement (a) certain capitalized terms have specifically defined meanings set forth below, (b) references to "Exhibits," "Recitals" and "Sections" are to Exhibits, Recitals and Sections of this Agreement, unless explicitly indicated otherwise, (c) references to statutes include all rules and regulations thereunder, and all amendments and successors thereto from time to time and (d) the word "including" shall be construed as "including without limitation."

"Act" means the Companies (Guernsey) Law 2008, as amended.

"Additional Consideration" is defined in Section 9.2(d).

"Affiliate" means, with respect to a specific Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including, without limitation, any general partner, managing member, officer, director or trustee of such Person, or any venture capital fund or other investment fund now or hereafter existing that is controlled by one or more general partners, managing members or investment advisers of, or shares the same management company or investment adviser with, such Person; and "control" (including the terms "controlling," "controlled by," and "under common control with") means, with respect to an entity, having the power to direct the affairs of the entity by reason of (a) having the power to elect or appoint, through ownership membership or otherwise, either directly or indirectly, more than fifty percent (50%) of the board of directors or other governing body of the entity, (b) owning or controlling the right to vote more than fifty percent (50%) of the voting right attaching to the shares or other voting interests of the entity or (c) having the right to direct the general management of the affairs or policies of the entity by contract or otherwise.

"Agreement" is defined in the Preamble.

"Anti-Bribery Laws" means laws, regulations or orders relating to anti-bribery or anti-corruption (governmental or commercial), without limitation, laws that prohibit the corrupt payment, offer, promise, or authorisation of the payment or transfer of anything of value (including gifts or entertainment), directly or indirectly, to any government official, commercial entity, or any other person to obtain a (business) advantage; such as, without limitation, the United Nations Convention Against Corruption approved by decree dated as of 12 June 2008, the U.S. Foreign Corrupt Practices Act of 1977, as amended from time to time, the Bribery Act 2010, as amended from time to time, and all national and international laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.

"Anti-Money Laundering Laws" means laws, regulations or orders relating to financial recordkeeping and reporting requirements, including those of the (i) European Union Money Laundering Directives and member states' implementing legislation, (ii) the UK Proceeds of Crime Act 2002, (iii) the U.S. Bank Secrecy Act, USA Patriot Act and other US legislation relating to money laundering, including the Currency and Foreign Transactions Reporting Act of 1970, as amended, and (iv) any other laws, regulations and orders relating to money laundering or the proceeds of criminal activity and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity.

"Articles" means the articles of incorporation of the Company as amended from time to time. For the sake of clarity, the Articles as in effect on the Effective Date shall be amended and restated at Completion to provide for the specific terms and conditions set forth in this Agreement and may be referred to herein as the "New Articles".

"Assignee" means any Person who acquires in any manner whatsoever from a Member any Shares or other Equity Interest in the Company.

"Board of Directors" is defined in Section 11.1(a).

"Budget" is defined in Section 13.5(d).

"Business" means the research, development or commercialization of Licensed Products and the Licensed Device (as such terms are defined in the Collaboration Agreement) in accordance with the terms and conditions of the Collaboration Agreement, or any other business that the Board of Directors may approve from time to time.

"Change of Control" means any of the following: (a) any acquisition of the Company by means of any transaction or series of related transactions to which the Company is party (including, without limitation, any stock acquisition, reorganization, merger, consolidation or equity financing) as a result of which a Person or group of related Persons that does not hold greater than fifty percent (50%) of the voting securities of the Company outstanding immediately prior to such transaction or series of transactions, acquires greater than fifty percent (50%) of the total voting power represented by the voting securities of the Company or the surviving entity (or, if the surviving entity is owned by a parent corporation, the surviving entity's parent corporation) outstanding immediately after such transaction or series of transactions, but excluding for these purposes: (i) a consolidation or merger with a wholly owned Subsidiary and (ii) a consolidation or merger effected exclusively to change the domicile of the Company; (b) a sale, lease, conveyance or other disposition of all or substantially all of the assets of the Company; or (c) the exclusive license (without any material field or geography limitation) of all or substantially all of the assets of the Company.

"Class A Shares" means the class A ordinary preference shares of US$0.01 par value each in the capital of the Company with such rights as are set out in the New Articles.

[***]

"Class B Shares" means the class B ordinary preference shares of US$0.01 par value each in the capital of the Company with such rights as are set out in the New Articles.

"Code" means the U.S. Internal Revenue Code of 1986, as amended.

"Collaboration Agreement" means the Collaboration and License Agreement in substantially the form provided in Schedule 6.2 Annex A, by and among MeiraGTx Licensor, MeiraGTx, MeiraGTx Holdings, Hologen, Hologen Neuro UK Limited and the Company, to be dated as of the Completion Date, as amended or restated in accordance with its terms.

"Company" is defined in the Recitals.

"Company Notice" means written notice from the Company notifying the selling Member that the Company intends to exercise its Right of First Refusal as to some or all the Transfer Shares with respect to any Proposed Transfer.

"Company Undersubscription Notice" is defined in Section 16.1(d).

"Competing Product" means [***].

"Competitor" means any Person that is engaged, directly or indirectly, in whole or in part, in the Business anywhere in the world.

"Completion" means completion of the MeiraGTx Subscription and the Hologen Subscription pursuant to the Subscription Agreement.

"Completion Conditions" is defined in Section 4.1(c).

"Completion Date" means the date of Completion.

"Confidential Information" is defined in Section 13.4(a).

"Convertible Shares" means evidences of indebtedness, Shares or other securities or obligations that are, directly or indirectly, convertible into or exercisable or exchangeable for, with or without payment of additional consideration, Equity Interests. Equity Interests issuable upon conversion of Convertible Shares shall be deemed outstanding and issued or sold at the time of such issue or sale.

"Deemed Liquidation Event" means a Change of Control or a liquidation pursuant to Section 17.3.

"Director(s)" is defined in Section 11.1(a).

"Director Supermajority" is defined in Section 11.1(b).

"Distributable Profits" is defined in Section 9.2(a)(i).

"Distribution" means cash distributed by the Company to a Member in respect of the Member's Shares whether by liquidating distribution, non-liquidating distribution or otherwise; provided, that a Distribution does not include any redemption or repurchase by the Company of any Shares or any recapitalization or exchange or distribution of Shares, any subdivision (by Share

split or otherwise) or any combination (by reverse Share split or otherwise) of any outstanding Shares.

"Effective Date" is defined in the Preamble.

"Encumbrance" means any mortgage, pledge, lien, charge, assignment, hypothecation, or other agreement or arrangement which has the same or a similar effect to the granting of security.

"Equity Interest" means (i) any equity interest, share, depositary receipt or other certificate representing any share, membership or other percentage interest or other equivalent (however designated) of an equity interest in any Person, and (ii) any options, warrants, purchase rights, subscription rights, conversion rights, exchange rights or other contractual obligations (including Convertible Shares) that would entitle the holder thereof to any share in the equity, profit, earnings, gains, losses, revenues or cash flows of such Person or any stock appreciation, phantom stock, profit participation or similar rights and other contractual obligations similar to such Equity Interests.

"Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended and applicable rules and regulations thereunder.

"Exercising Member" is defined in Section 16.1(d).

"Exercising Member Notice" means written notice from a Major Member notifying the Company and the selling Member that such Major Member intends to exercise its Secondary Refusal Right as to a portion of the Transfer Shares with respect to any Proposed Transfer.

"Exercising Member Notice Period" is defined in Section 16.1(d).

"Expenses" is defined in Section 18.1.

"FDI Authority" means the Investment Screening Unit of the UK Cabinet Office.

"Fiscal Year" means the fiscal year of the Company, which shall be the calendar year, or such other fiscal year as determined by the Board of Directors consistent with applicable law.

"Foreign Investment Clearances" means the Secretary of State notifying the Parties pursuant to Section 17(8) of the NSIA Act that no further action will be taken in relation to the matters described by this Agreement; or in the event that a call-in notice is given in relation to the matters described in this Agreement, the Secretary of State either giving a final notification that no further action will be taken in relation to the matters described under this Agreement under the NSIA Act or making a final order permitting the MeiraGTx Subscription and Hologen Subscription to proceed subject only to such remedies and requirements as are acceptable to the Parties, and such order not being revoked or varied before Completion.

"Foreign Investment Clearances Condition" is defined in Section 4.1(a).

"Fully Exercising Member" is defined in Section 16.4(b).

"GAAP" is defined in Section 13.2(b).

"Governmental Entity" means any government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any arbitrator or arbitral body.

"Hologen" is defined in the Preamble.

"Hologen AI License" means that certain license agreement in a form mutually agreeable to the Parties to be entered into between Hologen and the Company, pursuant to which Hologen shall license its proprietary AI technology to the Company.

"Hologen Director" is defined in Section 11.1(a).

"Hologen Financing Provider" means any person (including any individual, bank or credit institution) that lends money or provides credit to Hologen, any of the Hologen Investors, or their respective Affiliates for the purpose of allowing Hologen to satisfy its obligations to the Company pursuant to the Subscription Agreement.

"Hologen Investors" means those entities, together with the individuals and ultimate beneficial owners of each of them, each as disclosed in writing to MeiraGTx by Hologen not less than three (3) business days prior to Completion.

"Hologen Subscription" is defined in the Recitals.

"Indemnified Persons" is defined in Section 18.1.

"Initial Consideration" is defined in Section 9.2(d).

"Initial Public Offering" means the admission to, and to trading on, any recognized international stock exchange of any of the shares or securities representing shares of the Company.

"Intellectual Property" means all intellectual property rights, whether registered or unregistered, that are recognized in any jurisdiction of the world, including such rights in patents, utility models, trademarks and tradenames, copyrights, trade secrets, and domain names (and any registrations of or applications to register any of the foregoing).

"Issued Shares" means the Class A Shares and the Class B Shares.

"Key Management Personnel" means each Person holding any of the following titles: Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Executive Vice President, Vice President, Secretary, Treasurer or Controller.

[***]

"Liabilities" means all liabilities of the Company, which, in accordance with generally accepted accounting principles, should be carried as liabilities on the balance sheet of the Company.

"Listed Transaction" is defined in Section 14.3.

"Longstop Date" means the date which is the [***] anniversary of the Effective Date.

"Major Member" means each of Hologen and MeiraGTx and any other future member holding more than or equal to [***] of the share capital of the Company.

"Major Members Election" is defined in Section 16.5(a).

"MeiraGTx" is defined in the Preamble.

"MeiraGTx Director" is defined in Section 11.1(a).

"MeiraGTx Entities" is defined in Section 19.

"MeiraGTx Holdings" is defined in the Preamble.

"MeiraGTx Licensor" means MeiraGTx Neuro I, LLC, a Delaware limited liability company and having a place of business at 450 East 29th Street, 14th Floor, New York, NY 10016, USA.

"MeiraGTx Subscription" is defined in the Recitals.

"Member" means each Person who holds Shares in the Company and has executed this Agreement, and/or any other Person admitted to the Company as a Member, from time to time, in accordance with this Agreement.

"Member Financial Disclosure" is defined in Section 13.2(b).

[***]

"New Shares" means any shares (or securities exercisable for or convertible into shares) of any kind or class issued by the Company after the date hereof.

"NSIA Act" means the National Security and Investment Act 2021.

"Offer Notice" is defined in Section 16.4(a).

"Participating Member" is defined in Section 16.2(a).

"Parties" is defined in the Preamble.

"Party" is defined in the Preamble.

"Permitted Transferee" is defined in Section 15.2.

"Person" means any individual, partnership, joint venture, association, corporation, trust, estate, limited liability company, limited liability partnership, unincorporated entity of any kind, Governmental Entity, or other legal entity.

"Prohibited Transfer" is defined in Section 16.3(c).

"Proposed Sale" is defined in Section 16.5(c).

"Proposed Transfer" means any Transfer of any Transfer Shares (or any interest therein) proposed by any of the Members.

"Proposed Transferee" means the prospective purchaser or transferee of Transfer Shares.

"Representative" means, with respect to any Person, any director, officer, employee, agent, consultant, advisor, or other representative of such Person, including legal counsel, accountants and financial advisors.

"Restricted Period" is defined in Section 21.1(a).

"Retained Amounts" is defined in Section 9.2(a)(ii).

"Right of Co-Sale" means the right, but not an obligation, of a Major Member to participate in a Proposed Transfer on the terms and conditions specified in the Transfer Notice.

"Right of First Refusal" means the right, but not an obligation, of the Company, or its permitted transferees or assigns, to purchase some or all of the Transfer Shares with respect to a Proposed Transfer pursuant to Section 16.1, on the terms and conditions specified in the Transfer Notice.

"Sale of the Company" is defined in Section 16.5(a).

"Sanctioned Person" means a person (i) that is designated or listed under any Sanctions List by any Sanctions Authority, (ii) in which any persons so designated or listed (individual or collectively) have an interest or control with the consequence that such person's property is blocked pursuant to any Sanctions, or (iii) acting on behalf of any of the foregoing.

"Sanctions" means any laws, regulations or trade embargoes relating to blocking (asset freeze) sanctions that envisage blocking of the assets administered or enforced from time to time by any Sanctions Authority.

"Sanctions Authority" means (i) the United Nations Security Council; (ii) the United States government; (iii) the European Union; (iv) the United Kingdom government; (v) the government of Guernsey, (vi) the government of the Cayman Islands, (vii) the respective governmental institutions and agencies of any of the foregoing, including without limitation, the Office of Foreign Assets Control of the US Department of Treasury (OFAC), the United States Department of State and Department of Commerce, and His Majesty's Treasury and the UK Office of Financial Sanctions Implementation (OFSI); and (viii) any other governmental institution or agency with responsibility for imposing, administering or enforcing Sanctions with jurisdiction over any Party.

"Sanctions List" means the Specially Designated Nationals and Blocked Persons List maintained by OFAC, the Consolidated List of Financial Sanctions Targets maintained by His Majesty's Treasury (but only the sub-list for "Asset Freeze Targets" and not the sub-list for "Investment Ban Targets") or any similar list maintained by, or public announcement of sanctions designations made by a Sanctions Authority, each as amended, supplemented or substituted from time to time, provided that, in each case, any such list relates to the so called freezing or blocking sanctions and does not include sanctions known as "sectoral sanctions" that do not envisage blocking of the assets.

"Secondary Notice" means written notice from the Company notifying the Major Members and the selling Member that the Company does not intend to exercise its Right of First Refusal as to all Transfer Shares with respect to any Proposed Transfer.

"Secondary Refusal Right" means the right, but not an obligation, of each Major Member to purchase up to its pro rata portion of any Transfer Shares not purchased pursuant to the Right of First Refusal, on the terms and conditions specified in the Transfer Notice.

"Securities Act" means the U.S. Securities Act of 1933, as amended and applicable rules and regulations thereunder.

"Share Sale" is defined in Section 16.5(a).

"Shares" means the Issued Shares and any further shares in the capital of the Company issued by the Company from time to time during the term of this Agreement.

"Subscription Agreement" is defined in the Recitals.

"Subsidiary" has the meaning given in section 531 of the Act but excluding the provisions of sections 531(6) and (7) of the Act so that overseas companies are included. For purposes hereof, references to a "Subsidiary" of any Person shall be given effect only at such times that such Person has one or more Subsidiaries, and, unless otherwise indicated, the term "Subsidiary" refers to a Subsidiary of the Company.

"Subsidiary Change of Control" means any of the following: (a) any acquisition of a Subsidiary by means of any transaction or series of related transactions to which such Subsidiary is party (including, without limitation, any share acquisition, reorganization, merger, consolidation or equity financing) as a result of which a Person or group of related Persons that does not hold greater than fifty percent (50%) of the voting securities of such Subsidiary outstanding immediately prior to such transaction or series of transactions, acquires greater than fifty percent (50%) of the total voting power represented by the voting securities of such Subsidiary or the surviving entity (or, if the surviving entity is owned by a parent corporation, the surviving entity's parent corporation) outstanding immediately after such transaction or series of transactions, but excluding for these purposes: (i) a consolidation or merger with a wholly owned Subsidiary of such Subsidiary and (ii) a consolidation or merger effected exclusively to change the domicile of such Subsidiary; (b) a sale, lease, conveyance or other disposition of all or substantially all of the assets of such Subsidiary; or (c) the exclusive license (without any material field or geography limitation) of all or substantially all of the assets of such Subsidiary.

"Transaction Agreements" means the Subscription Agreement and this Agreement.

"Transfer" means any sale, assignment, offer to sell, pledge, mortgage, hypothecation, Encumbrance, abandonment, disposition or other transfer.

"Transfer Notice" means written notice that a Member gives of a Proposed Transfer.

"Transfer Shares" means all Shares and equivalent securities.

2. INCORPORATION MATTERS.

2.1 Incorporation. At Completion, the Company shall (or shall procure) the filing of the New Articles, which shall be in form mutually acceptable to both Hologen and MeiraGTx. At Completion, the Company shall have issued share capital comprised of Class A Shares, representing 30% of the entire issued share capital and Class B Shares, representing 70% of the entire issued share capital. The rights and liabilities of the Members shall be determined pursuant to the Act, this Agreement and the New Articles. To the extent that the rights or obligations of any Member are different by reason of any provision of this Agreement than they would be in the absence of such provision, this Agreement shall, to the extent permitted by the Act and the New Articles, control.

2.2 Name. The business of the Company may be conducted under its registered name or, upon compliance with applicable laws (including the passing of any requisite shareholder resolutions), any other name that the Board of Directors deems appropriate. The Board of Directors shall make, or shall cause to be made, any trading name registrations and similar filings, and any amendments thereto, that the Board of Directors deems appropriate.

2.3 Registered Office. The Company shall maintain a registered office required pursuant to the Act. The Company may, upon compliance with the applicable provisions of the Act, change its registered office from time to time in the discretion of the Board of Directors.

2.4 Term. Subject to the provisions of the Act, the term of the Company shall continue indefinitely unless sooner terminated as provided herein.

2.5 Purpose and Powers. The Company was formed for the object and purpose of, and the nature of the business to be conducted and promoted by the Company is, engaging in any lawful act or activity for which limited liability companies may be formed under the Act and engaging in any and all activities necessary, advisable, convenient or incidental thereto, including without limitation activities related to the Business. To the extent consistent with the Act and other applicable laws, the Company shall possess and may exercise such powers and privileges as are necessary, advisable, incidental or convenient to, or in furtherance of the conduct, promotion or attainment of, the business purposes or activities of the Company.

2.6 Limited Liability. Except as otherwise required by the Act, and save for in respect of the amount, if any, for the time being unpaid on the Shares held by such Member, the debts, obligations and liabilities of the Company, whether arising in contract, tort or otherwise, shall be solely the debts, obligations and liabilities of the Company, and no Member shall be obligated personally for any such debt, obligation or liability of the Company solely by reason of being a

Member. All Persons dealing with the Company shall have recourse solely to the assets of the Company for the payment of the debts, obligations or liabilities of the Company.

2.7 Principal Office. The principal executive office of the Company shall be located at such place as the Board of Directors shall establish from time to time. The Board of Directors may establish and maintain such additional offices and places of business of the Company, as it deems appropriate.

3. RELATIONSHIP BETWEEN THIS AGREEMENT AND THE ARTICLES.

3.1 No Amendment of the Articles. Each of the Parties agrees that nothing contained in this Agreement shall be deemed to constitute an amendment to the Articles.

3.2 Conflict. If, during the continuance of this Agreement, there is any conflict between the provisions of this Agreement and of the Articles, then as between the Members, during such period, the provisions of this Agreement shall prevail.

3.3 Compliance with the Articles. Subject to Section 3.2, each of the Parties agrees that at all times while this Agreement is in force and effect it shall fully and punctually perform and comply with all rights and obligations on its part under the Articles.

4. CONDITIONS TO COMPLETION.

4.1 Completion Conditions. Completion is conditional on the following conditions being satisfied:

(a) all Foreign Investment Clearances shall have been obtained (the "Foreign Investment Clearances Condition");

(b) [***]

(c) no law, injunction, order, or decree of any Governmental Entity or court is in effect which temporarily or permanently prohibits or enjoins the consummation of Completion in whole or a material portion thereof, and no Sanctions applying to any Party, nor any of the Hologen Investors or the Hologen Financing Providers, which have the effect of making unlawful, prohibiting, or otherwise restricting Completion or the performance by any Party of its obligations under this Agreement (including, for the avoidance of doubt, circumstances where a transfer of shares in the Company is prohibited or otherwise restricted) (each of Section 4.1(a), Section 4.1(b), and Section 4.1(c) a "Completion Condition" and together the "Completion Conditions"). None of the Completion Conditions may be waived by any Party.

4.2 Efforts to Satisfy the Foreign Investment Clearances Condition. The Parties shall be jointly responsible for contacting and corresponding with any relevant FDI Authority, including the preparation and submission of any necessary filings and notifications as soon as practicable following the date of this Agreement and the Parties agreeing which Foreign Investment Clearances are necessary to consummate the matters described under this Agreement. Each Party shall use all reasonable endeavours to cooperate and procure that the Foreign Investment

Clearances Condition is satisfied as soon as practicable and in any event on or before the Longstop Date and in respect of the foregoing shall:

(a) provide to the others such information and assistance as the others may reasonably request as soon as is reasonably practicable;

(b) as promptly as is reasonably practicable and in any event in accordance with any relevant time limit provide to an FDI Authority such information as it may require, including attending any meetings or calls with an FDI Authority as may be necessary;

(c) to the extent reasonably practicable, before sending any material communication to an FDI Authority provide a draft copy of such communication to the other Parties and allow reasonable time for comments to be provided thereon;

(d) promptly inform the other Parties of any material communication from or with an FDI Authority;

(e) provide to the other Parties copies of all material written communications received by it from, or sent by it to, an FDI Authority, and details of material non-written communications with an FDI Authority;

(f) to the extent reasonably practicable, each Party shall give the other Party reasonable notice of and the opportunity to participate in all meetings and material telephone calls with an FDI Authority unless prevented by the relevant FDI Authority from doing so; and

(g) if at any time any Party becomes aware of a fact or circumstance that is reasonably likely to prevent a Completion Condition being satisfied, it shall immediately inform the other Parties.

4.3 No Obligation to Disclose Sensitive Information. Nothing in Section 4.2 shall require a Party to share information, documents or communications with the other Parties if prohibited by an FDI Authority or any Governmental Entity from doing so. Nothing in Section 4.2 shall require a Party to disclose to or receive from the other Parties any competitively sensitive information or business secrets. In order to comply with their obligations within Section 4.2 the Parties will therefore make arrangements for the provision of copies of relevant information, documents and communications to the other Parties' external advisors on an external advisor only basis together with redacted versions excluding any such competitively sensitive information or business secrets to the other Party.

4.4 Non-Satisfaction of Conditions If one or more of the Completion Conditions remains unsatisfied at the Longstop Date, this Agreement will immediately cease to have any further force and effect except for:

(a) any provision of this Agreement that expressly or by implication is intended to come into or continue in force on or after termination (including Section 1 (*Definitions*), this Section 4.4 (*Non-Satisfaction of Completion Conditions*), Section 13.4 (*Non-Disclosure*) and Section 23 (*General*)), each of which shall remain in full force and effect; and

(b) any rights, remedies, obligations or liabilities of the Parties that have accrued up to the date of termination, including the right to claim damages in respect of any breach of the agreement which existed at or before the date of termination.

4.5 Notification of Satisfaction of Completion Condition. Each Party shall notify the other Parties of the satisfaction of the Foreign Investment Clearances Condition [***] as soon as possible after it has been satisfied and in any event within [***] of such satisfaction.

4.6 Conduct of Business Prior to Completion. Hologen and the Company shall procure that, unless otherwise agreed between the Parties in writing, until Completion, the operations of the Company shall be maintained and conducted in a manner consistent with its operations as at the date of this Agreement and so as to facilitate Completion in accordance with this Agreement.

5. POST COMPLETION MATTERS.

5.1 Effect from Completion. The following provisions of this Agreement are subject to, and will take effect from, Completion: Section 7 (*Funding*), Section 8.4 (*Specific Limitations*), Section 8.5 (*Additional Members and Shares*), Section 9 (*Distributions and Allocations of Profit and Loss*), Section 10 (*Status, Rights and Powers of Members*), Section 11 (*Board of Directors and Investor Rights*), Section 12 (*Key Management Personnel*), Section 13.2 (*Inspection*), Section 13.3 (*Filings*), Section 13.5 (*Information Rights*), Section 14 (*Tax Matters*), Section 15 (*Transfer of Shares*), Section 16 (*Right of First Refusal; Right of Co-Sale; Preemptive Rights; and Drag-Along Rights*), Section 17 (*Dissolution of the Company*), Section 18 (*Indemnification*) and Section 21 (*Additional Covenants*).

6. COMPLETION.

6.1 Completion. Completion will take place through the actions of the appointed solicitors for the Members at 5:00 pm New York time on the second business day following the date on which the Completion Conditions have been satisfied or such other date as may be agreed in writing by the Parties.

6.2 Completion Actions. At Completion, the Members will each comply with their obligations as set out in Schedule 6.2.

6.3 Failure to Comply with Obligation. If a Major Member does not comply with its obligations in Section 6.2 in any material respect, the other Major Member may (at its sole discretion and without prejudice to any other rights or remedies it has, including the right to claim damages for breach of this Agreement):

(a) proceed to Completion;

(b) defer Completion to a date no more than [***] after the date on which Completion would otherwise have taken place; or

(c) terminate this Agreement by notice in writing to the other Major Member (in which case Section 4.4 shall apply).

6.4 Right to Defer Completion. A Major Member may defer Completion under Section 6.3(b) only once, but otherwise this Section 6 applies to a Completion so deferred as it applies where Completion has not been deferred.

7. FUNDING

7.1 Hologen Commitment. Hologen shall fund the Company up to [***] pursuant to the terms and conditions of the Subscription Agreement, [***] of which shall be funded at Completion.

8. MEMBERSHIP AND SHARES.

8.1 Members. As of and subject to Completion, Hologen shall be committed to execute the Subscription Agreement, in exchange for that number of Class B Shares constituting seventy percent (70%) of the entire issued share capital of the Company, and MeiraGTx shall be committed to execute the Subscription Agreement, in exchange for the number of Class A Shares constituting thirty percent (30%) of the entire issued share capital of the Company.

8.2 Shares. The Company's share capital consists of the Class A Shares and the Class B Shares, which shall have the powers, preferences, rights and restrictions set forth in this Agreement and the New Articles (including the right to the Distributions provided for in Section 9).

8.3 Voting. Each Issued Share entitles its holder to one vote per Share.

8.4 Specific Limitations. Except for the consideration to be received for the Class B Shares, without the consent of the Board of Directors, no Member shall have the right or power to: (a) contribute any property to the Company other than cash; (b) cause the winding up and dissolution of the Company, except as set forth in this Agreement, the New Articles, or as required by the Act; or (c) require that property other than cash be distributed upon any Distribution.

8.5 Additional Members and Shares. Subject to Section 11.3, the Board of Directors may issue additional Shares, admit Persons as Members in exchange for such contributions to capital or such other consideration and on such terms and conditions (including vesting and forfeiture provisions in the case of Shares issued to employees and consultants) as it deems fit. Upon the execution of or a deed of adherence substantially in the form set out in Schedule 8.5, together with any other documents or instruments required by the Board of Directors in connection therewith, and the payment of the subscription price specified to be made at such time, a Person shall be admitted to the Company as a Member.

8.6 Certification. The Company may (at the election of the Board of Directors) issue share certificates to each Member in respect of the Shares to which it is entitled.

9. DISTRIBUTIONS.

9.1 Determination. Subject at all times to the provisions of the Act, the amount of any Distributions to any Member at any time shall be determined in accordance with Section 9.2; provided that [***].

9.2 Distributions.

(a) Distribution Amounts. The Parties agree that, subject at all times to the applicable provisions of the Act, and subject to Section 9.3, whenever the amount of a dividend to be paid is to be ascertained:

(i) the total profits of the Company available for distribution within the meaning given in the Act (the "Distributable Profits"), shall be determined by the Board of Directors by reference to the audited accounts for the relevant financial year;

(ii) the Board of Directors shall identify amounts (the "Retained Amounts") which they consider (having regard to all other sources of funding available to the Company) should be retained in order:

(A) to meet reasonably foreseeable commitments and contingencies;

(B) to develop the Business in accordance with the approved Budget and the terms of this Agreement;

(C) to ensure that there is no breach of any covenant or undertaking given by the Company to any lender at the time of the payment and, in the opinion of the Board of Directors, there is not likely to be such a breach within the following [***]; and

(D) to maintain the sound financial standing of the Company.

(iii) such percentage as the Board of Directors determines of the balance (if any) remaining after deducting the Retained Amounts from the Distributable Profits shall be used:

(A) first, to repay any outstanding loans owed to the Members, in accordance with any loan priority and otherwise on a pro rata basis, until all such shareholder loans have been repaid in full;

(B) second, to pay to the holders of Shares by way of dividend on their Shares in accordance with the Section 9.2.

(iv) the Board of Directors will ensure, having regard to the most recent accounts of the Company and any other relevant information / records they deem necessary that the Company satisfies the solvency test as set out in the Act, which requires that:

(A) the Company is able to pay its debts as they become due

(B) the value of the Company's assets is greater than the value of its liabilities; and

(C) the Company satisfies any other requirement in its New Articles or this Agreement.

(b) Liquidating and Non-Liquidating Distributions. Any Distributions, including any Distribution made in connection with any liquidation or winding up of the Company, any Deemed Liquidation Event or any Subsidiary Change of Control, shall be made as follows:

[***]

(c) Distributions – Payment Term. The Parties undertake to procure (so far as they are able) that interim and final dividends are declared or recommended, and approved and paid, in accordance with this Section 9, and that payment of Distribution is made within [***] of their having been declared or approved.

(d) Change of Control or a Subsidiary Change of Control. In the event of a Change of Control or a Subsidiary Change of Control, if any portion of the consideration payable to the Members is payable only upon satisfaction of contingencies (the "Additional Consideration"), the applicable acquisition documentation shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the "Initial Consideration") shall be allocated among the Members in accordance with this Section 9.2(d) as if the Initial Consideration were the only consideration payable in connection with such Change of Control; and (b) any Additional Consideration which becomes payable to the Members upon satisfaction of such contingencies shall be allocated among the Members in accordance with this Section 9.2(d) after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Section 9.2(d), consideration placed into escrow or retained as holdback to be available for satisfaction of indemnification or similar obligations in connection with such Change of Control shall be deemed to be Additional Consideration.

9.3 No Violation. Notwithstanding any provision to the contrary contained in this Agreement, the Company shall not make a Distribution to any Member on account of such Member's Shares in the Company if such Distribution would violate the Act or any other applicable law.

10. STATUS, RIGHTS AND POWERS OF MEMBERS.

10.1 No Management or Control. Except as expressly provided in this Agreement, no Member in its capacity as such shall take part in the conduct of the Company's business or interfere in any manner with the management of the business and affairs of the Company or have any right or authority to act for or bind the Company.

10.2 Member Duties.

(a) Subject at all times to any applicable provisions of the Act, no Member shall have any duty to the Company or to any other Member (including fiduciary duties) except as expressly set forth herein, pursuant to the New Articles, or in other written agreements.

(b) Subject to the approval of the Board of Directors, any Member may lend money to, borrow money from, act as a surety, guarantor or endorser for, guarantee or assume one or more obligations of, provide collateral for, and transact other business with, the Company and, subject to other applicable law, shall have the same rights and obligations with respect to any such matter as a Person who is not a Member.

11. BOARD OF DIRECTORS AND INVESTOR RIGHTS.

11.1 Board of Directors.

(a) Number and Composition. The business of the Company shall be managed by a Board of Directors (the "Board of Directors"), and the Persons constituting the Board of Directors shall be the directors of the Company for all purposes of the Act (each, a "Director", and collectively, the "Directors"). The number of Directors shall initially be five (5). Hologen is entitled to designate and elect three (3) Directors (each a "Hologen Director"). MeiraGTx is entitled to designate and elect two (2) Directors (each a "MeiraGTx Director"). Each Director shall have one vote, save that a Director who is also a proxy shall be entitled, in the absence of his appointor, to a separate vote on behalf of each appointor in addition to his own vote. The chairperson of the Board of Directors shall be a Hologen Director. The chairperson shall not have an additional or casting vote or other special voting powers.

(b) Variations. The provisions of Section 11.1(a) relating to the number of Directors serving on the Board of Directors may be increased or decreased by the approval of at least seventy percent (70%) of the Directors then in office (the "Director Supermajority").

(c) Resignation and Removal; Vacancies. Each Director shall, unless otherwise provided in this Agreement or by law, hold office until such individual resigns, dies or is removed by the Member, Members or Directors who have the right to designate him or her in accordance with this Agreement and the New Articles. A Director may be removed only by the Member, Members or Directors that designated such Director upon delivery of a written notice of removal to the Company and the other Directors. Any vacancy on the Board of Directors created by the resignation, removal, incapacity or death of any Director may only be filled by another Director designated by the Member, Members or Directors who have the right to designate him or her in accordance with this Agreement. Any vacancy on the Board of Directors created by an increase to the number of Directors may be filled by the approval of the Director Supermajority.

(d) Authority. Decisions of the Board of Directors shall be carried out by such Persons appointed by the Board of Directors in the resolution or consent reflecting such decision or in one or more standing resolutions or consents. A decision of the Board of Directors may be amended, modified or repealed, but no such amendment, modification or repeal shall affect any Person who has been furnished a copy of the original vote or resolution that is certified by a duly authorized officer of the Company, until such Person has been notified in writing of such amendment, modification or repeal.

(e) Committees. The Board of Directors may, by vote or resolution of the Board of Directors, delegate any or all of its powers to any committee thereof, and any such committee must consist of at least two (2) Directors. The audit committee of the Board of Directors shall have at least one MeiraGTx Director, provided that both MeiraGTx Directors shall have the opportunity to sit on the audit committee; and at least one MeiraGTx Director shall be given the opportunity to sit on any other committees of the Board of Directors.

(f) Meetings. Meetings of the Board of Directors and any committee thereof may be held at any time and at any place designated in the notice of the meeting, when called by

any Director, reasonable notice thereof being given to each Director by the Person or Persons calling the meeting. Regular or special meetings of the Board of Directors shall be held at the Company's principal offices or at such other place and at such time as shall be determined by the Board of Directors.

(g) Notice of a Meeting of the Board of Directors. It shall be reasonable and sufficient notice to a Director of a meeting of the Board of Directors (i) to send notice by electronic mail at least twenty-four (24) hours before the meeting addressed to such Director at such Director's last known electronic email address, (ii) to send notice by regular mail received at least twenty-four (24) hours before the meeting addressed to such Director at such Director's usual or last known business or residence address, or (iii) to give notice to such Director in person or by telephone at least twenty-four (24) hours before the meeting. Notice of a meeting need not be given to any Director if a written waiver of notice, executed by such Director before or after the meeting, is filed with the records of the meeting, or is delivered to any Director who attends the meeting, or if such Director attends the meeting and does not object to such meeting. Notice of any Directors' meeting must indicate (i) its proposed date and time; (ii) where it is to take place; and (iii) if it is anticipated that Directors participating in the meeting will not be in the same place, how it is proposed that they should communicate with each other during the meeting. Neither notice of a meeting nor a waiver of a notice need specify the purposes of the meeting.

(h) Quorum. Except as may be expressly set forth in this Agreement, at any meeting of the Board of Directors or any committee thereof, a majority of Directors then in office or then serving on such committee, which in the case of a meeting of the Board of Directors must include at least one MeiraGTx Director and two Hologen Directors, or in the case of a meeting of a committee of the Board of Directors, must include one MeiraGTx Director if there is a MeiraGTx Director on such committee and one Hologen Director if there is a Hologen Director on such committee, shall constitute a quorum for such meeting. Except as otherwise expressly set forth in this Agreement, including pursuant to Section 11.3, any action to be taken or approved by the Directors hereunder must be taken or approved by a vote of a majority of Directors present and voting in person at a meeting at which a quorum is present, and any action so taken or approved shall constitute the act of the Board of Directors. If a quorum is not present within thirty (30) minutes of the scheduled time of the meeting of the Board of Directors (or ceases to be present for half an hour) because of the absence of a MeiraGTx Director or a Hologen Director, the meeting shall be adjourned, to be held on the fifth (5th) business day following the date for which the meeting was originally convened with at least twenty-four (24) hours prior notice being given to all Directors (unless all Directors agree otherwise). The quorum for any such adjourned meeting shall be those Directors present (or represented) and entitled to vote at the time of the reconvened meeting. Any meeting may be adjourned from time to time by a majority of the votes cast upon the question, whether or not a quorum is present, and the meeting may be held as adjourned without further notice. Each Director may appoint an alternate director as a proxy for himself in accordance with the Articles.

(i) Written Consent. Except as otherwise expressly set forth in this Agreement, any action required or permitted to be taken at any meeting of the Board of Directors or committee thereof may be taken without a meeting if all of the members of the Board of Directors or a committee then in office or then serving on such committee pass a written resolution to that effect (where permitted under applicable law), and such writing or writings are filed with the records of

the meetings of the Board of Directors or such committee. Such consent shall be treated for all purposes as the act of the Board of Directors or of such committee, as the case may be.

(j) Telephonic Meetings. Directors may participate in a meeting of the Board of Directors by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other and each participant is able to address all of the other participants simultaneously or by any other means permitted by law. Such participation shall constitute presence in person at such meeting.

(k) Director Reimbursement. Each Director shall be reimbursed by the Company for such Director's reasonable out-of-pocket travel expenses incurred in the performance of such Director's duties as Director. Nothing contained in this Section 11.1 shall be construed to preclude any Director from serving the Company in any other capacity and receiving reasonable compensation therefor.

(l) Additional Rules. The Board of Directors may adopt such other rules for the conduct of its business as it may from time to time deem necessary or appropriate.

11.2 Authority of Board of Directors. Subject to applicable law and the provisions of this Agreement that require the consent or approval of one or more Members or other Persons, the Board of Directors shall have the exclusive power and authority to manage the business and affairs of the Company and to make all decisions with respect thereto. Except as otherwise expressly provided in this Agreement, the Board of Directors or Persons authorized by the Board of Directors, shall be the only Persons authorized to execute documents which shall be binding on the Company. Subject to applicable law and the provisions of this Agreement that require the consent or approval of one or more Members or other Persons, the power and authority granted to the Board of Directors hereunder shall include all power and authority necessary, convenient or incidental for the accomplishment of the purposes of the Company and the exercise of the powers of the Company set forth in Section 2.5 above and shall include the power to make, or to grant to other Persons the power to make, all decisions with regard to the management, operations, assets, financing and capitalization of the Company, including the power and authority to undertake and make decisions concerning: (a) hiring and firing employees, officers, attorneys, accountants, brokers, investment bankers and other advisors and consultants, (b) entering into leases for real or personal property, (c) opening bank and other deposit accounts and operations thereunder, (d) borrowing money, obtaining credit, issuing notes, debentures, securities, equity or other interests of or in the Company and securing the obligations undertaken in connection therewith with mortgages on, pledges of and security interests in all or any portion of the real or personal property of the Company, (e) making investments in or the acquisition of securities of any Person, (f) giving guarantees and indemnities, (g) entering into contracts or agreements, whether in the ordinary course of business or otherwise, (h) mergers with or acquisitions of other Persons, (i) dissolution, (j) the sale or lease of all or any portion of the assets of the Company, whether in the ordinary course of business or otherwise, (k) forming subsidiaries or joint ventures, (l) compromising, arbitrating, adjusting and litigating claims in favor of or against the Company, (m) appointment and termination of the auditor of the Company and each of its Subsidiaries, and (n) other matters as provided by resolution of the Board of Directors.

11.3 Actions Requiring Director Supermajority. Without limiting the other terms and conditions hereof or the requirements of the Act, the Company shall not take any of the following actions (or series of related actions) without the approval of the Director Supermajority:

[***]

12. KEY MANAGEMENT PERSONNEL.

12.1 Management Team. Unless otherwise agreed by the Members in writing, the Members shall procure that the Company shall establish a management team which shall consist of one or more Key Management Personnel.

12.2 Key Management Personnel. Each of the Key Management Personnel shall be appointed or removed by the simple majority approval of the Board of Directors. Each of the Key Management Personnel shall exercise such powers as contained in their contract of employment.

13. BOOKS, RECORDS, ACCOUNTING AND REPORTS.

13.1 Books and Records. The Company shall maintain at its principal office (in hard copy or electronic copy) or such other office as the Board of Directors shall determine such books and records with respect to the business of the Company and its Subsidiaries as are required by law and as the Board of Directors deems appropriate, including at least:

(a) A register of members, register of directors (to include, among other things, the directors' residential addresses), register of secretaries and register of people with significant control;

(b) A copy of the Articles, including any amendments thereto;

(c) The most recent financial statements of the Company and its Subsidiaries; and

(d) Copies of tax or information returns of the Company and its Subsidiaries.

13.2 Inspection.

(a) Any Major Member and any Director shall have the right, subject to such reasonable standards (including standards governing what information and documents are to be furnished at what time and location and at whose expense) as may be established by the Board of Directors, to obtain from the Company, from time to time upon reasonable demand for any purpose reasonably related to their respective holding of Shares, the information described in Section 13.1 and such other information regarding the affairs of the Company as is reasonably requested.

(b) In addition, to the extent that a Member's ownership of Shares is required under U.S. generally accepted accounting principles ("GAAP") and applicable rules and regulations promulgated by the Securities and Exchange Commission or any other relevant Governmental Entity to be reflected as an equity method investment in the financial statements of such Member, and such Member is as a result required by law, or such Member is otherwise

required by law, including the disclosure principles of Rule 10b-5 under the Exchange Act, or in connection with ordinary course financing matters, to disclose, with respect to any quarter or fiscal year, financial information (including appropriate treatment for tax matters) in relation to or derived from financial information of the Company (such disclosure, to such extent, a "Member Financial Disclosure"), the Company shall, subject to GAAP and applicable law and upon Member's reasonable prior notice, provide the aforementioned Company information at Member's expense at such times and in such detail as may be reasonably requested by the Member for the purposes of the Member Financial Disclosure (including affording access to Member's independent auditors to review, and if necessary audit, the financial information of the Company from which the Member Financial Disclosure is derived, which may include affording access to the Company's independent auditors (subject to customary indemnification and confidentiality agreements that may be requested by such auditors, and to the consent of such auditors for any reliance on or reference thereto), to the extent reasonably required for such purpose).

13.3 Filings. At the Company's expense, the Board of Directors shall cause the income tax returns for the Company to be prepared and timely filed with the appropriate authorities and to have prepared and to furnish to each Member, within ninety (90) days after the end of each year, such information with respect to the Company (including a schedule setting forth such Member's distributive share of the Company's income, gain, loss, deduction and credit as determined for federal income tax purposes) as is necessary to enable such Member to prepare such Member's federal and state income tax returns. The Company shall as promptly as practicable provide the Major Members with any information reasonably requested by a Major Member that is in the Company's possession (or that can be obtained without undue burden) in connection with the preparation of such Major Member's tax returns. The Board of Directors, at the Company's expense, shall also cause to be prepared and timely filed, with appropriate federal and state regulatory and administrative authorities, all reports required to be filed by the Company with those entities under then current applicable laws, rules and regulations.

13.4 Non-Disclosure.

(a) Each Party to this Agreement and any further Person admitted as a Member in accordance with the terms of this Agreement, agrees that (i) the terms of the Transaction Agreements, (ii) any information relating to the negotiation of the Transaction Agreements, and (iii) except as otherwise consented to by the Board of Directors in writing, all non-public information relating to the Company or its Subsidiaries furnished to Hologen, MeiraGTx or a Member, including but not limited to confidential information of the Company and its Subsidiaries regarding identifiable, specific and discrete business opportunities being pursued by the Company or its Subsidiaries (collectively, "Confidential Information"), shall be kept confidential, shall not be used for commercial or proprietary advantage and shall not be disclosed in any manner, in whole or in part, except that each of Hologen, MeiraGTx and such Member shall be permitted to disclose such Confidential Information (i) to those of Hologen, MeiraGTx or such Member's agents, Representatives and employees who need to be familiar with such Confidential Information in connection with Hologen, MeiraGTx or such Member's investment in the Company and who are charged with an obligation of confidentiality, (ii) to Hologen, MeiraGTx or a Member's existing or prospective partners and equity holders so long as they agree to keep such Confidential Information confidential on the terms set forth herein, (iii) with respect to Hologen, MeiraGTx or a Member that is a professionally managed unregistered investment fund, as part of Hologen,

MeiraGTx or such Member's normal reporting or review procedure, or in connection with Hologen, MeiraGTx or such Member's or its Affiliates' normal fund raising, marketing, informational or reporting activities, (iv) for general portfolio information that does not identify the Company or its Subsidiaries, (v) for complying with applicable laws, including regulations promulgated by securities exchanges, including any on which the securities of a Member or its Affiliates are listed, and accounting standards, or court or administrative orders (in such case only to the extent determined necessary based upon advice of counsel), which for the sake of clarity, shall include the right to utilize the name of the Company for the same purposes, (vi) to the extent necessary for the enforcement of any right of Hologen, MeiraGTx or a Member arising under this Agreement and (vii) to existing or potential equity or debt financing sources, so long as they agree to keep such Confidential Information confidential on the terms set forth herein. Notwithstanding the foregoing, Hologen, MeiraGTx or any Member and each of their respective Representatives may disclose to their respective legal advisors, tax advisors, or any applicable tax authority, without limitation of any kind, the tax treatment, tax strategies and structure of the Company and all materials of any kind (including opinions or other tax analyses) that are provided to Hologen, MeiraGTx or such Member and their respective Representatives relating to such tax treatment, tax strategies and tax structure. Each of Hologen, MeiraGTx and any other Member agrees that it shall be responsible for any breach or violation of the provisions of this Section 13.4(a) by any Person receiving Confidential Information from Hologen, MeiraGTx or such Member. Notwithstanding the foregoing, as of the Completion Date, each of Hologen and MeiraGTx is hereby granted an irrevocable right to disclose and use the Company's name and logo on their websites and in their respective marketing materials for the purpose of reflecting the investment in the Company.

(b) For purposes of this Section 13.4, "Confidential Information" shall not include any information: (i) of which such Person (or its Affiliates) learns from sources other than the Company or its Subsidiaries, whether prior to or after such information is actually disclosed by the Company or its Subsidiaries; or (ii) which is disclosed in documents available for dissemination to the public. Nothing in this Section 13.4 shall in any way limit or otherwise modify any confidentiality covenants entered into by Hologen, MeiraGTx or any Member pursuant to any other agreement to which Hologen, MeiraGTx or such Member and the Company or any of its Subsidiaries are parties. The provisions of this Section 13.4 shall survive any termination of this Agreement.

13.5 Information Rights. The Company shall deliver to each Major Member (on both a consolidated and consolidating basis including Subsidiaries, or separately for each Subsidiary, as determined by the Major Members):

(a) As soon as available, and in any event within thirty (30) days after the end of each Fiscal Year of the Company, audited financial statements consisting of the balance sheet of the Company and its Subsidiaries as at the end of such Fiscal Year and the statements of income, cash flows and changes in members' equity for such Fiscal Year of the Company and its Subsidiaries, setting forth in each case in comparative form the figures for the immediately preceding Fiscal Year, all such financial statements prepared in accordance with GAAP and accompanied by the report of independent certified public accountants of recognized national standing thereon, which accountants shall be selected by the Board of Directors;

(b) As soon as available, and in any event within twenty (20) days after the end of each fiscal quarter of the Company for the first three (3) fiscal quarters of a Fiscal Year, the unaudited balance sheet of the Company and its Subsidiaries as at the end of such quarter and the unaudited statements of income, cash flows and changes in members' equity for such quarter and the portion of the Fiscal Year then ended of the Company and its Subsidiaries, setting forth in each case the figures for the corresponding periods of the previous Fiscal Year, or, in the case of such balance sheet, for the last day of such Fiscal Year, in comparative form, all in reasonable detail, and all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) As soon as available, but in any event within fifteen (15) days after the end of each month, an unaudited balance sheet of the Company and its Subsidiaries as at the end of such month and the unaudited statements of income, cash flows and changes in members' equity for such month, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(d) As soon as available, and in any event thirty (30) days before the end of each Fiscal Year, a budget and business plan for the next Fiscal Year (collectively, the "Budget");

(e) Upon request by a Major Member, a statement showing the number of shares of each class and securities convertible into or exercisable for shares outstanding, all in sufficient detail as to permit such Major Members to calculate its respective percentage equity ownership in the Company and each of its Subsidiaries (including the Company's ownership in each such Subsidiary, direct or indirect), and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;

(f) Within sixty (60) days following the end of each Fiscal Year or as soon as practicable thereafter, an IRS Schedule K-1 (Form 1065) or any successor federal tax form (if applicable); and

(g) Such other information relating to the Company or any of its Subsidiaries as from time to time may reasonably be requested by such Major Member.

14. TAX MATTERS.

14.1 ECI. The Company shall not engage in, or invest in any person that is treated as a flow-through entity for U.S. federal income tax purposes that engages in, (i) any "commercial activity" as defined in Section 892(a)(2)(i) of the Code, (ii) a "trade or business within the United States," within the meaning of Section 864(b) of the Code, or (iii) any other activity that causes the Company or any other person (including any Member and any direct or indirect owner of a Member) to file a state income tax return during any taxable year of the Company. The Company shall not make any investment or acquire any interest that would be treated as a "U.S. real property interest," within the meaning of Section 897 of the Code.

14.2 Tax Residence. Unless the Parties otherwise expressly agree in writing, the Company shall at all times maintain tax residence solely in Guernsey for tax purposes.

14.3 Listed Transactions. The Company shall not engage, directly or indirectly, in any transaction that, as of the date the Company enters into a binding contract to engage in such transaction, is a "listed transaction" as defined in Treasury Regulations Section 1.6011-4(b)(2) where a Member would be treated as "party" to such transaction for purposes of Section 4965 of the Code (a "Listed Transaction"). If the Company has actual knowledge that it has engaged, directly or indirectly, in a Listed Transaction or a "reportable transaction" as defined in Treasury Regulations Section 1.6011-4(b)(1), it shall promptly notify the Members of such determination.

14.4 Tax Information. The Company shall promptly comply with any request made by a Member, to provide any documents, information and correspondence necessary (at the cost of the Party making the request) to enable the relevant Party to comply with its obligations in respect of filing, elections, returns or other tax requirements, and to comply with any other requirements of, any applicable tax authority.

15. TRANSFER OF SHARES.

15.1 Restricted Transfer.

No Member may directly or indirectly Transfer all or any of such Member's Shares, except in compliance with this Section 15. Any attempted Transfer of Shares not in compliance with the terms of this Section 15 shall be null and void and the Company shall not in any way give effect to any such Transfer. In addition to the foregoing, no Member may avoid the provisions of this Agreement by either making one or more Transfers to one or more Permitted Transferees and then disposing of all or any portion of such Party's interest in any such Permitted Transferee or by transferring the securities of any entity whose primary purpose is to hold (directly or indirectly) Shares (and, for the avoidance of doubt, any such Transfers will be deemed to be Transfers for purposes of this Agreement and subject to the restrictions in this Section 15). The Transfer restrictions set forth in this Section 15 do not apply to the sale of Shares in accordance with the drag-along right specified in Section 16.5, or to the Transfer of Shares in accordance with Section 16.1 or Section 16.2.

15.2 Permitted Transferees. A Member shall be entitled to Transfer such Member's Shares to a Person (a "Permitted Transferee"), provided that in each case such Person is not a Sanctioned Person, in accordance with the following and subject to the other provisions of this Section 15:

(a) Transfers to the Company. Each applicable Member shall be entitled to Transfer its Shares to the Company, provided that the Board of Directors has determined that the Company satisfies the solvency test as set out in the Act.

(b) Discretionary Transfers. Each Member shall be entitled to Transfer such Member's Shares to (a) an Affiliate of such Member or (b) to a third party if such Member obtains the prior written consent of the Director Supermajority prior to such Transfer.

15.3 Transfer Requirements. Subject to Section 15.1, no Assignee (including a Permitted Transferee) shall be admitted to the Company as a Member unless the following conditions are satisfied or such conditions are waived by the Board of Directors:

(a) A duly executed written instrument of Transfer is provided to the Board of Directors, specifying the Shares being transferred and setting forth the intention of the Member effecting the Transfer that the transferee succeed to a portion or all of such Member's Shares as a Member, and a deed of adherence substantially in the form set out in Schedule 8.5 duly executed and delivered by the transferee agreeing to be bound by this Agreement in respect of the Shares transferred;

(i) The Member effecting the Transfer and the Assignee execute any other instruments that the Board of Directors deems reasonably necessary or desirable for admission of the Assignee;

(b) All Transfers shall be made in compliance with applicable law and if any Transfer permitted hereunder would require the consent of or notice to a Governmental Entity, the Members and the Company shall cooperate to obtain such consent or prepare and deliver such notice;

(c) The Member effecting the Transfer or the Assignee pays to the Company a transfer fee in an amount sufficient to cover the reasonable expenses incurred by the Company in connection with the admission of the Assignee and provides to the Company any information necessary for the Company to make required basis adjustments and comply with tax reporting requirements; and

(d) The Assignee provides the Company with such information as the Company reasonably determines appropriate to conclude that the Transfer will not result in a withholding obligation on the Company under applicable tax laws.

15.4 Admission as a Member. Each Member hereby agrees that, upon satisfaction of the terms and conditions of this Section 15 with respect to any proposed Transfer, and the entry of the Assignee in the Company's register of members, the Assignee be admitted as a Member.

15.5 Withdrawal of Member. If a Member Transfers all of its Shares pursuant to Section 15.1 and the Assignee of such Shares is admitted as a Member pursuant to Section 15.3, such Assignee shall be admitted to the Company as a Member effective on the effective date of the Transfer or such other date as may be specified when the Assignee is admitted and then immediately following such admission the assignor shall cease to be a Member. Upon the assignor ceasing to be a Member, the assignor shall not be entitled to any Distributions. Notwithstanding the admission of an Assignee as a Member and, except as otherwise expressly approved by the Board of Directors, (a) the assignor shall not be released from any obligations to the Company under this Agreement that are existing as of the date of the Transfer, including without limitation the obligations set forth in Section 13.4 and Section 18 and (b) the assignor shall continue to have the rights set forth in, and be the beneficiary of, Section 18.

15.6 Additional Transfer Restrictions. [***]

16. RIGHT OF FIRST REFUSAL; RIGHT OF CO-SALE; PREEMPTIVE RIGHTS; AND DRAG-ALONG RIGHTS.

16.1 Right of First Refusal.

(a) Grant. Each Member holding Transfer Shares hereby unconditionally and irrevocably grants to the Company a Right of First Refusal to purchase all or any portion of Transfer Shares that such Member may propose to transfer in a Proposed Transfer, at the same price and on the same terms and conditions as those offered to the Proposed Transferee and each Member holding Transfer Shares undertakes to exercise his voting rights in the Shares to approve the Company's exercise of such Right of First Refusal in relation to such Transfer Shares.

(b) Notice. Each Member proposing to make a Proposed Transfer must deliver a Transfer Notice to the Company and each Major Member not later than [***] prior to the consummation of such Proposed Transfer. Such Transfer Notice shall contain the material terms and conditions (including price and form of consideration) of the Proposed Transfer and the identity of the Proposed Transferee. To exercise its Right of First Refusal under this Section 16.1, the Company must deliver a Company Notice to the selling Member within [***] after delivery of the Transfer Notice. In the event of a conflict between this Agreement and any other agreement that may have been entered into by a Member with the Company that contains a preexisting right of first refusal, the Company and the Member acknowledge and agree that the terms of this Agreement shall control and the preexisting right of first refusal shall be deemed satisfied by compliance with this Section 16.1. For the sake of clarity, if a Major Member is the Member proposing to make a Proposed Transfer, such Major Member shall not have to deliver any Transfer Notice to itself and shall not have any right to purchase any Transfer Shares in connection with such Major Member's Proposed Transfer.

(c) Grant of Secondary Refusal Right to Major Members. Subject to Section 15, each Member holding Transfer Shares hereby unconditionally and irrevocably grants to the Major Members a Secondary Refusal Right to purchase all or any portion of the Transfer Shares not purchased by the Company pursuant to the Right of First Refusal. If the Company does not intend to exercise its Right of First Refusal with respect to all Transfer Shares subject to a Proposed Transfer, the Company must deliver a Secondary Notice to the selling Member and to each Major Member to that effect no later than [***] after the selling Member delivers the Transfer Notice to the Company. To exercise its Secondary Refusal Right, a Major Member must deliver an Exercising Member Notice to the selling Member and the Company within [***] after the Company's deadline for its delivery of the Secondary Notice as provided in the preceding sentence.

(d) Undersubscription of Transfer Shares. If options to purchase have been exercised by the Company and the Major Members with respect to some but not all of the Transfer Shares by the end of the [***] period specified in the last sentence of Section 16.1(c) (the "Exercising Member Notice Period"), then the Company shall, immediately after the expiration of the Exercising Member Notice Period, send written notice (the "Company Undersubscription Notice") to those Major Members who fully exercised their Secondary Refusal Right within the Exercising Member Notice Period (the "Exercising Members"). Each Exercising Member shall, subject to the provisions of this Section 16.1(d), have an additional option to purchase all or any part of the balance of any such remaining unsubscribed Transfer Shares on the terms and conditions set forth in the Transfer Notice. To exercise such option, an Exercising Member must deliver a Company Undersubscription Notice to the selling Member and the Company within [***] after the expiration of the Exercising Member Notice Period. In the event there are two or more such Exercising Members that choose to exercise the last-mentioned option for a total number of remaining Shares in excess of the number available, the remaining Shares available for purchase

under this Section 16.1(d) shall be allocated to such Exercising Member pro rata based on the number of Transfer Shares such Exercising Members have elected to purchase pursuant to the Secondary Refusal Right (without giving effect to any Transfer Shares that any such Exercising Member has elected to purchase pursuant to the Company Undersubscription Notice). If the options to purchase the remaining Shares are exercised in full by the Exercising Member, the Company shall immediately notify all of the Exercising Members and the selling Member of that fact.

(e) Consideration; Closing. The consideration to be paid for the Transfer Shares must be cash. The closing of the purchase of Transfer Shares by the Company and the Major Members shall take place, and all payments from the Company and the Major Members shall have been delivered to the selling Member, by the later of [***].

16.2 Right of Co-Sale.

(a) Exercise of Right. If any Transfer Shares subject to a Proposed Transfer are not purchased pursuant to Section 16.1 above and thereafter are to be sold to a Proposed Transferee (subject to Section 15), each respective Major Member may elect to exercise its Right of Co-Sale and participate on a pro rata basis in the Proposed Transfer as set forth in Section 16.2(b) below and otherwise on the same terms and conditions specified in the Transfer Notice. Each Major Member who desires to exercise its Right of Co-Sale (each, a "Participating Member") must give the selling Member written notice to that effect within [***] after the deadline for delivery of the Secondary Notice described above, and upon giving such notice such Major Member shall be deemed to have effectively exercised the Right of Co-Sale. For the sake of clarity, a Major Member who has requested the Proposed Transfer shall not have the right to be a Participating Member with respect to such Proposed Transfer.

(b) Shares Includable. Each Participating Member may include in the Proposed Transfer all or any part of such Participating Member's Shares equal to the product obtained by multiplying (i) the aggregate number of Transfer Shares subject to the Proposed Transfer (excluding Shares purchased by the Company or the Participating Members pursuant to the Right of First Refusal or the Secondary Refusal Right) by (ii) a fraction, the numerator of which is the number of Shares owned by such Participating Member immediately before consummation of the Proposed Transfer and the denominator of which is the total number of Shares owned, in the aggregate, by all Participating Members immediately prior to the consummation of the Proposed Transfer, plus the number of Transfer Shares held by the selling Member. To the extent one or more of the Participating Members exercise such right of participation in accordance with the terms and conditions set forth herein, the number of Transfer Shares that the selling Member may sell in the Proposed Transfer shall be correspondingly reduced.

(c) Purchase Covenants. The Parties hereby agree that the terms and conditions of any sale pursuant to this Section 16.2 will be memorialized in, and governed by, a written purchase and sale agreement with customary terms and provisions for such a transaction and the Parties further covenant and agree to enter into such an agreement as a condition precedent to any sale or other transfer pursuant to this Section 16.2. Neither the Transfer of Transfer Shares by the selling Member nor the Transfer of Shares by a Participating Member shall be effective, unless, contemporaneously with such Transfer, the Proposed Transferee executes a counterpart to this

Agreement, thereby agreeing to be bound to all the terms and conditions of this Agreement. If any Proposed Transferee or Proposed Transferees refuse(s) to purchase securities subject to the Right of Co-Sale from any Participating Member exercising its Right of Co-Sale hereunder, no Member may sell any Transfer Shares to such Proposed Transferee or Proposed Transferees unless and until, simultaneously with such sale, such Member purchases all shares subject to the Right of Co-Sale from such Participating Member on the same terms and conditions (including the proposed purchase price) as set forth in the Transfer Notice.

(d) Additional Compliance. If any Proposed Transfer is not consummated within [***] after receipt of the Transfer Notice by the Company, the Member proposing the Proposed Transfer may not sell any Transfer Shares unless they first comply in full with each provision of Section 16.1 and this Section 16.2. The exercise or election not to exercise any right by any Major Member hereunder shall not adversely affect its right to participate in any other sales of Transfer Shares subject to this Section 16.2.

16.3 Effect of Failure to Comply with Right of First Refusal and Right of Co-Sale.

(a) Transfer Void; Equitable Relief. Any Proposed Transfer not made in compliance with the requirements of this Agreement shall be null and void ab initio, shall not be recorded on the books of the Company and shall not be recognized by the Company. Each Party hereto acknowledges and agrees that any breach of this Agreement would result in substantial harm to the other Parties hereto for which monetary damages alone could not adequately compensate. Therefore, the Parties hereto unconditionally and irrevocably agree that any non-breaching Party hereto shall be entitled to seek protective orders, injunctive relief and other remedies available at law or in equity (including, without limitation, seeking specific performance or the rescission of purchases, sales and other transfers of Transfer Shares not made in strict compliance with this Agreement).

(b) Violation of First Refusal Right. If any Member becomes obligated to sell any Transfer Shares to the Company or any Major Member under this Agreement and fails to deliver such Transfer Shares in accordance with the terms of this Agreement, such Member hereby appoints any Director or any Major Member (or, in the case of a Member who is a Major Member, the other Major Member) to be their true and lawful attorney to take such actions and to execute any documentation on their behalf which the attorney considers necessary or relevant to the making of such transfer. The Company and/or such Major Member may, at its option, in addition to all other remedies it may have, send to such Member the purchase price for such Transfer Shares as is herein specified and transfer to the name of the Company or such Major Member (or request that the Company effect such transfer in the name of a Major Member) on the Company's books the Transfer Shares to be sold.

(c) Violation of Co-Sale Right. If any Member purports to sell any Transfer Shares in contravention of the Right of Co-Sale (a "Prohibited Transfer"), each Major Member who desires to exercise its Right of Co-Sale under Section 16.2 may, in addition to such remedies as may be available by law, in equity or hereunder, require such Member to purchase from such Major Member the type and number of Shares that such Major Member would have been entitled to sell to the Proposed Transferee under Section 16.2 had the Prohibited Transfer been effected pursuant to and in compliance with the terms of Section 16.2. The sale will be made on the same

terms and subject to the same conditions as would have applied had the Member not made the Prohibited Transfer, except that the sale (including, without limitation, the delivery of the purchase price) must be made within [***] after the Major Member learns of the Prohibited Transfer, as opposed to the timeframe proscribed in Section 16.2. Such Member shall also reimburse each Major Member for any and all reasonable and documented out-of-pocket fees and expenses, including reasonable legal fees and expenses, incurred pursuant to the exercise or the attempted exercise of the Major Member's rights under Section 16.2.

(d) The covenants set forth in Sections 16.1, 16.2 and 16.3 shall terminate and be of no further force or effect immediately before the consummation of the Initial Public Offering or upon a Change of Control, whichever event occurs first.

16.4 Preemptive Rights. Subject to the terms and conditions of this Section 16.4 and applicable laws, if the Company proposes to issue, agree to issue, reserve or set aside or offer to issue any New Shares, the Company shall first offer such New Shares to each Major Member. A Major Member shall be entitled to apportion the right of first offer hereby granted to it among itself and its Affiliates in such proportions as it deems appropriate.

(a) The Company shall give notice (the "Offer Notice") to each such Major Member, stating (i) its bona fide intention to offer such New Shares, (ii) the number of such New Shares to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Shares, including a summary of the rights and privileges of such New Shares.

(b) By notification to the Company within [***] after the Offer Notice is given, each such Major Member may elect to subscribe, at the price and on the terms specified in the Offer Notice, for up to that portion of such New Shares which equals the proportion that the Shares then held by such Major Member bears to the total number of Shares then held by all Major Members. At the expiration of such [***] period, the Company shall promptly notify each Major Member that elects to subscribe for all the New Shares available to it (each, a "Fully Exercising Member") of any other Major Member's failure to do likewise. During the [***] period commencing after the Company has given such notice, each Fully Exercising Member may, by giving notice to the Company, elect to subscribe, in addition to the number of New Shares specified above, for up to that portion of the New Shares for which Major Members were entitled to subscribe but that were not subscribed for by the Major Members which is equal to the proportion that the Issued Shares then held, by such Fully Exercising Member bears to the Issued Shares then held, by all Fully Exercising Member who wish to purchase such unsubscribed New Shares. The closing of any sale pursuant to this Section 16.4(b) shall occur within [***].

(c) If all New Shares referred to in the Offer Notice are not elected to be subscribed for as provided in Section 16.4(b), the Company may, during the [***] period following the expiration of the periods provided in Section 16.4(b), offer and issue the remaining unsubscribed portion of such New Shares to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the issuance of the New Shares within such period, or if such agreement is not consummated within [***] of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Shares shall not be issued unless first reoffered to the Major Members in accordance with this Section 16.4.

(d) The covenants set forth in this Section 16.4 shall terminate and be of no further force or effect immediately before the consummation of an Initial Public Offering.

16.5 Drag-Along Right.

(a) Definitions. A "Sale of the Company" shall mean either: (a) a transaction or series of related transactions in which a Person, or a group of related Persons, that is or are not Affiliates of the Company, acquires from the Members' Shares representing more than fifty percent (50%) of the outstanding voting rights of the Company (a "Share Sale"); or (b) any other transaction that qualifies as a Deemed Liquidation Event or Change of Control.

(b) Actions to be Taken. In the event that (A) the Major Members, and (B) the Board of Directors approve a Sale of the Company in writing, specifying that this Section 16.5 shall apply to such transaction, then each Member hereby agrees:

(i) if such transaction requires Member approval, with respect to all Shares that such Member owns or over which such Member otherwise exercises voting power, to vote (in person, by proxy or by action by written consent, as applicable) all Shares in favor of, and adopt, such Sale of the Company (together with any related amendment to this Agreement required in order to implement such Sale of the Company) and to vote in opposition to any and all other proposals that could reasonably be expected to delay or impair the ability of the Company to consummate such Sale of the Company;

(ii) if such transaction is a Share Sale, to sell the same proportion of Shares beneficially held by such Member as is being sold by the Major Members to the Person to whom the Major Members propose to sell their Shares, and, except as permitted in Section 16.5(c) below, on the same terms and conditions as the Major Members;

(iii) to execute and deliver all related documentation (including a stock transfer form and relevant share certificate(s) or a suitable indemnity for any lost share certificate(s) in respect of the Member's Shares to be sold pursuant to this Section 16.5) and take such other action in support of the Sale of the Company as shall reasonably be requested by the Company or the Major Members in order to carry out the terms and provisions of this Section 16.5, any purchase agreement, merger agreement, indemnity agreement, escrow agreement, consent, waiver, governmental filing, and any similar or related documents;

(iv) not to deposit, and to cause their Affiliates not to deposit, except as provided in this Agreement, any Shares owned by such Party or Affiliate in a voting trust or subject any Shares to any arrangement or agreement with respect to the voting of such Shares, unless specifically requested to do so by the acquirer in connection with the Sale of the Company; and

(v) if the consideration to be paid in exchange for the Shares pursuant to this Section 16.5 includes any securities and due receipt thereof by any Member would require under applicable law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities or (y) the provision to any Member of any information other than such information as a prudent issuer would generally furnish in an offering made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act, the Company may cause to be paid to any such Member in lieu thereof, against surrender of

the Shares which would have otherwise been sold by such Member, an amount in cash equal to the fair value (as determined in good faith by the Company) of the securities which such Member would otherwise receive as of the date of the issuance of such securities in exchange for the Shares.

(c) Exceptions. Notwithstanding the foregoing, a Member will not be required to comply with Section 16.5(b) above in connection with any proposed Sale of the Company (the "Proposed Sale") unless:

(i) any representations and warranties to be made by such Member in connection with the Proposed Sale are limited to representations and warranties related to authority, ownership and the ability to convey title to such Shares, including but not limited to representations and warranties that (A) the Member holds all right, title and interest in and to the Shares such Member purports to hold, free and clear of all liens and Encumbrances, (B) the obligations of the Member in connection with the transaction have been duly authorized, if applicable, (C) the documents to be entered into by the Member have been duly executed by the Member and delivered to the acquirer and are enforceable against the Member in accordance with their respective terms and (D) neither the execution and delivery of documents to be entered into in connection with the transaction, nor the performance of the Member's obligations thereunder, will cause a breach or violation of the terms of any agreement, law or judgment, order or decree of any court or governmental agency;

(ii) the Member shall not be liable for the inaccuracy of any representation or warranty made by any other Person in connection with the Proposed Sale, other than for the inaccuracy of any representation or warranty made by the Company in connection with the Proposed Sale;

(iii) the liability for indemnification, if any, of such Member in the Proposed Sale and for the inaccuracy of any representations and warranties made by the Company in connection with such Proposed Sale, is several and not joint with any other Person;

(iv) the liability for indemnification shall be limited to such Member's applicable share (determined based on the respective proceeds payable to each Member in connection with such Proposed Sale in accordance with the provisions of this Agreement) of a negotiated aggregate indemnification amount that applies equally to all Members but that in no event exceeds the amount of consideration actually paid to such Member in connection with such Proposed Sale, except with respect to claims of fraud by such Member, the liability for which need not be limited as to such Member;

(v) upon the consummation of the Proposed Sale: (A) except as provided in Section 16.5(b)(v), each holder of each class or series of Shares will receive the same form of consideration for their Shares of such class as is received by other holders in respect of their Shares of such same class of Shares; and (B) unless the Major Members elect to receive a lesser amount by written notice given to the Company at least [***] prior to the effective date of any such Proposed Sale, the aggregate consideration receivable by all holders of Shares shall be allocated among the holders of Issued Shares pro rata to their holding of Issued Shares; provided, however, that, notwithstanding the foregoing provisions of this Subsection 16.5(b)(v), if the consideration to be paid in exchange for the Shares, as applicable, pursuant to this

Subsection 16.5(b)(v) includes any securities and due receipt thereof by any Member or would require under applicable law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities; or (y) provision to any Member of any information other than such information as a prudent issuer would generally furnish in an offering made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act, the Company may cause to be paid to any such Member in lieu thereof, against surrender of the Shares which would have otherwise been sold by such Member, an amount in cash equal to the fair value (as determined in good faith by the Board of Directors) of the securities which such Member would otherwise receive as of the date of the issuance of such securities in exchange for the Shares;

(vi) except as provided in Section 16.5(b)(v), subject to clause (v) above, requiring the same form of consideration to be available to the holders of any single class of Shares, if any holders of any Shares are given an option as to the form and amount of consideration to be received as a result of the Proposed Sale, all holders of such Shares will be given the same option; and

(vii) no Member who is not a current or former employee of the Company shall be required to agree to any restrictive covenant in connection with any Proposed Sale (including any covenant not to compete with or covenant not to solicit or hire customers, employees or suppliers of any party to the Proposed Sale).

(d) Restrictions on Change of Control. [***].

(e) Irrevocable Power of Attorney. As security for the performance of each Member's obligations in connection with such Sale of the Company, after the approval of the Board of Directors and the Major Members has been obtained pursuant to Section 16.5(b) above, each Member hereby irrevocably appoints each member of the Board of Directors, with full power of substitution and re-substitution, to be their true and lawful attorney (i) to vote all Shares at all meetings of the Members held or taken after the date of this Agreement with respect to a Sale of the Company, or (ii) to execute any written consent in lieu thereof, and (iii) to sign any documents with respect to any such vote or any actions by written consent of the Members taken after the date of this Agreement with respect to such Sale of the Company. This power of attorney shall terminate upon the consummation of, or termination of, negotiations with respect to, the applicable Sale of the Company.

17. DISSOLUTION OF COMPANY.

17.1 Termination of Membership. No Member may resign or withdraw from the Company except that, subject to the restrictions set forth in Section 15, any Member may Transfer such Member's Shares in the Company to a Permitted Transferee. The expulsion, bankruptcy or

dissolution of any Member shall not in and of itself cause the Company to be dissolved or its affairs to be wound up, and upon the occurrence of any such event, the Company shall be continued without dissolution.

17.2 Events of Dissolution. The Company shall be dissolved in accordance with the requirements of the Act upon the occurrence of the dissolution events specified in the New Articles.

17.3 Liquidation. The Company's property and assets or the proceeds from the liquidation thereof shall be distributed so as not to contravene the Act, the Insolvency Act 1986 and any other applicable laws.

17.4 No Action for Dissolution. The Members acknowledge that irreparable damage would be done to the goodwill and reputation of the Company if any Member should bring an action in court to dissolve the Company under circumstances where dissolution is not required by Section 17.2. This Agreement has been drawn carefully to provide fair treatment of all Parties and equitable payment in liquidation of the Shares of all Members.

17.5 No Further Claim. Upon dissolution, each Member shall have recourse solely to the assets of the Company for the return of such Member's capital, and if the Company's property remaining after payment or discharge of the debts and liabilities of the Company, including debts and liabilities owed to one or more of the Members, is insufficient to return each Member's capital, such Member shall have no recourse against the Company, the Board of Directors or any other Member.

18. INDEMNIFICATION.

18.1 General Indemnification Rights. Subject to the Act, the Company shall indemnify, defend and hold harmless each Member and each member of the Board of Directors and, to the extent applicable, each such Person's officers, directors, members, shareholders, and employees, (all such persons being referred to herein as "Indemnified Persons"), who is or was a party, witness or other participant, or is threatened or proposed to be made a party, witness or other participant, in any actual, threatened, pending or complete action, suit, proceeding, demand or investigation, whether civil, criminal, administrative, investigative, or an alternative dispute resolution proceeding (a) by reason of the fact that such Indemnified Person is or was a Member, a member of the Board of Directors, or an officer, member, shareholder or employee of such Indemnified Person, (b) by reason of the fact that such Indemnified Person is or was serving at the request of the Company as a director, officer or partner of another corporation, limited liability company, partnership, trust, plan or other organization or position or enterprise, and/or (c) with respect to Directors of the Company or any Subsidiary, that arises directly from Indemnified Person's actions and activities as a Director, as applicable, of the Company or any Subsidiary within the scope of this Agreement, from and against all expenses (including attorneys' and experts' fees and expenses) ("Expenses"), judgments, fines and amounts paid in settlement actually and reasonably incurred by such Indemnified Person in connection with such action, suit, proceeding, demand or investigation, unless it is determined by a court of competent jurisdiction in a judgment not subject to appeal or otherwise that (i) such Indemnified Person did not act in good faith and in a manner such Indemnified Person reasonably believed to be in or not opposed to the best interests of the

Company (or such organization or enterprise), and (ii) with respect to any criminal action or proceeding, such Indemnified Person had reasonable cause to believe such Indemnified Person's conduct was unlawful.

18.2 Indemnification for Claims Brought by Indemnified Person. No indemnification shall be available for any claim brought by an Indemnified Person unless and to the extent that such claim is brought (a) to determine and/or enforce the indemnification rights of such Indemnified Person, (b) to seek or obtain payment to or on behalf of such Indemnified Person under any liability insurance policy or (c) with the express consent of the Board of Directors.

18.3 Advancement of Defense Costs. The Company shall pay to or on behalf of an Indemnified Person all Expenses incurred by such Indemnified Person in connection with any actual, threatened, pending or complete action, suit, proceeding, demand or investigation as incurred in advance of the final disposition of such action, suit, proceeding, demand or investigation if such Indemnified Person furnishes the Company with a written undertaking to repay the amount of such Expenses advanced to such Indemnified Person if it is finally determined by a court of competent jurisdiction that such Indemnified Person is not entitled to indemnification with respect to such Expenses under this Agreement, which undertaking shall be an unsecured and interest-free general obligation of such Indemnified Person and shall be accepted as a sufficient undertaking without regard to such Indemnified Person's financial ability to repay such amounts.

18.4 Company as Primary Indemnitor. The Company hereby acknowledges that an Indemnified Person may have certain rights to indemnification, advancement of expenses and/or insurance provided by other sources. The Company hereby agrees (a) that it is the indemnitor of first resort (i.e., its obligations to an Indemnified Person are primary and any obligation of such other sources to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Indemnified Person are secondary) and (b) that it shall be required to advance the full amount of Expenses incurred by an Indemnified Person and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement without regard to any rights an Indemnified Person may have against the such other sources. The Company further agrees that no advancement or payment by such other sources on behalf of an Indemnified Person with respect to any claim for which such Indemnified Person has sought indemnification from the Company shall affect the foregoing, and such other sources shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of such Indemnified Person against the Company.

18.5 Persons Entitled to Indemnity. Any Person who is within the definition of "Indemnified Person" at the time of any action or inaction in connection with the business of the Company shall be entitled to the benefits of this Section 18 as an "Indemnified Person" with respect thereto, regardless of whether such Person continues to be within the definition of "Indemnified Person" at the time of such Indemnified Person's claim for indemnification or exculpation hereunder. Each Indemnified Person's right to indemnification vests by virtue of such Indemnified Person's status as such, and no repeal or modification of this Section 18 shall adversely affect any rights to indemnification or to the advancement of Expenses of any Person who is within the definition of "Indemnified Person" existing at the time of such repeal or modification with respect to any acts or omissions occurring prior to such repeal or modification.

Each Indemnified Person is an express third party beneficiary of this Section 18 who may rely on and enforce the provisions of this Section 18.

18.6 Obligation to Indemnify is Non-Recourse. Indemnification under this Section 18 shall be recoverable only from the assets of the Company and not from any assets of the Members.

18.7 Procedure Agreements. The Company may enter into an agreement with any Indemnified Person setting forth procedures consistent with applicable law for implementing the indemnities provided in this Section 18.

18.8 Reliance, etc. An Indemnified Person acting under this Agreement shall not be liable to the Company or to any other Indemnified Person for its good faith reliance on the provisions of this Agreement. The provisions of this Agreement, to the extent that they restrict the duties (including fiduciary duties) and liabilities of an Indemnified Person otherwise existing at law or in equity, are agreed by the Parties hereto to replace such other duties and liabilities of such Indemnified Person.

18.9 Directors' and Officers' Insurance. The Company will ensure that its Directors and officers are covered under a directors and officers' insurance policy for so long as it is available at commercially reasonable rates, as determined by the Board of Directors, provided, that such insurance policy shall provide at least [***] in coverage and be on terms acceptable to the Director Supermajority.

18.10 Limitations. The provisions of this Section 18 shall be subject to the Act and will not extend to matters which are not permitted by the Act.

18.11 Period. The provisions of this Section 18 shall survive any termination of this Agreement.

19. WARRANTIES BY THE MEMBERS.

Hologen hereby warrants to the Board of Directors, MeiraGTx, MeiraGTx Holdings and the Company, severally and not jointly and solely on its own behalf, as of the date of this Agreement and on Completion, as applicable, as follows:

19.1 Financial Capability. Hologen has immediately available funds sufficient to enable Hologen to pay in full on the date on which they become due and payable all amounts contemplated to be paid and to satisfy all other obligations hereunder by Hologen in connection with this Agreement, the Subscription Agreement and the transactions contemplated hereby.

19.2 Compliance with Anti-Bribery Laws and Anti-Money Laundering Laws.

(a) In connection with the transactions contemplated by this Agreement Hologen is in compliance with all applicable Anti-Bribery Laws and Anti-Money Laundering Laws and has instituted and maintained policies and procedures reasonably designed to promote and achieve compliance with such laws. None of Hologen, the Hologen Investors nor any of their respective Affiliates has in connection with the transactions contemplated by this Agreement: (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful

expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government employee or official from corporate funds; or (iii) violated or is in violation of any provision of any applicable Anti-Bribery Laws or Anti-Money Laundering Laws.

(b) No action, suit or proceeding by or before any court or Governmental Entity or any arbitrator involving Hologen or any Hologen Investor with respect to Anti-Bribery Laws or Anti-Money Laundering Laws is pending or, to the knowledge of Hologen, threatened.

(c) The funds that Hologen will use for the transactions contemplated by this Agreement do not derive, directly or indirectly, from criminal activity.

19.3 Beneficial Ownership. [***]

19.4 Compliance with Sanctions Laws.

(a) None of Hologen, the Hologen Investors, the Hologen Financing Provider, nor any of their respective subsidiaries or directors, nor, to Hologen's knowledge, any agent, or Affiliate of Hologen, the Hologen Investors, the Hologen Financing Provider, nor any of their respective subsidiaries, is currently the target of any Sanctions, owned or controlled by any Sanctioned Person or designated on any Sanctions List nor has any of the foregoing persons taken any steps, performed any acts or omissions, taken any action or is party to any agreement, arrangement or understanding which would or could reasonably be expected to cause or result in any such persons being deemed a Sanctioned Person on the date hereof, in each case to the extent relevant Sanctions have the effect of making unlawful, prohibiting or otherwise restricting Completion, the transactions contemplated by this Agreement or performance by any party of its obligations under this Agreement.

(b) The funds that Hologen will use for the transactions contemplated by this Agreement do not derive in any way from any transaction with or action involving a Sanctioned Person, to the extent the use of such funds have the effect of making unlawful, prohibiting or otherwise restricting Completion, the transactions contemplated by this Agreement or performance by any Party of its obligations under this Agreement.

19.5 Competing Product. Hologen hereby covenants that, during the period beginning on the Effective Date and ending upon [***], neither Hologen (nor any of its Affiliates) shall, alone or with any third parties (including through licensing to or from any third party), research, develop, manufacture, commercialize or otherwise exploit any Competing Product anywhere in the world, in each case, without the prior written consent of MeiraGTx.

Each of Hologen, MeiraGTx and (save for in respect of the warranty at Section 19.6, which MeiraGTx Holdings does not warrant) MeiraGTx Holdings (collectively, the "MeiraGTx Entities") hereby warrants to the Board of Directors and the other Parties to this Agreement, severally and not jointly and solely on its own behalf, as of the date of this Agreement and on Completion, as applicable, and each Person admitted to the Company as a Member following the Effective Date hereby warrants to the Board of Directors and the other Parties to this Agreement, severally and not jointly and solely on its own behalf, as of the date of it is admitted to the Company as a Member as follows:

19.6 Purchase for Own Account. It is entering into this Agreement and the transactions contemplated hereby as principal, for its own account (and in the case of Hologen, its Hologen Investors and Affiliates) solely for the purpose of investment, and not as nominee or agent. It has (and in the case of Hologen, each Hologen Investor has) no present agreement, undertaking, arrangement, obligation, or commitment providing for the direct or indirect disposition of the Shares.

19.7 Duly Formed. It is duly incorporated and validly existing under the laws of its jurisdiction.

19.8 Knowledge and Experience. It has such knowledge and experience in financial, tax and business matters as to enable it to evaluate the merits and risks of its investment in the Company and to make an informed investment decision with respect thereto.

19.9 Economic Risk. It is able to bear the economic risk of its investment in its Shares for an indefinite period of time, and it is aware that it may lose the entire amount of its investment in the Company.

19.10 Solvency. No order has been made, petition presented or meeting convened for its or any of its Affiliates' winding up, nor any other action taken in relation to the appointment of an administrator, liquidator, receiver, administrative receiver, compulsory manager or any provisional liquidator (or equivalent in any other jurisdiction) (or other process whereby the business is terminated and the assets of the company concerned are distributed amongst the creditors or shareholders or any other contributors), and there are no proceedings under any applicable insolvency, reorganisation or similar laws in any relevant jurisdiction, and no events have occurred that, under applicable law, would justify any such proceedings.

19.11 Binding Agreement. It has all requisite power and authority to enter into and perform this Agreement, and has taken all necessary action to authorise the execution of and the performance of its obligations under this Agreement, and this Agreement is and shall remain its valid and binding agreement, enforceable in accordance with its terms (subject, as to the enforcement of remedies, to any applicable bankruptcy, insolvency or other laws affecting the enforcement of creditors' rights).

19.12 No Breach. The execution and delivery by it of, and the performance by it of its obligations under, this Agreement and any agreement entered into pursuant to the terms of this Agreement will not:

(a) result in a breach of or conflict with any provision of its constitutional documents;

(b) result in a material breach of, or constitute a material default under, any instrument to which it is a Party or by which it is bound; or

(c) result in a breach of any applicable law.

19.13 Disputes. There are no:

(a) outstanding judgments, orders, injunctions or decrees of any governmental or regulatory body or arbitration tribunal against or affecting it or any of its Affiliates;

(b) lawsuits, actions or proceedings pending or, to its knowledge, threatened against or affecting it or any of its Affiliates; or

(c) investigations by any governmental or regulatory body which are pending or, to its knowledge, threatened against it or any of its Affiliates,

which, in each case, has or could have a material adverse effect on its ability to perform its obligations under this Agreement or any other agreements entered into pursuant to the terms of this Agreement.

19.14 Consents. All consents, permissions, authorisations, approvals and agreements of third parties and all authorisations, registrations, declarations, filings with any Governmental Entity or other organisation having jurisdiction over it that are necessary or desirable for it to obtain in order to enter into and perform this Agreement and any agreement entered into pursuant to the terms of this Agreement in accordance with its terms, have been unconditionally obtained in writing and have been disclosed in writing to the other Parties.

19.15 Company Covenants. It shall not take any action that would cause or further any violation by the Company of the covenants contained in Sections 18.4 and 18.5.

20. COMPANY WARRANTIES.

The Company hereby warrants (in respect of itself) to each of Hologen and the MeiraGTx Entities, as of the date of this Agreement and on Completion, as follows:

20.1 Duly Formed. The Company is a duly incorporated and validly existing non-cellular company under the Act, with all necessary power and authority under the Act to issue the Shares to be issued to the Members hereunder.

20.2 Activities in Other Jurisdictions. The Company shall not invest in Subsidiaries organized in, or open an office or other place of business in, any jurisdiction other than Guernsey (including its territories and possessions) or the UK, unless, it (1) has consulted with reputable local counsel as to whether such jurisdiction will recognize the limited liability of the Members to the same extent as provided under the laws of Guernsey, and (2) shall have obtained advice of reputable local counsel or an internationally or regionally recognized firm of independent public accountants, that such activity will not result in any Member (solely by virtue of being a Member) becoming subject to a requirement to either (x) file income tax returns in such jurisdiction or (y) pay tax in such jurisdiction, in each case with respect to the Member's income other than income from the Company.

21. ADDITIONAL COVENANTS.

21.1 Non-Competition; Non-Solicitation**.**

(a) Except for performance of a Member or its Affiliates under the Collaboration Agreement, each Member hereby agrees that, for so long as it or its Permitted Transferee, directly or indirectly, owns any Shares and for a period of [***] thereafter (the "Restricted Period"), such Member shall not (and it shall cause its Affiliates not to) [***]; *provided*, that nothing in this Section 21.1(a) shall prohibit such Member or any of its Affiliates from acquiring or owning, directly or indirectly:

(i) up to five percent (5%) of the aggregate voting securities of any Competitor that is a publicly traded Person; or

(ii) up to five percent (5%) of the aggregate voting securities of any Competitor that is not a publicly traded Person, so long as such interest is passive and neither such Member nor any of its Affiliates, directly or indirectly, designates a member of the board of directors (or similar body) of such Competitor or its Affiliates or otherwise has an active role in the management or governance of such Person.

(b) In light of each Member's access to Confidential Information and position of trust and confidence with the Company, each Member further agrees that, during the Restricted Period, it shall not, directly or indirectly through one or more of any of its Affiliates, hire or solicit, or encourage any other Person to hire or solicit, any individual who has been employed by the Company or any of its Subsidiaries within [***] prior to the date of such hiring or solicitation, or encourage any such individual to leave such employment. This Section 21.1(b) shall not prevent a Member or its controlled Affiliates from hiring or soliciting any employee or former employee of the Company or any of its Subsidiaries who responds to a general solicitation that is a public solicitation of prospective employees and not directed specifically to any of the Company's or its Subsidiary's employees.

(c) In light of each Member's access to Confidential Information and position of trust and confidence with the Company, each Member further agrees that, during the Restricted Period, it shall not, directly or indirectly through one or more of any of its Affiliates, solicit or entice, or attempt to solicit or entice, any clients, customers, or suppliers of the Company or any of its Subsidiaries for purposes of diverting their business or services from the Company or any of its Subsidiaries.

(d) Each Member acknowledges and agrees that a breach or threatened breach of this Section would give rise to irreparable harm to the other Member and the Company or any of its Subsidiaries, for which monetary damages would not be an adequate remedy, and hereby agrees that in the event of a breach or a threatened breach by such Member of any such obligations, the other Member and the Company and each of its Subsidiaries shall, in addition to any and all other rights and remedies that may be available to it in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance, as well as an equitable account of all earnings, profits, and other benefits arising from any such breach, and any other relief that may be available from a court of competent jurisdiction (without any requirement to post bond).

(e) Each Member acknowledges that the restrictions contained in this Section are reasonable and necessary to protect the Members' legitimate interests and constitute a material

inducement to the other Member to enter into this Agreement and consummate the transactions contemplated hereby. If any court of competent jurisdiction determines that any of the covenants set forth in this Section, or any part thereof, is unenforceable because of the duration or geographic scope of such provision, such court shall have the power to modify any such unenforceable provision in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Section, or by making such other modifications as it deems warranted to carry out the intent and agreement of the Parties, as embodied herein, to the maximum extent permitted by applicable law. The Parties hereto expressly agree that this Agreement as so modified by the court shall be binding on and enforceable against each of them.

21.2 Change of Control Notice. In the event of a Change of Control of a Major Member, such Major Member shall promptly, but not later than [***] following such Change of Control, notify the other Major Member in writing thereof (a "Change of Control Notice"), setting forth the date of such Change of Control.

21.3 Licenses and Permits. Each Member shall cooperate in providing such information, in signing such documents and in taking any other action as may reasonably be requested by the Company in connection with obtaining any license or permit needed to operate its business or the business of any entity in which the Company invests.

21.4 Compliance with Laws. The Company shall, and to procure that its Subsidiaries shall, operate in accordance with all applicable laws, statutes, rules, regulations, orders, permits or any similar provision having the force or effect of law.

21.5 Unrelated Business Taxable Income. The Company shall conduct its affairs in a manner that does not cause any Member (or the equity owners of any Member) to have any "unrelated business taxable income" (as that term is defined in Section 512 through Section 514 of the Code) or any item of gross income that would be included in determining such Member's unrelated business taxable income.

21.6 United States Trade or Business. The Company shall not engage in, or invest in any person that is treated as a flow-through entity for U.S. federal income tax purposes that engages in, (i) any "commercial activity" as defined in Section 892(a)(2)(i) of the Code, (ii) a "trade or business within the United States," within the meaning of Section 864(b) of the Code, or (iii) any other activity that causes the Company or any other person (including any Member and any direct or indirect owner of a Member) to file a state income tax return during any taxable year of the Company. The Company shall not make any investment or acquire any interest that would be treated as a "U.S. real property interest," within the meaning of Section 897 of the Code.

21.7 PFIC/CFC. The Company shall make a qualified electing fund election within the meaning of Section 1295 of the Code, with respect to any direct Subsidiary of the Company that is a passive foreign investment company within the meaning of the Code.

21.8 Notice of Noncompliance. Notwithstanding anything else in this Agreement, in the event that the Company fails to comply with its obligations under Sections 21.5 through Section 21.7, the Company will promptly provide notice to each Member of such noncompliance and

provide in a timely fashion as may be requested by a Member all necessary and reasonably available tax-related information in order to permit such Member to make accurate and timely tax filings for so long as such filings may be required to be made by such Member under applicable U.S. tax law.

22. AMENDMENTS TO AGREEMENT.

22.1 Amendments. This Agreement may only be modified or amended by written agreement of the Company and the Major Members signed by or on behalf of each of the Company and the Major Members, provided, that, notwithstanding the foregoing, any right of a Party hereto may be waived by such Party on its own behalf, without the consent of any other Party.

22.2 Binding Effect. Any modification or amendment to this Agreement pursuant to this Section 22 shall be binding on all Parties hereto (and any future parties from time to time that have executed and delivered a deed of adherence substantially in the form set out in Schedule 8.5).

23. GENERAL

23.1 Successors; Governing Law. This Agreement shall be binding upon the executors, administrators, estates, heirs and legal successors of Hologen, the MeiraGTx Entities and any other Members and permitted assigns of Hologen, the MeiraGTx Entities and any other Members. This Agreement and the rights of the Parties hereunder arising out of or related to this Agreement or the transactions contemplated hereunder shall be governed by and construed in accordance with the laws of England and Wales, without regard to any conflicts-of-laws principles that would cause the application of laws of any jurisdiction other than those of England and Wales.

23.2 Notices. All notices and other communications required or permitted hereunder shall be in writing must be delivered, given or otherwise provided (a) by hand (in which case, it will be effective upon delivery if received by the recipient before 5:00 P.M. local time at the recipient's location on a business day, otherwise effective the next business day), (b) by facsimile (in which case, it will be effective upon receipt of confirmation of good transmission), so long as such notice is also delivered by mail, postage prepaid, (c) by email (in which case, it will be effective upon transmission), so long as such notice is also delivered by mail, postage prepaid or (d) by overnight delivery by a nationally recognized, reputable courier service (in which case, it will be effective on the business day after being deposited with such courier service), in each case addressed (i) if to Hologen, MeiraGTx and any other Member, at the address, facsimile number or email address, as applicable, of Hologen, MeiraGTx or such Member designated herein below or at such other address, facsimile number or email address as Hologen, MeiraGTx or such Member shall have furnished to the Company in writing as the address, facsimile number or email address to which notices are to be sent hereunder and (ii) if to the Company or to the Board of Directors, to it at:

To MeiraGTx:

MeiraGTx Holdings:

[***]

MeiraGTx:

[***]

To Hologen:

[***]

To Company:

[***]

23.3 Severability. If any provision of this Agreement is determined by a court to be invalid or unenforceable, that determination shall not affect the other provisions hereof, each of which shall be construed and enforced as if the invalid or unenforceable portion were not contained herein. Such invalidity or unenforceability shall not affect any valid and enforceable application thereof, and each such provision shall be deemed to be effective, operative, made, entered into or taken in the manner and to the full extent permitted by law. Notwithstanding the foregoing, if any such invalidity or unenforceability shall deprive any Party hereto of a material portion of the benefits intended to be provided to such Party hereby, the Parties shall in good faith seek to negotiate a substitute benefit for such Person, it being understood that it is possible that no such substitute benefit is susceptible to being negotiated or given, in which event the other provisions of this Section 23.3 shall continue to apply.

23.4 Construction. The Parties agree that they have been represented by, or had the opportunity to consult with, counsel during the negotiation and execution of this Agreement and have together drafted this Agreement and, therefore, waive the application of any law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document.

23.5 Table of Contents, Headings. The table of contents and headings used in this Agreement are used for administrative convenience only and do not constitute substantive matter to be considered in construing this Agreement.

23.6 No Third Party Rights. Except as expressly provided herein, including with respect to the rights set forth in Section 18, the provisions of this Agreement are solely for the benefit of the Company, the Board of Directors, Hologen, the MeiraGTx Entities and any other Members, and no other Person, including creditors of the Company, shall have any right or claim against the Company, the Board of Directors, Hologen, the MeiraGTx Entities and any other Member by reason of this Agreement or any provision hereof or be entitled to enforce any provision of this Agreement.

23.7 Entire Agreement. The Transaction Agreements that certain guarantee letter between Hologen, MeiraGTx Holdings, and certain investors a party thereto, and the other agreements contemplated hereby constitute the entire agreement of Hologen, MeiraGTx and any other Members and their Affiliates relating to the Company and supersede all prior meetings, communications, representations, negotiations, contracts or agreements (including any prior drafts

thereof) with respect to the Company, whether oral or written, none of which shall be used as evidence of the Parties' intent.

23.8 Effect of Waiver or Consent. A waiver or consent, express or implied, to or of any breach or default by any Person in the performance by that Person of its obligations with respect to the Company is not a consent or waiver to or of any other breach or default in the performance by that Person of the same or any other obligations of that Person with respect to the Company. Failure on the part of a Person to complain of any act of any Person or to declare any Person in default with respect to the Company, irrespective of how long that failure continues, does not constitute a waiver by that Person of its rights with respect to that default until the applicable statute-of-limitations period has run.

23.9 Counterparts and Electronic Delivery. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, may be executed in one or more counterparts, all of which shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a facsimile machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

23.10 Jurisdiction and Venue.

(a) Each Party irrevocably agrees that the Courts of England shall have exclusive jurisdiction in relation to any dispute or claim arising out of or in connection with this Agreement or its subject matter, existence, negotiation, validity, termination or enforceability (including non-contractual disputes or claims).

(b) To the extent not prohibited by applicable law, each Party hereto waives and agrees not to assert, by way of motion, as a defense or otherwise, in any such proceeding brought in the above-named court, any claim that such Party is not subject personally to the jurisdiction of such court, that such Party's property is exempt or immune from attachment or execution, that such proceeding is brought in an inconvenient forum, that the venue of such proceeding is improper, or that this Agreement or the subject matter thereof, may not be enforced in or by such court.

23.11 Business Days. If any time period for giving notice or taking action hereunder expires on a day which is a Saturday, Sunday, or public holiday in London, England, Guernsey, the Bailiwick of Guernsey or New York, United States of America, then the time period shall automatically be extended to the business day immediately following such Saturday, Sunday or public holiday.

23.12 Survival. Section 1 (*Definitions*), Section 13.4 (*Non-Disclosure*) and Section 18 (*Indemnification*) shall survive and continue in full force in accordance with their terms notwithstanding any termination of this Agreement or the dissolution of the Company.

23.13 Gender. Any reference to the masculine gender shall be deemed to include the feminine and neuter genders unless the context otherwise requires.

23.14 Currency.

(a) In this Agreement a reference to "$", "USD" or "Dollars" is to the lawful currency of the United States of America. A reference to "£", "GBP" or "Pounds" is to the lawful currency of England.

(b) Any amount to be converted from Dollars to Pounds or vice versa for the purposes of this Agreement shall be converted into an equivalent amount of the second currency at the Barclays FX spot rate.

SCHEDULE 6.2

COMPLETION DELIVERIES

1. At Completion MeiraGTx shall deliver or procure the delivery of:

1.1. a copy of the Subscription Agreement duly executed by MeiraGTx;

1.2. a copy of the Collaboration Agreement duly executed by MeiraGTx and MeiraGTx Licensor;

1.3. a copy of the resolutions (whether in the form of minutes or written resolutions) passed by the board of MeiraGTx which approve and authorise the execution and completion of (i) the Subscription Agreement, (ii) this Agreement, and (iii) the Collaboration Agreement; and

1.4. and copy of the resolutions (whether in the form of minutes or written resolutions) passed by the sole member of MeiraGTx Licensor which approves and authorises the execution and completion of the Collaboration Agreement.

2. At Completion Hologen and MeiraGTx shall deliver or procure the delivery of the resolutions (whether in the form of minutes or written resolutions) passed by the board of the Company or by Hologen and MeiraGTx in their capacity as Members of the Company (as appropriate) as may be necessary to:

2.1. adopt the New Articles;

2.2. appoint the initial MeiraGTx Directors and appoint the initial Hologen Directors and the chairperson of the Board of Directors; and

2.3. instruct the secretary of the Company to (i) make the necessary filings and (ii) update the company books and records to reflect the appointment of the new directors and MeiraGTx and Hologen as shareholders of the Company.

3. At Completion the Company shall deliver or procure deliver of the resolutions (whether in the form of minutes or written resolutions) passed by the Company in its capacity as the sole shareholder (as appropriate) as may be necessary to:

3.1. adopt the Collaboration Agreement.

4. At Completion Hologen shall deliver or procure the delivery of:

4.1. a copy of the Subscription Agreement duly executed by Hologen; and

4.2. a copy of the resolutions (whether in the form of minutes or written resolutions) passed by the board of Hologen which approve and authorize the execution and completion of (i) this Agreement and (ii) the Subscription Agreement.

SCHEDULE 6.2 – ANNEX A

COLLABORATION AND LICENSE AGREEMENT

SCHEDULE 8.5

DEED OF ADHERENCE

Reference is made to the framework agreement (the "Agreement") dated [_____], 2025 among Hologen Limited, MeiraGTx Neuro UK Limited, MeiraGTx Holdings PLC, and Hologen Neuro AI Limited. Once executed, this deed of adherence (this "Deed") will be supplemental to and will form part of the Agreement, and at no time shall the provisions of this Deed be used to contravene, derogate or detract from the Agreement, unless to the extent otherwise expressly provided in this Deed.

Capitalised terms used but not defined in this Deed shall have the meanings given to such terms in the Agreement.

1. Adherence. For good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the undersigned (the "Adhering Party"), a transferee of Transfer Shares pursuant to the terms of the Agreement, by executing this Deed and upon the satisfaction of the conditions to the admission of the Adhering Party as a Member pursuant to Section 8.5 of the Agreement, (a) agrees to become a party to the Agreement as a Member with the same force and effect as if originally named [Hologen][MeiraGTx] in the Agreement, fully bound by, and subject to, all of the covenants, terms and conditions of the Agreement as though so originally named; and (b) without limiting the generality of the foregoing, assumes all of the rights and obligations of [Hologen][MeiraGTx] under the Agreement, in each case, as of the time of delivery of this Deed, with effect from [date][FOR PERMITTED TRANSFEREES, INCLUDE:; provided that, [Hologen][MeiraGTx] is and shall remain obligated for and will be deemed to have guaranteed, the performance by the Adhering Party of any and all of the obligations of the Adhering Party under the Agreement]. The Adhering Party acknowledges that it has received and reviewed a complete copy of the Agreement and of the Articles. The Adhering Party agrees and undertakes to exercise all rights and perform all obligations in a manner consistent with the exercise of such rights (including with respect of voting) and performance of such obligations by [Hologen][MeiraGTx].

2. Warranties. (a) Each of [Hologen][MeiraGTx] and the Adhering Party warrants to [Hologen][MeiraGTx] and the Company that the warranties made by [Hologen][MeiraGTx] in Section 19 to the Agreement are true and correct as of the date of this Deed with respect to [Hologen][MeiraGTx] and the Adhering Party (i.e., all references in such warranties to a warranting party will be deemed to refer to each of [Hologen] [MeiraGTx] and the Adhering Party), and (b) each of [Hologen][MeiraGTx] and the Adhering Party additionally and severally warrants to [Hologen][MeiraGTx] that either the Adhering Party is a Permitted Transferee or the Transfer of Shares to the Adhering Party has complied with all applicable provisions in Section 15 of the Agreement.

3. Notices. For purposes of Section 23.2 of the Agreement, the notice information of the Adhering Party shall be (subject to the provisions of such Section 23.2):

   Name: [*Name of Adhering Party*]

Address: [*Address*]

Attention: [*Name; Title*]

4. Governing Law. This Deed and its enforcement shall be governed by, and construed and enforced in accordance with, the laws of England and Wales, without regard to any conflicts-of-laws principles that would cause the application of laws of any jurisdiction other than those of England and Wales.

5. Counterparts. This Deed may be executed in more than one counterpart, each of which upon execution and delivery will constitute an original and all of which when taken together will constitute one agreement.

6. Other Terms and Agreements. Sections 1, 22 and 23 of the Agreement are deemed to be incorporated in this Deed and shall apply *mutatis mutandis*.

Executed as a **DEED** by

[**Adhering Party]**

Director

acting by a director in the presence of:

Witness' signature:

Name (print):

Occupation:

Address:

[*Remainder of Page Left Intentionally Blank; Signature Pages Follow*]

IN WITNESS WHEREOF, the parties intending to be bound have caused this Agreement to be executed and delivered as a DEED on the date specified at the beginning of this Agreement by their duly authorized representatives.

Executed as a **DEED** by	/s/Andrew Henton
Hologen Limited	Director
acting by a director in the presence of:	
Witness' signature:	/s/ Jamie Oldfield
Name (print):	Jamie Oldfield
Occupation:	[***]
Address:	[***]

[*Signature page to Framework Agreement*]

Executed as a **DEED** by **Hologen Neuro AI Limited** acting by a director in the presence of:	/s/ Andrew Henton Director
Witness' signature:	/s/ Jamie Oldfield
Name (print):	Jamie Oldfield
Occupation:	[***]
Address:	[***]

[*Signature page to Framework Agreement*]

Executed as a **DEED** by **MeiraGTx Neuro UK Limited** acting by a director in the presence of:	/s/ Alexandria Forbes Director
Witness' signature:	/s/ Robert Wollin
Name (print):	Robert Wollin
Occupation:	[***]
Address:	[***]

[*Signature page to Framework Agreement*]

Executed as a **DEED** by **MeiraGTx Holdings plc** acting by a director in the presence of:	/s/ Alexandria Forbes Director
Witness' signature:	/s/ Robert Wollin
Name (print):	Robert Wollin
Occupation:	[***]
Address:	[***]

Exhibit 10.50

Certain information marked as [***] has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

FORM OF

COLLABORATION AND LICENSE AGREEMENT

by and among

HOLOGEN NEURO AI LTD,

HOLOGEN NEURO AI UK LIMITED,

HOLOGEN LIMITED,

MEIRAGTX HOLDINGS PLC,

MEIRAGTX NEURO UK LIMITED

and

MEIRAGTX NEURO I, LLC

_____, 2025

TABLE OF CONTENTS

	Page
ARTICLE 1 DEFINITIONS	2
ARTICLE 2 LICENSE GRANTS	13
2.1 License Grants	13
2.2 Sublicenses	14
2.3 No Implied Licenses; Retained Rights	15
ARTICLE 3 DEVELOPMENT	16
3.1 General	16
3.2 Transition Services	16
3.3 Development Plan	17
3.4 Performance of Development Activities	17
3.5 Reporting	17
3.6 Recordkeeping	17
3.7 Regulatory Matters	17
ARTICLE 4 MANUFACTURING AND SUPPLY	19
4.1 General	19
4.2 Clinical Supply Agreement	20
4.3 Commercial Supply Agreement	20
4.4 Manufacture and Supply of Licensed Device	20
ARTICLE 5 COMMERCIALIZATION	20
5.1 General	20
5.2 Diligence	20
ARTICLE 6 ADDITIONAL COLLABORATION TERMS	21
6.1 Subcontracting	21
6.2 Compliance	21
6.3 Limitations on Obligations	21
6.4 Other Obligations	22
6.5 Material Transfers	22
ARTICLE 7 GOVERNANCE	23
7.1 Development Board	23
7.2 Alliance Managers	24
ARTICLE 8 Financial Terms	24
8.1 Upfront Payment	24

8.2 Equity Consideration 24
8.3 Transition Services Costs 25
8.4 Development Costs 25
8.5 Payment Terms 26
8.6 Late Payments 26
8.7 Taxes 26
8.8 Records; Audits 26
ARTICLE 9 INTELLECTUAL PROPERTY 27
9.1 Background IP 27
9.2 Arising IP 27
9.3 Prosecution and Maintenance 29
9.4 Enforcement Rights 30
9.5 Defense of Third Party Actions 32
ARTICLE 10 CONFIDENTIALITY 33
10.1 Confidential Information 33
10.2 Confidentiality and Non-Use Obligations 33
10.3 Exceptions 33
10.4 Permitted Disclosures 34
10.5 Return or Destruction of Confidential Information 34
10.6 Public Disclosure 34
10.7 Clinical Trial Data 34
10.8 Scientific Publications 35
10.9 Use of Name 35
10.10 Equitable Relief 35
ARTICLE 11 REPRESENTATIONS, WARRANTIES AND COVENANTS 35
11.1 Mutual Representations and Warranties 35
ARTICLE 12 INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE 36
12.1 Indemnification by Company 36
12.2 Indemnification by MeiraGTx 37
12.3 Indemnification Process 37
12.4 Limitation on Liability 38
12.5 Insurance 38

ARTICLE 13 TERM AND TERMINATION 38
13.1 Term 38
13.2 Termination 38
13.3 Effects of Termination 40
13.4 Survival; Accrued Rights and Obligations 41
ARTICLE 14 MISCELLANEOUS PROVISIONS 42
14.1 Binding Effect; Entire Agreement 42
14.2 Amendments 42
14.3 Further Assurances 42
14.4 Assignment 42
14.5 Performance by Affiliates 43
14.6 Equitable Relief; Cumulative Remedies 43
14.7 Governing Law 43
14.8 Disputes 43
14.9 Notice 43
14.10 Severability 44
14.11 Independent Contractor; No Third-Party Beneficiary 44
14.12 Force Majeure Events 44
14.13 Headings, Constructions 44
14.14 Counterparts 45

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (this "**Agreement**") dated as of ____, 2025 (the "**Effective Date**"), is entered into by and among (a) (i) **HOLOGEN NEURO AI UK LIMITED**, a private company limited by shares incorporated in England with company number 16283812 and having a place of business at 86-87 Campden Street, London W8 7EN, UK ("**Hologen UK**"), and (ii) **HOLOGEN NEURO AI LTD**, a non-cellular company limited by shares incorporated in Guernsey with company number 74942 whose registered office is at c/o Elysium Fund Management, 1st Floor, Royal Chambers, St Julian's Avenue, St Peter Port, GY1 3JX, Guernsey ("**Hologen Guernsey**" and, together with Hologen UK, "**Company**"); (b) **HOLOGEN LIMITED**, a non-cellular company limited by shares incorporated in Guernsey with company number 74905 whose registered office is at c/o Elysium Fund Management, 1st Floor, Royal Chambers, St. Julian's Avenue, St. Peter Port, GY1 3JX, Guernsey ("**HGL**"); and (c) (i) **MEIRAGTX NEURO I, LLC**, a Delaware limited liability company, with a principal office at 450 East 29th Street, 14th Floor, New York, NY 10016, USA ("**MeiraGTx Neuro US**"), (ii) **MEIRAGTX NEURO UK LIMITED**, a private company limited by shares incorporated in England with company number 16108121 and having a place of business at 34-38 Provost Street, London N1 7NQ, UK ("**MeiraGTx Neuro UK**") and (iii) **MEIRAGTX HOLDINGS PLC**, a Cayman Islands exempted company with a principal office at 450 East 29th Street, 14th Floor, New York, NY 10016, USA ("**MeiraGTx Holdings**" and, together with MeiraGTx Neuro US and MeiraGTx Neuro UK, "**MeiraGTx**"). Hologen UK, Hologen Guernsey, HGL, MeiraGTx Neuro US, MeiraGTx Neuro UK and MeiraGTx Holdings are each referred to herein as a "**Party**" and collectively as the "**Parties**".

R E C I T A L S:

WHEREAS, MeiraGTx is a clinical-stage gene therapy company and has developed certain Patents, Know-How and other intellectual property rights with respect to the Licensed Products and Licensed Device;

WHEREAS, Hologen Limited, a private company limited by shares incorporated in England with company number 14666561 ("**Hologen**") and its Affiliates have expertise in financing or co-investment in certain pharmaceutical assets whose regulatory approval and trial designs can be optimized using their large medicine models, which use generative artificial intelligence trained on large sets of real-word, multi-modal clinical data to help develop, accelerate, or derisk commercial opportunities;

WHEREAS, MeiraGTx Holdings and Hologen have entered into [***], pursuant to which, among other things, (i) Hologen (or its Affiliate HGL) has formed Hologen Guernsey as a biopharmaceutical company dedicated to the Development and Commercialization of gene therapy products, including the Licensed Device and Licensed Products, and (ii) Hologen Guernsey has formed Hologen UK;

WHEREAS, HGL, Hologen Guernsey, MeiraGTx Neuro UK and MeiraGTx Holdings have entered into that certain Framework Agreement, dated as of March 9, 2025 (the "**Hologen Guernsey Framework Agreement**"), pursuant to which, among other things, on the Effective Date, (a) MeiraGTx Neuro UK shall acquire Class A Shares constituting thirty percent (30%) of the entire issued share capital of Hologen Guernsey; and (b) MeiraGTx, HGL and Company have agreed to enter into this Agreement pursuant to which, among other things, MeiraGTx Neuro UK and Company shall collaborate to continue Development, Manufacture and Commercialization of the Licensed Device and Licensed Products in accordance with the terms set forth herein; and

WHEREAS, in furtherance thereof, MeiraGTx Neuro US desires to grant to Company, and Company desires to receive from MeiraGTx Neuro US, an exclusive license under the MeiraGTx Licensed Technology to Develop, Manufacture and Commercialize the Licensed Device and Licensed Products in the Field in the Territory in accordance with the terms set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises contained herein, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise defined elsewhere in this Agreement, all capitalized terms shall have the following meanings (and cognates of such terms shall have correlative meanings):

1.1 "**AAV**" means adeno-associated virus.

1.2 "**Acquirer**" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates, determined as of immediately prior to the closing of such Change of Control.

1.3 "**Additional Licensed Products**" means any gene therapy product that comprises or otherwise incorporates any MeiraGTx Local Delivery Technology.

1.4 "**Adverse Event**" means any serious untoward medical occurrence in a patient or subject who is administered any product, but only if and to the extent that such serious untoward medical occurrence is required under any Laws to be reported to applicable Regulatory Authorities, including any Adverse Drug Reaction (ADR) which is noxious and unintended and which occurs at doses normally used in a human subject for prophylaxis, diagnosis, or therapy of a disease or for the modification of physiologic function with a causal link to such product.

1.5 "**Affiliate**" means, with respect to a Party, any person or entity directly or indirectly controlling, controlled by, or under common control with a Party, but only for so long as such control exists, and, for this purpose, "control," "controlling" and "controlled by" shall mean the ownership and control of more than fifty percent (50%) of the outstanding voting securities or interest in capital or profits of any person or entity, or the right to direct or control the management or affairs of any person or entity by contract or similar arrangement; *provided* that, for clarity, for purposes of this Agreement, in no event shall MeiraGTx (or any of its Affiliates) be deemed an Affiliate of Company or HGL (or any of their Affiliates) or *vice versa*.

1.6 "**Agreement**" has the meaning set forth in the preamble.

1.7 "**Alliance Manager**" has the meaning set forth in Section 7.2.

1.8 "**Arising IP**" means any and all Arising Know-How and Arising Patents.

1.9 "**Arising Know-How**" means any Know-How that is first discovered, developed, generated, invented, derived, created, conceived or reduced to practice during the Term by or on behalf of a Party (or any of its Affiliates, Subcontractors or Sublicensees), either alone or jointly with any other Party (or any of its Affiliates, Subcontractors or Sublicensees), in each case, in the performance of activities under this Agreement, including in the performance of the Development Plan.

1.10 "**Arising Patent**" means any Patent (a) with a priority date on or after the Effective Date; and (b) that claims or otherwise discloses any Arising Know-How.

1.11 "**Background IP**" means, individually or collectively, as applicable, (a) the MeiraGTx Background IP; and (b) the Company Background IP.

1.12 "**BDNF**" has the meaning set forth in Section 1.84.

1.13 "**BPCIA**" means the Biologics Price Competition and Innovation Act of 2009 (42 U.S.C. § 262 *et seq*.) or any similar provisions in a country outside the United States.

1.14 "**Business Day**" shall mean a day other than a Saturday, Sunday or public holiday in New York, NY when banks in New York, NY are open for normal banking business.

1.15 "**Calendar Quarter**" means each three (3) month period commencing January 1, April 1, July 1 or October 1 of any Calendar Year; *provided* that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.16 "**Calendar Year**" means the period beginning on January 1 and ending on December 31 of the same year; *provided* that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same year; and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.17 "**Change of Control**" means, with respect to a Party, an event or transaction or series of events or transactions by which: (a) any Third Party (or group of Third Parties acting in concert) becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the outstanding securities of such Party or the total voting power of such securities normally entitled to vote in elections of directors for such Party; (b) (i) such Party reorganizes, consolidates or comes under common control with, or merges into a Third Party, or (ii) any Third Party entity reorganizes, consolidates or comes under common control with, or merges into, such Party, in either event of the foregoing ((i) or (ii)), where more than fifty percent (50%) of the total voting power of the securities outstanding of the surviving entity normally entitled to vote in elections of directors for such surviving entity is not held by the Persons holding at least fifty percent (50%) of the outstanding shares of such Party, or the total voting power of such securities normally entitled to vote in elections of directors for such Party, immediately preceding such reorganization, consolidation or merger; or (c) such Party conveys, transfers or leases to a Third Party all or substantially all of its assets or business relating to this Agreement.

1.18 "**Clinical Manufacturing**" means the Manufacture of a Licensed Device or Licensed Product or the acquisition of such Licensed Device or Licensed Product from a CMO, in each case, for use in Clinical Trials or other Development activities.

1.19 "**Clinical Supply Agreement**" has the meaning set forth in Section 4.2.

1.20 "**Clinical Trial**" means a clinical trial in human subjects that has been approved by an institutional review board or ethics committee, as applicable, and is designed to measure the safety or efficacy of a therapeutic product, including any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, any study incorporating more than one (1) of these phases, or any clinical trial (whether required or optional) commenced after Marketing Approval.

1.21 "**CMO**" means any Third Party contract manufacturing organizations and similar contractors.

1.22 "**Collaboration Activities**" has the meaning set forth in Section 6.1.

1.23 "**Commercial Manufacturing**" means the Manufacture of a Licensed Device or Licensed Product or acquisition of such Licensed Device or Licensed Product from a CMO, in each case, for Commercialization of such Licensed Device or Licensed Product, as applicable.

1.24 "**Commercial Supply Agreement**" has the meaning set forth in Section 4.3.

1.25 "**Commercialize**" means, with respect to any product or device, any and all activities directed or related to promoting, marketing, distributing, selling (including offering for sale or contracting to sell), importing, exporting or otherwise commercially exploiting such product or device, or providing product or device support for such product or device and to conduct activities in preparation for conducting the foregoing activities, including interactions with Regulatory Authorities prior to or following the receipt of Marketing Approval in the applicable country or region for such product or device, or activities to produce commercialization support data or to secure or maintain market access and reimbursement; *provided* that Commercialization does not include Development or interacting with Regulatory Authorities regarding the foregoing.

1.26 "**Commercially Reasonable Efforts**" means, with respect to applicable activities or obligations of a Party under this Agreement, such efforts and resources that are consistent with the commercially reasonable practices of a pharmaceutical or biotechnology company of similar size and resources as such Party, in the exercise of its reasonable business discretion, in connection with performance of similar activities or obligations relating to the Development and Commercialization of a similarly situated product or device owned by it, or to which it has exclusive rights, with similar characteristics as the applicable Licensed Device or Licensed Product hereunder, that is of similar market potential at a similar stage in its development or lifecycle as such Licensed Device or Licensed Product, taking into account all relevant factors, including technical, legal, scientific or medical factors.

1.27 "**Company**" has the meaning set forth in the preamble.

1.28 "**Company Arising IP**" has the meaning set forth in Section 9.2.3(c).

1.29 "**Company Arising Know-How**" has the meaning set forth in Section 9.2.3(a).

1.30 "**Company Arising Patents**" has the meaning set forth in Section 9.2.3(c).

1.31 "**Company Background IP**" means, collectively, the Company Background Know-How and the Company Background Patents.

1.32 "**Company Background Know-How**" means any and all Know-How that is owned or otherwise Controlled by Company (or any of its Affiliates) prior to the Effective Date, or that otherwise comes to be owned or under the Control of Company (or any of its Affiliates) during the Term independently of the performance of the Development Activities or any other activities under this Agreement, that is necessary for the performance of the Development Activities allocated to MeiraGTx Neuro UK under the Development Plan or any of MeiraGTx Neuro UK's other obligations under this Agreement (including under the Transition Services Plan or any Supply Agreement), including any Company Materials provided by Company (or any of its Affiliates) to MeiraGTx Neuro UK (or any of its Affiliates) under this Agreement, but, in each case, excluding any Arising Know-How.

1.33 "**Company Background Patents**" means any and all Patents that are owned or otherwise Controlled by Company (or any of its Affiliates) prior to the Effective Date, or that otherwise come to be owned by, or under the Control of, Company (or any of its Affiliates) during the Term

independently of the performance of the Development Activities or any other activities under this Agreement, that claim or otherwise Cover (a) any Company Background Know-How; or (b) are otherwise necessary for the performance of the Development Activities allocated to MeiraGTx Neuro UK under the Development Plan or any of MeiraGTx Neuro UK's other obligations under this Agreement (including under the Transition Services Plan or any Supply Agreement) but, in each case ((a) or (b)), excluding any Arising Patents.

1.34 "**Company Formation Agreements**" means (a) the Hologen Guernsey Framework Agreement; and (b) that certain Subscription Agreement among Hologen Guernsey, HGL and MeiraGTx Neuro UK, dated as of the Effective Date.

1.35 "**Company Indemnitees**" has the meaning set forth in Section 12.2.

1.36 "**Company Licensed Technology**" means, collectively, the Company Background IP, the Company Arising IP and Company's interest in any Joint Arising IP.

1.37 "**Company Materials**" means any and all Materials delivered by Company to MeiraGTx Neuro UK under the Development Plan or that are otherwise provided or made available by or on behalf of Company (or any of its Affiliates) to MeiraGTx Neuro UK (or any of its Affiliates) under this Agreement but, in each case, specifically excluding any Materials in the Arising Know-How.

1.38 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.39 "**Control**" means, with respect to any Know-How, Patent, Regulatory Documents, Regulatory Approval or other intellectual property, the possession (whether by sole or joint ownership or license or otherwise, other than the licenses granted hereunder) of the ability to grant access, a right to use, or a license, sublicense or any other right to exploit, as set forth in this Agreement, such Know-How, Patent, Regulatory Documents, Regulatory Approval or other intellectual property, as applicable, in each case, without: (a) violating the terms of any agreement or other arrangement with any Third Party or any Law; or (b) incurring any incremental payment obligation to a Third Party associated with making such grant (unless, and except to the extent, the Parties have agreed in writing to an allocation of such payment obligation); *provided* that, notwithstanding anything in this Agreement to the contrary, a Party or its Affiliates will be deemed not to Control any Know-How, Patents, Regulatory Documents, Regulatory Approval or other intellectual property that are owned or in-licensed by an Acquirer except (i) if such Know-How, Patents, Regulatory Documents, Regulatory Approval or other intellectual property owned or in-licensed by the Acquirer were generated from participation by employees or agents of such Acquirer in furtherance of Development, Manufacturing or Commercialization activities with respect to any Licensed Device or Licensed Product under this Agreement after such Change of Control, (ii) for any Know-How, Patents, Regulatory Documents, Regulatory Approval or other intellectual property owned or in-licensed by such Acquirer not used in the performance of Development, Manufacturing or Commercialization activities with respect to any Licensed Device or Licensed Product under this Agreement prior to the consummation of such Change of Control that, after the consummation of such Change of Control, are used by such acquired Party or any of its Affiliates in the performance of Development, Manufacturing or Commercialization activities with respect to any Licensed Device or Licensed Product under this Agreement, or (iii) if, prior to the consummation of such Change of Control, such acquired Party or any of its Affiliates also Controlled such Know-How, Patents, Regulatory Documents, Regulatory Approval or other intellectual property owned or in-licensed by such Acquirer, in each of which cases ((i)–(iii)), such Know-How, Patents, Regulatory Documents, Regulatory Approval or other intellectual property owned or in-licensed by such Acquirer will be deemed Controlled by the acquired Party or its Affiliates for purposes of this Agreement.

1.40 [***]

1.41 "**Cover**" means, with respect to a given Licensed Device or Licensed Product in a given country and a given Patent, that the making, offering for sale, selling, importing or using of such Licensed Device or Licensed Product would, but for a license granted under such Patent (assuming, with respect to a patent application, as if such application was then issued), infringe any claim of such Patent in such country in which that activity occurs.

1.42 "**Data Protection Laws**" means any Laws relating to privacy and data protection, direct marketing or the interception or communication of electronic messages, including, to the extent applicable, (a) the United States Health Insurance Portability and Accountability Act of 1996 and its implementing regulations; (b) the California Consumer Privacy Act of 2018; (c) the General Data Protection Regulation 2016/679, the e-Privacy Directive 2002/58/EC, the Privacy and Electronic Communications Regulations 2003, the UK Data Protection Act 2018 ("DPA"), the UK General Data Protection Regulation as defined by the DPA, as amended by the Data Protection, Privacy and Electronic Communications (EU Exit) Regulations 2019; and (d) any relevant law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding instrument which implements such Laws from time to time.

1.43 "**DB**" has the meaning of "Development Board", as set forth in Section 7.1.

1.44 "**Develop**" means, with respect to any molecule, product or device, the performance of any and all research, discovery, pre-clinical or clinical development activities (including toxicology, pharmacology, statistical analysis, Clinical Trials and all other regulatory trials), as well as any and all activities pertaining to supporting, securing or maintaining Regulatory Approval of such molecule, product or device in a given country or territory or any Manufacturing activities in connection with any of the foregoing (including development of test methods, stability testing, formulation development, process development, quality assurance activities, quality control activities, qualification and validation activities, analytic process development, Manufacturing process validation, scale-up, and all other similar activities).

1.45 "**Development Activities**" has the meaning set forth in Section 3.3.

1.46 "**Development Costs**" means all costs and expenses incurred by or on behalf of MeiraGTx Neuro UK (or any of its Affiliates) in connection with the performance of any of the Development Activities allocated to MeiraGTx Neuro UK under the Development Plan.

1.47 "**Development Plan**" has the meaning set forth in Section 3.3.

1.48 "**Development Plan Budget**" has the meaning set forth in Section 3.3.

1.49 "**Development Term**" means the period beginning on the Effective Date and ending upon the date on which all Development Activities have been completed under and in accordance with the then-current Development Plan.

1.50 "**Disclosing Party**" has the meaning set forth in Section 10.1.

1.51 "**Disputes**" has the meaning set forth in Section 14.8.

1.52 "**Dollars**" or "**$**" means the official currency of the United States of America.

1.53 "**Effective Date**" has the meaning set forth in the preamble.

1.54 "**EMA**" means the European Medicines Agency, or any successor entity thereto performing similar functions for the European Union.

1.55 "**Enforcement Action**" has the meaning set forth in Section 9.4.2.

1.56 "**European Union**" or "**E.U.**" means the economic, scientific, and political organization of member states of the European Union as it may be constituted from time to time.

1.57 "**Existing AAV-BDNF Product**" has the meaning set forth in Section 1.84.

1.58 "**Existing AAV-GAD Product**" has the meaning set forth in Section 1.84.

1.59 [***]

1.60 "**FDA**" means the U.S. Food and Drug Administration, or any successor entity thereto performing similar functions in the United States.

1.61 "**Field**" means local delivery for any gene therapy in the CNS or any topographic or subcutaneous tissue modification on the face and scalp, of humans or animals.

1.62 "**FTE**" means employees or other personnel of MeiraGTx Neuro UK (or any of its Affiliates) performing Collaboration Activities allocated to MeiraGTx Neuro UK under this Agreement, including pursuant to the Development Plan or the Transition Services Plan, as applicable.

1.63 "**FTE Costs**" means, with respect to a given period, [***].

1.64 "**FTE Rate**" means [***].

1.65 "**GAD**" has the meaning set forth in Section 1.84.

1.66 "**GCP**" means all applicable then-current good clinical practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those as set forth in FDA regulations in 21 C.F.R. Parts 11, 50, 54, 56, 312, 314, and 320 and all related FDA rules, regulations, orders, and guidance, and by the International Council for Harmonization E6: Good Clinical Practices Consolidated Guideline (the "**ICH Guidelines**").

1.67 "**GLP**" means all applicable then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those as set forth in FDA regulations in 21 C.F.R. Part 58 and all applicable FDA rules, regulations, orders, and guidance, and the requirements with respect to good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and the ICH Guidelines.

1.68 "**GMP**" means all applicable then-current good manufacturing practices, including: (a) the applicable part of quality assurance to ensure that products or devices are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice; (b) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601, 610 and 820; (c) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal

Products; (d) the principles detailed in the ICH Q7A guidelines; and (e) the equivalent applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.69 "**Government Official**" means: (a) any officer or employee of a Governmental Body or any department, agency or instrumentality of a Governmental Body (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organization such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under applicable local Laws (including anti-bribery and corruption Laws) and not already covered by any of the above; or (e) any person acting in an official capacity for or on behalf of any of the above. For the purposes of clarity, "Government Official" shall include any person with close family members who are Government Officials with the capacity, actual or perceived, to influence or make official decisions affecting Company's or its Affiliates' business.

1.70 "**Governmental Body**" means any (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) supranational, federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or tax authority or power of any nature.

1.71 "**HGL**" has the meaning set forth in the preamble.

1.72 "**Hologen**" has the meaning set forth in the recitals.

1.73 "**Hologen Guernsey Framework Agreement**" has the meaning set forth in the recitals.

1.74 "**Hologen Guernsey**" has the meaning set forth in the preamble.

1.75 "**Hologen UK**" has the meaning set forth in the preamble.

1.76 "**IND**" means, in the United States, an effective Notice of a Claimed Investigational New Drug Application filed with the FDA as more fully defined in 21 C.F.R. § 312.3, and, with respect to every other country or jurisdiction, the Clinical Trial notification, Clinical Trial application or other equivalent application (i.e., a filing that must be made prior to commencing clinical testing of any product in humans) filed with the applicable Regulatory Authority in such country.

1.77 "**Indemnitees**" has the meaning set forth in Section 12.2.

1.78 "**Joint Arising IP**" has the meaning set forth in Section 9.2.4(b).

1.79 "**Joint Arising Know-How**" has the meaning set forth in Section 9.2.4(a).

1.80 "**Joint Arising Patents**" has the meaning set forth in Section 9.2.4(b).

1.81 "**Know-How**" means any: (a) proprietary, scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including Manufacturing processes, specifications and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological,

biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or other Development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and Manufacturing process and Development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in any Patent; and (b) Materials, in each case ((a) or (b)), that is not in the public domain or otherwise publicly known. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, or a development relating to the item, is (and remains) not known to the public. "Know-How" includes any rights (other than Patents but including any copyright, database or design rights) protecting such Know-How.

1.82 "**Law**" means, individually or collectively, any and all applicable national, supranational, regional, state and local laws, statutes, rules, regulations, ordinances, treaties, administrative codes, guidance, judgments, decrees, directives, injunctions, orders, permits, of or from any court, Regulatory Authority or Governmental Body having jurisdiction over or that may be in effect from time to time and apply to a Party's applicable activities or obligations under or in connection with this Agreement, including GCP, GLP, GMP, Data Protection Laws, export control and economic sanctions regulations, anti-bribery and anti-corruption laws, in each case, together with all applicable implementing regulations for the foregoing and any foreign equivalents to any of the foregoing, as applicable.

1.83 "**Licensed Device**" means MeiraGTx Neuro US' proprietary device designed to effect the local delivery of a gene therapy product into the central nervous system of humans or animals, as more fully described on **Schedule 1.83**, including any modifications or improvements thereto.

1.84 "**Licensed Product**" means (a) (i) MeiraGTx Neuro US' proprietary gene therapy product comprising AAV-mediated delivery of glutamic acid decarboxylase ("**GAD**") (with internal designation AAV-GAD), in the form existing as of the Effective Date (the "**Existing AAV-GAD Product**") and (ii) [***]; and (b) (i) MeiraGTx Neuro US' proprietary gene therapy product comprising AAV-mediated delivery of brain-derived neurotrophic factor ("**BDNF**") (with internal designation AAV-BDNF), in the form existing as of the Effective Date (the "**Existing AAV-BDNF Product**") and (ii) [***]; and (c) the Additional Licensed Products, in each case ((a), (b), or (c)), in any and all forms, presentations, strengths, doses, formulations or regimens.

1.85 "**Losses**" has the meaning set forth in Section 12.1.

1.86 "**Manufacture**" means, with respect to any molecule, product or device (including any active therapeutic ingredient and other material contained therein), the performance of all activities directed to any stage of manufacture of such molecule, product or device, as applicable, including the planning, purchasing of materials or intermediates, making, having made, producing, manufacturing, process development, processing, filling, finishing, packaging, labeling, leafleting, in-process testing, waste disposal, quality control testing and quality assurance release, disposition, sample retention, stability testing, preparation for shipping, shipping or storage of such molecule, product or device, as applicable.

1.87 "**Marketing Approval**" means the approval by the applicable Regulatory Authority in a given country or regulatory jurisdiction to sell a pharmaceutical or biological product or device in such particular country or regulatory jurisdiction, including (a) with respect to the U.S., (i) any Biologics License Application (as more fully defined in 21 C.F.R. 601.2 et seq. or its successor regulation) filed with the FDA or (ii) any premarket approval application or pre-market notification for a medical device and all other applicable authorizations, registrations or clearances filed with the

FDA; (b) with respect to the European Union, (i) any application for Marketing Approval for a biologic product filed with the EMA or (ii) any required certification or confirmation that a medical device meets the applicable safety and performance in the European Union ((i) or (ii)), pursuant to the centralized approval procedure or with the applicable national Regulatory Authority of a country in the European Union with respect to the mutual recognition procedure, decentralized procedure or any other national approval; or (c) any equivalent marketing authorization application, certification or confirmation submitted in any other country or regulatory jurisdiction, in each case ((a), (b) or (c)), including all additions, deletions, amendments or supplements thereto filed pursuant to the applicable requirements of such Regulatory Authority, and as any and all such requirements may be amended, or supplemented, at any time.

1.88 "**Materials**" means any physical, biological or chemical materials, including compositions of matter, assays, animal models, drug or biologic substance samples, intermediates of pharmaceutical or biologic substance samples, pharmaceutical or biologic product or device samples, and intermediates of pharmaceutical or biologic product or device samples.

1.89 "**MeiraGTx**" has the meaning set forth in the preamble.

1.90 "**MeiraGTx Arising IP**" has the meaning set forth in Section 9.2.2(b).

1.91 "**MeiraGTx Arising Know-How**" has the meaning set forth in Section 9.2.2(a).

1.92 "**MeiraGTx Arising Patents**" has the meaning set forth in Section 9.2.2(b).

1.93 "**MeiraGTx Background IP**" mean the MeiraGTx Background Know-How and the MeiraGTx Background Patents.

1.94 "**MeiraGTx Background Know-How**" means any and all Know-How that is owned or otherwise Controlled by MeiraGTx Neuro US (or any of its Affiliates) prior to the Effective Date, or that otherwise comes to be owned or under the Control of MeiraGTx Neuro US (or any of its Affiliates) during the Term independently of the performance of the Development Activities or any other activities under this Agreement, that is (a) necessary for the performance of the Development Activities allocated to Company under the Development Plan, including any MeiraGTx Materials provided by MeiraGTx Neuro UK (or any of its Affiliates) to Company (or any of its Affiliates) under this Agreement; or (b) otherwise necessary for the Development, Manufacture or Commercialization of any Licensed Device or Licensed Product in the Field in the Territory but, in each case ((a) or (b)), excluding [***].

1.95 "**MeiraGTx Background Patents**" means any and all Patents that are owned or otherwise Controlled by MeiraGTx Neuro US (or any of its Affiliates) prior to the Effective Date, or that otherwise come to be owned by, or under the Control of, MeiraGTx Neuro US (or any of its Affiliates) during the Term independently of the performance of the Development Activities or any other activities under this Agreement, that claim or otherwise Cover (a) any MeiraGTx Background Know-How; or (b) any Licensed Device or Licensed Product (including the Development, Manufacture or Commercialization thereof), but, in each case ((a) or (b)), excluding [***].

1.96 "**MeiraGTx Holdings**" has the meaning set forth in the preamble.

1.97 "**MeiraGTx Indemnitees**" has the meaning set forth in Section 12.1.

1.98 "**MeiraGTx Licensed Technology**" means, collectively, the MeiraGTx Background IP, the MeiraGTx Arising IP and MeiraGTx Neuro US' interest in any Joint Arising IP.

1.99 "**MeiraGTx Local Delivery Technology**" means MeiraGTx Licensed Technology that specifically relates to local delivery of gene therapies into the central nervous system, or of any topographic or subcutaneous tissue modification on the face and scalp, of humans or other animals, in each case, using gene therapy agents Manufactured by MeiraGTx Neuro US (or MeiraGTx Neuro US' successor(s) in title) and delivered locally but, in each case, excluding [***].

1.100 "**MeiraGTx Materials**" means any and all Materials that are owned or otherwise Controlled by MeiraGTx Neuro US (or any of its Affiliates) and delivered by MeiraGTx Neuro UK to Company under the Development Plan or that are otherwise provided or made available by or on behalf of MeiraGTx Neuro UK (or any of its Affiliates) to Company (or any of its Affiliates) under this Agreement but, in each case, specifically excluding any Materials in the Arising Know-How.

1.101 "**MeiraGTx Neuro UK**" has the meaning set forth in the preamble.

1.102 "**MeiraGTx Neuro US**" has the meaning set forth in the preamble.

1.103 "**MeiraGTx Patents**" means, collectively, the MeiraGTx Background Patents and the MeiraGTx Arising Patents.

1.104 [***]

1.105 [***]

1.106 "**Out-of-Pocket Costs**" means the actual amounts paid by or on behalf of MeiraGTx Neuro UK (or any its Affiliates) to a Third Party in connection with the performance of any Collaboration Activities allocated to MeiraGTx Neuro UK under this Agreement, including pursuant to the Development Plan or the Transition Services Plan, as applicable in accordance with the applicable approved budget, as agreed in writing.

1.107 "**Party**" or "**Parties**" has the meaning set forth in the preamble.

1.108 "**Patent**" means any and all (a) issued or granted patents, including any extensions, supplemental protection certificates, registrations, confirmations, reissues, reexaminations or renewals thereof; (b) pending patent applications, including any continuations, divisionals, continuations-in-part, substitutes or provisional applications; and (c) counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction.

1.109 "**Patent Challenge**" means any Proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of any MeiraGTx Patent or Joint Arising Patent [***].

1.110 "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

1.111 "**Priority Review Voucher**" means a priority review voucher issued by the United States Department of Health and Human Services that entitles the holder of such voucher to priority review of a single human drug application submitted under Section 505(b)(1) of the Act or Section 351(a) of the United States Public Health Service Act, as further defined in Section 529(a)(2) of the Act (21 U.S.C. § 360ff(a)(2)).

1.112 "**Proceeding**" means any action, arbitration, investigation, litigation or suit commenced, brought, conducted, or heard by or before, or otherwise involving, any Governmental Body or arbitrator.

1.113 "**Product-Specific Arising Know-How**" has the meaning set forth in Section 9.2.3(a).

1.114 "**Receiving Party**" has the meaning set forth in Section 10.1.

1.115 "**Regulatory Approval**" means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority necessary for the Development, Manufacture, storage, transport or Commercialization of a pharmaceutical or biological product or device in a particular country or regulatory jurisdiction, including any Marketing Approval or any pricing or reimbursement approval or determination, as applicable.

1.116 "**Regulatory Authority**" means (a) in the U.S., the FDA; (b) in the E.U., the EMA; or (c) in any other jurisdiction anywhere in the world, any regulatory body with similar regulatory authority over any pharmaceutical or biological products or devices (including the Pharmaceuticals and Medical Devices Agency in Japan).

1.117 "**Regulatory Documents**" means, with respect a given pharmaceutical or biological product or device, any and all applications and filings (and any supplement or amendment thereto) made with any Regulatory Authority in a given country or regulatory jurisdiction, including any IND, Marketing Approval or orphan drug designations, import/export applications, or any other application for regulatory consultations or consideration (including sponsorship thereof) and any and all associated source documents, related communication, correspondence and documentation submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), regulatory drug lists, Adverse Event files and complaint files, and submissions to regulatory advisory boards, in each case, for such product or device, as applicable.

1.118 "**Representatives**" has the meaning set forth in Section 6.5.2.

1.119 "**Safety Data Exchange Agreement**" has the meaning set forth in Section 3.7.4.

1.120 "**Subcontractor**" has the meaning set forth in Section 6.1.

1.121 "**Sublicensee**" means (a) any Third Party to which Company or any of its Affiliates has granted or grants any sublicense, covenant not to sue or other rights under any of the rights or licenses granted to Company under this Agreement, including pursuant to Section 2.1.1; and (b) any further sublicensee of such Third Party or any of its respective Affiliates (regardless of the number of tiers, layers or levels of sublicenses, covenants not to sue or other rights), in each case, as permitted under this Agreement.

1.122 "**Supply Agreements**" mean the Clinical Supply Agreement and the Commercial Supply Agreement.

1.123 "**Tax**" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

1.124 "**Term**" has the meaning set forth in Section 13.1.

1.125 "**Termination and Wind-Down Plan**" has the meaning set forth in Section 13.3.2.

1.126 "**Territory**" means worldwide.

1.127 "**Third Party**" means any Person other than Company, HGL, MeiraGTx or any of their respective Affiliates.

1.128 "**Third Party Action**" means any claim or other similar action made by a Third Party against any Party that claims that any Licensed Device or Licensed Product, or its Development, Manufacture or Commercialization, or any Know-How, Patents or other intellectual property rights claiming or Covering the foregoing, infringes or misappropriates such Third Party's intellectual property rights.

1.129 "**Third Party Claims**" has the meaning set forth in Section 12.1.

1.130 "**Third Party Infringement**" has the meaning set forth in Section 9.4.1.

1.131 "**Transferred Regulatory Document**" has the meaning set forth in Section 3.7.3.

1.132 "**Transition Services**" has the meaning set forth in Section 3.2.1.

1.133 "**Transition Services Period**" has the meaning set forth in Section 3.2.1.

1.134 "**Transition Services Plan**" has the meaning set forth in Section 3.2.1.

1.135 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.136 "**VAT and Indirect Taxes**" means any value added, sales, purchase, turnover or consumption Tax as may be applicable in any relevant jurisdiction, including value-added Tax chargeable under legislation implementing E.U. Council Directive 2006/112/EC on the common system of value-added Tax.

ARTICLE 2
LICENSE GRANTS

2.1 License Grants.

2.1.1 License Grants to Company. Subject to the terms and conditions of this Agreement, MeiraGTx Neuro US shall, and hereby does, grant to Company:

(a) an exclusive, royalty-free, fully-paid up (subject to ARTICLE 8), sublicensable (solely in accordance with Section 2.2), transferable (solely in accordance with Section 14.4) license under the MeiraGTx Licensed Technology to Develop, Manufacture and Commercialize the Licensed Products (other than the Additional Licensed Products) in the Field in the Territory, including to conduct the activities allocated to Company under and in accordance with the Development Plan, as applicable; and

(b) an exclusive, royalty-free, fully-paid up (subject to ARTICLE 8), sublicensable (solely in accordance with Section 2.2), transferable (solely in accordance with Section 14.4) license under the MeiraGTx Local Delivery Technology to Develop, Manufacture and Commercialize Additional Licensed Products in the Field in the Territory;

(c) an exclusive, royalty-free, fully-paid up (subject to ARTICLE 8), sublicensable (solely in accordance with Section 2.2), transferable (solely in accordance with Section 14.4) license under the MeiraGTx Licensed Technology to Develop, Manufacture and Commercialize the Licensed Device for use as a local delivery mechanism for any gene therapy product (including any Licensed Product) in the central nervous system, or of any topographic or subcutaneous tissue modification on the face and scalp, of humans or animals in the Field in the Territory, including in connection with the Development, Manufacture or Commercialization of any such gene therapy product in the Field in the Territory.

2.1.2 License Grants to MeiraGTx Neuro UK. Subject to the terms and conditions of this Agreement, Company shall, and hereby does, grant to MeiraGTx Neuro UK a non-exclusive, worldwide, royalty-free, fully-paid up, sublicensable (solely in accordance with Section 2.2), transferable (solely in accordance with Section 14.4) license under the Company Licensed Technology to (a) conduct any activities allocated to MeiraGTx Neuro UK under and in accordance with the Development Plan or the Transition Services Plan, as applicable; (b) perform any of MeiraGTx Neuro UK's obligations under any Supply Agreements, including to Manufacture Licensed Products thereunder; or (c) otherwise to perform any of MeiraGTx's obligations under and in accordance with this Agreement.

2.2 Sublicenses.

2.2.1 General. Neither Company nor MeiraGTx Neuro UK (nor any of their respective Affiliates) shall have the right to grant sublicenses, in whole or in part, under the licenses granted to such Party under Section 2.1 to any Third Party without the prior written consent of the other Party; *provided*, *however*, that, subject to the terms and conditions of this Agreement, including Section 2.2.2, Section 2.2.3 and Section 6.2, (a) each of Company and MeiraGTx Neuro UK shall have the right to grant a sublicense under the licenses granted to such Party under Section 2.1 to any of its Affiliates (*provided* that any such sublicense shall automatically terminate upon the date that such Affiliate ceases to be an Affiliate of such Party); and (b) each of Company and MeiraGTx Neuro UK (or any of their respective Affiliates) shall have the right to grant a sublicense under the licenses granted to such Party under Section 2.1 to any Subcontractor that is performing any of the activities allocated to such Party under the Development Plan, the Transition Services Plan or any Supply Agreement, in each case, solely to the extent necessary to permit such Subcontractor to perform such activities.

2.2.2 Sublicensing Conditions. Each Party shall ensure that its Affiliates, and require any Sublicensees to, comply with the applicable terms and conditions of this Agreement. With respect to any sublicense granted by Company and MeiraGTx Neuro UK (or any of its Affiliates or Sublicensees, as applicable) under the licenses granted to such Party under Section 2.1, or the performance by an Affiliate or Sublicensee of any of such Party's obligations hereunder, such Party shall remain responsible for the performance of any of its obligations under this Agreement, and remain liable for any act or omission of any of such Party's Affiliates or its or their respective Sublicensees and, to the extent that any such act or omission would constitute a breach of this Agreement by such Party of this Agreement if such act or omission were taken or made by such Party directly, such act or omission shall be deemed a breach of this Agreement by such Party and such Affiliate or Sublicensee.

2.2.3 Additional Third Party Sublicensing Conditions. Any sublicense granted by a Company and MeiraGTx Neuro UK (or any of its Affiliates or Sublicensees) to any Third Party under

the licenses granted to such Party pursuant to Section 2.1 shall be in writing and subject to, and consistent with, the terms and conditions of this Agreement, including ownership and assignment of Arising IP in accordance with Section 9.2 and confidentiality and non-use obligations no less stringent than those provided in ARTICLE 10.

2.3 No Implied Licenses; Retained Rights.

2.3.1 No Implied Licenses. No right or license is granted to any Party hereunder by implication, estoppel or otherwise to any Know-How, Patents or other intellectual property right owned or otherwise Controlled by any other Party or its Affiliates (for clarity, including that no such right or license is granted to MeiraGTx Neuro UK hereunder by Company with respect to any Know-How, Patents or other intellectual property right owned or otherwise Controlled by Company that was licensed to Company by Hologen, in each case, except to the extent necessary for MeiraGTx to perform any of MeiraGTx's obligations under and in accordance with this Agreement), except as expressly set forth in this Agreement. Without limiting the foregoing, Company will not (and shall ensure that its Affiliates and require that its Sublicensees and any other Third Party performing on behalf of Company, its Affiliates or Sublicensees shall not) practice or otherwise exploit the MeiraGTx Licensed Technology outside the scope of the licenses grant to Company under Section 2.1.1 or otherwise in violation of this Agreement. Notwithstanding anything to the contrary set forth herein, the license or rights granted pursuant to Section 2.1.1 shall not include any license or right under the MeiraGTx Licensed Technology (or any other Know-How, Patents or other intellectual property right owned or otherwise Controlled by MeiraGTx or any of its Affiliates) to Develop, Manufacture or Commercialize (a) any molecule, product or device that is not a Licensed Device or Licensed Product; or (b) any other therapeutically active agents or devices incorporated in or used with any Licensed Product or Licensed Device that is not itself a Licensed Device or Licensed Product.

2.3.2 Retained Rights. All rights in and to any Know-How, Patents or other intellectual property rights owned or otherwise Controlled by a Party or its Affiliates not expressly licensed or otherwise granted to any other Party under this Agreement are hereby retained by such Party (or its Affiliates, as applicable). Without limiting the foregoing, as among the Parties, MeiraGTx hereby retains (a) the right to practice, use or reference any MeiraGTx Licensed Technology to the extent necessary for MeiraGTx to perform any of MeiraGTx's obligations under and in accordance with this Agreement (i) conduct any activities allocated to MeiraGTx Neuro UK under and in accordance with the Development Plan or the Transition Services Plan, as applicable, (ii) perform any of MeiraGTx Neuro UK's obligations under any Supply Agreements, including to Manufacture Licensed Products thereunder or (iii) otherwise to perform any of MeiraGTx's obligations under and in accordance with this Agreement; and (b) (i) the exclusive right to practice, use or reference (including the right to grant licenses or sublicenses thereunder through multiple tiers) any MeiraGTx Licensed Technology to Develop, Manufacture or Commercialize any molecule, product or device that is not a Licensed Device or Licensed Product in any field or territory, and (ii) the exclusive right (together with Company and its Affiliates or Sublicensees) to practice, use or reference (including the right to grant licenses or sublicenses thereunder through multiple tiers) any MeiraGTx Licensed Technology to Develop, Manufacture or Commercialize any Licensed Device in the Field in the Territory, in each case ((i) or (ii)), independent of the performance of the Development Activities or any other activities under this Agreement.

ARTICLE 3
DEVELOPMENT

3.1 **General**. Subject to the terms and conditions of this Agreement (including Section 2.3, this ARTICLE 3, ARTICLE 6 and ARTICLE 7), as among the Parties, Company shall have (a) the exclusive right to conduct (directly or indirectly through any of its Affiliates, Sublicensees or Subcontractors), and the sole responsibility for, the Development of all Licensed Products; and (b) the exclusive right to conduct (directly or indirectly through any of its Affiliates, Sublicensees or Subcontractors), and the responsibility for, the Development of the Licensed Device, in each case, throughout the Territory, at Company's sole cost and expense; *provided*, *however*, that notwithstanding anything to the contrary set forth herein, (i) Company shall (directly or indirectly through any of its Affiliates, Sublicensees or Subcontractors) conduct any Development of the Licensed Device or any Licensed Products in collaboration with MeiraGTx Neuro UK under and in accordance with this Agreement, including the then-current Transition Services Plan approved in accordance with Section 3.2.1 or the then-current Development Plan approved in accordance with Section 3.3, as applicable.

3.2 **Transition Services**.

3.2.1 Transition Services Plan. As soon as reasonably possible following the Effective Date, the DB shall prepare, discuss and agree on a written plan with respect to the provision of certain services (each, a "**Transition Service**") to be provided by or on behalf of MeiraGTx Neuro UK to Company under this Agreement (such plan, as mutually agreed by Company and MeiraGTx Neuro UK (subject to Section 7.1.2, via the DB in accordance with Section 7.1.3), and as the same may be subsequently amended from time to time in accordance with this Section 3.2, the "**Transition Services Plan**"). Subject to the terms and conditions of this Agreement (including this ARTICLE 3, ARTICLE 6 and ARTICLE 7), MeiraGTx Neuro UK shall (directly, or through any of its Affiliates or Subcontractors) use Commercially Reasonable Efforts to provide to Company, at Company's cost and expense with prior approval by Company the Transition Services, in each case, in accordance with the applicable terms and conditions set forth in the Transition Services Plan; *provided* that MeiraGTx Neuro UK shall only be obligated to perform a given Transition Service during the applicable period specified for such Transition Service in the Transition Services Plan (each, a "**Transition Period**"). Company shall be responsible for any FTE Costs or Out-of-Pocket Costs incurred by or on behalf of MeiraGTx Neuro UK (or any of its Affiliates) in connection with the provision of the Transition Services in accordance with Section 8.3. From time to time, Company and MeiraGTx Neuro UK (via the DB) may amend the Transition Services Plan, including with respect to any Transition Service or the corresponding Transition Period, by mutual agreement; *provided, however*, that (a) MeiraGTx Neuro UK will not be obligated to provide any additional services or extend any Transition Services beyond its corresponding Transition Period unless otherwise agreed in any such amendment to the Transition Services Plan; and (b) no amendments or modifications to the Transition Services Plan shall be effective unless and until approved by the DB in accordance with Section 7.1.3.

3.2.2 Termination of Transition Services. MeiraGTx Neuro UK's obligations and rights under this Section 3.2 shall continue with respect to each Transition Service until the expiration of the corresponding Transition Period, unless such Transition Service is earlier terminated pursuant to this Section 3.2.2 or this Agreement is earlier terminated pursuant to Section 13.2, as applicable, in which case, MeiraGTx Neuro UK's obligations with respect to such Transition Service shall cease upon the effective date of such earlier termination. During the applicable Transition Period for any Transition Service, Company may elect to

terminate MeiraGTx Neuro UK's provision of such Transition Service by delivering written notice of such election to MeiraGTx Neuro UK in accordance with this Agreement, which termination will be effective no earlier than [***] following delivery of such notice, unless MeiraGTx consents to a shorter period; *provided*, *however*, that Company shall pay MeiraGTx Neuro UK for any FTE Costs and Out-of-Pocket Costs incurred with respect to such terminated Transition Service in accordance with Section 8.3 prior to the effective date of such termination, together with any such pre-approved costs contracted for by MeiraGTx Neuro UK, or any other pre-approved non-cancellable obligations of MeiraGTx Neuro UK incurred, prior to such effective date in connection with such terminated Transition Service.

3.3 **Development Plan**. Within [***] following the Effective Date, the DB shall prepare, discuss and agree on a written plan with respect to the Development of the Licensed Device and any Licensed Products in the Field in the Territory under this Agreement (such plan, as mutually agreed by Company and MeiraGTx Neuro UK (subject to Section 7.1.2, via the DB in accordance with Section 7.1.3), and as the same may be subsequently amended from time to time in accordance with this Section 3.3, the "**Development Plan**"). The Development Plan shall specify (a) the Development activities to be performed with respect to the Development of the Licensed Device or any Licensed Product, as applicable, including any deliverables to be generated thereunder (such activities, "**Development Activities**"); (b) the estimated timelines for the performance and completion of the Development Activities; (c) the corresponding budget for Development Costs expected to be incurred in connection with the performance of the Development Activities (the "**Development Plan Budget**"); and (d) [***]. From time to time, either Company or MeiraGTx Neuro UK may [***].

3.4 **Performance of Development Activities**. Subject to the terms and conditions of this Agreement (including this ARTICLE 3, ARTICLE 6 and ARTICLE 7), each of Company and MeiraGTx Neuro UK shall (directly, or through any of its Affiliates, Sublicensees or Subcontractors) use Commercially Reasonable Efforts to perform the Development Activities allocated to such Party under and in accordance with the then-current Development Plan, including in accordance with the corresponding timelines set forth therein. [***].

3.5 **Reporting**. Each Party will respond to the reasonable questions or requests of any other Party for additional information relating to such Party's Development Activities in a timely manner.

3.6 **Recordkeeping**. Each Party and its Affiliates will, and will require its Sublicensees and Subcontractors to, maintain written or electronic records, in sufficient detail, in a good scientific manner, in accordance with applicable Laws (including GLP, GCP, and GMP, as applicable), and appropriate for regulatory and patent purposes, and that are complete and accurate in all material respects and properly reflect all Development Activities performed and results achieved, in each case, by or on behalf of such Party and its Affiliates and Sublicensees under this Agreement, which records shall not include or commingle records of activities outside the scope of this Agreement. Such records will be retained for at least [***] following expiration or termination of the Development Term, or for such longer period as may be required by applicable Law or the retaining Party's internal policies. Each Party shall have the right, during normal business hours and upon at least [***] notice at a time agreed to by the Parties, to inspect and copy any records kept by any other Party in accordance with this Section 3.6 to verify such other Party's compliance with its obligations under this Agreement.

3.7 **Regulatory Matters**.

3.7.1 General. Subject to the terms and conditions of this Agreement (including this ARTICLE 3, ARTICLE 6 and ARTICLE 7), each of Company and MeiraGTx Neuro UK shall (directly, or through any of its Affiliates, Sublicensees or Subcontractors) conduct any regulatory activities with respect to any Development of the Licensed Device or any Licensed Products in accordance with the corresponding regulatory strategy set forth in the Development Plan with respect to such Licensed Device or Licensed Product, as applicable, and otherwise in accordance with the terms of this Section 3.7; *provided* that (a) the DB will oversee the implementation of, and discuss progress regarding, such regulatory strategy under the Development Plan; and (b) unless and until otherwise decided by the DB, MeiraGTx Neuro UK (or any of its Affiliates) shall remain sponsor of the Existing AAV-GAD Product and the Existing AAV-BDNF Product and for these products file in its name all Regulatory Documents and applicable Regulatory Approvals for the Licensed Device and all Licensed Products in the Territory and will be responsible for (i) overseeing, monitoring and coordinating all applicable regulatory actions, communications and filings with, and submissions to, each applicable Regulatory Authority with respect to such Licensed Device or Licensed Product, (ii) interfacing, corresponding and meeting with each applicable Regulatory Authority in the Territory with respect to such Licensed Device or Licensed Product, (iii) seeking and maintaining all applicable Regulatory Approvals (including any INDs or Marketing Approvals) in the Territory with respect to such Licensed Device or Licensed Product, and (iv) obtaining and maintaining all other necessary authorizations, consents and approvals of any Regulatory Authority or other Governmental Body that is required for the Collaboration Activities to be performed under this Agreement with respect to such Licensed Device or Licensed Products, in each case ((i), (ii), (iii) and (iv)), at Company's sole cost and expense, subject to prior approval by Company in accordance with this Agreement (including Section 3.3 and Section 8.4).

3.7.2 Communications with Regulatory Authorities. Each Party will keep the other Parties reasonably informed of any material communications from, or meetings with, any Regulatory Authority pertaining to such Party's Collaboration Activities performed under this Agreement promptly following receipt thereof. To the extent that any Party (or any of its Affiliates, Sublicensees or Subcontractors) receives any material written or oral communications from the FDA or any other Regulatory Authority relating to the Licensed Device, any Licensed Product or any Collaboration Activities under this Agreement, such Party shall notify the other Parties and promptly provide a copy of any such written communications to such other Parties. In addition, to the extent not already provided pursuant to this Agreement, upon the reasonable request of any other Party, each Party shall provide copies of any other documents, reports or communications from or to Regulatory Authorities relating to the Licensed Device or any Licensed Product in such Party's possession and control.

3.7.3 Transfer of Regulatory Documents. [***].

3.7.4 Safety Data Exchange Agreement. Company and MeiraGTx Neuro UK will cooperate with regard to the reporting and handling of safety information relating to the Licensed Device, any Licensed Products and any Collaboration Activities hereunder in accordance with applicable Law, including applicable regulatory requirements and regulations on pharmacovigilance and clinical safety. In furtherance thereof, as soon as possible following the decision by the DB for Company to become the regulatory lead in accordance with Section 3.7.1, and using Commercially Reasonable Efforts, following the Effective Date, Company and MeiraGTx Neuro UK shall meet and agree upon a written safety data exchange agreement for exchanging such adverse event and other safety information and timelines (the "**Safety Data Exchange Agreement**"), which Safety Data Exchange

Agreement will also provide for the transfer of MeiraGTx Neuro UK's then-current safety database for the Licensed Device and any Licensed Products to Company, including the timing for such transfer (which shall not be earlier than the transfer of the Transferred Regulatory Documents to Company in accordance with Section 3.7.2).

3.7.5 Right of Reference. Each of Company and MeiraGTx Neuro UK shall have the right, without obtaining any additional approval of any other Party and without any additional payment to any other Party (other than payments expressly provided in this Agreement), to reference (including a "Right of Reference" as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule), and corresponding rights under the foreign equivalents of 21 C.F.R. § 314.3(b) in the applicable countries in the Territory), copy, access and use any data, reports, Regulatory Documents, Regulatory Approvals or other information developed by such other Party (or any of its Affiliates, Sublicensees or Subcontractors) that is derived from or includes such data or information, in each case, that is necessary to Develop, Manufacture or Commercialize the Licensed Device or a Licensed Product, or otherwise to perform any Collaboration Activities of such Party under this Agreement, and that is Controlled by such other Party (or any of its Affiliates) for purposes of preparing and submitting any Regulatory Approvals (including any INDs or Marketing Approvals) or other Regulatory Documents for such Licensed Device or Licensed Products, as applicable; subject to and in accordance with this Agreement.

3.7.6 Regulatory Vouchers for Licensed Product. If a Priority Review Voucher is issued to MeiraGTx or Company for any Licensed Product, then, if issued to MeiraGTx, MeiraGTx will transfer such Priority Review Voucher to Company. If Company elects to transfer to a Third Party or otherwise monetize such Priority Review Voucher for monetary consideration, the proceeds thereof will be allocated [***]. If Company uses such Priority Review Voucher for one of its programs or for the programs of one of its Affiliates (or if Company elects to transfer to a Third Party or otherwise monetize such Priority Review Voucher for non-monetary consideration), then: (a) the value of such Priority Review Voucher will be determined by [***]; and (b) the determined value of such Priority Review Voucher will be allocated [***].

ARTICLE 4
MANUFACTURING AND SUPPLY

4.1 **General**. Subject to the terms and conditions of this Agreement (including Section 2.3, this ARTICLE 4, ARTICLE 6 and ARTICLE 7), as among the Parties, Company shall have (a) the exclusive right to conduct (directly, or through any of its Affiliates, Sublicensees or Subcontractors), and the sole responsibility for, the Manufacturing of all Licensed Products; and (b) the exclusive right to conduct (directly, or through any of its Affiliates, Sublicensees or Subcontractors), and the responsibility for, the Manufacturing of the Licensed Device, in each case ((a) or (b)), throughout the Territory, at Company's sole cost and expense; *provided*, *however*, that notwithstanding anything to the contrary set forth herein, (i) the DB shall oversee the Clinical Manufacturing, Commercial Manufacturing and supply of any Licensed Device or Licensed Product, including determining supply chain strategy and establishment of Manufacturing sources, capacity or supply chains with respect thereto, in accordance with this ARTICLE 4, and (ii) subject to the commercially reasonable terms and satisfactory performance under the Clinical Supply Agreement to be entered into pursuant to Section 4.2 and under the Commercial Supply Agreement to be entered into pursuant to Section 4.3, unless otherwise expressly agreed by MeiraGTx in writing, MeiraGTx Neuro UK shall (directly, or through any of its Affiliates or Subcontractors) have the exclusive right to (A) Clinically Manufacture and supply all Licensed Products as required for any Development of any Licensed Product in the Territory under this Agreement, including as

required for the performance of any Transition Services or Development Activities of any Party, which Clinical Manufacturing and supply of the Licensed Products by MeiraGTx Neuro UK will be pursuant to, and subject to the terms of, the Clinical Supply Agreement; and (B) Commercially Manufacture and supply all Licensed Products as required for any Commercialization of any Licensed Product in the Territory under this Agreement, which Commercial Manufacturing and supply of the Licensed Products by MeiraGTx Neuro UK will be pursuant to, and subject to the terms of, the Commercial Supply Agreement to be entered into pursuant to Section 4.3.

4.2 **Clinical Supply Agreement**. [***] following the Effective Date, Company and MeiraGTx Neuro UK shall negotiate in good faith and enter into a clinical supply agreement (together with any related quality agreement, the "**Clinical Supply Agreement**") pursuant to which MeiraGTx Neuro UK shall (directly, or through any of its Affiliates or Subcontractors) Clinically Manufacture and supply the Licensed Products as required for the performance of any Development of any Licensed Product in the Territory under this Agreement, including as required for the performance of any Transition Services or Development Activities of any Party; [***].

4.3 **Commercial Supply Agreement**. [***] following the Effective Date, Company and MeiraGTx Neuro UK shall negotiate in good faith and enter into a commercial supply agreement (together with any related quality agreement, the "**Commercial Supply Agreement**") pursuant to which MeiraGTx Neuro UK shall (directly, or through any of its Affiliates or Subcontractors) Commercially Manufacture and supply all Licensed Products as required for any Commercialization of any Licensed Product in the Territory under this Agreement, including as required for the performance of any Commercialization activities of any Party hereunder; [***].

4.4 **Manufacture and Supply of Licensed Device**. Notwithstanding anything to the contrary set forth herein, (a) Company shall (directly, or through any of its Affiliates, Sublicensees or Subcontractors) conduct (i) any Clinical Manufacture or supply of the Licensed Device for the Development of the Licensed Device in the Territory under this Agreement, including as required for the performance of any Transition Services or Development Activities of any Party, in each case, under and in accordance with the then-current Transition Services Plan or Development Plan, as applicable and (ii) any Manufacture or supply of the Licensed Device for the Commercialization of the Licensed Device in the Territory under this Agreement; and (b) Company shall not (nor shall it permit any of its Affiliates, Sublicensees or Subcontractors to) Clinically Manufacture or supply the Licensed Device independent of the Licensed Products, without the prior written consent of MeiraGTx.

ARTICLE 5
COMMERCIALIZATION

5.1 **General**. Subject to the terms and conditions of this Agreement (including Section 2.3, this ARTICLE 5, ARTICLE 6 and ARTICLE 7), as among the Parties, Company shall have (a) the exclusive right to conduct (directly, or through any of its Affiliates, Sublicensees or Subcontractors), and the sole responsibility for, the Commercialization of all Licensed Products; and (b) the co-exclusive right to conduct (directly, or through any of its Affiliates, Sublicensees or Subcontractors), and the responsibility for, the Commercialization of the Licensed Device, in each case ((a) or (b)), throughout the Territory, at Company's sole cost and expense.

5.2 **Diligence**. During the Term until the earlier to occur of [***] Company shall (directly, or through any of its Affiliates, Sublicensees or Subcontractors) use Commercially Reasonable Efforts to Develop (including to seek and obtain Marketing Approval) the Licensed Device and Licensed Products in the Territory.

ARTICLE 6
ADDITIONAL COLLABORATION TERMS

6.1 **Subcontracting**. Company and MeiraGTx Neuro UK (and any of their respective Affiliates or Sublicensees) shall be permitted to perform all or any portion of such Party's obligations or other activities under this Agreement, including the performance of (a) any Development Activities under the Development Plan; (b) with respect to MeiraGTx Neuro UK, any Transition Services under the Transition Services Plan or any Supply Agreement, as applicable; and (c) with respect to Company, any Development, Manufacture or Commercialization of any Licensed Device or Licensed Product by or on behalf of a Company (or any of its Affiliates or Sublicensees) (collectively, such obligations or other activities, "**Collaboration Activities**") through any Third Party (each such Third Party subcontractor, a "**Subcontractor**"). Any Party engaging an Subcontractor to perform all or any portion of such Party's Collaboration Activities under this Agreement shall have first entered into a written agreement with such Subcontractor, which shall (A) contain provisions to ensure that such Subcontractor complies with the applicable terms and conditions of this Agreement, including ownership and assignment of Arising IP in accordance with Section 9.2 and confidentiality and non-use obligations no less stringent than those provided in ARTICLE 10; and (B) prohibit such Subcontractor from any further subcontracting of any Collaboration Activities (in each case, except to the extent expressly permitted under the then-current Transition Services Plan, Development Plan or Supply Agreement, or otherwise with the express prior written consent of the other Party, as applicable). For clarity, each Party engaging such Subcontractor to perform any of such Party's Collaboration Activities shall remain responsible and liable to the other Parties for any performance or non-performance of any such Collaboration Activities by such Subcontractor hereunder.

6.2 **Compliance**. Each Party shall (and shall cause its Affiliates and require its Sublicensees or Subcontractors, as applicable, to) conduct all of its Collaboration Activities under this Agreement, including the performance of any Transition Services, or Development Activities, as applicable, in a good scientific manner, in accordance with this Agreement and in compliance with all applicable Laws, including anti-corruption and sanctions Laws. Each Party and its Affiliates have not, and will not (and will require its Sublicensees and Subcontractors to not), in connection with the performance of any such Collaboration Activities of such Party under this Agreement (directly or indirectly) make, promise, authorize, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage, or improperly assisting such Party or any of its Affiliates in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery. Each Party warrants that it and its Affiliates have taken, and will take (and will require its Sublicensees and Subcontractors to take), reasonable measures to prevent any Third Parties subject to their control or determining influence, from doing so in connection with this Agreement. For the avoidance of doubt, this includes facilitating payments which are unofficial, improper, small payments or gifts offered or made to Government Officials to secure or expedite a routine or necessary action to which such Party (or any of its Affiliates or Sublicensees) is legally entitled. Each Party shall not (and shall cause its Affiliates and require its Sublicensees and Subcontractors performing any such Collaboration Activities on behalf of such Party not to) employ or otherwise use in any capacity, the services of any Person debarred under United States Law, including under 21 U.S.C. Section 335a or any foreign equivalent thereof.

6.3 **Limitations on Obligations**. Notwithstanding anything to the contrary set forth herein, nothing in this Agreement shall require a Party (or any of its Affiliates) to perform or cause to be performed any of such Party's Collaboration Activities under this Agreement (including any of its obligations under the Transition Services Plan, the Development Plan, or any Supply Agreement, as applicable) in a manner that would constitute a violation of (a) applicable Law; (b) any contract to which such

Party (or any of its Affiliates) is a party as of the Effective Date; (c) the certificate of incorporation or by-laws (or the comparable governing instruments) of such Party (or any of its Affiliates); (d) any obligations of such Party (or any of its Affiliates) as required to maintain any licenses, permits or authorizations required by Regulatory Authorities in the Territory with respect to the operation of any Manufacturing facility used in connection with the Manufacture or supply of any Licensed Product hereunder, including under any Supply Agreement; or (e) the rights of any Third Party (including, in the event that the performance of any such Collaboration Activities requires the consent of a Third Party which has not been obtained). For the avoidance of doubt, except as may be set forth in a separate written agreement by the Parties, neither MeiraGTx nor any of its Affiliates are under any obligation to second or procure the secondment to Company of any employee or other personnel in connection with the performance of any Collaboration Activities under this Agreement. The Parties hereto agree that nothing in this Agreement is intended to transfer the employment of any employees, contract employees or secondees of MeiraGTx or its respective Affiliates engaged in the performance of any such Collaboration Activities.

6.4 **Other Obligations**. Each Party (itself or through any of its Affiliates or its or their Sublicensees or Subcontractors, as applicable) shall reasonably cooperate with the other Parties (and its Affiliates or Subcontractors, as applicable) in connection with the performance of any Collaboration Activities under this Agreement (including any obligations under the Transition Services Plan, the Development Plan, or any Supply Agreement, as applicable), including by providing to any other Party such information or Materials as set forth in the then-current Transition Services Plan, Development Plan or Supply Agreement, or as may otherwise be necessary for such other Party to perform such Collaboration Activities in accordance with this Agreement, as applicable. In the event that one Party fails to provide any such information or Materials to another Party, then, upon such other Party's request, the Alliance Managers of the Parties shall discuss and work together in good faith to resolve any impact such failure may have to the performance of the applicable Collaboration Activities. [***].

6.5 **Material Transfers**.

6.5.1 MTR. During the course of the performance of the Collaboration Activities, any Party (or such Party's designee) may transfer to any other Party (or its designee) certain Materials within such Party's Background IP for use in connection with such Collaboration Activities, including as contemplated under the Transition Services Plan or the Development Plan, as applicable, and any such Materials shall be provided to such other Party under and subject to the terms and conditions of this Agreement (including this Section 6.5) and in such amount as are described in a material transfer record for such particular transfer of Materials. For clarity, this Section 6.5 shall not apply with respect to the supply of any Licensed Products or Licensed Device by or on behalf of MeiraGTx Neuro UK, which shall be governed under ARTICLE 4.

6.5.2 Restrictions on Transfer of Materials. Each Party shall limit transfer and disclosure of any other Party's Materials, (including any Background IP or other Confidential Information of such other Party embodied therein) on a need-to-know basis, as necessary for the performance of any of such Party's Collaboration Activities under this Agreement, to any of its Affiliates, Subcontractors (subject to Section 6.1), Sublicensees (subject to Section 2.2) or its and their respective directors, officers or employees (collectively, "**Representatives**"); *provided* that, except as otherwise expressly permitted herein (including as otherwise expressly provided under the Transition Services Plan or the Development Plan, as applicable), each Party shall not (and will require its Representatives to not) transfer or disclose any other Party's Materials to any Third Party without the prior express written consent of such other Party (such consent not to be unreasonably withheld,

conditioned or delayed). Each Party shall notify such other Party promptly upon discovery of any unauthorized use or disclosure of such other Party's Materials.

6.5.3 Return of Materials. Upon termination of the relevant activities requiring use of any other Party's Materials or the termination of this Agreement in its entirety, as applicable, except for any continuing rights as set forth in this Agreement (including as set forth in Section 13.3, as applicable), each Party shall (and shall cause its Representatives that receive any of such other Party's Materials, as applicable, to) discontinue its use of such other Party's Materials and shall, upon direction of such other Party, return or destroy (and certify destruction of) any such remaining Materials in compliance with Law.

6.5.4 DISCLAIMER. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN ARTICLE 11, EACH PARTY HEREBY ACKNOWLEDGES AND AGREES THAT (A) ANY OTHER PARTY'S MATERIALS ARE EXPERIMENTAL IN NATURE AND THAT THEY ARE PROVIDED "AS IS"; (B) SUCH OTHER PARTY MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITH RESPECT TO SUCH PARTY'S MATERIALS OR THE USE THEREOF; (C) SUCH OTHER PARTY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT; AND (D) SUCH OTHER PARTY'S MATERIALS ARE PROVIDED SOLELY FOR CERTAIN RESEARCH USE ONLY AND HAVE NOT BEEN APPROVED FOR HUMAN USE.

ARTICLE 7
GOVERNANCE

7.1 **Development Board**. On the Effective Date, Company and MeiraGTx Neuro UK shall establish a development board (the "**DB**") to oversee the Development, Manufacture and Commercialization of the Licensed Device and any Licensed Product in the Territory under this Agreement; *provided* that, as of the Effective Date the DB shall be composed of: (a) MeiraGTx DB members: [***] and (b) Company DB members: [***]. During the Term, each of Company and MeiraGTx Neuro UK may replace its DB members upon written notice to the other Party, subject to such other Party's approval, which approval shall not be unreasonably withheld; *provided* that each of Company and MeiraGTx Neuro UK shall have an equal number of members on the DB. Each of Company and MeiraGTx Neuro UK shall ensure that its DB member(s) are bound by written obligations of confidentiality and non-use substantially consistent with the terms set forth in ARTICLE 10.

7.1.1 Meetings of DB. During the Term, the DB shall meet [***] (or more or less frequently as agreed by Company and MeiraGTx Neuro UK). Unless otherwise agreed by Company and MeiraGTx Neuro UK, the DB shall be chaired by one representative of Company, who shall be responsible for convening and presiding at meetings of the DB, including (a) providing reasonable advance notice to representatives of any DB meeting; (b) preparing and circulating agendas in advance of each DB meeting; and (c) preparing and circulating minutes following each DB meeting, in each case ((a), (b) and (c)), in accordance with this Section 7.1.1; *provided* that, for clarity, the DB chair will have no additional powers or rights beyond those held by the other DB representatives. Meetings of the DB will be effective only if an equal number of DB member(s) from each Company and MeiraGTx Neuro UK are present or participating (including by videoconference or teleconference) in such meeting. As appropriate, the DB may invite a reasonable number of non-voting observers to attend its meetings; *provided* that such invitees are bound by appropriate confidentiality, non-disclosure and non-use obligations which are no less stringent than those set forth in ARTICLE 10. Minutes will be kept of all DB meetings in English, which

minutes shall be circulated via e-mail for review and approval within [***] after each DB meeting.

7.1.2 DB Responsibilities. The DB's responsibilities shall include the following: (a) oversee, review and discuss the Development, Manufacture and Commercialization of the Licensed Device and Licensed Products in the Territory, including the performance of any Collaboration Activities by the Parties; (b) discuss, review and determine whether to approve any amendments to the Transition Services Plan, including any changes to the scope of any Transition Services or the corresponding Transition Services Period; (c) discuss, review and determine whether to approve the Development Plan, including the corresponding Development Plan Budget, and any subsequent amendments thereto; (d) serve as an information exchange platform between the Company and MeiraGTx Neuro UK with respect to the Development, Manufacture and Commercialization of the Licensed Device and Licensed Products in the Territory, including to review and discuss any data, results, reports or other information generated in connection therewith; (e) establish, as appropriate, additional working groups; and (f) perform such other functions as are assigned to the DB in this Agreement, or otherwise mutually agreed by Company and MeiraGTx Neuro UK in writing; *provided*, *however*, that, [***].

7.1.3 DB Decision-Making. Decisions of the DB shall be made by majority vote, with each DB member having one vote. If the DB does not reach a decision with respect to any matter over which it has decision-making authority pursuant to Section 7.1.2 after endeavoring to agree in good faith for at least [***], then, such matter will be referred to [***]; *provided*, *however*, that approval of any matter covered under Section 7.1.2(b) or Section 7.1.2(c) shall require [***].

7.1.4 Limitations of DB Authority. For the avoidance of doubt, the DB shall have only the powers as are specifically delegated to it pursuant to Section 7.1.2 and shall not have the authority to (a) resolve any other Disputes arising out of this Agreement, which, for clarity, shall be resolved in accordance with Section 14.8; (b) amend, modify or waive any term or condition of this Agreement (including expanding a Party's rights or reducing a Party's obligations), except with respect to amendments to the Development Plan approved in accordance with Section 7.1.3; or (c) determine that any Party has fulfilled any obligations under this Agreement or that any Party or any of its Affiliates have breached any obligation under this Agreement.

7.2 **Alliance Managers**. On the Effective Date, each of Company and MeiraGTx shall appoint an individual who shall serve as the primary point of contact between Company and MeiraGTx with regard to questions relating to this Agreement or the overall business relationship and related matters among the Parties (each, an "**Alliance Manager**"). During the Term, each of Company and MeiraGTx may replace its Alliance Manager at any time upon written notice to the other Party.

ARTICLE 8
FINANCIAL TERMS

8.1 **Upfront Payment**. In consideration for the rights and licenses granted by MeiraGTx Neuro US to Company under Section 2.1, on the Effective Date, Company shall pay to MeiraGTx Neuro US a one-time, non-refundable, non-creditable payment of [***].

8.2 **Equity Consideration**. In partial consideration for the collaboration and rights granted by MeiraGTx Neuro UK to Company hereunder, on the Effective Date, pursuant to the Company

Formation Agreements, Hologen Guernsey shall issue Class A Shares constituting thirty percent (30%) of the share capital of Hologen Guernsey to MeiraGTx Neuro UK.

8.3 **Transition Services Costs**. In consideration for the Transition Services provided by or on behalf of MeiraGTx Neuro UK pursuant to Section 3.2, within [***] following receipt by Company of an invoice from MeiraGTx Neuro UK in accordance with Section 8.5, Company shall (a) pay to MeiraGTx Neuro UK the FTE Costs incurred in connection with the performance of any Transition Services by any employee or other personnel of MeiraGTx Neuro UK (or any of its Affiliates) pursuant to Section 3.2; and (b) reimburse MeiraGTx Neuro UK for any Out-of-Pocket Costs incurred with respect thereto, in each case ((a) or (b)), which payments shall be non-creditable and non-refundable; *provided*, *however*, that Company and MeiraGTx Neuro UK shall agree in advance upon a budget for any FTE Costs or Out-of-Pocket Costs to be paid by Company pursuant to this Section 8.3, including the scope of the Transition Services to be performed.

8.4 **Development Costs**.

8.4.1 Development Cost Reports. Within [***] following the end of each month during the Development Term in which any Development Costs are incurred, MeiraGTx Neuro UK shall deliver to Company a report of the Development Costs incurred by or on behalf of MeiraGTx Neuro UK (or any of its Affiliates) in connection with the performance of its Development Activities under the Development Plan during such month, together with an invoice for the amount of such Development Costs (each, a "**Development Cost Report**").

8.4.2 Development Cost Overruns. Notwithstanding anything to the contrary set forth herein, any Development Costs incurred by or on behalf of MeiraGTx Neuro UK (or any of its Affiliates) during a given Calendar Year within the Development Term in connection with the performance of its Development Activities under the Development Plan that do not exceed [***] of the amounts budgeted under the approved Development Plan Budget for such Calendar Year shall be included in the calculation of the applicable Development Costs for the purposes of determining the amounts to be paid by Company to MeiraGTx Neuro UK pursuant to Section 8.4.3. In the event that, at any time during the Development Term, the anticipated amount of the Development Costs expected to be incurred by or on behalf of MeiraGTx Neuro UK (or any of its Affiliates) within a given Calendar Year in connection with the performance of its Development Activities under the Development Plan is likely to exceed [***] of the amounts budgeted under the approved Development Plan Budget for such Calendar Year (a) MeiraGTx Neuro UK shall notify Company thereof; and (b) [***].

8.4.3 Payment of Development Costs. As consideration for the performance of the Development Activities allocated to MeiraGTx Neuro UK under the Development Plan, within [***] following Company's receipt of a Development Costs Report, Company shall pay to MeiraGTx Neuro UK a non-creditable, non-refundable payment for the total Development Costs as set forth in such Development Costs Report.

8.4.4 Cost of Company's Development Activities. For clarity, as among the Parties, Company shall solely be responsible for any costs or expenses incurred by or on behalf of Company (or any of its Affiliates or Sublicensees) in connection with its performance of any Development Activities or otherwise in connection with the Development of the Licensed Device or any Licensed Product under this Agreement, including any payments invoiced by, or any other costs and expenses otherwise incurred in connection with, any Subcontractor(s) engaged by or on behalf of a Company (or any of its Affiliates or Sublicensees) in connection therewith, *provided* that such costs or expenses were incurred

under the approved Development Plan Budget, or otherwise received prior approval by the Company.

8.5 **Payment Terms**. All payments due and payable to a Party hereunder shall be made in U.S. dollars ($). The Parties may vary the method of payment set forth herein at any time upon mutual agreement, and any change shall be consistent with the local applicable law at the place of payment or remittance. Unless otherwise provided herein, including Section 8.1, all amounts due and payable by Company to MeiraGTx hereunder shall be payable within [***] following receipt by Company of an invoice from MeiraGTx, which invoice shall be sent via email [***].

8.6 **Late Payments**. Without limiting MeiraGTx's remedies under this Agreement, any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of (a) the sum of [***] plus the prime rate of interest quoted in the Money Rates (or equivalent) section of The Wall Street Journal, Eastern Edition (or any substitute source agreed by the Parties), calculated daily on the basis of a three hundred sixty (360) day year; and (b) the maximum interest rate allowed by Law.

8.7 **Taxes**. If applicable law requires that any Taxes be deducted and withheld from payments paid by Company to MeiraGTx under this Agreement, Company shall (a) pay such Taxes to the proper governmental entity; (b) send evidence of the obligation together with proof of Tax payment to MeiraGTx promptly following such payment; (c) remit the net amount, after deductions or withholding made under this Section 8.6; and (d) if requested by MeiraGTx, cooperate with MeiraGTx to obtain available reductions, credits or refunds of such Taxes. All amounts payable by Company to MeiraGTx under or in connection with this Agreement are exclusive of VAT and Indirect Taxes. Any VAT and Indirect Taxes payable on the consideration paid to MeiraGTx hereunder shall be paid by Company at the same time as the payment or provision of such consideration to which it relates, subject to the production of an invoice in accordance with Section 8.5. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate Tax withholding or similar obligations in respect of any payments paid by Company to MeiraGTx under this Agreement, including that Company will provide MeiraGTx with any tax forms that may be necessary in order for MeiraGTx not to withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income Tax treaty.

8.8 **Records; Audits**.

8.8.1 Financial Recordkeeping. MeiraGTx Neuro UK shall, and shall cause its Affiliates and require its Subcontractors to, keep complete and accurate records in accordance with its record retention policies applicable to such books and records, but in any event for a period of at least [***] after the end of the Calendar Year in which any Development Costs, FTE Costs or Out-of-Pocket Costs becomes payable to MeiraGTx Neuro UK pursuant to this ARTICLE 8, as applicable (or such longer period as required under the applicable Law) (the "**Retention Period**"), in sufficient detail to confirm the accuracy of the calculations hereunder and in accordance with the applicable accounting standard that is normally applied by such Party with respect to the filing of its reporting.

8.8.2 Audit. During the applicable Retention Period, but not more than once in each Calendar Year, MeiraGTx Neuro UK shall permit, and shall cause its Affiliates and require its Subcontractors to permit, an independent certified public accounting firm of nationally recognized standing selected by Company, and reasonably acceptable to MeiraGTx Neuro UK (or such Affiliate or Subcontractor, as applicable), to have access to and to review, during normal business hours upon not less than [***] prior notice, the applicable records of MeiraGTx Neuro UK (or such Affiliate or Subcontractor, as applicable) to verify the

accuracy of any statement of Development Costs, FTE Costs or Out-of-Pocket Costs provided by MeiraGTx Neuro UK pursuant to this ARTICLE 8. Such review may cover such records for any Calendar Year ending not more than [***] prior to the date of such notice (provided that any such Calendar Year may only be subject to audit one time, unless for cause). The accounting firm shall disclose to MeiraGTx Neuro UK and Company only whether such statements of Development Costs, FTE Costs or Out-of-Pocket Costs are correct or incorrect and the amount of any discrepancies and no other information shall be provided to Company. If such accounting firm concludes that additional amounts were owed during such period, Company shall pay the additional undisputed amount within [***] after the date such accounting firm delivers such written report to Company. If such accounting firm concludes that an overpayment was made, and MeiraGTx Neuro UK agrees with such calculation, such overpayment shall be fully creditable against amounts payable in subsequent payment periods (or reimbursed to the extent there are no subsequent payment periods). If MeiraGTx Neuro UK disagrees with such calculation, MeiraGTx Neuro UK and Company shall work together reasonably and in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such Dispute within [***], then, notwithstanding Section 14.8, the Dispute shall be [***], Company shall make the required payment within [***] after the date Company receives the report of its accounting firm. [***].

8.8.3 Confidentiality of Financial Information. Each Party shall treat all information that it receives under this ARTICLE 8 in accordance with the confidentiality provisions of ARTICLE 10, and shall cause its accounting firm to enter into an acceptable, reasonable confidentiality agreement with such other Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for such Party to enforce its rights under this Agreement.

ARTICLE 9
INTELLECTUAL PROPERTY

9.1 **Background IP**. Subject to the licenses granted by MeiraGTx Neuro US to Company or by Company to MeiraGTx Neuro UK under this Agreement, as among the Parties, (a) MeiraGTx Neuro US shall retain all of its rights, title and interests in, to and under the MeiraGTx Background IP; and (b) Company shall retain all of its rights, title and interests in, to and under the Company Background IP.

9.2 **Arising IP**.

9.2.1 Inventorship. For purposes of this Agreement, the determination of inventorship of any inventions included in the Arising Know-How (including any Arising Patent that claims such Arising Know-How) shall be made in accordance with United States patent law, regardless of where the applicable activities occurred.

9.2.2 MeiraGTx Arising IP. As among the Parties, regardless of inventorship, MeiraGTx Neuro US shall solely own all rights, title and interest in, to and under any and all:

(a) Arising Know-How that [***] (such Arising Know-How, collectively, the "**MeiraGTx Arising Know-How**"); and

(b) Arising Patents that [***] (such Arising Patents, collectively, the "**MeiraGTx Arising Patents**" and, together with the MeiraGTx Arising Know-How, the "**MeiraGTx Arising IP**").

9.2.3 Company Arising IP. As among the Parties, regardless of inventorship, Company shall solely own all rights, title and interest in, to and under any and all:

(a) Arising Know-How that [***] (such Arising Know-How, the "**Product-Specific Arising Know-How**");

(b) Arising Know-How that [***] (such Arising Know-How, together with the Product-Specific Arising Know-How, the "**Company Arising Know-How**"); and

(c) Arising Patents that (i) [***] (such Arising Patents, the "**Product-Specific Arising Patents**"), and (ii) [***] (such Arising Patents, collectively, with the Product-Specific Arising Patents, the "**Company Arising Patents**" and, together with the Company Arising Know-How, the "**Company Arising IP**").

9.2.4 Joint Arising IP. Subject to any rights or licenses expressly granted by [***]:

(a) Arising Know-How (other than any Product-Specific Arising Know-How, MeiraGTx Arising Know-How or Company Arising Know-How) (such Arising Know-How, collectively, the "**Joint Arising Know-How**"); and

(b) Arising Patents (other than any MeiraGTx Arising Patents or Company Arising Patents), including any other Joint Arising Know-How (such Arising Patents, collectively, the "**Joint Arising Patents**" and, together with the Joint Arising Know-How, the "**Joint Arising IP**").

9.2.5 Disclosure of Arising Know-How. During the Term, (a) each Party shall promptly disclose to Company and MeiraGTx Neuro US, as applicable, any inventions within the Joint Arising Know-How; (b) MeiraGTx Neuro US shall promptly disclose to Company any inventions that fall within the Company Arising Know-How; or (c) Company shall promptly disclose to MeiraGTx Neuro US any inventions that fall within the MeiraGTx Arising Know-How, in each case ((a), (b) or (c)), that is first discovered, developed, generated, invented, derived, created, conceived or reduced to practice by or on behalf of such Party and of which such Party becomes aware.

9.2.6 Assignment Obligations. Subject to the terms and conditions of this Agreement, including any rights or licenses expressly granted by MeiraGTx Neuro US to Company or by Company to MeiraGTx Neuro UK under this Agreement, as applicable, (a) Company will assign, and hereby does assign, to MeiraGTx Neuro US any and all of Company's (and its Affiliates') rights, title and interest in, to or under any MeiraGTx Arising IP, and MeiraGTx Neuro US hereby accepts such assignment; (b) MeiraGTx Neuro US will assign, and hereby does assign, to Company any and all of MeiraGTx Neuro US' (and its Affiliates') rights, title and interest in, to or under any Company Arising IP, and Company hereby accepts such assignment; and (c) (i) MeiraGTx agrees to assign, and hereby does assign, to Company and (ii) Company agrees to assign, and hereby does assign, to MeiraGTx Neuro US, in each case ((i) or (ii)), an undivided interest in any and all of such Party's (and its Affiliates') rights, title and interest in, to or under any Joint Arising IP; *provided* that, subject to any rights or licenses expressly granted by MeiraGTx Neuro US to Company or by Company to MeiraGTx Neuro UK under this Agreement, including the licenses granted pursuant to Section 2.1, each of Company and MeiraGTx Neuro US will [***]. During the Term, each Party shall have appropriate agreements in place with its and its Representatives performing any activities under this Agreement on such Party's behalf to provide such Party with exclusive ownership in and to any Arising IP hereunder of such

Representatives. The Parties agree to reasonably cooperate with each other, including executing and recording documents, to effectuate the intellectual property ownership provisions set forth in this Section 9.2.

9.3 Prosecution and Maintenance.

9.3.1 General. Subject to the remainder of this Section 9.3, during the Term, as among the Parties, Company shall have the first right, but not the obligation, at its own cost and expense, to control the preparation, filing, prosecution (including any interferences, oppositions, *inter partes* review or other post-grant proceedings, reissue reexaminations, revocations or nullifications) and maintenance of the MeiraGTx Patents, any Product-Specific Arising Patents and any Joint Arising Patents in Territory. Company shall keep MeiraGTx Neuro US reasonably informed of the status of the preparation, filing, prosecution and maintenance of each such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent (*e.g.*, interferences, oppositions, *inter partes* review or other post-grant proceedings reexaminations, reissues, revocations or nullifications) in a timely manner, including by providing MeiraGTx Neuro US (a) copies of any material communications or correspondence received from relevant patent authorities; (b) a reasonable opportunity to review and comment on any proposed filing or material correspondence with any patent authority to the extent related to any such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent at least [***] prior to the anticipated filing or submission date thereof, and Company shall consider in good faith any of MeiraGTx Neuro US' reasonable comments with respect thereto; and (c) copies of all final filings and responses made to any patent authority with respect to any such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent in a timely manner following submission thereof.

9.3.2 Step-In Rights. If Company elects not to file or to continue to prosecute or maintain any such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent in any country in the Territory pursuant to Section 9.3.1, then, Company shall notify MeiraGTx Neuro US [***] after making such election (but, in any event, at least [***] before any deadline applicable to the filing, prosecution or maintenance of such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent in such country). In such case, MeiraGTx Neuro US shall have the right, but not the obligation, to pursue the filing, prosecution or maintenance of such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent in such country, at its own cost and expense. If MeiraGTx Neuro US elects to continue prosecution or maintenance of any such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent pursuant to this Section 9.3.2, then, Company shall [***] deliver to MeiraGTx Neuro US all prosecution files associated with such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent in such country and use reasonable efforts to make its employees, agents and consultants reasonably available to MeiraGTx Neuro US, at no additional cost, to the extent necessary to enable MeiraGTx Neuro US to continue prosecution or maintenance of any such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent in such country.

9.3.3 Patent Term Extensions; BPCIA. As among the Parties, with respect to any MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent, Company shall have sole and final decision making authority with respect to (a) filing for any patent term extension pursuant to 35 U.S.C. §§ 154-156 or, as applicable, any foreign equivalent patent term extension or supplemental protection certificates on any such MeiraGTx Patent, Product-

Specific Arising Patent or Joint Arising Patent in the Territory; *provided* that Company shall keep MeiraGTx Neuro US reasonably informed of the status of any such patent term extension or supplemental protection certificate (including any decision with respect thereto) with respect to any such MeiraGTx Patents, Product-Specific Arising Patents or Joint Arising Patents in a timely manner, including giving MeiraGTx Neuro US a reasonable opportunity to comment on any such filing and decisions regarding such patent term extension or supplemental protection certificate and incorporating any reasonable comments provided by MeiraGTx Neuro US with respect thereto; or (b) the determination, as a reference product sponsor, of whether or not to privately exchange any such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent with respect to such Licensed Product with a biosimilar applicant, and take other steps, pursuant to the requirements of the BPCIA.

9.3.4 Patent Costs. Except as otherwise agreed by the Parties, the Party controlling the preparation, filing, prosecution and maintenance of a given MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent pursuant to this Section 9.3 shall be responsible for all costs and expenses (including any attorney fees) incurred in connection therewith.

9.4 Enforcement Rights.

9.4.1 Notice. If any Party (or any of its Affiliates or Sublicensees) learns of any infringement or misappropriation, or threatened or suspected infringement or misappropriation, of (a) any MeiraGTx Licensed Technology is occurring or is likely, in each case, solely to the extent that such infringement, unauthorized use or misappropriation relates to the Development, Manufacture or Commercialization by a Third Party of a product that competes with the Licensed Device or any Licensed Product, including any notification of the submission of an Abbreviated Biologic License Application wherein a Licensed Product is the "Reference Product" under the BPCIA or receipt of manufacturing process from a subsection (k) applicant or other similar procedure where a response is required under applicable Law (in order to avoid waiving rights); or (b) any Joint Arising IP by a Third Party, whether or not such Third Party infringement is by a product that competes with the Licensed Device or any Licensed Product (any such activity or claims by a Third Party, a "**Third Party Infringement**"), such Party shall notify Company and MeiraGTx Neuro US, as applicable, and provide it with details of such infringement or misappropriation or claim that are known by such Party and its Affiliates.

9.4.2 Enforcement Actions. As among the Parties, Company shall have the first right, at its own cost and expense, but not the obligation, to attempt to resolve any Third Party Infringement in the Territory with respect to any MeiraGTx Licensed Technology, Product-Specific Arising Patents or Joint Arising IP, including by filing an infringement suit, defending against such claim or taking other similar action (each, an "**Enforcement Action**") and, subject to Section 9.4.5, to compromise or settle any such infringement or claim.

9.4.3 Step-In Rights. In the event that Company does not intend to initiate, defend or otherwise attempt to settle an Enforcement Action with respect to any such Third Party Infringement pursuant to Section 9.4.2, then, Company shall, within [***] of having received or sent notice with respect to such Third Party Infringement pursuant to Section 9.4.1, inform MeiraGTx Neuro US thereof and MeiraGTx Neuro US shall have the right, but not the obligation, to attempt to resolve such Third Party Infringement solely with respect to the subject MeiraGTx Licensed Technology, Product-Specific Arising Patents or Joint Arising IP, as applicable, as the Party controlling such Enforcement Action.

9.4.4 Cooperation. The Party bringing an Enforcement Action pursuant to Section 9.4.2 or Section 9.4.3, as applicable, shall have the sole and exclusive right to select counsel for such Enforcement Action. Each of Company or MeiraGTx Neuro US, as applicable, shall have the right to join an Enforcement Action (including the right to be represented by independent counsel of its own choice) initiated by the Party controlling such Enforcement Action pursuant to Section 9.4.2 or Section 9.4.3, as applicable, in each case, at its own expense (except any required joinder pursuant to this Section 9.4.4). The Party controlling such Enforcement Action (a) shall keep such other Party promptly informed with respect to such Enforcement Action; (b) shall, acting reasonably and in good faith, consult with, and give reasonable consideration to, any comments made by such other Party related to such Enforcement Action; and (c) shall provide such other Party with copies of all material documents (*e.g.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such Enforcement Action. Upon the request of the controlling Party, such other Party shall provide reasonable assistance to the controlling Party, including providing access to relevant documents and other evidence, making its employees available, and, solely to the extent that such other Party is a necessary or indispensable plaintiff party for such Enforcement Action (or such joinder is required under Law in order to enable such enforcing Party to pursue such Enforcement Action), joining such Enforcement Action or taking such other actions as are necessary for standing with respect to such Enforcement Action (including the right to be represented by independent counsel of its own choice), in each case, subject to the controlling Party's reimbursement of any reasonable out-of-pocket expenses (including reasonable attorney fees) incurred on an on-going basis by the non-controlling Party in providing such assistance. The Parties shall, acting reasonably and in good faith, cooperate to ensure that each Person that participates in, or receives any information about, any Enforcement Action in accordance with this Section 9.4.4 shall use reasonable efforts to protect all applicable Confidential Information and preserve all applicable attorney-client privilege and work product protections.

9.4.5 Restrictions on Settlement. Notwithstanding anything to the contrary set forth herein, (a) Company shall not settle or otherwise compromise any Enforcement Action by admitting that any MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent is invalid or unenforceable, whether in whole or in part, or in a way that adversely affects or would be reasonably expected to materially adversely affect the validity or enforceability of any such MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent, in each case, without MeiraGTx Neuro US' prior consent (such consent not to be unreasonably withheld, conditioned or delayed); (b) MeiraGTx Neuro US shall not settle or otherwise compromise any Enforcement Action by admitting that any MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent is invalid or unenforceable, whether in whole or in part, or in a way that adversely affects or would be reasonably expected to materially adversely affect the validity or enforceability of any such MeiraGTx Patent, in each case, without Company's prior consent (such consent not to be unreasonably withheld, conditioned or delayed); and (c) no Party shall settle or otherwise compromise any Enforcement Action in a way that adversely affects or would be reasonably expected to materially adversely affect the rights or benefits of any other Party hereunder or that otherwise imposes any costs or liability on, or involves any admission by, such other Party, in each case, without such other Party's prior consent (such consent not to be unreasonably withheld, conditioned or delayed).

9.4.6 Costs and Recoveries. Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 12, the Party taking an Enforcement Action under this Section 9.4 shall pay all costs associated with such Enforcement Action, other than the expenses of the other Party if such other Party elects to join such Enforcement Action as provided in Section 9.4.4 (but, for clarity, not any required joinder pursuant to Section 9.4.4). Any amounts recovered by the Party taking an Enforcement Action pursuant to this Section 9.4, whether by settlement or judgment, shall be allocated in the following order: (i) first, to reimburse the Party taking such Enforcement Action for any costs incurred; (ii) second, to reimburse the Party not taking such Enforcement Action for costs incurred by it at the request of the Party taking such Enforcement Action and (iii) finally, any remaining amount of such recovery shall be [***].

9.4.7 Other Infringement of MeiraGTx Licensed Technology. For the avoidance of doubt, as among the Parties, MeiraGTx Neuro US shall have the sole right at its own cost and expense, but not the obligation, to attempt to resolve any infringement or misappropriation, or threatened or suspected infringement or misappropriation, of any MeiraGTx Licensed Technology that does not constitute a Third Party Infringement.

9.5 Defense of Third Party Actions.

9.5.1 Notice. If any Party or any of its Affiliates becomes aware of any Third Party Action with respect to the Licensed Device or any Licensed Product in the Territory, such Party shall promptly notify Company and MeiraGTx, as applicable, of all details regarding such claim or action that is reasonably available to such Party or such Affiliate.

9.5.2 Control of Defense. As among the Parties, Company shall have the first right, at its sole cost and expense, but not the obligation, to defend against any Third Party Action with respect to a Licensed Product in the Field in the Territory and, subject to Section 9.5.5, to settle or otherwise compromise such Third Party Action. If Company declines or fails to assert its intention to defend such Third Party Action with respect to MeiraGTx Licensed Technology within [***] after sending (in the event that Company is the notifying Party) or receiving (in the event that MeiraGTx is the notifying Party) notice under Section 9.5.1, then, MeiraGTx Neuro US shall have the right, but not the obligation, to assume control of the defense against such Third Party Action solely with respect to MeiraGTx Licensed Technology. The Party defending such Third Party Action shall have the sole and exclusive right to select counsel for such Third Party Action.

9.5.3 Cooperation. The Party defending a Third Party Action (the "**Defending Party**") pursuant to Section 9.5.2 shall consult with the non-Defending Party on all material aspects of the defense. The non-Defending Party, at its own cost and expense, shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy and the Defending Party shall, acting reasonably and in good faith, consider the non-Defending Party's comments. The Parties shall reasonably cooperate with each other in all such Third Party Actions. The non-Defending Party will be entitled to be represented by independent counsel of its own choice at its own expense.

9.5.4 Costs of Defense. Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 12, the Defending Party shall pay all costs incurred by the Parties associated with such Third Party Action other than the expenses of the non-Defending Party if the non-Defending Party elects to join such Third Party Action pursuant to Section 9.5.3.

9.5.5 Consent for Certain Settlements and other Compromises of Third Party Actions.

(a) MeiraGTx Neuro US shall not settle or otherwise compromise any Third Party Action (i) by admitting that any MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent is invalid or unenforceable, whether in whole or in part, (ii) in a manner that adversely affects or would be reasonably expected to materially adversely affect any rights or benefits of Company or its Affiliates, or (iii) in a way that imposes any costs or liability on, or involves any admission by, Company or its Affiliates, in each case ((i), (ii) or (iii)), without Company's prior consent (such consent not to be unreasonably withheld, conditioned or delayed).

(b) Company shall not settle or otherwise compromise any Third Party Action (i) by admitting that any MeiraGTx Patent, Product-Specific Arising Patent or Joint Arising Patent is invalid or unenforceable, whether in whole or in part, (ii) in a manner that adversely affects or would be reasonably expected to materially adversely affect any rights or benefits of MeiraGTx Neuro US (or any of its Affiliates), or (iii) in a way that imposes any costs or liability on, or involves any admission by, MeiraGTx Neuro US (or any of its Affiliates), in each case ((i), (ii) or (iii)), without MeiraGTx Neuro US' prior consent (such consent not to be unreasonably withheld, conditioned or delayed).

ARTICLE 10
CONFIDENTIALITY

10.1 **Confidential Information**. Except as otherwise expressly provided in this ARTICLE 10, any and all confidential or proprietary information or Materials, including any Know-How or other information that is owned or controlled by a Party (the "**Disclosing Party**") and is disclosed or provided to (or has otherwise become known to) any other Party (the "**Receiving Party**"), whether directly or indirectly, intentionally or unintentionally, in connection with the activities under this Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the Receiving Party by the Disclosing Party in oral, written, visual, graphic, or electronic form (collectively, "**Confidential Information**") shall be deemed the Confidential Information of the Disclosing Party and subject to the terms and conditions of this ARTICLE 10. [***]

10.2 **Confidentiality and Non-Use Obligations**. Except as otherwise expressly provided in this ARTICLE 10, during the Term and for a period of [***] thereafter, the Receiving Party shall (a) hold any Confidential Information of the Disclosing Party in strict confidence using at least that degree of care used by the Receiving Party in dealing with its own confidential information of a similar nature, which shall in no event be less than a reasonable degree of care; (b) not disclose such Confidential Information to any Third Party, except to its agents or Subcontractors who have a "need to know" to conduct the activities under the Development Plan; provided, however, that such agents or Subcontractors agree in writing to abide by the confidentiality and non-use provisions no less stringent than those set forth herein prior to any disclosure of Confidential Information thereto; and (c) use such Confidential Information only as necessary to perform the Development Plan or as otherwise expressly provided herein, and not for any other purpose.

10.3 **Exceptions**. Notwithstanding the foregoing, the confidentiality and non-use obligations with respect to the Disclosing Party's Confidential Information under this Agreement, including as set forth in Section 10.2, will not include any information (and such information will not be considered Confidential Information) that the Receiving Party can show by competent written evidence: (a) is or hereafter becomes available to the public other than by reason of any breach hereof; (b) was already known to the Receiving Party, prior to the date of disclosure, as demonstrated by written records; (c) is disclosed to the Receiving Party by a Third Party who has the right to disclose such

information without any obligations of confidentiality or non-use; or (d) is developed by or on behalf of the Receiving Party independently, without use of, reference to or reliance on Confidential Information of the Disclosing Party received hereunder.

10.4 **Permitted Disclosures**. Notwithstanding anything to the contrary, a Receiving Party may, in connection with performing its obligations or exercising its rights and performing its obligations under this Agreement, disclose the Confidential Information of the Disclosing Party for purposes of (a) prosecuting or defending litigation or arbitration; (b) complying with applicable law or any ruling or order of a court of competent jurisdiction, including any applicable securities regulations and the rules of any securities exchange or market on which such Receiving Party's (or its Affiliate's) securities are or are planned to be listed or traded (provided that (i) the Receiving Party promptly notifies the Disclosing Party of the obligation to disclose in order to allow the Disclosing Party to object or seek a protective order, and reasonably cooperates with the Disclosing Party in connection therewith, (ii) the Receiving Party only discloses the minimum amount of Confidential Information that is necessary to comply with the required disclosure and (iii) such information remains Confidential Information in accordance with the terms and conditions of this ARTICLE 10 for all other purposes); or (c) to such Receiving Party's actual or potential Third Party acquirers and their respective personnel, in each case, for the limited purpose of such acquisition activities, each of whom prior to disclosure shall be bound by similar obligations of confidentiality and non-use at least as restrictive as those set forth in this ARTICLE 10.

10.5 **Return or Destruction of Confidential Information**. Except as otherwise provided in this Agreement, including as set forth in Section 13.3, upon the termination or expiration of this Agreement, the Receiving Party shall destroy or return to the Disclosing Party, at the Disclosing Party's direction, all tangible Confidential Information of the Disclosing Party in its possession and in the possession of any Affiliates, agents or subcontractors, subject to the Receiving Party's right to retain one (1) copy of the Confidential Information in its secure files as a record of its obligations under this Agreement; provided that back-up copies of electronic documents that are created by the Receiving Party in the ordinary course of business will remain within the Receiving Party's electronic systems until deleted in the ordinary course of business and in accordance with applicable laws and regulations and shall otherwise remain subject to the terms and conditions of this ARTICLE 10 for so long as such copy is retained.

10.6 **Public Disclosure**. Subject to Section 10.4, no Party (nor any of its respective Affiliates or, in the case of Company, any Sublicensees) shall have the right to make press releases or public announcements regarding this Agreement, including the terms of this Agreement or any Collaboration Activities, in each case, without the prior consent of the other Parties; *provided* that (a) MeiraGTx and Company may each (separately) issue a press release regarding this transaction following the Effective Date in the form, manner and on a date mutually agreed upon by the Parties; and (b) no Party will be prevented from complying with any duty of disclosure it may have pursuant to Laws. Each Party (or any of its respective Affiliates or, in the case of Company, any Sublicensees) may publish or publicly announce any information relating to this Agreement that is substantially similar to information that has already been publicly disclosed in accordance with this ARTICLE 10, including with respect to information disclosed by a Party pursuant to Section 10.4; *provided* that as of such time, such information continues to be accurate.

10.7 **Clinical Trial Data**. Notwithstanding the provisions of Section 10.2 and Section 10.8, to the extent that there are any Clinical Trials or studies (including observational studies and other studies, such as meta analyses) conducted by or on behalf of MeiraGTx (or any of its Affiliates) with respect to the Licensed Device or any Licensed Product prior to the Effective Date, as applicable, MeiraGTx (or any of its Affiliates) shall have the right (in their sole discretion, at any time) to publish (a) the results or summaries of results of any such Clinical Trial or study in any register maintained by

MeiraGTx or any of its Affiliates; or (b) the protocols of any such Clinical Trial on www.clinicaltrials.gov, within such timescales as required by Law or MeiraGTx's or any of its Affiliates' standard operating procedures, irrespective of the outcome of any such Clinical Trial or study; *provided* that MeiraGTx (or any of its Affiliates, as applicable) shall (i) submit to Company a copy of any such publication for Company's review and comment (but not approval) at least [***] prior to submission for the proposed date of publication (which period may be extended by up to an additional [***] in the event that Company believes in good faith that such publication may form the basis of patentable intellectual property) and (ii) consider any Company's comments thereto in good faith.

10.8 **Scientific Publications**. Subject to the terms and conditions of this Agreement, without limiting its rights under this Agreement (including under ARTICLE 9 and Section 10.2), Company (or any of its Affiliates or Sublicensees) shall have the right to make publications regarding the Development and Commercialization of the Licensed Device or any Licensed Products by or on behalf of Company (or any of its Affiliates or Sublicensees); *provided* that (a) Company shall deliver to MeiraGTx for review and comment a copy of any proposed publication at least [***] before its intended submission for publication; and (b) MeiraGTx shall have the right to (i) provide comments on such proposed publication (provided that Company shall incorporate any reasonable comments provided by MeiraGTx with respect thereto), (ii) require the removal of any of MeiraGTx's Confidential Information from the proposed publication or presentation, or (iii) require the delay of the submission of such proposed publication or presentation for a period up to [***] to permit the preparation and filing of a patent application as needed to preserve the patentability of any Confidential Information of MeiraGTx. Company (and its Affiliates and Sublicensees) will ascribe authorship of any proposed publication or presentation under this Section 10.8 using accepted standards used in peer-reviewed, academic journals at the time of the publication or presentation, and any such publication or presentation made by Company (or any of its Affiliates or Sublicensees) under this Section 10.8 shall contain appropriate acknowledgements of the contribution of MeiraGTx to the Development activities that are the subject of such publication or presentation, in accordance with generally accepted academic practices. Once any such publication is accepted for publication, Company shall provide MeiraGTx with a copy of the final version of such publication.

10.9 **Use of Name**. Notwithstanding any provision to the contrary set forth in this Agreement, nothing in this Agreement grants any Party a right to use any other Party's name or logo in any press release, without first obtaining such other Party's consent (except for any reference to such other Party as a party to this Agreement or as a developer of the Licensed Device or any Licensed Product, subject to the other terms and conditions of this Agreement).

10.10 **Equitable Relief**. Due to the unique nature of the Confidential Information, the Parties agree that any breach or threatened breach by a Party of this ARTICLE 10 with respect to any other Party's Confidential Information will cause not only financial harm to such other Party, but also irreparable harm for which money damages will not be an adequate remedy. Therefore, such other Party shall be entitled, in addition to any other legal or equitable remedies, to seek an injunction or similar equitable relief against any such breach or threatened breach by such Party without the necessity of proving actual damages or posting any bond.

ARTICLE 11
REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Parties, as of the Effective Date, that:

11.1.1 such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;

11.1.2 such Party has all right, power and authority to enter into this Agreement and to perform its obligations under this Agreement, and has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

11.1.3 this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms and conditions of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles;

11.1.4 the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (i) such Party's charter documents, bylaws, or other organizational documents, (ii) any agreement, instrument, or contractual obligation to which such Party is bound, (iii) any requirement of any applicable law or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party;

11.1.5 such Party is not under any obligation, contractual or otherwise, to any Person that conflicts with the terms or conditions of this Agreement, or that would otherwise materially impede the fulfillment of its obligations hereunder;

11.1.6 such Party has the right to grant to each other Party (and its Affiliates, as applicable) the rights and licenses granted to such other Party pursuant to this Agreement;

11.1.7 there is no pending proceeding that has been commenced against such Party that challenges, or would reasonably be expected to have the effect of preventing, delaying, making illegal, or otherwise interfering with, any of the transactions contemplated hereby; and

11.1.8 no consent by any Third Party or governmental body is required with respect to the execution and delivery of this Agreement by it or the consummation by it of the transactions contemplated hereby.

ARTICLE 12
INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

12.1 **Indemnification by Company and HGL**. Each of Company and HGL shall indemnify, defend and hold harmless MeiraGTx, its Affiliates and each of their respective officers, directors, representatives and employees ("**MeiraGTx Indemnitees**") from and against any and all liability, damage, loss, fines, penalties, cost or expense (including reasonable attorneys' fees) ("**Losses**") incurred by or rendered against any such MeiraGTx Indemnitees in connection with Third Party claims, investigations, demands or suits ("**Third Party Claims**") to the extent arising out of or resulting from (a) Company's or any of its Company Indemnitees' gross negligence or willful misconduct relating to this Agreement; (b) any material breach by Company of any of its representations and warranties, covenants or obligations set forth in this Agreement; (c) MeiraGTx Neuro UK's (or its Affiliate's) provision of any Development Activities or Transition Services in accordance with the terms of this Agreement; or (d) the Development, Manufacture or

Commercialization of the Licensed Device or any Licensed Product by or on behalf of Company (or any of its Affiliates or Sublicensees) in the Territory, in each case ((a), (b), (c) or (d)), except to the extent that such Losses are covered by MeiraGTx's indemnification obligations under Section 12.2, as applicable.

12.2 Indemnification by MeiraGTx. MeiraGTx shall indemnify, defend and hold harmless Company, HGL, its and their Affiliates, and each of its and their respective officers, directors, representatives and employees ("**Company Indemnitees**" and, together with MeiraGTx Indemnitees, "**Indemnitees**"), from and against any and all Third Party Claims for Losses incurred by any such Indemnitee to the extent arising out of or resulting from (a) MeiraGTx's or any of its MeiraGTx Indemnitees' gross negligence or willful misconduct relating to this Agreement, including the Supply Agreements or the Safety Data Exchange Agreement; (b) any material breach by MeiraGTx of its representations and warranties, covenants or obligations set forth in this Agreement; (c) the Development, Manufacture or Commercialization of (i) the Licensed Device or any Licensed Product by or on behalf of MeiraGTx or any of its Affiliates prior to the Effective Date or (ii) the Licensed Device by or on behalf of MeiraGTx or any of its Affiliates in the Territory independent of the performance of its obligations under this Agreement, in each case ((a), (b) or (c)), except to the extent that such Losses are covered by Company's and HGL's indemnification obligations under Section 12.1, as applicable.

12.3 Indemnification Process.

12.3.1 Notification of Claims; Conditions to Indemnification Obligations. Each Party seeking indemnification or defense under Section 12.1 or Section 12.2, as applicable, shall (a) [***] notify the other Parties as soon as it becomes aware of a Third Party Claim for which indemnification may be sought pursuant to Section 12.1 or Section 12.2, as applicable (*provided* that the failure to give such notice will not relieve the indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices the indemnifying Party); (b) cooperate, and cause the applicable Indemnitee(s) to cooperate, with the indemnifying Party in the defense, settlement or compromise of such Third Party Claim; and (c) permit the indemnifying Party to control the defense, settlement or compromise of such Third Party Claim, including the right to select defense counsel (*provided* that in no event shall the indemnifying Party compromise or settle any Third Party Claim in a manner which admits fault or negligence on the part of the indemnified Party or any Indemnitee without the prior consent of the indemnified Party). Each Party shall reasonably cooperate with the indemnifying Party and its counsel in the course of the defense of any such Third Party Claim, such cooperation to include using reasonable efforts to provide or make available documents, information and witnesses. In any such Proceeding, the indemnified Party will have the right to retain its own counsel, but the fees and expenses of such counsel will be at the expense of the indemnified Party, unless (i) the indemnifying Party will have agreed to the retention of such counsel and its obligation to pay the fees and expenses of such counsel, or (ii) the named parties to any such Proceeding (including any impleaded parties) include both the indemnifying Party and the indemnified Party and representation of each Party by the same counsel would be inappropriate due to actual or potential differing interests between them. The indemnified Party shall have no right to settle any such Third Party Claim without the prior written consent of the indemnifying Party.

12.3.2 Certain Limitations. In the case where the indemnifying Party refrains (in its sole discretion) from defending any Third Party Claim and an indemnified Party recovers from Third Parties any amount in respect of a matter with respect to which an indemnifying Party has indemnified it pursuant to Section 12.1 or Section 12.2, as applicable, such

indemnified Party shall [***] pay over to the indemnifying Party the amount so recovered (after deducting therefrom the full amount of the expenses incurred by it in procuring such recovery), but not in excess of the sum of: (a) any amount previously so paid by the indemnifying Party to or on behalf of the indemnified Party in respect of such matter; and (b) any amount expended by the indemnifying Party in pursuing or defending any Third Party Claim arising out of such matter. Each Party agrees to take all reasonable steps to mitigate their respective Losses upon and after becoming aware of any event or condition which could reasonably be expected to give rise to any Losses that are indemnifiable hereunder.

12.4 **Limitation on Liability**. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, TO THE MAXIMUM EXTENT PERMITTED BY LAW, EXCEPT WITH RESPECT TO (A) A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 12.1 OR SECTION 12.2, AS APPLICABLE; (B) ANY BREACHES OF A PARTY'S OBLIGATIONS OF ASSIGNMENT OF INTELLECTUAL PROPERTY RIGHTS AS SET FORTH IN SECTION 9.1; OR (C) ANY BREACHES OF A PARTY'S OBLIGATIONS OF CONFIDENTIALITY OR NON-USE AS SET FORTH IN ARTICLE 10, (I) NO PARTY, NOR ITS AFFILIATES, SHALL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY, PUNITIVE OR MULTIPLE OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING FOR LOST REVENUES AND LOST PROFITS (WHETHER DIRECT OR INDIRECT)), WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR BREACH OF STATUTORY DUTY OR OTHERWISE, IN EACH CASE, ARISING FROM OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF, IRRESPECTIVE OF WHETHER SUCH PARTY OR ANY REPRESENTATIVE OF SUCH PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE OR WHETHER SUCH LOSS OR DAMAGE WAS REASONABLY FORESEEABLE, AND (II) EACH PARTY'S MAXIMUM LIABILITY FOR DAMAGES OF ANY KIND ARISING FROM OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF, SHALL NOT EXCEED [***].

12.5 **Insurance**. During the Term, each Party shall maintain in full force and effect, at its cost, reasonable insurance against liability and other risks associated with its activities contemplated by this Agreement, including its indemnification obligations herein, with limits not less than [***] per each occurrence or [***] annual aggregate. Upon another Party's reasonable request, each Party will furnish to such other Party certificates of insurance or other reasonable written evidence of such Party's insurance coverage required under this Section 12.5. Each Party shall provide the other Parties with at least [***] notice prior to cancelling, not renewing or materially adversely changing such insurance coverage.

ARTICLE 13
TERM AND TERMINATION

13.1 **Term**. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to Section 13.2, shall remain in full force and effect until the date of on which Company permanently ceases (directly, or through any of its Affiliates, Subcontractors or Sublicensees) all Development or Commercialization of the Licensed Device and all Licensed Products under this Agreement in the Territory (the "**Term**").

13.2 **Termination**.

13.2.1 Termination by Company for Convenience. At any time during the Term, Company may terminate this Agreement in its entirety upon (a) not less than [***] prior written notice to MeiraGTx if such notice is provided prior to receipt of the first Marketing Approval for any Licensed Product in the Territory; and (b) not less than [***] prior written notice to MeiraGTx if such notice is provided following receipt of the first Marketing Approval for any Licensed Product in the Territory.

13.2.2 Termination for Material Breach. Upon any material breach of this Agreement by (a) MeiraGTx; or (b) Company or HGL, then, (i) Company (in the case of the foregoing clause (a)) or (ii) MeiraGTx (in the case of the foregoing clause (b)), will have the right, but not the obligation, to terminate this Agreement in its entirety upon notice of termination to such breaching Party if such breach remains uncured following [***] notice to such breaching Party of the applicable breach; *provided* that, if such material breach, by its nature, is curable, but is not reasonably curable within the applicable cure period, then, such cure period will be extended (but in no event for longer than an additional [***] unless otherwise agreed by all Parties) if the breaching Party provides a written plan for curing such breach to the non-breaching Parties and uses Commercially Reasonable Efforts to cure such breach in accordance with such written plan; *provided*, *further*, that, notwithstanding the foregoing, if the breaching Party disputes, acting reasonably and in good faith, the existence of, materiality of, or failure to cure any such breach, and provides notice to the non-breaching Parties of such dispute within the relevant cure period, such non-breaching Parties will not have the right to terminate this Agreement in accordance with this Section 13.2.2 unless and until the relevant Dispute has been resolved in accordance with Section 14.8 and, during the pendency of such Dispute, all the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

13.2.3 Termination for Insolvency. In the event that a Party (a) files for protection under bankruptcy or insolvency laws; (b) makes an assignment for the benefit of creditors; (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] following such filing; (d) proposes a written agreement of composition or extension of its debts; (e) proposes or is a party to any dissolution or liquidation of such Party; (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged or dismissed within [***] following the filing thereof; or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then any other Party may terminate this Agreement in its entirety effective immediately upon notice to the other Parties.

13.2.4 Termination for Patent Challenge. If Company, HGL or any of its Affiliates or Sublicensees (a) commences or actively and voluntarily participates in a Patent Challenge; or (b) actively and voluntarily assists any other Third Party in bringing or prosecuting a Patent Challenge, then, to the extent permitted by Law, MeiraGTx shall have the right to terminate this Agreement (in its entirety) upon [***] notice to Company, unless Company, HGL and its Affiliates withdraw their participation in such Patent Challenge on or before the [***] following the date of MeiraGTx's notice of such termination.

13.2.5 Termination for Breach of Minimum Cash Reserves Funding Commitment. In the event that, at any time during the Term, Company breaches its obligations to contribute the Minimum Cash Reserves (as defined in the Company Formation Agreements) under and in accordance with the Company Formation Agreements, then, MeiraGTx will have the right, but not the obligation, to terminate this Agreement in its entirety upon notice of

termination to Company if such breach remains uncured following [***] notice to Company of the applicable breach.

13.3 **Effects of Termination**. Upon the termination of this Agreement pursuant to Section 13.2 (but not the expiration of the Term pursuant to Section 13.1), the following shall apply as of the effective date of such termination (in each case, as applicable):

13.3.1 Except as otherwise set forth in this Section 13.3 or the Termination and Wind-Down Plan, and except with respect to any termination by Company pursuant to Section 13.2.2, (a) each Party's rights and obligations under this Agreement shall automatically terminate and have no further force and effect; and (b) Company and its Affiliates and Sublicensees shall cease any and all Development, Manufacture and Commercialization of the Licensed Device and any Licensed Products in the Territory.

13.3.2 [***] following the effective date of such termination, the Parties will cooperate diligently, reasonably and in good faith to prepare a written termination and wind-down plan to govern the activities described in this Section 13.3 ("**Termination and Wind-Down Plan**"), including, upon the written request of MeiraGTx (and subject to the remainder of this Section 13.3), to effectuate the timely reversion to MeiraGTx of the Licensed Device and any Licensed Product Developed, Manufactured or Commercialized by or on behalf of Company (or any of its Affiliates or Sublicensees) in the Territory prior to such effective date of termination; *provided* that such Termination and Wind-Down Plan (including any amendments thereto) shall be subject to the agreement of the Parties.

13.3.3 [***] following the effective date of such termination, Company shall make payment to MeiraGTx Neuro UK for any unpaid Development Costs, Commercialization costs, FTE Costs and Out-of-Pocket Costs incurred with respect to any Collaboration Activities performed by or on behalf of MeiraGTx Neuro UK in accordance this Agreement prior to the effective date of such termination, together with any such pre-approved costs contracted for by MeiraGTx Neuro UK, or any other pre-approved non-cancellable obligations of MeiraGTx Neuro UK incurred, prior to such effective date in connection with any Collaboration Activities of MeiraGTx Neuro UK hereunder.

13.3.4 In the event of a termination of this Agreement by Company pursuant to Section 13.2.1 or by MeiraGTx pursuant to Section 13.2.2, Section 13.2.4 or Section 13.2.5, as applicable, then, in each case, upon MeiraGTx's request, Company shall, and hereby does, grant (on behalf of itself and its Affiliates) to MeiraGTx and its Affiliates an exclusive (even as to Company and its Affiliates), perpetual, irrevocable, transferable, royalty-free, fully-paid up license, with the right to freely sublicense (including through multiple tiers), under any Patents, Know-How or other intellectual property owned or otherwise Controlled by Company (or any of its Affiliates) as of the effective date of such termination that is necessary or reasonably useful to Develop, Manufacture or Commercialize the Licensed Device or any Licensed Products that were Developed or Commercialized in the Field in the Territory during the Term prior to the effective date of such termination; *provided* that, in addition to the foregoing, the Parties shall also cooperate in good faith to effect the transfer to MeiraGTx of all Clinical Trial data and results developed by or on behalf of Company (or any of its Affiliates) related to such Licensed Device or Licensed Products.

13.3.5 Except with respect to any termination by Company pursuant to Section 13.2.2, upon MeiraGTx's written request, Company shall cooperate with MeiraGTx and provide assistance reasonably requested in writing by MeiraGTx (including as set forth in the Termination and Wind-Down Plan, as applicable) for the transfer to MeiraGTx of (i) the

responsibility for filing, prosecution and maintenance of any MeiraGTx Patents for which Company (or any of its Affiliates or Sublicensees) had controlled pursuant to Section 9.3, (ii) the conduct of any Enforcement Action being conducted by or on behalf of Company (or any of its Affiliates or Sublicensees) pursuant to Section 9.4 solely with respect to MeiraGTx Licensed Technology or (iii) the conduct of any Third Party Action being conducted by or on behalf of Company (or any of its Affiliates or Sublicensees) pursuant to Section 9.5 solely with respect to MeiraGTx Licensed Technology, as applicable.

13.3.6 Except with respect to any termination by Company pursuant to Section 13.2.2, upon the written request of MeiraGTx, at MeiraGTx's cost and expense, Company shall use reasonable efforts to transfer to MeiraGTx (or its designee), all Regulatory Documents and Regulatory Approvals transferred to Company hereunder or otherwise prepared or obtained by or on behalf of Company (or any of its Affiliates or Sublicensees) prior to the effective date of such termination with respect to the Licensed Device or any Licensed Products in the Territory that Company is permitted to transfer, and MeiraGTx shall assume full responsibility for such Regulatory Documents and Regulatory Approvals; *provided* that, to the extent any such Regulatory Documents or Regulatory Approvals cannot be assigned to MeiraGTx, Company agrees to grant to MeiraGTx and its Affiliates a non-exclusive, fully paid, royalty-free, irrevocable, perpetual, sublicensable, worldwide license and right of reference under Company's interest in such Regulatory Documents and Regulatory Approvals (with the right to sublicense and grant further rights of reference, if permitted) as necessary to Develop, Manufacture and Commercialize such Licensed Device or Licensed Products in the Territory.

13.3.7 Except with respect to any termination by Company pursuant to Section 13.2.2, each sublicense granted by or on behalf of Company (or any of its Affiliates or Sublicensees) under the licenses granted pursuant to Section 2.1.1 shall automatically terminate upon the effective date of such termination, unless such Sublicensee elects to become a direct licensee of MeiraGTx Neuro US under rights and terms equivalent to the sublicense rights and terms that were previously granted to such Sublicensee by Company; *provided* that (a) such Sublicensee may not elect to become a direct licensee of MeiraGTx Neuro US in the event that such Sublicense has contributed to the circumstances that led to such termination of this Agreement or is in material breach of the applicable sublicense agreement; and (b) in the event that such Sublicensee does elect to become a direct licensee of MeiraGTx Neuro US in accordance with this Section 13.3.7, MeiraGTx shall not be obligated to fulfill any obligations to any Sublicensees beyond those obligations required of MeiraGTx as if this Agreement has not terminated; *provided*, *further*, that, Company shall facilitate an introduction to such Sublicensee and otherwise reasonably cooperate with MeiraGTx and such Sublicensee in connection with MeiraGTx's assumption of such sublicense agreement, as applicable.

13.4 Survival; Accrued Rights and Obligations.

13.4.1 Survival. In addition to the consequences set forth in Section 13.3, and any other provisions of this Agreement that expressly survive pursuant to the terms herein, as applicable, the following provisions shall survive expiration or termination of this Agreement in its entirety for any reason: ARTICLE 1, Section 2.3, Section 3.6, Section 6.5.3, Section 6.5.4, ARTICLE 8 (with respect to any payment obligations that have accrued prior to the effective date of such expiration or termination or that otherwise accrue pursuant to Section 13.3), Section 9.1, Section 9.2, Section 10.1, Section 10.2, Section 10.3, Section 10.4, Section 10.5, Section 10.9, Section 10.10, ARTICLE 12, Section 13.3, Section 13.4 and ARTICLE 14.

13.4.2 Accrued Rights and Obligations. Expiration or termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration and shall not relieve the Parties of any obligation or liability that accrued hereunder prior to, or that are expressly indicated to survive, such termination or expiration of this Agreement. In addition, termination of this Agreement shall not preclude any Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

ARTICLE 14
MISCELLANEOUS PROVISIONS

14.1 **Binding Effect; Entire Agreement**. As of the Effective Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and assigns. This Agreement, the Company Formation Agreements, the Safety Data Exchange Agreement and the Supply Agreements, including the Development Plan, the Transition Services Plan, the Termination and Wind-Down Plan (if any) and any other Schedules or Exhibits hereto and thereto, represent the entire agreement among the Parties regarding the subject matter hereof and shall supersede all previous communications, representations, understandings and agreements, whether oral or written, by or among the Parties with respect to the subject matter hereof. The Parties acknowledge that, as of the Effective Date, this Agreement shall supersede the [***], which shall be of no further force or effect, and all discussions and exchanges of information thereunder shall be governed by this Agreement; provided that, for clarity, all "Confidential Information" disclosed or provided by or on behalf of any Party under the [***] shall be deemed Confidential Information of the applicable Disclosing Party hereunder and shall be subject to the terms and conditions of this Agreement. In the event of any inconsistency or conflict between this Agreement and (a) any Company Formation Agreement, any Supply Agreement or any Schedule or Exhibit hereto or thereto, including the Development Plan, the Transition Services Plan or the Termination and Wind-Down Plan (if any), the terms and conditions of this Agreement shall govern unless expressly provided otherwise in such Company Formation Agreement, Supply Agreement, Schedule or Exhibit, as applicable; or (b) any [***], the terms and conditions of this Agreement shall govern.

14.2 **Amendments**. No change, modification, extension, termination or waiver of this Agreement, or any of the provisions herein contained, shall be valid unless made in writing and signed by duly authorized representatives of the Parties. A waiver by any Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.

14.3 **Further Assurances**. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.4 **Assignment**. No Party may assign or otherwise transfer this Agreement, whether voluntarily, by operation of law or otherwise, without the prior express written consent of the other Parties; *provided*, *however*, that either Company or MeiraGTx may, without such consent, assign this Agreement and its rights and obligations hereunder to (a) an Affiliate (provided that any assigning Party remains fully liable for the performance of its obligations hereunder by any such Affiliate); or (b) to a Third Party (i) successor-in-interest in connection with a merger, consolidation, change in control or other similar transaction, or (ii) acquirer in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates. As a condition of such assignment, the assignee shall agree in writing to be bound by all obligations of the assigning Party hereunder. Subject to the foregoing, this Agreement shall be binding on and inure to the benefit of

the Parties and their permitted successors and assigns. Any purported assignment or transfer of this Agreement in violation of this Section 14.4 shall be null and void.

14.5 **Performance by Affiliates**. Each Party shall be entitled to perform any or all of its obligations or exercise any of its rights or licenses under this Agreement through any of its Affiliates; provided that such Party shall remain fully liable for any acts or omissions of such Affiliates and for such Affiliates' performance and observance of all duties and obligations under this Agreement.

14.6 **Equitable Relief; Cumulative Remedies**. A breach of any of the promises or agreements contained herein may result in irreparable and continuing damage for which there may be no adequate remedy at law, and therefore each Party shall be entitled to seek injunctive relief or a decree for specific performance, and such other relief as may be proper (including monetary damages if appropriate). Each Party further agrees that no bond or other security shall be required in seeking any equitable relief. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of any Party.

14.7 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law principles thereof.

14.8 **Disputes**. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any dispute, controversy, claim or difference which may arise among the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach of, this Agreement, or any issue relating to the interpretation or application of this Agreement (a "**Dispute**"), then, upon the request of any Party by written notice, the Parties agree to discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one discussion between the executive officers of each Party (or their designees who are at least Vice President level or higher). If the Dispute is not resolved within [***] following the written request for discussions, each Party shall have the right to pursue the matter in a court of competent jurisdiction.

14.9 **Notice**. All requests, notices, approvals, acceptances and other communications shall be in writing and delivered via nationally recognized overnight express courier or registered or certified mail with postage prepaid and return receipt requested, to the addresses set forth below. Each Party may update the applicable address at any time by providing written notice of the new address to the other Parties in accordance with this Section 14.9.

To Company:

[***]

To Hologen UK:

[***]

To HGL:

[***]

To MeiraGTx:

MeiraGTx Holdings:

[***]
MeiraGTx Neuro UK:

[***]
MeiraGTx Neuro US:

[***]
With copies, which shall not constitute notice, to:

[***]

14.10 **Severability**. If any provision of this Agreement is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by applicable laws.

14.11 **Independent Contractor; No Third-Party Beneficiary**. In executing this Agreement, the Parties intend to create an independent contractor relationship among the Parties. Nothing shall be construed as creating a partnership, joint venture, agency or any other relationship among the Parties. No Party has the authority to act on behalf of any other Party, or to commit any other Party in any manner at all or cause any other Party's name to be used in any way not specifically authorized by this Agreement, in each case, pursuant to this Agreement. Except as set forth in Section 12.1 or Section 12.2, as applicable, nothing in this Agreement, express or implied, is intended to confer on any Person other than the Parties or their respective successors and permitted assigns, any benefits, rights, responsibilities or remedies.

14.12 **Force Majeure Events**. No Party will be liable to any other Party for any delay or failure to (either totally or in part) fulfill obligations under this Agreement caused by circumstances which were beyond its reasonable control, including war, riots, terrorism, sanctions legislation on Third Parties, fire, explosion, flood, sabotage, epidemics, pandemics and subsequent government measures (e.g., lockdowns). The Party affected by a force majeure event shall (a) promptly provide notice of such force majeure event to the other Parties; (b) use reasonable endeavors to mitigate the effect of such force majeure events; and (c) recommence performance of its obligations affected by such force majeure event as soon as reasonably possible.

14.13 **Headings, Constructions**. All headings, titles and subtitles used in this Agreement (including any Schedules hereto) are for convenience only and are not to be considered when construing or interpreting any term or provision of this Agreement (or any Schedules hereto). All references herein to Articles, Sections and Schedules shall be deemed references to Articles or Sections of, and Schedules to, this Agreement unless the context shall otherwise require. Except where the context otherwise requires, wherever used, (a) the singular shall include the plural, the plural the singular; (b) the use of any gender shall be applicable to all genders; (c) the word "or" is used in the inclusive sense (and/or); (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; (e) the word "will" will be construed to have the same meaning and effect as the word "shall"; (f) the words "herein," "hereof" and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; and (g) reference to a number of days, unless otherwise specified, such number refers to calendar days. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions. The official language of this Agreement and among the Parties for all correspondence shall be the English language.

14.14 **Counterparts**. This Agreement may be executed in any number of counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument. Signatures may be delivered via portable document format (".pdf") or other means of electronic transmission.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have entered into this Agreement signed by their respective duly authorized representatives as of the Effective Date.

HOLOGEN GUERNSEY:

HOLOGEN NEURO AI LTD

By: _____

Name: _____

Title: _____

MEIRAGTX HOLDINGS:

MEIRAGTX HOLDINGS PLC

By: _____

Name: _____

Title: _____

HOLOGEN UK:

HOLOGEN NEURO AI UK LIMITED

By: _____

Name: _____

Title: _____

MEIRAGTX NEURO UK:

MEIRAGTX NEURO UK LIMITED

By: _____

Name: _____

Title: _____

HGL:

HOLOGEN LIMITED

By: _____

Name: _____

Title: _____

MEIRAGTX NEURO US:

MEIRAGTX NEURO I, LLC

By: _____

Name: _____

Title: _____

[Signature Page to Collaboration and License Agreement]

Schedule 1.83
Licensed Device

[***]

Exhibit 10.51

EXECUTION VERSION

Certain information marked as [***] has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

MEIRAGTX MANUFACTURING LIMITED

FRAMEWORK AGREEMENT

Dated as of March 9, 2025

TABLE OF CONTENTS

		Page
1.	DEFINITIONS	2
2.	FORMATION AND PURPOSE	12
	2.1 Formation	12
	2.2 Name	12
	2.3 Registered Office	12
	2.4 Term	12
	2.5 Purpose and Powers	12
	2.6 Limited Liability	12
	2.7 Principal Office	12
3.	RELATIONSHIP BETWEEN THIS AGREEMENT AND THE ARTICLES	13
	3.1 No Amendment of the Articles	13
	3.2 Conflict	13
	3.3 Compliance with the Articles	13
4.	CONDITIONS TO COMPLETION	13
	4.1 Conditions	13
	4.2 The Carve-Out Condition	13
	4.3 Efforts to Satisfy the Foreign Investment Clearances Condition	13
	4.4 No Obligation to Disclose Sensitive Information	14
	4.5 Waiver of Conditions	14
	4.6 Non-Satisfaction of Conditions	14
	4.7 Notification of Satisfaction of Condition	15
	4.8 Funding Notice	15
5.	CONDUCT OF THE BUSINESS	15
	5.1 Conduct of Business	15
	5.2 Effect from Completion	15
6.	COMPLETION	15
	6.1 Completion	15
	6.2 Completion Actions	15
	6.3 Failure to Comply with Obligation	15
	6.4 Right to Defer Completion	16

TABLE OF CONTENTS
(continued)

		Page
7.	HOLOGEN OPTION	16
	7.1 Option Grant	16
	7.2 Option Exercise	16
8.	MEIRAGTX OPTION	16
	8.1 MeiraGTx Option Grant	16
	8.2 MeiraGTx Option Exercise	16
9.	MEIRAGTX NON-MANUFACTURING BUSINESS CARVE-OUT	17
	9.1 Retained Contract Assignment	17
	9.2 Third Party Consent	17
	9.3 Services Agreement	17
10.	FUNDING	17
	10.1 Initial Contributions	17
	10.2 Required Contributions	18
	10.3 Failure to Fund	18
11.	MEMBERSHIP AND SHARES	18
	11.1 Members	18
	11.2 Shares	18
	11.3 Issued Capital	18
	11.4 Voting	18
	11.5 Specific Limitations	19
	11.6 Additional Members and Shares	19
	11.7 Certification	19
12.	DISTRIBUTIONS AND ALLOCATIONS OF PROFIT AND LOSS	19
	12.1 Board of Directors Determination	19
	12.2 Distributions	19
	12.3 No Violation	20
13.	STATUS, RIGHTS AND POWERS OF MEMBERS	20
	13.1 No Management or Control	20
	13.2 Member Duties	20

TABLE OF CONTENTS
(continued)

		Page
14.	BOARD OF DIRECTORS AND INVESTOR RIGHTS	21
	14.1 Board of Directors	21
	14.2 Authority of Board of Directors	23
	14.3 Actions Requiring Director Supermajority	24
15.	KEY MANAGEMENT PERSONNEL	24
	15.1 Management Team	24
	15.2 Key Management Personnel	24
16.	ALLIANCE COMMITTEE AND ALLIANCE MANAGERS	24
	16.1 Alliance Committee	24
	16.2 Meetings of the Alliance Committee	24
	16.3 Alliance Committee Responsibilities	25
	16.4 Alliance Committee Decision-Making	25
	16.5 Limitations of Alliance Committee Authority	25
	16.6 Alliance Managers	25
17.	BOOKS, RECORDS, ACCOUNTING AND REPORTS	25
	17.1 Books and Records	25
	17.2 Inspection	26
	17.3 Filings	26
	17.4 Non-Disclosure	27
	17.5 Information Rights	28
18.	TAX MATTERS	29
	18.1 ECI	29
	18.2 Tax Residence	29
	18.3 Listed Transactions	29
	18.4 Notice of Non-compliance	29
	18.5 Use of Losses	29
	18.6 Tax Information	29
19.	TRANSFER OF SHARES	30
	19.1 Restricted Transfer	30
	19.2 Permitted Transferees	30

TABLE OF CONTENTS
(continued)

		Page
	19.3 Transfer Requirements	30
	19.4 Admission as a Member	31
	19.5 Withdrawal of Member	31
	19.6 Additional Transfer Restrictions	31
20.	RIGHT OF FIRST REFUSAL; RIGHT OF CO-SALE; PREEMPTIVE RIGHTS; AND DRAG-ALONG RIGHTS	31
	20.1 Right of First Refusal	31
	20.2 Right of Co-Sale	33
	20.3 Effect of Failure to Comply with Right of First Refusal and Right of Co-Sale	34
	20.4 Preemptive Rights	35
	20.5 Drag-Along Right	35
21.	DISSOLUTION OF COMPANY	38
	21.1 Termination of Membership	38
	21.2 Events of Dissolution	39
	21.3 Liquidation	39
	21.4 No Action for Dissolution	39
	21.5 No Further Claim	39
22.	INDEMNIFICATION	39
	22.1 General Indemnification Rights	39
	22.2 Indemnification for Claims Brought by Indemnified Person	40
	22.3 Advancement of Defense Costs	40
	22.4 Company as Primary Indemnitor	40
	22.5 Persons Entitled to Indemnity	40
	22.6 Obligation to Indemnify is Non-Recourse	41
	22.7 Procedure Agreements	41
	22.8 Reliance, etc.	41
	22.9 Directors' and Officers' Insurance	41
	22.10 Period	41
	22.11 Compliance with the Act	41

TABLE OF CONTENTS
(continued)

		Page
23.	WARRANTIES BY THE MEMBERS	41
	23.1 Financial Capability	41
	23.2 Compliance with Anti-Bribery Laws and Anti-Money Laundering Laws	41
	23.3 Beneficial Ownership	42
	23.4 Compliance with Sanctions Laws	42
	23.5 Purchase for Own Account	42
	23.6 Competing Product	42
	23.7 Duly Formed	43
	23.8 Knowledge and Experience	43
	23.9 Economic Risk	43
	23.10 Solvency	43
	23.11 Binding Agreement	43
	23.12 No Breach	43
	23.13 Disputes	44
	23.14 Consents	44
	23.15 Company Covenants	44
	23.16 Hologen Covenant	44
24.	COMPANY WARRANTIES	44
	24.1 Duly Formed	44
	24.2 Activities in Other Jurisdictions	44
25.	ADDITIONAL COVENANTS	45
	25.1 Non-Solicitation	45
	25.2 Change of Control Notice	46
	25.3 Licenses and Permits	46
	25.4 Compliance with Laws	46
	25.5 Unrelated Business Taxable Income	46
	25.6 United States Trade or Business	46
	25.7 PFIC/CFC	46
26.	AMENDMENTS TO AGREEMENT	46
	26.1 Amendments	46

TABLE OF CONTENTS
(continued)

		Page
	26.2 Binding Effect	46
27.	GENERAL	47
	27.1 Successors; Governing Law	47
	27.2 Notices	47
	27.3 Severability	47
	27.4 Construction	48
	27.5 Table of Contents, Headings	48
	27.6 No Third Party Rights	48
	27.7 Entire Agreement	48
	27.8 Effect of Waiver or Consent	48
	27.9 Counterparts and Electronic Delivery	48
	27.10 Jurisdiction and Venue	48
	27.11 Business Days	49
	27.12 Currency	49
	27.13 Survival	49
	27.14 Gender	49
SCHEDULE 6.2 COMPLETION ACTIONS		50
SCHEDULE 6.2 – ANNEX A SHARE PURCHASE AGREEMENT		51
SCHEDULE 6.2 – ANNEX B SHARE SUBSCRIPTION LETTER – MEIRAGTX		52
SCHEDULE 6.2 – ANNEX C SHARE SUBSCRIPTION LETTER – HOLOGEN		53
SCHEDULE 7 HOLOGEN OPTION SHARE PURCHASE AGREEMENT		54
SCHEDULE 8.1 MEIRAGTX OPTION SHARE PURCHASE AGREEMENT		55
SCHEDULE 9.3 SERVICES AGREEMENT		56
SCHEDULE 11.6 DEED OF ADHERENCE		57

MEIRAGTX MANUFACTURING LIMITED

FRAMEWORK AGREEMENT

This Framework Agreement (as may be amended from time to time, this "Agreement"), dated as of March 9, 2025 (the "Effective Date"), is made as a DEED by and among:

(1) MeiraGTx Manufacturing Limited, a private company limited by shares incorporated in England with company number 16128294 (the "Company");

(2) MeiraGTx Limited, a private company limited by shares incorporated in England with company number 09501998, whose registered office is at 92 Britannia Walk, London, England, N1 7NQ ("MeiraGTx"); and

(3) Hologen Limited, a non-cellular company limited by shares incorporated in Guernsey with company number 74905 whose registered office is at c/o Elysium Fund Management, 1st Floor, Royal Chambers, St. Julian's Avenue, St. Peter Port, GY1 3JX, Guernsey ("Hologen"),

and each other Person who at any time after the Effective Date becomes a Member in accordance with the terms of this Agreement and the Act.

RECITALS

WHEREAS, the Company was incorporated in England as a private company limited by shares on December 10, 2024, whose registered office is at 92 Britannia Walk, London, England, N1 7NQ and which has an issued share capital of £100;

WHEREAS, the Company is a wholly owned subsidiary of MeiraGTx;

WHEREAS, subject to and conditional upon Completion, Hologen shall acquire from MeiraGTx such number of Shares constituting [***] of the entire issued share capital of the Company (the "Sale Shares") in consideration for a payment of [***] (the "Hologen Acquisition");

WHEREAS, following Completion, MeiraGTx wishes to grant to Hologen an option (the "Hologen Option") to acquire from MeiraGTx an additional number of Shares (the "Hologen Option Shares") in consideration for a payment of [***] such that, upon exercise of the Option, Hologen shall hold in aggregate a number of Shares constituting forty percent (40%) of the entire issued share capital of the Company;

WHEREAS, if Hologen does not exercise the Hologen Option, Hologen wishes to grant MeiraGTx an option (the "MeiraGTx Option") to acquire all of the Shares held by Hologen (the "MeiraGTx Option Shares") on such terms as are further set out in this Agreement;

WHEREAS, following the Effective Date, MeiraGTx and the Company shall continue to implement the Non-Manufacturing Business Carve-Out;

WHEREAS, following Completion, each Major Member and the Company wishes to give effect to the Non-Manufacturing Business Carve-Out;

WHEREAS, the Company and the Members desire to enter into this Agreement to provide for, among other things, the management of the business and affairs of the Company, the allocation of profits and losses among the Members, the respective rights and obligations of the Members to each other and to the Company and certain other matters as described herein.

NOW, THEREFORE, in consideration of the mutual covenants expressed herein, the parties hereby agree as follows:

AGREEMENT

1. DEFINITIONS.

For purposes of this Agreement (a) certain capitalized terms have specifically defined meanings set forth below, (b) references to "Exhibits," "Recitals" and "Sections" are to Exhibits, Recitals and Sections of this Agreement, unless explicitly indicated otherwise, (c) references to statutes include all rules and regulations thereunder, and all amendments and successors thereto from time to time and (d) the word "including" shall be construed as "including without limitation."

"Act" means the Companies Act 2006.

"Additional Consideration" is defined in Section 12.2(c).

"Affiliate" means, with respect to a specific Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including, without limitation, any general partner, managing member, officer, director or trustee of such Person, or any venture capital fund or other investment fund now or hereafter existing that is controlled by one or more general partners, managing members or investment advisers of, or shares the same management company or investment adviser with, such Person; and "control" (including the terms "controlling," "controlled by," and "under common control with") means, with respect to an entity, having the power to direct the affairs of the entity by reason of (a) having the power to elect or appoint, through ownership membership or otherwise, either directly or indirectly, more than fifty percent (50%) of the board of directors or other governing body of the entity, (b) owning or controlling the right to vote more than fifty percent (50%) of the voting right attaching to the shares or other voting interests of the entity or (c) having the right to direct the general management of the affairs or policies of the entity by contract or otherwise.

"Agreement" is defined in the Preamble.

"Alliance Committee" is defined in Section 16.1.

"Alliance Manager" is defined in Section 16.6.

"Anti-Bribery Laws" means laws, regulations or orders relating to anti-bribery or anti-corruption (governmental or commercial), without limitation, laws that prohibit the corrupt payment, offer, promise, or authorisation of the payment or transfer of anything of value (including gifts or entertainment), directly or indirectly, to any government official, commercial entity, or any other person to obtain a (business) advantage; such as, without limitation, the United Nations Convention Against Corruption approved by decree dated as of 12 June 2008, the U.S. Foreign Corrupt Practices Act of 1977, as amended from time to time, the Bribery Act 2010, as amended from time to time, and all national and international laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.

"Anti-Money Laundering Laws" means laws, regulations or orders relating to financial recordkeeping and reporting requirements, including those of the (i) European Union Money Laundering Directives and member states' implementing legislation, (ii) the UK Proceeds of Crime Act 2002, (iii) the U.S. Bank Secrecy Act, USA Patriot Act and other US legislation relating to money laundering, including the Currency and Foreign Transactions Reporting Act of 1970, as amended, and (iv) any other laws, regulations and orders relating to money laundering or the proceeds of criminal activity and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity.

"Articles" means the articles of association of the Company as amended from time to time.

"Assignee" means any Person who acquires in any manner whatsoever from a Member any Shares or other equity interests in the Company.

"Board of Directors" is defined in Section 14.1(a).

"Budget" is defined in Section 17.5(d).

"Business" means flexible and scalable end-to-end genetic medicines manufacturing capabilities, including internal plasmid production for good manufacturing practices (GMP), two GMP viral vector production facilities, an in-house quality control hub for stability and release, a proprietary manufacturing platform with leading yield and quality aspects and commercial readiness, fill and finish and warehousing.

"Carve Out Condition" is defined in Section 4.1(a).

"Change of Control" means any of the following: (a) any acquisition of the Company by means of any transaction or series of related transactions to which the Company is party (including, without limitation, any stock acquisition, reorganization, merger, consolidation or equity financing) as a result of which a Person or group of related Persons that does not hold greater than fifty percent (50%) of the voting securities of the Company outstanding immediately prior to such transaction or series of transactions, acquires greater than fifty percent (50%) of the total voting power represented by the voting securities of the Company or the surviving entity (or, if the surviving entity is owned by a parent corporation, the surviving entity's parent corporation) outstanding immediately after such transaction or series of transactions, but excluding for these purposes: (i) a consolidation or merger with a wholly owned Subsidiary and (ii) a consolidation or merger effected exclusively to change the domicile of the Company; (b) a sale, lease, conveyance or other disposition of all or substantially all of the assets of the Company; or (c) the exclusive

license (without any material field or geography limitation) of all or substantially all of the assets of the Company.

"Code" means the U.S. Internal Revenue Code of 1986, as amended.

"Company" is defined in the Preamble.

"Company Notice" means written notice from the Company notifying the selling Member that the Company intends to exercise its Right of First Refusal as to some or all the Transfer Shares with respect to any Proposed Transfer.

"Company Undersubscription Notice" is defined in Section 20.1(d).

"Competing Product" means [***].

"Competitor" means any Person that is engaged, directly or indirectly, in whole or in part, in the Business anywhere in the world.

"Completion" means completion of the Hologen Acquisition pursuant to the Share Purchase Agreement.

"Completion Date" means the date of Completion.

"Condition" is defined in Section 4.1(d).

"Confidential Information" is defined in Section 17.4(a).

"Convertible Shares" means evidences of indebtedness, Shares or other securities or obligations that are, directly or indirectly, convertible into or exercisable or exchangeable for, with or without payment of additional consideration, Equity Interests. Equity Interests issuable upon conversion of Convertible Shares shall be deemed outstanding and issued or sold at the time of such issue or sale.

"Deemed Liquidation Event" means a Change of Control or a liquidation pursuant to Section 21.3.

"Director(s)" is defined in Section 14.1(a).

"Director Supermajority" is defined in Section 14.1(a).

"Distributable Profits" is defined in Section 12.2(a)(i).

"Distribution" means cash or property (valued at its fair value and net of liabilities assumed or to which the property is subject) distributed by the Company to a Member in respect of the Member's Shares whether by liquidating distribution, non-liquidating distribution or otherwise; provided, that a Distribution does not include any redemption or repurchase by the Company of any Shares or any recapitalization or exchange or distribution of Shares, any subdivision (by Share split or otherwise) or any combination (by reverse Share split or otherwise) of any outstanding Shares.

"Effective Date" is defined in the Preamble.

"Encumbrance" means any mortgage, pledge, lien, charge, assignment, hypothecation, or other agreement or arrangement which has the same or a similar effect to the granting of security.

"Equity Interest" means (i) any equity interest, share, depositary receipt or other certificate representing any share, membership or other percentage interest or other equivalent (however designated) of an equity interest in any Person, and (ii) any options, warrants, purchase rights, subscription rights, conversion rights, exchange rights or other contractual obligations (including Convertible Shares) that would entitle the holder thereof to any share in the equity, profit, earnings, gains, losses, revenues or cash flows of such Person or any stock appreciation, phantom stock, profit participation or similar rights and other contractual obligations similar to such Equity Interests.

"Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended and applicable rules and regulations thereunder.

"Exercising Member" is defined in Section 20.1(d).

"Exercising Member Notice" means written notice from a Major Member notifying the Company and the selling Member that such Major Member intends to exercise its Secondary Refusal Right as to a portion of the Transfer Shares with respect to any Proposed Transfer.

"Exercising Member Notice Period" is defined in Section 20.1(d).

"Expenses" is defined in Section 22.1.

"FDI Authority" means the Investment Screening Unit of the UK Cabinet Office.

"Fiscal Year" means the fiscal year of the Company, which shall be the calendar year, or such other fiscal year as determined by the Board of Directors consistent with applicable tax law.

"Foreign Investment Clearances" means the Secretary of State notifying the parties pursuant to Section 17(8) of the NSIA Act that no further action will be taken in relation to the matters described by this Agreement; or in the event that a call-in notice is given in relation to the matters described in this Agreement, the Secretary of State either giving a final notification that no further action will be taken in relation to the matters described under this Agreement under the NSIA Act or making a final order permitting the Hologen Acquisition to proceed subject only to such remedies and requirements as are acceptable to the parties, and such order not being revoked or varied before Completion.

"Foreign Investment Clearances Condition" is defined in Section 4.1(b).

"Foreign Investment Laws" means the NSIA Act.

"Fully Exercising Member" is defined in Section 20.4(b).

"Funding Date" is defined in Section 10.2(a).

"Funding Default" is defined in Section 10.3.

"Funding Notice" is defined in Section 4.8.

"Funding Party" is defined in Section 10.3(b).

"GAAP" is defined in Section 15.2(b).

"Governmental Entity" means any government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any arbitrator or arbitral body.

"HMRC" means His Majesty's Revenue and Customs.

"Hologen" is defined in the Recitals.

"Hologen Acquisition" is defined in the Recitals.

"Hologen Director" is defined in Section 14.1(a).

"Hologen Financing Provider" means any person (including any individual, bank or credit institution) that lends money or provides credit to Hologen, any of the Hologen Investors, or their respective Affiliates for the purposes of any payment to be made, either by or on behalf of, Hologen in connection with this Agreement, or otherwise makes any payment on behalf of Hologen in connection with this Agreement.

[***]

"Hologen Investors" means those entities, together with the individuals and ultimate beneficial owners of each of them, each as disclosed in writing to MeiraGTx by Hologen [***] prior to Completion.

"Hologen Member" means Hologen and its Affiliates who hold Shares (other than, with effect from Completion, the Company or any of its Subsidiaries).

"Hologen Option" is defined in the Recitals.

"Hologen Option Exercise Notice" is defined in Section 7.1.

"Hologen Option Exercise Period" is defined in Section 7.1.

"Hologen Option Share Purchase Agreement" means the share purchase agreement, in substantially the form provided in Schedule 7, between MeiraGTx and Hologen relating to the sale of the Hologen Option Shares from MeiraGTx.

"Hologen Option Shares" is defined in the Recitals.

"Hologen Option Termination Date" means the twelve (12) months anniversary of the Completion Date.

"Hologen Subscription Letter" means the subscription letter, in substantially the form provided in Schedule 6.2 Annex C, pursuant to which Hologen shall subscribe for Shares in accordance with Section 10.1.

"Indemnified Persons" is defined in Section 22.1.

"Initial Consideration" is defined in Section 12.2(c).

"Initial Public Offering" means the admission to, and to trading on, any recognized international stock exchange of any of the shares or securities representing shares of the Company.

"Intellectual Property" means all intellectual property rights, whether registered or unregistered, that are recognized in any jurisdiction of the world, including such rights in patents, utility models, trademarks and tradenames, copyrights, trade secrets, and domain names (and any registrations of or applications to register any of the foregoing).

"Key Management Personnel" means each Person holding any of the following titles: Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Executive Vice President, Vice President, Secretary, Treasurer or Controller.

[***]

"Liabilities" means all liabilities of the Company, which, in accordance with generally accepted accounting principles, should be carried as liabilities on the balance sheet of the Company.

"Listed Transaction" is defined in Section 18.3.

"Longstop Date" means the date which is the [***] anniversary of the Effective Date.

"Major Member" means each of the MeiraGTx Member and, following Completion, the Hologen Member.

"Major Members Election" is defined in Section 20.5(a).

"Manufacturing Business" means (a) the business of manufacturing any gene therapy molecule or product (or component thereof) for the diagnosis, treatment or prevention of any disease, disorder or condition in humans or animals (each, a "Gene Therapy Product"), as conducted by MeiraGTx (or any of its Affiliates) as of the Effective Date; and (b) any assets, properties or rights that are necessary for the business set forth in the foregoing clause (a); provided, however, that Manufacturing Business shall exclude (i) the business of developing, commercializing or otherwise exploiting (but excluding manufacturing) (A) any molecule or product (or component thereof) for the control of therapeutic gene expression in humans or animals, including any capsids or promoters, including the MeiraGTx Riboswitch Platform; or (B)

any Gene Therapy Product, and (ii) any assets, properties or rights that are necessary or reasonably useful for, or otherwise used in connection with, the business set forth in the foregoing clause (i).

"MeiraGTx" is defined in the Preamble.

"MeiraGTx Director" is defined in Section 14.1(a).

"MeiraGTx Irish Subsidiary" means MeiraGTx Ireland DAC, a designated activity company incorporated in Ireland with company number 672472.

"MeiraGTx Member" means MeiraGTx and its Affiliates who hold Shares (other than the Company or any of its Subsidiaries).

"MeiraGTx Option" is defined in the Recitals.

"MeiraGTx Option Effective Date" is defined in Section 8.1.

"MeiraGTx Option Exercise Notice" is defined in Section 8.2.

"MeiraGTx Option Exercise Period" is defined in Section 8.1.

"MeiraGTx Option Share Purchase Agreement" means the share purchase agreement, in substantially the form provided in Schedule 8.1, between MeiraGTx and Hologen relating to the sale of the Shares from Hologen.

"MeiraGTx Option Shares" is defined the Recitals.

"MeiraGTx Option Termination Date" means the date that is the 3rd anniversary of the MeiraGTx Option Effective Date.

"MeiraGTx Retained Contracts" means all contracts, agreements and arrangements of whatever nature entered into by MeiraGTx UK II Subsidiary or MeiraGTx Irish Subsidiary, to the extent not relating to the Business as carried on by the Company and its Affiliates, which are in full force and effect as at the Completion Date.

"MeiraGTx Riboswitch Platform" means MeiraGTx's riboswitch technology, which directly relates to the inducible expression of a transgene of interest using an RNA aptamer and small molecule inducer.

"MeiraGTx Subscription Letter" means the subscription letter, in substantially the form provided in Schedule 6.2 Annex B, pursuant to which MeiraGTx shall subscribe for Shares in accordance with Section 10.1.

"MeiraGTx UK II Subsidiary" means MeiraGTx UK II Limited, a private company limited by shares incorporated in England and Wales with company number 09348737.

"MeiraGTx UK Limited" means MeiraGTx UK Limited, a private company limited by shares incorporated in England with company number 09535413, whose registered office is at 92 Britannia Walk, London, England, N1 7NQ.

"Member" means each Person who holds Shares in the Company and has executed this Agreement, and/or any other Person admitted to the Company as a Member, from time to time, in accordance with this Agreement.

"Member Financial Disclosure" is defined in Section 17.2(b).

[***]

"New Articles" means the articles of association of the Company to be adopted on Completion, which shall be in a form compatible with this Agreement and which shall be agreed by the parties acting reasonably prior to Completion.

"New Shares" means any shares (or securities exercisable for or convertible into shares) of any kind or class issued by the Company after the date hereof.

"Non-Funding Party" is defined in Section 10.3.

"Non-Manufacturing Business" means (a) any business conducted by or on behalf of MeiraGTx (or any of its Affiliates) other than the Manufacturing Business; and (b) any assets, properties or rights of MeiraGTx (or any of its Affiliates) other than the Manufacturing Assets.

"Non-Manufacturing Business Carve-Out" means the separation of the Non-Manufacturing Business from the Manufacturing Business, including the transfer and assignment of any assets, properties or rights in the Non-Manufacturing Business to MeiraGTx (or any of its Affiliates).

"NSIA Act" means the National Security and Investment Act 2021.

"Offer Notice" is defined in Section 20.4(a).

"Ordinary Share" is defined in Section 11.2.

"Participating Member" is defined in Section 20.2(a).

"Permitted Transferee" is defined in Section 19.2.

"Person" means any individual, partnership, joint venture, association, corporation, trust, estate, limited liability company, limited liability partnership, unincorporated entity of any kind, Governmental Entity, or other legal entity.

"Prohibited Transfer" is defined in Section 20.3(c).

"Proposed Sale" is defined in Section 20.5(c).

"Proposed Transfer" means any Transfer of any Transfer Shares (or any interest therein) proposed by any of the Members.

"Proposed Transferee" means the prospective purchaser or transferee of Transfer Shares.

"Remedy Period" is defined in Section 10.3(a).

"Representative" means, with respect to any Person, any director, officer, employee, agent, consultant, advisor, or other representative of such Person, including legal counsel, accountants and financial advisors.

"Required Contribution" is defined in Section 10.2(a).

"Restricted Period" is defined in Section 25.1(a).

"Retained Amounts" is defined in Section 12.2(a)(ii).

"Right of Co-Sale" means the right, but not an obligation, of a Major Member to participate in a Proposed Transfer on the terms and conditions specified in the Transfer Notice.

"Right of First Refusal" means the right, but not an obligation, of the Company, or its permitted transferees or assigns, to purchase some or all of the Transfer Shares with respect to a Proposed Transfer pursuant to Section 20.1, on the terms and conditions specified in the Transfer Notice.

"Sale of the Company" is defined in Section 20.5(a).

"Sale Shares" is defined in the Recitals.

"Sanctioned Person" means a person (i) that is designated or listed under any Sanctions List by any Sanctions Authority, (ii) in which any persons so designated or listed (individual or collectively) have an interest or control with the consequence that such person's property is blocked pursuant to any Sanctions, or (iii) acting on behalf of any of the foregoing.

"Sanctions" means any laws, regulations or trade embargoes relating to blocking (asset freeze) sanctions that envisage blocking of the assets administered or enforced from time to time by any Sanctions Authority.

"Sanctions Authority" means (i) the United Nations Security Council; (ii) the United States government; (iii) the European Union; (iv) the United Kingdom government; (v) the respective governmental institutions and agencies of any of the foregoing, including without limitation, the Office of Foreign Assets Control of the US Department of Treasury (OFAC), the United States Department of State and Department of Commerce, and His Majesty's Treasury and the UK Office of Financial Sanctions Implementation (OFSI); and (vi) any other governmental institution or agency with responsibility for imposing, administering or enforcing Sanctions with jurisdiction over any party.

"Sanctions List" means the Specially Designated Nationals and Blocked Persons List maintained by OFAC, the Consolidated List of Financial Sanctions Targets maintained by His Majesty's Treasury (but only the sub-list for "Asset Freeze Targets" and not the sub-list for "Investment Ban Targets") or any similar list maintained by, or public announcement of sanctions designations made by a Sanctions Authority, each as amended, supplemented or substituted from time to time, provided that, in each case, any such list relates to the so called freezing or blocking

sanctions and does not include sanctions known as "sectoral sanctions" that do not envisage blocking of the assets.

"Secondary Notice" means written notice from the Company notifying the Major Members and the selling Member that the Company does not intend to exercise its Right of First Refusal as to all Transfer Shares with respect to any Proposed Transfer.

"Secondary Refusal Right" means the right, but not an obligation, of each Major Member to purchase up to its pro rata portion of any Transfer Shares not purchased pursuant to the Right of First Refusal, on the terms and conditions specified in the Transfer Notice.

"Securities Act" means the U.S. Securities Act of 1933, as amended and applicable rules and regulations thereunder.

"Services Agreement" means the services agreement, in substantially the form provided in Schedule 9.3, between MeiraGTx UK Limited and the Company.

"Share Purchase Agreement" means the share purchase agreement, in substantially the form provided in Schedule 6.2 Annex A, between MeiraGTx and Hologen relating to the sale of the Sale Shares from MeiraGTx.

"Share Sale" is defined in Section 20.5(a).

"Shares" means the Ordinary Shares and any further shares in the capital of the Company issued by the Company from time to time during the term of this Agreement.

"Subsidiary" has the meaning given in article 1159 of the Act. For purposes hereof, references to a "Subsidiary" of any Person shall be given effect only at such times that such Person has one or more Subsidiaries, and, unless otherwise indicated, the term "Subsidiary" refers to a Subsidiary of the Company.

"Subsidiary Change of Control" means any of the following: (a) any acquisition of a Subsidiary by means of any transaction or series of related transactions to which such Subsidiary is party (including, without limitation, any share acquisition, reorganization, merger, consolidation or equity financing) as a result of which a Person or group of related Persons that does not hold greater than fifty percent (50%) of the voting securities of such Subsidiary outstanding immediately prior to such transaction or series of transactions, acquires greater than fifty percent (50%) of the total voting power represented by the voting securities of such Subsidiary or the surviving entity (or, if the surviving entity is owned by a parent corporation, the surviving entity's parent corporation) outstanding immediately after such transaction or series of transactions, but excluding for these purposes: (i) a consolidation or merger with a wholly owned Subsidiary of such Subsidiary and (ii) a consolidation or merger effected exclusively to change the domicile of such Subsidiary; (b) a sale, lease, conveyance or other disposition of all or substantially all of the assets of such Subsidiary; or (c) the exclusive license (without any material field or geography limitation) of all or substantially all of the assets of such Subsidiary.

"Subscription Letters" means the MeiraGTx Subscription Letter and the Hologen Subscription Letter.

"Transfer" means any sale, assignment, offer to sell, pledge, mortgage, hypothecation, Encumbrance, abandonment, disposition or other transfer.

"Transfer Notice" means written notice that a Member gives of a Proposed Transfer.

"Transfer Shares" means all Shares and equivalent securities.

2. FORMATION AND PURPOSE.

2.1 Formation. The Company was incorporated as an English private company limited by shares on December 10, 2024. The rights and liabilities of the Members shall be determined pursuant to the Act, this Agreement and the Articles. To the extent that the rights or obligations of any Member are different by reason of any provision of this Agreement than they would be in the absence of such provision, this Agreement shall, to the extent permitted by the Act and the Articles, control.

2.2 Name. The name of the Company is "MeiraGTx Manufacturing Limited". The business of the Company may be conducted under that name or, upon compliance with applicable laws, any other name that the Board of Directors deems appropriate. The Board of Directors shall make, or shall cause to be made, any trading name registrations and similar filings, and any amendments thereto, that the Board of Directors deems appropriate.

2.3 Registered Office. The Company may, upon compliance with the applicable provisions of the Act, change its registered office from time to time in the discretion of the Board of Directors.

2.4 Term. The term of the Company shall continue indefinitely unless sooner terminated as provided herein.

2.5 Purpose and Powers. The Company is formed for the object and purpose of, and the nature of the business to be conducted and promoted by the Company is, engaging in any lawful act or activity for which limited liability companies may be formed under the Act and engaging in any and all activities necessary, advisable, convenient or incidental thereto, including without limitation activities related to the Business. To the extent consistent with the Act and other applicable laws, the Company shall possess and may exercise such powers and privileges as are necessary, advisable, incidental or convenient to, or in furtherance of the conduct, promotion or attainment of, the business purposes or activities of the Company.

2.6 Limited Liability. Except as otherwise required by the Act, and save for in respect of the amount, if any, for the time being unpaid on the Shares held by such Member, the debts, obligations and liabilities of the Company, whether arising in contract, tort or otherwise, shall be solely the debts, obligations and liabilities of the Company, and no Member shall be obligated personally for any such debt, obligation or liability of the Company solely by reason of being a Member. All Persons dealing with the Company shall have recourse solely to the assets of the Company for the payment of the debts, obligations or liabilities of the Company.

2.7 Principal Office. The principal executive office of the Company shall be located at such place as the Board of Directors shall establish from time to time within England and Wales.

The Board of Directors may establish and maintain such additional offices and places of business of the Company, either within or without England and Wales, as it deems appropriate.

3. RELATIONSHIP BETWEEN THIS AGREEMENT AND THE ARTICLES.

3.1 No Amendment of the Articles. Each of the parties agrees that nothing contained in this Agreement shall be deemed to constitute an amendment to the Articles.

3.2 Conflict. If, during the continuance of this Agreement, there is any conflict between the provisions of this Agreement and of the Articles, then as between the Members, during such period, the provisions of this Agreement shall prevail.

3.3 Compliance with the Articles. Subject to Section 3.2, each of the parties agrees that at all times while this Agreement is in force and effect it shall fully and punctually perform and comply with all rights and obligations on its part under the Articles.

4. CONDITIONS TO COMPLETION.

4.1 Conditions. Completion is conditional on the following conditions being satisfied:

(a) completion of the Non-Manufacturing Business Carve-Out (the "Carve Out Condition");

(b) all Foreign Investment Clearances shall have been obtained (the "Foreign Investment Clearances Condition");

(c) [***]; and

(d) no law, injunction, order, or decree of any Governmental Entity or court is in effect which temporarily or permanently prohibits or enjoins the consummation of Completion in whole or a material portion thereof, and no Sanctions applying to any party, nor any of the Hologen Investors or the Hologen Financing Providers, which have the effect of making unlawful, prohibiting, or otherwise restricting Completion or the performance by any party of its obligations under this Agreement (including, for the avoidance of doubt, circumstances where a transfer of shares in the Company is prohibited or otherwise restricted)

(each of Section 4.1(a), Section 4.1(b), Section 4.1(c) and Section 4.1(d) a "Condition" and together the "Conditions").

4.2 The Carve-Out Condition. Each of MeiraGTx and the Company shall be entitled to take such actions as they deem appropriate to effect the Non-Manufacturing Business Carve-Out.

4.3 Efforts to Satisfy the Foreign Investment Clearances Condition. The parties shall be jointly responsible for contacting and corresponding with any relevant FDI Authority, including the preparation and submission of any necessary filings and notifications as soon as practicable following the date of this Agreement and the parties agreeing which Foreign Investment Clearances are necessary to consummate the matters described under this Agreement. Each party shall use all reasonable endeavours to cooperate and procure that the Foreign Investment

Clearances Condition is satisfied as soon as practicable and in any event on or before the Longstop Date and in respect of the foregoing shall:

(a) provide to the others such information and assistance as the others may reasonably request as soon as is reasonably practicable;

(b) as promptly as is reasonably practicable and in any event in accordance with any relevant time limit provide to an FDI Authority such information as it may require, including attending any meetings or calls with an FDI Authority as may be necessary;

(c) to the extent reasonably practicable, before sending any material communication to an FDI Authority provide a draft copy of such communication to the other parties and allow reasonable time for comments to be provided thereon;

(d) promptly inform the other parties of any material communication from or with an FDI Authority;

(e) provide to the other parties copies of all material written communications received by it from, or sent by it to, an FDI Authority, and details of material non-written communications with an FDI Authority;

(f) to the extent reasonably practicable, each party shall give the other party reasonable notice of and the opportunity to participate in all meetings and material telephone calls with an FDI Authority unless prevented by the relevant FDI Authority from doing so;

(g) if at any time any party becomes aware of a fact or circumstance that is reasonably likely to prevent a Condition being satisfied, it shall immediately inform the other parties.

4.4 No Obligation to Disclose Sensitive Information. Nothing in Section 4.3 shall require a party to share information, documents or communications with the others if prohibited by an FDI Authority or any Governmental Entity from doing so. Nothing in Section 4.3 shall require a party to disclose to or receive from the others any competitively sensitive information or business secrets. In order to comply with their obligations within Section 4.3 the parties will therefore make arrangements for the provision of copies of relevant information, documents and communications to the other parties' external advisors on an external advisor only basis together with redacted versions excluding any such competitively sensitive information or business secrets to the other party.

4.5 Waiver of Conditions [***]

4.6 Non-Satisfaction of Conditions If one or more of the Conditions remains unsatisfied or [***], at the Longstop Date, this Agreement will immediately cease to have any further force and effect except for:

(a) any provision of this Agreement that expressly or by implication is intended to come into or continue in force on or after termination (including Section 1 (Definitions), this

Section 4.4 (Non-Satisfaction of Conditions), Section 17.4 (Non-Disclosure) and Section 27 (General)), each of which shall remain in full force and effect; and

(b) any rights, remedies, obligations or liabilities of the parties that have accrued up to the date of termination, including the right to claim damages in respect of any breach of the agreement which existed at or before the date of termination.

4.7 Notification of Satisfaction of Condition. Each party shall notify the other parties of the satisfaction of each of the Carve Out Condition, [***] and the Foreign Investment Clearances Condition as soon as possible after such condition has been satisfied and in any event within [***] of such satisfaction.

4.8 Funding Notice. [***].

5. CONDUCT OF THE BUSINESS.

5.1 Conduct of Business. MeiraGTx and the Company shall procure that, unless otherwise agreed between the parties in writing, until Completion, the business of the Company shall be maintained and conducted in the usual course of business without any material interruption or alteration in the nature, scope or manner of the business, provided that the Company shall be entitled to take any actions to effect the Non-Manufacturing Business Carve-Out.

5.2 Effect from Completion. The following provisions of this Agreement are subject to, and will take effect from, Completion: Section 7 (Hologen Option), Section 8 (MeiraGTx Option), Section 10 (Funding), Section 11.5 (Specific Limitations), Section 11.6 (Additional Members and Shares), Section 12 (Distributions and Allocations of Profit and Loss), Section 13 (Status, Rights and Powers of Members), Section 14 (Board of Directors and Investor Rights), Section 15 (Key Management Personnel), Section 17.2 (Inspection), Section 17.3 (Filings), Section 17.5 (Information Rights), Section 18 (Tax Matters), Section 19 (Transfer of Shares), Section 20 (Right of First Refusal; Right of Co-Sale; Preemptive Rights; and Drag-Along Rights), Section 21 (Dissolution of the Company), Section 22 (Indemnification) and Section 25 (Additional Covenants).

6. COMPLETION

6.1 Completion. Completion will take place through the actions of the appointed solicitors for the parties at 5:00 pm New York time on the second business day following the date on which the final Condition has been satisfied or [***] or such other date as may be agreed in writing by the parties.

6.2 Completion Actions. At Completion, the Members will each comply with their obligations as set out in Schedule 6.2.

6.3 Failure to Comply with Obligation. If Hologen does not comply with its obligations in Section 6.2 in any material respect, MeiraGTx may (at its sole discretion and without prejudice

to any other rights or remedies it has, including the right to claim damages for breach of this Agreement):

(a) proceed to Completion;

(b) defer Completion to a date no more than [***] after the date on which Completion would otherwise have taken place; or

(c) terminate this Agreement by notice in writing to Hologen (in which case Section 4.6 shall apply).

6.4 Right to Defer Completion. MeiraGTx may defer Completion under Section 6.3(b) only once, but otherwise this Section 6 applies to a Completion so deferred as it applies where Completion has not been deferred.

7. HOLOGEN OPTION

7.1 Option Grant. Subject to and conditional upon Completion having occurred and Hologen having complied with its obligations under this Agreement, MeiraGTx grants Hologen the exclusive, irrevocable option, on the terms and conditions set forth in this Agreement, to purchase the Hologen Option Shares in consideration for a payment of [***] on the terms set out in the Hologen Option Share Purchase Agreement, which Hologen Option is exercisable at any time beginning on the Completion Date and ending at 11:59 pm on the Hologen Option Termination Date (the "Option Exercise Period").

7.2 Option Exercise. During the Hologen Option Exercise Period, Hologen shall have the right to elect, in its sole discretion, to cause MeiraGTx to sell to Hologen the Hologen Option Shares on the terms of the Hologen Option Share Purchase Agreement by delivery to MeiraGTx of a written notice of such election (the "Hologen Option Exercise Notice"). [***] Completion of the Hologen Option Share Purchase Agreement shall occur within [***] of delivery by Hologen of the Hologen Option Exercise Notice, unless otherwise agreed by the parties in writing, and subject to applicable law. The purchase of the Hologen Option Shares by Hologen pursuant to the Hologen Option shall not be subject to the restrictions on the transfer of Shares set out in this Agreement (including Sections 19 and 20) or the Articles.

8. MEIRAGTX OPTION

8.1 MeiraGTx Option Grant. If Hologen does not exercise the Hologen Option during the Hologen Option Exercise Period in accordance with Section 7 such that the Hologen Option shall have lapsed, Hologen grants MeiraGTx the exclusive, irrevocable option, on the terms and conditions set forth in this Agreement, to purchase the MeiraGTx Option Shares from Hologen in exchange for a payment of [***], which MeiraGTx Option is exercisable at any time beginning on the third (3rd) anniversary of the Completion Date (the "MeiraGTx Option Effective Date") and ending at 11:59 pm on the MeiraGTx Option Termination Date (the "MeiraGTx Option Exercise Period").

8.2 MeiraGTx Option Exercise. During the MeiraGTx Option Exercise Period, MeiraGTx shall have the right to elect, in its sole discretion, to cause Hologen to sell to MeiraGTx

the MeiraGTx Option Shares on the terms set out in the MeiraGTx Option Share Purchase Agreement by delivery to Hologen of a written notice of such election (the "MeiraGTx Option Exercise Notice"). [***] Completion of the MeiraGTx Option Share Purchase Agreement shall occur within [***] of delivery by MeiraGTx of the MeiraGTx Option Exercise Notice, unless otherwise agreed by the parties in writing, and subject to applicable law. The purchase of the MeiraGTx Option Shares by MeiraGTx pursuant to the MeiraGTx Option shall not be subject to the restrictions on the transfer of Shares set out in this Agreement (including Sections 19 and 20) or the Articles.

9. MEIRAGTX NON-MANUFACTURING BUSINESS CARVE-OUT.

9.1 Retained Contract Assignment. The Company shall use, and shall cause each of its respective Subsidiaries who is a party to any of the MeiraGTx Retained Contracts to use, commercially reasonable efforts to assign the MeiraGTx Retained Contracts to MeiraGTx or an Affiliate designated by MeiraGTx and, for the period after Completion, until such MeiraGTx Retained Contract is assigned, separated or expires in accordance with its terms and in each case, with effect from Completion; provided that such assignment or attempted assignment would not constitute a breach of such MeiraGTx Retained Contract:

(a) the rights and benefits under each MeiraGTx Retained Contract are to be enjoyed by MeiraGTx or its Affiliates;

(b) the Company shall, and shall procure that its Subsidiaries shall, hold each MeiraGTx Retained Contract and any monies, goods, or other benefits received thereunder as trustee for MeiraGTx or its Affiliates and its or their successors in title absolutely;

(c) the economic burden under each MeiraGTx Retained Contract shall be borne by MeiraGTx or its Affiliates; and

(d) any obligation to perform under each MeiraGTx Retained Contract be borne by the Company or one of its Subsidiaries including, as appropriate, in any sub-contractor capacity.

9.2 Third Party Consent. This Agreement shall constitute an assignment to MeiraGTx or its Affiliates of the benefit and obligations of all MeiraGTx Retained Contracts that are capable of assignment without the consent of any third party, in each case with effect from Completion.

9.3 Services Agreement. Each of MeiraGTx and Hologen acknowledges that, following Completion, the Company and its Subsidiaries will depend on certain services to be provided by MeiraGTx UK Limited, pursuant to the terms and conditions set out in the Services Agreement.

10. FUNDING

10.1 Initial Contributions. Immediately following Completion, MeiraGTx shall subscribe for and the Company shall issue to MeiraGTx such number of Shares pro rata to its existing shareholding in the Company in consideration for a payment of [***] and Hologen shall subscribe for and the Company shall issue to Hologen such number of Shares pro rata to its existing shareholding in the Company in consideration for a payment of [***].

10.2 Required Contributions.

(a) From the Completion Date, and subject to Section 10.2(b), the Members shall be required to fund the activities of the Company and its Subsidiaries on a quarterly basis, unless agreed otherwise, by way of subscription for Shares in the Company as approved by the Board of Directors, in each case pro rata to each Member's respective ownership of Shares (each such required pro rata contribution, a "Required Contribution") All Required Contributions shall be funded on or prior to a date determined by the Board of Directors for the applicable funding consistent with the applicable business plan and which, unless the Board of Directors determines otherwise, shall be [***] (with respect to Required Contributions, the "Funding Date"). Each Member shall be required to fund, by no later than the applicable Funding Date, the entire portion, and not less than the entire portion, of its Required Contributions, to an account specified by the Company. The Company shall deliver a notice with respect to the Required Contribution to each Member in accordance with the timelines prescribed by applicable law and in any case no later than [***] prior to the corresponding Funding Date; provided that if the notice is not timely delivered, then the corresponding Funding Date will be extended to the date that is [***] following the date on which such notice is delivered.

(b) [***]

10.3 Failure to Fund. If a Member (any such Member being a "Non-Funding Party") fails to fund by the required Funding Date all or any portion of its respective Required Contributions (a "Funding Default") then:

(a) such Non-Funding Party shall be permitted to cure such Funding Default within [***] following the Funding Date ("Remedy Period"); and

(b) if the Non-Funding Party fails to remedy the Funding Default within such Remedy Period the other Members (each a "Funding Party") shall have the right (but not the obligation) to fund any portion of the amount left unfunded.

11. MEMBERSHIP AND SHARES.

11.1 Members. As of and subject to Completion, MeiraGTx shall hold such number of Shares constituting [***] of the entire issued share capital of the Company and Hologen shall hold the Sale Shares, constituting [***] of the entire issued share capital of the Company.

11.2 Shares. The Company's share capital consists of "Ordinary Shares" which shall mean a Share of £1 designated as an Ordinary Share in the capital of the Company, which shall have the powers, preferences, rights and restrictions set forth in this Agreement and the Articles for Ordinary Shares (including the right to the Distributions provided for in Section 12).

11.3 Issued Capital. As at the date of this Agreement the share capital of the Company consists of 100 Ordinary Shares.

11.4 Voting. Each Ordinary Share entitles its holder to one vote per Share.

11.5 Specific Limitations. Except as otherwise provided herein, without the consent of the Board of Directors, no Member shall have the right or power to: (a) contribute any property to the Company other than cash; (b) cause the winding up and dissolution of the Company, except as set forth in this Agreement or as required by the Act; or (c) require that property other than cash be distributed upon any Distribution.

11.6 Additional Members and Shares. Subject to Section 14.3, the Board of Directors may issue additional Shares, admit Persons as Members in exchange for such contributions to capital or such other consideration and on such terms and conditions (including vesting and forfeiture provisions in the case of Shares issued to employees and consultants) as it deems fit. Upon the execution of or a deed of adherence substantially in the form set out in Schedule 11.6, together with any other documents or instruments required by the Board of Directors in connection therewith, and the payment of the subscription price specified to be made at such time, a Person shall be admitted to the Company as a Member.

11.7 Certification. The Company shall issue share certificates to each Member in respect of the Shares to which it is entitled.

12. DISTRIBUTIONS AND ALLOCATIONS OF PROFIT AND LOSS.

12.1 Board of Directors Determination. The amount of any Distributions to any Member at any time shall be determined in accordance with Section 12.2.

12.2 Distributions.

(a) Distribution Amounts. The parties agree that, subject to Section 12.3, whenever the amount of a dividend to be paid is to be ascertained:

(i) the total profits of the Company available for distribution within the meaning given in the Act (the "Distributable Profits"), shall be determined by the Directors by reference to the audited accounts for the relevant financial year;

(ii) the Directors shall identify amounts (the "Retained Amounts") which they consider (having regard to all other sources of funding available to the Company) should be retained in order:

(A) to meet reasonably foreseeable commitments and contingencies;

(B) to develop the Business in accordance with the approved Budget and the terms of this Agreement;

(C) to ensure that there is no breach of any covenant or undertaking given by the Company to any lender at the time of the payment and, in the opinion of the Board of Directors, there is not likely to be such a breach within the following [***]; and

(D) to maintain the sound financial standing of the Company.

(iii) such percentage as the Board of Directors determines of the balance (if any) remaining after deducting the Retained Amounts from the Distributable Profits shall be used:

(A) first, to repay any outstanding loans owed to the Members, in accordance with any loan priority and otherwise on a *pro rata* basis, until all such shareholder loans have been repaid in full;

(B) second, to pay to the holders of Shares by way of dividend on their Shares.

(b) Distributions – Payment Term. The parties undertake to procure (so far as they are able and subject to this Section 12.2) that interim and final dividends are declared or recommended, and approved and paid, in accordance with this Section 12, and that payment of dividends is made within [***] of their having been declared or approved.

(c) Change of Control or a Subsidiary Change of Control. In the event of a Change of Control or a Subsidiary Change of Control, if any portion of the consideration payable to the Members is payable only upon satisfaction of contingencies (the "Additional Consideration"), the applicable acquisition documentation shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the "Initial Consideration") shall be allocated among the Members in accordance with this Section 12.2 as if the Initial Consideration were the only consideration payable in connection with such Change of Control; and (b) any Additional Consideration which becomes payable to the Members upon satisfaction of such contingencies shall be allocated among the Members in accordance with this Section 12.2 after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Section 12.2(c), consideration placed into escrow or retained as holdback to be available for satisfaction of indemnification or similar obligations in connection with such Change of Control shall be deemed to be Additional Consideration.

12.3 No Violation. Notwithstanding any provision to the contrary contained in this Agreement, the Company shall not make a Distribution to any Member on account of such Member's Shares in the Company if such Distribution would violate the Act or any other applicable law.

13. STATUS, RIGHTS AND POWERS OF MEMBERS.

13.1 No Management or Control. Except as expressly provided in this Agreement, no Member in its capacity as such shall take part in the conduct of the Company's business or interfere in any manner with the management of the business and affairs of the Company or have any right or authority to act for or bind the Company.

13.2 Member Duties.

(a) No Member shall have any duty to the Company or to any other Member (including fiduciary duties) except as expressly set forth herein, pursuant to the Articles, or in other written agreements.

(b) Subject to the approval of the Board of Directors, any Member may lend money to, borrow money from, act as a surety, guarantor or endorser for, guarantee or assume one or more obligations of, provide collateral for, and transact other business with, the Company and, subject to other applicable law, shall have the same rights and obligations with respect to any such matter as a Person who is not a Member.

14. BOARD OF DIRECTORS AND INVESTOR RIGHTS.

14.1 Board of Directors.

(a) Number and Composition. The business of the Company shall be managed by a Board of Directors (the "Board of Directors"), and the Persons constituting the Board of Directors shall be the "directors" of the Company for all purposes of the Act (each, a "Director", and collectively, the "Directors"). The number of Directors shall initially be five (5). The MeiraGTx Member is entitled to designate and elect three (3) Directors (each a "MeiraGTx Director"). The Hologen Member is entitled to designate and elect two (2) Directors (each a "Hologen Director"). Each Director shall have one vote, save that a Director who is also a proxy shall be entitled, in the absence of his appointor, to a separate vote on behalf of each appointor in addition to his own vote. The Chairperson of the Board of Directors shall be a MeiraGTx Director. The Chairperson shall not have an additional or casting vote or other special voting powers.

(b) Variations. The provisions of Section 14.1(a) relating to the number of Directors serving on the Board of Directors may be increased or decreased by the approval of at least seventy percent (70%) of the Directors then in office (the "Director Supermajority").

(c) Resignation and Removal; Vacancies. Each Director shall, unless otherwise provided in this Agreement or by law, hold office until such individual resigns, dies or is removed by the Member, Members or Directors who have the right to designate him or her in accordance with this Agreement and the Articles. A Director may be removed only by the Member, Members or Directors that designated such Director upon delivery of a written notice of removal to the Company and the other Directors. Any vacancy on the Board of Directors created by the resignation, removal, incapacity or death of any Director may only be filled by another Director designated by the Member, Members or Directors who have the right to designate him or her in accordance with this Agreement. Any vacancy on the Board of Directors created by an increase to the number of Directors may be filled by the approval of the Director Supermajority.

(d) Authority. Decisions of the Board of Directors shall be carried out by such Persons appointed by the Board of Directors in the resolution or consent reflecting such decision or in one or more standing resolutions or consents. A decision of the Board of Directors may be amended, modified or repealed, but no such amendment, modification or repeal shall affect any Person who has been furnished a copy of the original vote or resolution that is certified by a duly authorized officer of the Company, until such Person has been notified in writing of such amendment, modification or repeal.

(e) Committees. The Board of Directors may, by vote or resolution of the Board of Directors, delegate any or all of its powers to any committee thereof, and any such committee must consist of at least two (2) Directors. The audit committee of the Board of Directors shall have

at least one Hologen Director, provided that both Hologen Directors shall have the opportunity to sit on the audit committee; and at least one Hologen Director shall be given the opportunity to sit on any other committees of the Board of Directors. Provisions relating to the Alliance Committee are set out in Section 16.

(f) Meetings. Meetings of the Board of Directors and any committee thereof may be held at any time and at any place, whether within or outside of England, designated in the notice of the meeting, when called by any Director, reasonable notice thereof being given to each Director by the Person or Persons calling the meeting. Regular or special meetings of the Board of Directors shall be held at the Company's principal offices or at such other place and at such time as shall be determined by the Board of Directors.

(g) Notice of a Meeting of the Board of Directors. It shall be reasonable and sufficient notice to a Director of a meeting of the Board of Directors (i) to send notice by electronic mail at least twenty-four (24) hours before the meeting addressed to such Director at such Director's last known electronic email address, (ii) to send notice by regular mail received at least twenty-four (24) hours before the meeting addressed to such Director at such Director's usual or last known business or residence address, or (iii) to give notice to such Director in person or by telephone at least twenty-four (24) hours before the meeting. Notice of a meeting need not be given to any Director if a written waiver of notice, executed by such Director before or after the meeting, is filed with the records of the meeting, or is delivered to any Director who attends the meeting, or if such Director attends the meeting and does not object to such meeting. Notice of any Directors' meeting must indicate (i) its proposed date and time; (ii) where it is to take place; and (iii) if it is anticipated that Directors participating in the meeting will not be in the same place, how it is proposed that they should communicate with each other during the meeting. Neither notice of a meeting nor a waiver of a notice need specify the purposes of the meeting.

(h) Quorum. Except as may be expressly set forth in this Agreement, at any meeting of the Board of Directors or any committee thereof, a majority of Directors then in office or then serving on such committee, which in the case of a meeting of the Board of Directors must include at least one Hologen Director and two MeiraGTx Directors, or in the case of a meeting of a committee of the Board of Directors, must include one Hologen Director if there is a Hologen Director on such committee and one MeiraGTx Director if there is a MeiraGTx Director on such committee, shall constitute a quorum for such meeting. Except as otherwise expressly set forth in this Agreement, including pursuant to Section 14.3, any action to be taken or approved by the Directors hereunder must be taken or approved by a vote of a majority of Directors present and voting in person at a meeting at which a quorum is present, and any action so taken or approved shall constitute the act of the Board of Directors. If a quorum is not present within thirty (30) minutes of the scheduled time of the meeting of the Board of Directors (or ceases to be present for half an hour) because of the absence of a MeiraGTx Director or a Hologen Director, the meeting shall be adjourned, to be held on the fifth (5th) business day following the date for which the meeting was originally convened with at least twenty-four (24) hours prior notice being given to all Directors (unless all Directors agree otherwise). The quorum for any such adjourned meeting shall be those Directors present (or represented) and entitled to vote at the time of the reconvened meeting. Any meeting may be adjourned from time to time by a majority of the votes cast upon the question, whether or not a quorum is present, and the meeting may be held as adjourned without

further notice. Each Director may appoint an alternate director as a proxy for himself in accordance with the Act.

(i) Written Consent. Except as otherwise expressly set forth in this Agreement, any action required or permitted to be taken at any meeting of the Board of Directors or committee thereof may be taken without a meeting if all of the members of the Board of Directors or a committee then in office or then serving on such committee pass a written resolution to that effect (where permitted under applicable law), and such writing or writings are filed with the records of the meetings of the Board of Directors or such committee. Such consent shall be treated for all purposes as the act of the Board of Directors or of such committee, as the case may be.

(j) Telephonic Meetings. Directors may participate in a meeting of the Board of Directors by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other and each participant is able to address all of the other participants simultaneously or by any other means permitted by law. Such participation shall constitute presence in person at such meeting.

(k) Director Reimbursement. Each Director shall be reimbursed by the Company for such Director's reasonable out-of-pocket travel expenses incurred in the performance of such Director's duties as Director. Nothing contained in this Section 14.1 shall be construed to preclude any Director from serving the Company in any other capacity and receiving reasonable compensation therefor.

(l) Additional Rules. The Board of Directors may adopt such other rules for the conduct of its business as it may from time to time deem necessary or appropriate.

14.2 Authority of Board of Directors. Subject to applicable law and the provisions of this Agreement that require the consent or approval of one or more Members or other Persons, the Board of Directors shall have the exclusive power and authority to manage the business and affairs of the Company and to make all decisions with respect thereto. Except as otherwise expressly provided in this Agreement, the Board of Directors or Persons authorized by the Board of Directors shall be the only Persons authorized to execute documents which shall be binding on the Company. Subject to applicable law and the provisions of this Agreement that require the consent or approval of one or more Members or other Persons, the power and authority granted to the Board of Directors hereunder shall include all power and authority necessary, convenient or incidental for the accomplishment of the purposes of the Company and the exercise of the powers of the Company set forth in Section 2.5 and shall include the power to make, or to grant to other Persons the power to make, all decisions with regard to the management, operations, assets, financing and capitalization of the Company, including the power and authority to undertake and make decisions concerning: (a) hiring and firing employees, officers, attorneys, accountants, brokers, investment bankers and other advisors and consultants, (b) entering into leases for real or personal property, (c) opening bank and other deposit accounts and operations thereunder, (d) borrowing money, obtaining credit, issuing notes, debentures, securities, equity or other interests of or in the Company and securing the obligations undertaken in connection therewith with mortgages on, pledges of and security interests in all or any portion of the real or personal property of the Company, (e) making investments in or the acquisition of securities of any Person, (f) giving guarantees and indemnities, (g) entering into contracts or agreements, whether in the ordinary

course of business or otherwise, (h) mergers with or acquisitions of other Persons, (i) dissolution, (j) the sale or lease of all or any portion of the assets of the Company, whether in the ordinary course of business or otherwise, (k) forming subsidiaries or joint ventures, (l) compromising, arbitrating, adjusting and litigating claims in favor of or against the Company, (m) appointment and termination of the auditor of the Company and each of its Subsidiaries, and (n) other matters as provided by resolution of the Board of Directors.

14.3 Actions Requiring Director Supermajority. Without limiting the other terms and conditions hereof or the requirements of the Act, and save for any action(s) in relation to the Non-Manufacturing Business Carve-Out or any contracts, agreements and arrangements of whatever nature entered into by MeiraGTx or any of its Affiliates prior to the Completion Date, the Company shall not take any of the following actions (or series of related actions) without the approval of the Director Supermajority, [***]:

[***]

15. KEY MANAGEMENT PERSONNEL.

15.1 Management Team. Unless otherwise agreed by the Members in writing, the Members shall procure that the Company shall establish a management team which shall consist of one or more Key Management Personnel.

15.2 Key Management Personnel. Each of the Key Management Personnel shall be appointed or removed by the simple majority approval of the Board of Directors. Each of the Key Management Personnel shall exercise such powers as contained in their contract of employment.

16. ALLIANCE COMMITTEE AND ALLIANCE MANAGERS

16.1 Alliance Committee. On the Completion Date, the Major Members shall establish an alliance committee (the "Alliance Committee") to discuss the operations of the Business and any issues communicated by the Major Members in respect of the same. At the Completion Date, each Major Member shall appoint one or more members to the Alliance Committee. Each Major Member may replace its Alliance Committee members upon written notice to the other Major Member, subject to the other Major Member's approval, which approval shall not be unreasonably withheld. Each Major Member shall have an equal number of members on the Alliance Committee. Each Major Member shall ensure that its Alliance Committee member(s) are bound by and comply with the obligations of confidentiality set out in Section 17.4.

16.2 Meetings of the Alliance Committee. The Alliance Committee shall meet [***] (or more or less frequently as agreed by the parties). The Alliance Committee members may, upon reasonable notice, request to meet with the relevant employees of the Company and its Subsidiaries to discuss technical aspects of the Business. Unless otherwise agreed by the Major Members, the Alliance Committee shall be chaired by one representative of MeiraGTx, who shall be responsible for convening and presiding at meetings of the Alliance Committee, including (a) providing reasonable advance notice to representatives of any Alliance Committee meeting; (b) preparing and circulating agendas in advance of each Alliance Committee meeting; and (c) preparing and circulating minutes following each Alliance Committee meeting. The Alliance Committee chair will have no additional powers or rights beyond those held by the other Alliance Committee

representatives. Meetings of the Alliance Committee will be effective only if an equal number of Alliance Committee members from each Major Member are present or participating (including by videoconference or teleconference) in such meeting. As appropriate, the Alliance Committee may invite a reasonable number of non-voting observers to attend its meetings, provided that such invitees are bound by appropriate confidentiality, non-disclosure and non-use obligations which are no less stringent than those set forth in Section 17.4. Minutes will be kept of all Alliance Committee meetings in English, which minutes shall be circulated via e-mail for review and approval within [***] after each Alliance Committee meeting.

16.3 Alliance Committee Responsibilities. The Alliance Committee shall (a) review and discuss the Businesses' manufacturing and development plans and schedules; (b) discuss, review and determine whether to propose any amendments to such plans and schedules for the approval of the Board of Directors; and (c) serve as an information exchange platform between the parties with respect to the Businesses' manufacturing and development plans and schedules, including to review and discuss any data, results, reports or other information generated in connection therewith.

16.4 Alliance Committee Decision-Making. Decisions of the Alliance Committee shall be made by majority vote, with each Alliance Committee member having one vote. If the Alliance Committee does not reach a decision with respect to any matter after endeavoring to agree in good faith for at least [***], then, the matter shall be referred to the Board of Directors for resolution.

16.5 Limitations of Alliance Committee Authority. For the avoidance of doubt, the Alliance Committee shall not have the authority to (a) resolve any disputes arising out of this Agreement, which shall be resolved in accordance with Section 27.10; (b) amend, modify or waive any term or condition of this Agreement (including expanding a party's rights or reducing a party's obligations); or (c) determine that a party has fulfilled any obligations under this Agreement or that either party or any of its Affiliates has breached any obligation under this Agreement.

16.6 Alliance Managers. On the Completion Date, each party shall appoint an individual who shall serve as the primary point of contact between the parties with regard to questions relating to this Agreement or the overall business relationship and related matters between the parties (each, an "Alliance Manager"). Each party may replace its Alliance Manager at any time upon written notice to the other party.

17. BOOKS, RECORDS, ACCOUNTING AND REPORTS.

17.1 Books and Records. The Company shall maintain at its principal office or such other office as the Board of Directors shall determine such books and records with respect to the business of the Company and its Subsidiaries as are required by law and as the Board of Directors deems appropriate, including at least:

(a) A register of members, register of directors, register of directors' residential addresses, register of secretaries and register of people with significant control;

(b) A copy of the Articles, including any amendments thereto;

(c) The most recent financial statements of the Company and its Subsidiaries; and

(d) Copies of tax or information returns of the Company and its Subsidiaries.

17.2 Inspection.

(a) The Major Members shall have the right, subject to such reasonable standards (including standards governing what information and documents are to be furnished at what time and location and at whose expense) as may be established by the Board of Directors, to obtain from the Company, from time to time upon reasonable demand for any purpose reasonably related to their respective holding of Shares, the information described in Section 17.1 and such other information regarding the affairs of the Company as is reasonably requested.

(b) In addition, to the extent that a Member's ownership of Shares is required under U.S. generally accepted accounting principles ("GAAP") and applicable rules and regulations promulgated by the Securities and Exchange Commission or any other relevant Governmental Entity to be reflected as an equity method investment in the financial statements of such Member, and such Member is as a result required by law, or such Member is otherwise required by law, including the disclosure principles of Rule 10b-5 under the Exchange Act, or in connection with ordinary course financing matters, to disclose, with respect to any quarter or fiscal year, financial information (including appropriate treatment for tax matters) in relation to or derived from financial information of the Company (such disclosure, to such extent, a "Member Financial Disclosure"), the Company shall, subject to GAAP and applicable law and upon Member's reasonable prior notice, provide the aforementioned Company information at Member's expense at such times and in such detail as may be reasonably requested by the Member for the purposes of the Member Financial Disclosure (including affording access to Member's independent auditors to review, and if necessary audit, the financial information of the Company from which the Member Financial Disclosure is derived, which may include affording access to the Company's independent auditors (subject to customary indemnification and confidentiality agreements that may be requested by such auditors, and to the consent of such auditors for any reliance on or reference thereto), to the extent reasonably required for such purpose).

17.3 Filings. At the Company's expense, the Board of Directors shall cause the income tax returns for the Company to be prepared and timely filed with the appropriate authorities and to have prepared and to furnish to each Member, within [***] after the end of each year, such information with respect to the Company (including a schedule setting forth such Member's distributive share of the Company's income, gain, loss, deduction and credit as determined for federal income tax purposes) as is necessary to enable such Member to prepare such Member's federal and state income tax returns. The Company shall as promptly as practicable provide the Major Members with any information reasonably requested by a Major Member that is in the Company's possession (or that can be obtained without undue burden) in connection with the preparation of such Major Member's tax returns. The Board of Directors, at the Company's expense, shall also cause to be prepared and timely filed, with appropriate federal and state regulatory and administrative authorities, all reports required to be filed by the Company with those entities under then current applicable laws, rules and regulations.

17.4 Non-Disclosure.

(a) Each of MeiraGTx, Hologen and any further Person admitted as a Member in accordance with the terms of this Agreement, agrees that (i) the terms of this Agreement and any other agreement contemplated by this Agreement to which it is a party, (ii) any information relating to their negotiation, and (iii) except as otherwise consented to by the Board of Directors, all non-public information relating to the Company furnished to MeiraGTx, Hologen or such Member, including but not limited to confidential information of the Company and its Subsidiaries regarding identifiable, specific and discrete business opportunities being pursued by the Company or its Subsidiaries (collectively, "Confidential Information"), shall be kept confidential, shall not be used for commercial or proprietary advantage and shall not be disclosed by MeiraGTx, Hologen or such Member in any manner, in whole or in part, except that each of MeiraGTx, Hologen and such Member shall be permitted to disclose such Confidential Information (i) to those of MeiraGTx, Hologen or such Member's agents, Representatives and employees who need to be familiar with such Confidential Information in connection with MeiraGTx, Hologen or such Member's investment in the Company and who are charged with an obligation of confidentiality, (ii) to MeiraGTx, Hologen or such Member's existing or prospective partners and equity holders so long as they agree to keep such Confidential Information confidential on the terms set forth herein, (iii) with respect to MeiraGTx, Hologen or a Member that is a professionally managed unregistered investment fund, as part of MeiraGTx, Hologen or such Member's normal reporting or review procedure, or in connection with such MeiraGTx, Hologen or Member's or its Affiliates' normal fund raising, marketing, informational or reporting activities, (iv) for general portfolio information that does not identify the Company or its Subsidiaries, (v) for complying with applicable laws, including regulations promulgated by securities exchanges, including any on which the securities of a Member or its Affiliates are listed, and accounting standards, or court or administrative orders (in such case only to the extent determined necessary based upon advice of counsel), which for the sake of clarity, shall include the right to utilize the name of the Company for the same purposes, (vi) to the extent necessary for the enforcement of any right of MeiraGTx, Hologen or such Member arising under this Agreement and (vii) to existing and potential equity or debt financing sources, so long as they agree to keep such Confidential Information confidential on the terms set forth herein. Notwithstanding the foregoing, MeiraGTx, Hologen or any Member and each of their respective Representatives may disclose to their respective legal advisers, tax advisers, HMRC or any other tax authority, without limitation of any kind, the tax treatment, tax strategies and structure of the Company and all materials of any kind (including opinions or other tax analyses) that are provided to MeiraGTx, Hologen or the Member and their respective Representatives relating to such tax treatment, tax strategies and tax structure. Each of MeiraGTx, Hologen and Member agrees that it shall be responsible for any breach or violation of the provisions of this Section 17.4(a) by any Person receiving Confidential Information from MeiraGTx, Hologen or such Member. Notwithstanding the foregoing, as of the Effective Date, any MeiraGTx Member and as of the Completion Date, any Hologen Member is hereby granted an irrevocable right to disclose and use the Company's name and logo on their websites and in their respective marketing materials for the purpose of reflecting the investment in the Company.

(b) For purposes of this Section 17.4, "Confidential Information" shall not include any information: (i) of which such Person (or its Affiliates) learns from sources other than the Company or its Subsidiaries, whether prior to or after such information is actually disclosed by the Company or its Subsidiaries; or (ii) which is disclosed in documents available for

dissemination to the public. Nothing in this Section 17.4 shall in any way limit or otherwise modify any confidentiality covenants entered into by MeiraGTx, Hologen or any Member pursuant to any other agreement to which MeiraGTx, Hologen or such Member and the Company or any of its Subsidiaries are parties. The provisions of this Section 17.4 shall survive any termination of this Agreement.

17.5 Information Rights. The Company shall deliver to each Major Member (on both a consolidated and consolidating basis including Subsidiaries, or separately for each Subsidiary, as determined by the Major Members):

(a) As soon as available, and in any event within [***] after the end of each Fiscal Year of the Company, audited financial statements consisting of the balance sheet of the Company and its Subsidiaries as at the end of such Fiscal Year and the statements of income, cash flows and changes in members' equity for such Fiscal Year of the Company and its Subsidiaries, setting forth in each case in comparative form the figures for the immediately preceding Fiscal Year, all such financial statements prepared in accordance with GAAP and accompanied by the report of independent certified public accountants of recognized national standing thereon, which accountants shall be selected by the Board of Directors;

(b) As soon as available, and in any event within [***] after the end of each fiscal quarter of the Company for the first three (3) fiscal quarters of a Fiscal Year, the unaudited balance sheet of the Company and its Subsidiaries as at the end of such quarter and the unaudited statements of income, cash flows and changes in members' equity for such quarter and the portion of the Fiscal Year then ended of the Company and its Subsidiaries, setting forth in each case the figures for the corresponding periods of the previous Fiscal Year, or, in the case of such balance sheet, for the last day of such Fiscal Year, in comparative form, all in reasonable detail, and all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) As soon as available, but in any event within [***] after the end of each month, an unaudited balance sheet of the Company and its Subsidiaries as at the end of such month and the unaudited statements of income, cash flows and changes in members' equity for such month, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(d) As soon as available, and in any event [***] before the end of each Fiscal Year, a budget and business plan for the next Fiscal Year (collectively, the "Budget");

(e) Upon request by a Major Member, a statement showing the number of shares of each class and securities convertible into or exercisable for shares outstanding, all in sufficient detail as to permit such Major Members to calculate its respective percentage equity ownership in the Company and each of its Subsidiaries (including the Company's ownership in each such Subsidiary, direct or indirect), and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;

(f) Within [***] following the end of each Fiscal Year or as soon as practicable thereafter, an IRS Schedule K-1 (Form 1065) or any successor federal tax form (if applicable); and

(g) Such other information relating to the Company or any of its Subsidiaries as from time to time may reasonably be requested by such Major Member.

18. TAX MATTERS.

18.1 ECI. The Company shall not engage in, or invest in any person that is treated as a flow-through entity for U.S. federal income tax purposes that engages in, (i) any "commercial activity" as defined in Section 892(a)(2)(i) of the Code, (ii) a "trade or business within the United States," within the meaning of Section 864(b) of the Code, or (iii) any other activity that causes the Company or any other person (including any Member and any direct or indirect owner of a Member) to file a state income tax return during any taxable year of the Company. The Company shall not make any investment or acquire any interest that would be treated as a "U.S. real property interest," within the meaning of Section 897 of the Code.

18.2 Tax Residence. Unless the parties otherwise expressly agree in writing, the Company shall at all times maintain tax residence solely in the UK for tax purposes.

18.3 Listed Transactions. The Company shall not engage, directly or indirectly, in any transaction that, as of the date the Company enters into a binding contract to engage in such transaction, is a "listed transaction" as defined in Treasury Regulations Section 1.6011-4(b)(2) where a Member would be treated as "party" to such transaction for purposes of Section 4965 of the Code (a "Listed Transaction"). If the Company has actual knowledge that it has engaged, directly or indirectly, in a Listed Transaction or a "reportable transaction" as defined in Treasury Regulations Section 1.6011-4(b)(1), it shall promptly notify the Members of such determination.

18.4 Notice of Non-compliance. Notwithstanding anything else in this Agreement, in the event that the Company fails to comply with its obligations under Section 25.5 through Section 25.7, the Company will promptly provide notice to each Member of such non-compliance and provide in a timely fashion as may be requested by a Member all necessary and reasonably available tax-related information in order to permit such Member to make accurate and timely tax filings for so long as such filings may be required to be made by such Member under applicable U.S. tax law.

18.5 Use of Losses. Unless the parties otherwise expressly agree in writing, the parties shall procure that all of the Company's trading losses and all other amounts eligible for relief from taxation shall be carried forward by the Company or surrendered to one or more of the Subsidiaries and not surrendered (wholly or partly) to either Member.

18.6 Tax Information. The Company shall promptly comply with any request made by a Member, to provide any documents, information and correspondence necessary (at the cost of the party making the request) to enable the relevant party to comply with its obligations in respect of filing, elections, returns or other tax requirements, and to comply with any other requirements of, or requests by, HMRC or of any other tax authority.

19. TRANSFER OF SHARES.

19.1 Restricted Transfer.

(a) No Member may directly or indirectly Transfer all or any of such Member's Shares, except in compliance with this Section 19. Any attempted Transfer of Shares not in compliance with the terms of this Section 19 shall be null and void and the Company shall not in any way give effect to any such Transfer. In addition to the foregoing, no Member may avoid the provisions of this Agreement by either making one or more Transfers to one or more Permitted Transferees and then disposing of all or any portion of such party's interest in any such Permitted Transferee or by transferring the securities of any entity whose primary purpose is to hold (directly or indirectly) Shares (and, for the avoidance of doubt, any such Transfers will be deemed to be Transfers for purposes of this Agreement and subject to the restrictions in this Section 19). The Transfer restrictions set forth in this Section 19 do not apply to the sale of Shares in accordance with the drag-along right specified in Section 20.5, or to the Transfer of Shares in accordance with Section 20.1 or Section 20.2.

19.2 Permitted Transferees. A Member shall be entitled to Transfer such Member's Shares to a Person (a "Permitted Transferee"), provided that in each case such person is not a Sanctioned Person, in accordance with the following and subject to the other provisions of this Section 19:

(a) To the Company. Each applicable Member shall be entitled to Transfer its Shares to the Company.

(b) Discretionary Transfers. Each Member shall be entitled to Transfer such Member's Shares to (a) an Affiliate of such Member or (b) to a third party if such Member obtains the prior written consent of the Director Supermajority prior to such Transfer.

19.3 Transfer Requirements. Subject to Section 19.1, no Assignee (including a Permitted Transferee) shall be admitted to the Company as a Member unless the following conditions are satisfied or such conditions are waived by the Board of Directors:

(a) A duly executed written instrument of Transfer is provided to the Board of Directors, specifying the Shares being transferred and setting forth the intention of the Member effecting the Transfer that the transferee succeed to a portion or all of such Member's Shares as a Member, and a deed of adherence substantially in the form set out in Schedule 11.6 duly executed and delivered by the transferee agreeing to be bound by this Agreement in respect of the Shares transferred;

(i) The Member effecting the Transfer and the Assignee execute any other instruments that the Board of Directors deems reasonably necessary or desirable for admission of the Assignee;

(b) All Transfers shall be made in compliance with applicable law and if any Transfer permitted hereunder would require the consent of or notice to a Governmental Entity, the Members and the Company shall cooperate to obtain such consent or prepare and deliver such notice;

(c) The Member effecting the Transfer or the Assignee pays to the Company a transfer fee in an amount sufficient to cover the reasonable expenses incurred by the Company in connection with the admission of the Assignee and provides to the Company any information necessary for the Company to make required basis adjustments and comply with tax reporting requirements; and

(d) The Assignee provides the Company with such information as the Company reasonably determines appropriate to conclude that the Transfer will not result in a withholding obligation on the Company under applicable tax laws.

19.4 Admission as a Member. Each Member hereby agrees that, upon satisfaction of the terms and conditions of this Section 19 with respect to any proposed Transfer, and subject to the instrument of transfer being duly stamped by HMRC and the entry of the Assignee in the Company's register of members, the Assignee be admitted as a Member.

19.5 Withdrawal of Member. If a Member Transfers all of its Shares pursuant to Section 19.1 and the Assignee of such Shares is admitted as a Member pursuant to Section 19.3, such Assignee shall be admitted to the Company as a Member effective on the effective date of the Transfer or such other date as may be specified when the Assignee is admitted and then immediately following such admission the assignor shall cease to be a Member. Upon the assignor ceasing to be a Member, the assignor shall not be entitled to any Distributions from and after the date of such Transfer. Notwithstanding the admission of an Assignee as a Member and, except as otherwise expressly approved by the Board of Directors, (a) the assignor shall not be released from any obligations to the Company as a Member (or otherwise) existing as of the date of the Transfer, including without limitation the obligations set forth in Section 17.4 and Section 22 and (b) the assignor shall continue to have the rights set forth in, and be the beneficiary of, Section 22.

19.6 Additional Transfer Restrictions. Notwithstanding anything to the contrary contained herein, (i) all grants of security over Shares held by a Member shall only be made with the written consent of the Director Supermajority, or by operation of law and (ii) no Member shall transfer any Shares to any entity that the Board of Directors has reasonably determined is a Competitor, other than in connection with a Sale of the Company.

20. RIGHT OF FIRST REFUSAL; RIGHT OF CO-SALE; PREEMPTIVE RIGHTS; AND DRAG-ALONG RIGHTS.

20.1 Right of First Refusal.

(a) Grant. Each Member holding Transfer Shares hereby unconditionally and irrevocably grants to the Company a Right of First Refusal to purchase all or any portion of Transfer Shares that such Member may propose to transfer in a Proposed Transfer, at the same price and on the same terms and conditions as those offered to the Proposed Transferee and each Member holding Transfer Shares undertakes to exercise his voting rights in the Shares to approve the Company's exercise of such Right of First Refusal in relation to such Transfer Shares.

(b) Notice. Each Member proposing to make a Proposed Transfer must deliver a Transfer Notice to the Company and each Major Member not later than [***] prior to the consummation of such Proposed Transfer. Such Transfer Notice shall contain the material terms

and conditions (including price and form of consideration) of the Proposed Transfer and the identity of the Proposed Transferee. To exercise its Right of First Refusal under this Section 20.1, the Company must deliver a Company Notice to the selling Member within [***] after delivery of the Transfer Notice. In the event of a conflict between this Agreement and any other agreement that may have been entered into by a Member with the Company that contains a preexisting right of first refusal, the Company and the Member acknowledge and agree that the terms of this Agreement shall control and the preexisting right of first refusal shall be deemed satisfied by compliance with this Section 20.1. For the sake of clarity, if a Major Member is the Member proposing to make a Proposed Transfer, such Major Member shall not have to deliver any Transfer Notice to itself and shall not have any right to purchase any Transfer Shares in connection with such Major Member's Proposed Transfer.

(c) Grant of Secondary Refusal Right to Major Members. Subject to Section 19, each Member holding Transfer Shares hereby unconditionally and irrevocably grants to the Major Members a Secondary Refusal Right to purchase all or any portion of the Transfer Shares not purchased by the Company pursuant to the Right of First Refusal. If the Company does not intend to exercise its Right of First Refusal with respect to all Transfer Shares subject to a Proposed Transfer, the Company must deliver a Secondary Notice to the selling Member and to each Major Member to that effect no later than [***] after the selling Member delivers the Transfer Notice to the Company. To exercise its Secondary Refusal Right, a Major Member must deliver an Exercising Member Notice to the selling Member and the Company within [***] after the Company's deadline for its delivery of the Secondary Notice as provided in the preceding sentence.

(d) Undersubscription of Transfer Shares. If options to purchase have been exercised by the Company and the Major Members with respect to some but not all of the Transfer Shares by the end of the [***] specified in the last sentence of Section 20.1(c) (the "Exercising Member Notice Period"), then the Company shall, immediately after the expiration of the Exercising Member Notice Period, send written notice (the "Company Undersubscription Notice") to those Major Members who fully exercised their Secondary Refusal Right within the Exercising Member Notice Period (the "Exercising Members"). Each Exercising Member shall, subject to the provisions of this Section 20.1(d), have an additional option to purchase all or any part of the balance of any such remaining unsubscribed Transfer Shares on the terms and conditions set forth in the Transfer Notice. To exercise such option, an Exercising Member must deliver a Company Undersubscription Notice to the selling Member and the Company within [***] after the expiration of the Exercising Member Notice Period. In the event there are two or more such Exercising Members that choose to exercise the last-mentioned option for a total number of remaining Shares in excess of the number available, the remaining Shares available for purchase under this Section 20.1(d) shall be allocated to such Exercising Member pro rata based on the number of Transfer Shares such Exercising Members have elected to purchase pursuant to the Secondary Refusal Right (without giving effect to any Transfer Shares that any such Exercising Member has elected to purchase pursuant to the Company Undersubscription Notice). If the options to purchase the remaining Shares are exercised in full by the Exercising Member, the Company shall immediately notify all of the Exercising Members and the selling Member of that fact.

(e) Consideration; Closing. The consideration to be paid for the Transfer Shares must be cash. The closing of the purchase of Transfer Shares by the Company and the Major

Members shall take place, and all payments from the Company and the Major Members shall have been delivered to the selling Member, by the later of [***].

20.2 Right of Co-Sale.

(a) Exercise of Right. If any Transfer Shares subject to a Proposed Transfer are not purchased pursuant to Section 20.1 above and thereafter are to be sold to a Proposed Transferee (subject to Section 19), each respective Major Member may elect to exercise its Right of Co-Sale and participate on a pro rata basis in the Proposed Transfer as set forth in Section 20.2(b) below and otherwise on the same terms and conditions specified in the Transfer Notice. Each Major Member who desires to exercise its Right of Co-Sale (each, a "Participating Member") must give the selling Member written notice to that effect within [***] after the deadline for delivery of the Secondary Notice described above, and upon giving such notice such Major Member shall be deemed to have effectively exercised the Right of Co-Sale. For the sake of clarity, a Major Member who has requested the Proposed Transfer shall not have the right to be a Participating Member with respect to such Proposed Transfer.

(b) Shares Includable. Each Participating Member may include in the Proposed Transfer all or any part of such Participating Member's Shares equal to the product obtained by multiplying (i) the aggregate number of Transfer Shares subject to the Proposed Transfer (excluding Shares purchased by the Company or the Participating Members pursuant to the Right of First Refusal or the Secondary Refusal Right) by (ii) a fraction, the numerator of which is the number of Shares owned by such Participating Member immediately before consummation of the Proposed Transfer and the denominator of which is the total number of Shares owned, in the aggregate, by all Participating Members immediately prior to the consummation of the Proposed Transfer, plus the number of Transfer Shares held by the selling Member. To the extent one or more of the Participating Members exercise such right of participation in accordance with the terms and conditions set forth herein, the number of Transfer Shares that the selling Member may sell in the Proposed Transfer shall be correspondingly reduced.

(c) Purchase Covenants. The parties hereby agree that the terms and conditions of any sale pursuant to this Section 20.2 will be memorialized in, and governed by, a written purchase and sale agreement with customary terms and provisions for such a transaction and the parties further covenant and agree to enter into such an agreement as a condition precedent to any sale or other transfer pursuant to this Section 20.2. Neither the Transfer of Transfer Shares by the selling Member nor the Transfer of Shares by a Participating Member shall be effective, unless, contemporaneously with such Transfer, the Proposed Transferee executes a counterpart to this Agreement, thereby agreeing to be bound to all the terms and conditions of this Agreement. If any Proposed Transferee or Proposed Transferees refuse(s) to purchase securities subject to the Right of Co-Sale from any Participating Member exercising its Right of Co-Sale hereunder, no Member may sell any Transfer Shares to such Proposed Transferee or Proposed Transferees unless and until, simultaneously with such sale, such Member purchases all shares subject to the Right of Co-Sale from such Participating Member on the same terms and conditions (including the proposed purchase price) as set forth in the Transfer Notice.

(d) Additional Compliance. If any Proposed Transfer is not consummated within [***] after receipt of the Transfer Notice by the Company, the Member proposing the

Proposed Transfer may not sell any Transfer Shares unless they first comply in full with each provision of Section 20.1 and this Section 20.2. The exercise or election not to exercise any right by any Major Member hereunder shall not adversely affect its right to participate in any other sales of Transfer Shares subject to this Section 20.2.

20.3 Effect of Failure to Comply with Right of First Refusal and Right of Co-Sale.

(a) Transfer Void; Equitable Relief. Any Proposed Transfer not made in compliance with the requirements of this Agreement shall be null and void ab initio, shall not be recorded on the books of the Company and shall not be recognized by the Company. Each party hereto acknowledges and agrees that any breach of this Agreement would result in substantial harm to the other parties hereto for which monetary damages alone could not adequately compensate. Therefore, the parties hereto unconditionally and irrevocably agree that any non-breaching party hereto shall be entitled to seek protective orders, injunctive relief and other remedies available at law or in equity (including, without limitation, seeking specific performance or the rescission of purchases, sales and other transfers of Transfer Shares not made in strict compliance with this Agreement).

(b) Violation of First Refusal Right. If any Member becomes obligated to sell any Transfer Shares to the Company or any Major Member under this Agreement and fails to deliver such Transfer Shares in accordance with the terms of this Agreement, such Member hereby appoints any Director or any Major Member (or, in the case of a Member who is a Major Member, the other Major Member) to be their true and lawful attorney to take such actions and to execute any documentation on their behalf which the attorney considers necessary or relevant to the making of such transfer. The Company and/or such Major Member may, at its option, in addition to all other remedies it may have, send to such Member the purchase price for such Transfer Shares as is herein specified and transfer to the name of the Company or such Major Member (or request that the Company effect such transfer in the name of a Major Member) on the Company's books the Transfer Shares to be sold.

(c) Violation of Co-Sale Right. If any Member purports to sell any Transfer Shares in contravention of the Right of Co-Sale (a "Prohibited Transfer"), each Major Member who desires to exercise its Right of Co-Sale under Section 20.2 may, in addition to such remedies as may be available by law, in equity or hereunder, require such Member to purchase from such Major Member the type and number of Shares that such Major Member would have been entitled to sell to the Proposed Transferee under Section 20.2 had the Prohibited Transfer been effected pursuant to and in compliance with the terms of Section 20.2. The sale will be made on the same terms and subject to the same conditions as would have applied had the Member not made the Prohibited Transfer, except that the sale (including, without limitation, the delivery of the purchase price) must be made within [***] after the Major Member learns of the Prohibited Transfer, as opposed to the timeframe proscribed in Section 20.2. Such Member shall also reimburse each Major Member for any and all reasonable and documented out-of-pocket fees and expenses, including reasonable legal fees and expenses, incurred pursuant to the exercise or the attempted exercise of the Major Member's rights under Section 20.2.

(d) The covenants set forth in Sections 20.1, 20.2 and 20.3 shall terminate and be of no further force or effect immediately before the consummation of the Initial Public Offering or upon a Change of Control, whichever event occurs first.

20.4 Preemptive Rights. Subject to the terms and conditions of this Section 20.4 and applicable laws, if the Company proposes to issue, agree to issue, reserve or set aside or offer to issue any New Shares, the Company shall first offer such New Shares to each Major Member. A Major Member shall be entitled to apportion the right of first offer hereby granted to it among itself and its Affiliates in such proportions as it deems appropriate.

(a) The Company shall give notice (the "Offer Notice") to each such Major Member, stating (i) its bona fide intention to offer such New Shares, (ii) the number of such New Shares to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Shares, including a summary of the rights and privileges of such New Shares.

(b) By notification to the Company within [***] after the Offer Notice is given, each such Major Member may elect to subscribe, at the price and on the terms specified in the Offer Notice, for up to that portion of such New Shares which equals the proportion that the Shares then held by such Major Member bears to the total number of Shares then held by all Major Members. At the expiration of such [***] period, the Company shall promptly notify each Major Member that elects to subscribe for all the New Shares available to it (each, a "Fully Exercising Member") of any other Major Member's failure to do likewise. During the [***] period commencing after the Company has given such notice, each Fully Exercising Member may, by giving notice to the Company, elect to subscribe, in addition to the number of New Shares specified above, for up to that portion of the New Shares for which Major Members were entitled to subscribe but that were not subscribed for by the Major Members which is equal to the proportion that the Ordinary Shares then held, by such Fully Exercising Member bears to the Ordinary Shares then held, by all Fully Exercising Member who wish to purchase such unsubscribed New Shares. The closing of any sale pursuant to this Section 20.4(b) shall occur within [***].

(c) If all New Shares referred to in the Offer Notice are not elected to be subscribed for as provided in Section 20.4(b), the Company may, during the [***] period following the expiration of the periods provided in Section 20.4(b), offer and issue the remaining unsubscribed portion of such New Shares to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the issuance of the New Shares within such period, or if such agreement is not consummated within [***] of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Shares shall not be issued unless first reoffered to the Major Members in accordance with this Section 20.4.

(d) The covenants set forth in this Section 20.4 shall terminate and be of no further force or effect immediately before the consummation of an Initial Public Offering.

20.5 Drag-Along Right.

(a) Definitions. A "Sale of the Company" shall mean either: (a) a transaction or series of related transactions in which a Person, or a group of related Persons, that is or are not

Affiliates of the Company, acquires from the Members' Shares representing more than fifty percent (50%) of the outstanding voting rights of the Company (a "Share Sale"); or (b) any other transaction that qualifies as a Deemed Liquidation Event or Change of Control.

(b) Actions to be Taken. In the event that (A) the Major Members, and (B) the Board of Directors approve a Sale of the Company in writing, specifying that this Section 20.5 shall apply to such transaction, then each Member hereby agrees:

(i) if such transaction requires Member approval, with respect to all Shares that such Member owns or over which such Member otherwise exercises voting power, to vote (in person, by proxy or by action by written consent, as applicable) all Shares in favor of, and adopt, such Sale of the Company (together with any related amendment to this Agreement required in order to implement such Sale of the Company) and to vote in opposition to any and all other proposals that could reasonably be expected to delay or impair the ability of the Company to consummate such Sale of the Company;

(ii) if such transaction is a Share Sale, to sell the same proportion of Shares beneficially held by such Member as is being sold by the Major Members to the Person to whom the Major Members propose to sell their Shares, and, except as permitted in Section 20.5(c) below, on the same terms and conditions as the Major Members;

(iii) to execute and deliver all related documentation (including a stock transfer form and relevant share certificate(s) or a suitable indemnity for any lost share certificate(s) in respect of the Member's Shares to be sold pursuant to this Section 20.5) and take such other action in support of the Sale of the Company as shall reasonably be requested by the Company or the Major Members in order to carry out the terms and provisions of this Section 20.5, any purchase agreement, merger agreement, indemnity agreement, escrow agreement, consent, waiver, governmental filing, and any similar or related documents;

(iv) not to deposit, and to cause their Affiliates not to deposit, except as provided in this Agreement, any Shares owned by such party or Affiliate in a voting trust or subject any Shares to any arrangement or agreement with respect to the voting of such Shares, unless specifically requested to do so by the acquirer in connection with the Sale of the Company; and

(v) if the consideration to be paid in exchange for the Shares pursuant to this Section 20.5 includes any securities and due receipt thereof by any Member would require under applicable law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities or (y) the provision to any Member of any information other than such information as a prudent issuer would generally furnish in an offering made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act, the Company may cause to be paid to any such Member in lieu thereof, against surrender of the Shares which would have otherwise been sold by such Member, an amount in cash equal to the fair value (as determined in good faith by the Company) of the securities which such Member would otherwise receive as of the date of the issuance of such securities in exchange for the Shares.

(c) Exceptions. Notwithstanding the foregoing, a Member will not be required to comply with Section 20.5(b) above in connection with any proposed Sale of the Company (the "Proposed Sale") unless:

(i) any representations and warranties to be made by such Member in connection with the Proposed Sale are limited to representations and warranties related to authority, ownership and the ability to convey title to such Shares, including but not limited to representations and warranties that (A) the Member holds all right, title and interest in and to the Shares such Member purports to hold, free and clear of all liens and Encumbrances, (B) the obligations of the Member in connection with the transaction have been duly authorized, if applicable, (C) the documents to be entered into by the Member have been duly executed by the Member and delivered to the acquirer and are enforceable against the Member in accordance with their respective terms and (D) neither the execution and delivery of documents to be entered into in connection with the transaction, nor the performance of the Member's obligations thereunder, will cause a breach or violation of the terms of any agreement, law or judgment, order or decree of any court or governmental agency;

(ii) the Member shall not be liable for the inaccuracy of any representation or warranty made by any other Person in connection with the Proposed Sale, other than for the inaccuracy of any representation or warranty made by the Company in connection with the Proposed Sale;

(iii) the liability for indemnification, if any, of such Member in the Proposed Sale and for the inaccuracy of any representations and warranties made by the Company in connection with such Proposed Sale, is several and not joint with any other Person;

(iv) the liability for indemnification shall be limited to such Member's applicable share (determined based on the respective proceeds payable to each Member in connection with such Proposed Sale in accordance with the provisions of this Agreement) of a negotiated aggregate indemnification amount that applies equally to all Members but that in no event exceeds the amount of consideration actually paid to such Member in connection with such Proposed Sale, except with respect to claims of fraud by such Member, the liability for which need not be limited as to such Member;

(v) upon the consummation of the Proposed Sale: (A) except as provided in Section 20.5(b)(v), each holder of each class or series of Shares will receive the same form of consideration for their Shares of such class as is received by other holders in respect of their Shares of such same class of Shares; and (B) unless the Major Members elect to receive a lesser amount by written notice given to the Company at least [***] prior to the effective date of any such Proposed Sale, the aggregate consideration receivable by all holders of Shares shall be allocated among the holders of Ordinary Shares pro rata to their holding of Ordinary Shares; provided, however, that, notwithstanding the foregoing provisions of this Subsection 20.5(b)(v), if the consideration to be paid in exchange for the Shares, as applicable, pursuant to this Subsection 20.5(b)(v) includes any securities and due receipt thereof by any Member or would require under applicable law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities; or (y) provision to any Member of any information other than such information as a prudent issuer would generally furnish in an offering

made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act, the Company may cause to be paid to any such Member in lieu thereof, against surrender of the Shares which would have otherwise been sold by such Member, an amount in cash equal to the fair value (as determined in good faith by the Board of Directors) of the securities which such Member would otherwise receive as of the date of the issuance of such securities in exchange for the Shares;

(vi) except as provided in Section 20.5(b)(v), subject to clause (v) above, requiring the same form of consideration to be available to the holders of any single class of Shares, if any holders of any Shares are given an option as to the form and amount of consideration to be received as a result of the Proposed Sale, all holders of such Shares will be given the same option; and

(vii) no Member who is not a current or former employee of the Company shall be required to agree to any restrictive covenant in connection with any Proposed Sale (including any covenant not to compete with or covenant not to solicit or hire customers, employees or suppliers of any party to the Proposed Sale).

(d) Restrictions on Change of Control. [***].

(e) Irrevocable Power of Attorney. As security for the performance of each Member's obligations in connection with such Sale of the Company, after the approval of the Board of Directors and the Major Members has been obtained pursuant to Section 20.5(b) above, each Member hereby irrevocably appoints each member of the Board of Directors, with full power of substitution and resubstitution, to be their true and lawful attorney (i) to vote all Shares at all meetings of the Members held or taken after the date of this Agreement with respect to a Sale of the Company, or (ii) to execute any written consent in lieu thereof, and (iii) to sign any documents with respect to any such vote or any actions by written consent of the Members taken after the date of this Agreement with respect to such Sale of the Company. This power of attorney shall terminate upon the consummation of, or termination of, negotiations with respect to, the applicable Sale of the Company.

21. DISSOLUTION OF COMPANY.

21.1 Termination of Membership. No Member may resign or withdraw from the Company except that, subject to the restrictions set forth in Section 19, any Member may Transfer such Member's Shares in the Company to a Permitted Transferee. The expulsion, bankruptcy or dissolution of any Member shall not in and of itself cause the Company to be dissolved or its affairs to be wound up, and upon the occurrence of any such event, the Company shall be continued without dissolution.

21.2 Events of Dissolution. The Company shall be dissolved upon the happening of any of the following events: (a) the passing of a resolution by shareholders or creditors, or an order is made by a court or other competent body or person instituting a process that shall lead to the Company being wound up and its assets being distributed among the Company's creditors, shareholders or other contributors, (b) the determination of the Director Supermajority, (c) unless otherwise determined by the Board of Directors, the disposition of substantially all of the Company's assets or (d) the termination of the legal existence of the last remaining Member or the occurrence of any other event which by law terminates the continued membership of the last remaining Member in the Company.

21.3 Liquidation. The Company's property and assets or the proceeds from the liquidation thereof shall be distributed so as not to contravene the Act, the Insolvency Act 1986 and any other applicable laws.

21.4 No Action for Dissolution. The Members acknowledge that irreparable damage would be done to the goodwill and reputation of the Company if any Member should bring an action in court to dissolve the Company under circumstances where dissolution is not required by Section 21.2. This Agreement has been drawn carefully to provide fair treatment of all parties and equitable payment in liquidation of the Shares of all Members.

21.5 No Further Claim. Upon dissolution, each Member shall have recourse solely to the assets of the Company for the return of such Member's capital, and if the Company's property remaining after payment or discharge of the debts and liabilities of the Company, including debts and liabilities owed to one or more of the Members, is insufficient to return each Member's capital, such Member shall have no recourse against the Company, the Board of Directors or any other Member.

22. INDEMNIFICATION.

22.1 General Indemnification Rights. The Company shall indemnify, defend and hold harmless each Member and each member of the Board of Directors and, to the extent applicable, each such Person's officers, directors, members, shareholders, and employees, (all such persons being referred to herein as "Indemnified Persons"), who is or was a party, witness or other participant, or is threatened or proposed to be made a party, witness or other participant, in any actual, threatened, pending or complete action, suit, proceeding, demand or investigation, whether civil, criminal, administrative, investigative, or an alternative dispute resolution proceeding (a) by reason of the fact that such Indemnified Person is or was a Member, a member of the Board of Directors, or an officer, member, shareholder or employee of such Indemnified Person, (b) by reason of the fact that such Indemnified Person is or was serving at the request of the Company as a director, officer or partner of another corporation, limited liability company, partnership, trust, plan or other organization or position or enterprise, and/or (c) with respect to Directors of the Company or any Subsidiary, that arises directly from Indemnified Person's actions and activities as a Director, as applicable, of the Company or any Subsidiary within the scope of this Agreement, from and against all expenses (including attorneys' and experts' fees and expenses) ("Expenses"), judgments, fines and amounts paid in settlement actually and reasonably incurred by such Indemnified Person in connection with such action, suit, proceeding, demand or investigation, unless it is determined by a court of competent jurisdiction in a judgment not subject to appeal or

otherwise that (i) such Indemnified Person did not act in good faith and in a manner such Indemnified Person reasonably believed to be in or not opposed to the best interests of the Company (or such organization or enterprise), and (ii) with respect to any criminal action or proceeding, such Indemnified Person had reasonable cause to believe such Indemnified Person's conduct was unlawful.

22.2 Indemnification for Claims Brought by Indemnified Person. No indemnification shall be available for any claim brought by an Indemnified Person unless and to the extent that such claim is brought (a) to determine and/or enforce the indemnification rights of such Indemnified Person, (b) to seek or obtain payment to or on behalf of such Indemnified Person under any liability insurance policy or (c) with the express consent of the Board of Directors.

22.3 Advancement of Defense Costs. The Company shall pay to or on behalf of an Indemnified Person all Expenses incurred by such Indemnified Person in connection with any actual, threatened, pending or complete action, suit, proceeding, demand or investigation as incurred in advance of the final disposition of such action, suit, proceeding, demand or investigation if such Indemnified Person furnishes the Company with a written undertaking to repay the amount of such Expenses advanced to such Indemnified Person if it is finally determined by a court of competent jurisdiction that such Indemnified Person is not entitled to indemnification with respect to such Expenses under this Agreement, which undertaking shall be an unsecured and interest-free general obligation of such Indemnified Person and shall be accepted as a sufficient undertaking without regard to such Indemnified Person's financial ability to repay such amounts.

22.4 Company as Primary Indemnitor. The Company hereby acknowledges that an Indemnified Person may have certain rights to indemnification, advancement of expenses and/or insurance provided by other sources. The Company hereby agrees (a) that it is the indemnitor of first resort (i.e., its obligations to an Indemnified Person are primary and any obligation of such other sources to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Indemnified Person are secondary) and (b) that it shall be required to advance the full amount of Expenses incurred by an Indemnified Person and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement without regard to any rights an Indemnified Person may have against the such other sources. The Company further agrees that no advancement or payment by such other sources on behalf of an Indemnified Person with respect to any claim for which such Indemnified Person has sought indemnification from the Company shall affect the foregoing, and such other sources shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of such Indemnified Person against the Company.

22.5 Persons Entitled to Indemnity. Any Person who is within the definition of "Indemnified Person" at the time of any action or inaction in connection with the business of the Company shall be entitled to the benefits of this Section 22 as an "Indemnified Person" with respect thereto, regardless of whether such Person continues to be within the definition of "Indemnified Person" at the time of such Indemnified Person's claim for indemnification or exculpation hereunder. Each Indemnified Person's right to indemnification vests by virtue of such Indemnified Person's status as such, and no repeal or modification of this Section 22 shall adversely affect any rights to indemnification or to the advancement of Expenses of any Person

who is within the definition of "Indemnified Person" existing at the time of such repeal or modification with respect to any acts or omissions occurring prior to such repeal or modification. Each Indemnified Person is an express third party beneficiary of this Section 22 who may rely on and enforce the provisions of this Section 22.

22.6 Obligation to Indemnify is Non-Recourse. Indemnification under this Section 22 shall be recoverable only from the assets of the Company and not from any assets of the Members.

22.7 Procedure Agreements. The Company may enter into an agreement with any Indemnified Person setting forth procedures consistent with applicable law for implementing the indemnities provided in this Section 22.

22.8 Reliance, etc.. An Indemnified Person acting under this Agreement shall not be liable to the Company or to any other Indemnified Person for its good faith reliance on the provisions of this Agreement. The provisions of this Agreement, to the extent that they restrict the duties (including fiduciary duties) and liabilities of an Indemnified Person otherwise existing at law or in equity, are agreed by the parties hereto to replace such other duties and liabilities of such Indemnified Person.

22.9 Directors' and Officers' Insurance. The Company will ensure that its Directors and officers are covered under a directors and officers' insurance policy for so long as it is available at commercially reasonable rates, as determined by the Board of Directors, provided, that such insurance policy shall provide at least [***] in coverage and be on terms acceptable to the Director Supermajority.

22.10 Period. The provisions of this Section 22 shall survive any termination of this Agreement.

22.11 Compliance with the Act. The provisions of this Section 22 shall be subject to the Act and will not extend to matters which are not permitted by the Act.

23. WARRANTIES BY THE MEMBERS.

Hologen hereby warrants to the Board of Directors, MeiraGTx and the Company, severally and not jointly and solely on its own behalf, as of the date of this Agreement and on Completion, as follows:

23.1 Financial Capability. Hologen has immediately available funds sufficient to enable Hologen to pay in full on the date on which they become due and payable all amounts contemplated to be paid and to satisfy all other obligations hereunder by Hologen in connection with this Agreement, the Share Purchase Agreement and the transactions contemplated hereby. Giving effect thereto, following Completion, Hologen will have capital resources sufficient to satisfy its ongoing financial obligations in respect of the Company pursuant to, *inter alia*, Section 10.

23.2 Compliance with Anti-Bribery Laws and Anti-Money Laundering Laws.

(a) In connection with the transactions contemplated by this Agreement Hologen is and will be in compliance with all applicable Anti-Bribery Laws and Anti-Money

Laundering Laws and has instituted and maintained policies and procedures reasonably designed to promote and achieve compliance with such laws. None of Hologen, the Hologen Investors nor any of their respective Affiliates has in connection with the transactions contemplated by this Agreement: (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government employee or official from corporate funds; or (iii) violated or is in violation of any provision of any applicable Anti-Bribery Laws or Anti-Money Laundering Laws.

(b) No action, suit or proceeding by or before any court or Governmental Entity or any arbitrator involving Hologen or any Hologen Investor with respect to Anti-Bribery Laws or Anti-Money Laundering Laws is pending or, to the knowledge of Hologen, threatened.

(c) The funds that Hologen will use for the transactions contemplated by this Agreement do not derive directly or indirectly from criminal activity.

23.3 Beneficial Ownership. [***]

23.4 Compliance with Sanctions Laws.

(a) None of Hologen, the Hologen Investors, the Hologen Financing Provider, nor any of their respective subsidiaries or directors, nor, to Hologen's knowledge, any agent, or Affiliate of Hologen, the Hologen Investors, the Hologen Financing Provider, nor any of their respective subsidiaries, is currently the target of any Sanctions, owned or controlled by any Sanctioned Person or designated on any Sanctions List nor has any of the foregoing persons taken any steps, performed any acts or omissions, taken any action or is party to any agreement, arrangement or understanding which would or could reasonably be expected to cause or result in any such persons being deemed a Sanctioned Person on the date hereof, in each case to the extent relevant Sanctions have the effect of making unlawful, prohibiting or otherwise restricting Completion, the transactions contemplated by this Agreement or performance by any party of its obligations under this Agreement.

(b) The funds that Hologen will use for the transactions contemplated by this Agreement do not derive in any way from any transaction with or action involving a Sanctioned Person, to the extent the use of such funds have the effect of making unlawful, prohibiting or otherwise restricting Completion, the transactions contemplated by this Agreement or performance by any party of its obligations under this Agreement.

23.5 Purchase for Own Account. Hologen is entering into this Agreement and the transactions contemplated hereby as principal, for its own account (and those of its Hologen Investors and Affiliates) solely for the purpose of investment, and not as nominee or agent. Hologen has (and each Hologen Investor has) no present agreement, undertaking, arrangement, obligation, or commitment providing for the direct or indirect disposition of the Sale Shares.

23.6 Competing Product. Hologen hereby covenants that, during the period beginning on the Effective Date and ending upon [***], neither Hologen (nor any of its Affiliates) shall, alone or with any Third Parties (including through licensing to or from any Third Party), research,

develop, manufacture, commercialize or otherwise exploit any Competing Product anywhere in the world, in each case, without the prior written consent of MeiraGTx.

Each of MeiraGTx and Hologen hereby warrants to the Board of Directors and the other parties to this Agreement, severally and not jointly and solely on its own behalf, as of the date of this Agreement and on Completion, as applicable, and each Person admitted to the Company as a Member following the Effective Date hereby warrants to the Board of Directors and the other parties to this Agreement, severally and not jointly and solely on its own behalf, as of the date of it is admitted to the Company as a Member as follows:

23.7 Duly Formed. It is duly incorporated and validly existing under the laws of its jurisdiction.

23.8 Knowledge and Experience. It has such knowledge and experience in financial, tax and business matters as to enable it to evaluate the merits and risks of its investment in the Company and to make an informed investment decision with respect thereto.

23.9 Economic Risk. It is able to bear the economic risk of its investment in its Shares for an indefinite period of time, and it is aware that it may lose the entire amount of its investment in the Company.

23.10 Solvency. No order has been made, petition presented or meeting convened for its or any of its Affiliates' winding up, nor any other action taken in relation to the appointment of an administrator, liquidator, receiver, administrative receiver, compulsory manager or any provisional liquidator (or equivalent in any other jurisdiction) (or other process whereby the business is terminated and the assets of the company concerned are distributed amongst the creditors or shareholders or any other contributors), and there are no proceedings under any applicable insolvency, reorganisation or similar laws in any relevant jurisdiction, and no events have occurred that, under applicable law, would justify any such proceedings.

23.11 Binding Agreement. It has all requisite power and authority to enter into and perform this Agreement, and has taken all necessary action to authorise the execution of and the performance of its obligations under this Agreement, and this Agreement is and shall remain its valid and binding agreement, enforceable in accordance with its terms (subject, as to the enforcement of remedies, to any applicable bankruptcy, insolvency or other laws affecting the enforcement of creditors' rights).

23.12 No Breach. The execution and delivery by it of, and the performance by it of its obligations under, this Agreement and any agreement entered into pursuant to the terms of this Agreement will not:

(a) result in a breach of or conflict with any provision of its constitutional documents;

(b) result in a material breach of, or constitute a material default under, any instrument to which it is a party or by which it is bound; or

(c) result in a breach of any applicable law.

23.13 Disputes. There are no:

(a) outstanding judgments, orders, injunctions or decrees of any governmental or regulatory body or arbitration tribunal against or affecting it or any of its Affiliates;

(b) lawsuits, actions or proceedings pending or, to its knowledge, threatened against or affecting it or any of its Affiliates; or

(c) investigations by any governmental or regulatory body which are pending or, to its knowledge, threatened against it or any of its Affiliates,

which, in each case, has or could have a material adverse effect on its ability to perform its obligations under this Agreement or any other agreements entered into pursuant to the terms of this Agreement.

23.14 Consents. All consents, permissions, authorisations, approvals and agreements of third parties and all authorisations, registrations, declarations, filings with any Governmental Entity or other organisation having jurisdiction over it that are necessary or desirable for it to obtain in order to enter into and perform this Agreement and any agreement entered into pursuant to the terms of this Agreement in accordance with its terms, have been unconditionally obtained in writing and have been disclosed in writing to the other parties.

23.15 Company Covenants. It shall not take any action that would cause or further any violation by the Company of the covenants contained in Sections 22.4 and 22.5.

23.16 Hologen Covenant. From the Completion Date, within [***] of the end of each fiscal quarter, Hologen shall provide a written certification to MeiraGTx confirming that [***]. Such written certification shall be executed by the Chief Executive Officer or Chief Financial Officer of Hologen.

24. COMPANY WARRANTIES.

The Company hereby warrants to each of MeiraGTx and Hologen, as of the date of this Agreement and on Completion, as follows:

24.1 Duly Formed. The Company is a duly incorporated and validly existing private company limited by shares under the Act, with all necessary power and authority under the Act to issue the Shares to be issued to the Members hereunder.

24.2 Activities in Other Jurisdictions. The Company shall not invest in Subsidiaries organized in, or open an office or other place of business in, any jurisdiction other than England or Ireland (including its territories and possessions), unless, the Company (1) have consulted with reputable local counsel as to whether such jurisdiction will recognize the limited liability of the Members to the same extent as provided under English law, and (2) shall have obtained advice of reputable local counsel or an internationally or regionally recognized firm of independent public accountants, that such activity will not result in any Member (solely by virtue of being a Member) becoming subject to a requirement to either (x) file tax returns in respect of net income in such

jurisdiction or (y) pay tax in such jurisdiction, in each case with respect to the Member's income other than income from the Company.

25. ADDITIONAL COVENANTS.

25.1 Non-Solicitation**.**

(a) In light of each Member's access to Confidential Information and position of trust and confidence with the Company, each Member further agrees that, for so long as it or its Permitted Transferee, directly or indirectly, owns any Shares and for a period of [***] thereafter (the "Restricted Period"), it shall not, directly or indirectly through one or more of any of its Affiliates, hire or solicit, or encourage any other Person to hire or solicit, any individual who has been employed by the Company or any of its Subsidiaries within [***] prior to the date of such hiring or solicitation, or encourage any such individual to leave such employment. This Section 25.1(a) shall not prevent a Member or its controlled Affiliates from hiring or soliciting any employee or former employee of the Company or any of its Subsidiaries who responds to a general solicitation that is a public solicitation of prospective employees and not directed specifically to any of the Company's or its Subsidiary's employees.

(b) In light of each Member's access to Confidential Information and position of trust and confidence with the Company, each Member further agrees that, during the Restricted Period, it shall not, directly or indirectly through one or more of any of its Affiliates, solicit or entice, or attempt to solicit or entice, any clients, customers, or suppliers of the Company or any of its Subsidiaries for purposes of diverting their business or services from the Company or any of its Subsidiaries.

(c) Each Member acknowledges and agrees that a breach or threatened breach of this Section would give rise to irreparable harm to the other Member and the Company or any of its Subsidiaries, for which monetary damages would not be an adequate remedy, and hereby agrees that in the event of a breach or a threatened breach by such Member of any such obligations, the other Member and the Company and each of its Subsidiaries shall, in addition to any and all other rights and remedies that may be available to it in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance, as well as an equitable account of all earnings, profits, and other benefits arising from any such breach, and any other relief that may be available from a court of competent jurisdiction (without any requirement to post bond).

Each Member acknowledges that the restrictions contained in this Section are reasonable and necessary to protect the Members' legitimate interests and constitute a material inducement to the other Member to enter into this Agreement and consummate the transactions contemplated hereby. If any court of competent jurisdiction determines that any of the covenants set forth in this Section, or any part thereof, is unenforceable because of the duration or geographic scope of such provision, such court shall have the power to modify any such unenforceable provision in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Section, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties, as embodied herein, to the maximum extent permitted by applicable

law. The parties hereto expressly agree that this Agreement as so modified by the court shall be binding on and enforceable against each of them.

25.2 Change of Control Notice. In the event of a Change of Control of a Major Member, such Major Member shall promptly, but not later than [***] following such Change of Control, notify the other Major Member in writing thereof (a "Change of Control Notice"), setting forth the date of such Change of Control.

25.3 Licenses and Permits. Each Member shall cooperate in providing such information, in signing such documents and in taking any other action as may reasonably be requested by the Company in connection with obtaining any license or permit needed to operate its business or the business of any entity in which the Company invests.

25.4 Compliance with Laws. The Company shall, and to procure that its Subsidiaries shall, operate in accordance with all applicable laws, statutes, rules, regulations, orders, permits or any similar provision having the force or effect of law.

25.5 Unrelated Business Taxable Income. The Company shall conduct its affairs in a manner that does not cause any Member (or the equity owners of any Member) to have any "unrelated business taxable income" (as that term is defined in Section 512 through Section 514 of the Code) or any item of gross income that would be included in determining such Member's unrelated business taxable income.

25.6 United States Trade or Business. The Company shall not engage in, or invest in any person that is treated as a flow-through entity for U.S. federal income tax purposes that engages in, (i) any "commercial activity" as defined in Section 892(a)(2)(i) of the Code, (ii) a "trade or business within the United States," within the meaning of Section 864(b) of the Code, or (iii) any other activity that causes the Company or any other person (including any Member and any direct or indirect owner of a Member) to file a state income tax return during any taxable year of the Company. The Company shall not make any investment or acquire any interest that would be treated as a "U.S. real property interest," within the meaning of Section 897 of the Code.

25.7 PFIC/CFC. The Company shall make a qualified electing fund election within the meaning of Section 1295 of the Code, with respect to any direct Subsidiary of the Company that is a passive foreign investment company within the meaning of the Code.

26. AMENDMENTS TO AGREEMENT.

26.1 Amendments. This Agreement may only be modified or amended by written agreement of the Company and the Major Members signed by or on behalf of each of the Company and the Major Members, provided, that, notwithstanding the foregoing, any right of a party hereto may be waived by such party on its own behalf, without the consent of any other party.

26.2 Binding Effect. Any modification or amendment to this Agreement pursuant to this Section 26 shall be binding on all parties hereto (and any future parties from time to time that have executed and delivered a deed of adherence substantially in the form set out in Schedule 11.6).

27. GENERAL

27.1 Successors; Governing Law. This Agreement shall be binding upon the executors, administrators, estates, heirs and legal successors of MeiraGTx, Hologen and any other Members and permitted assigns of MeiraGTx, Hologen and any other Members. This Agreement and the rights of the parties hereunder arising out of or related to this Agreement or the transactions contemplated hereunder shall be governed by and construed in accordance with the laws of England and Wales, without regard to any conflicts-of-laws principles that would cause the application of laws of any jurisdiction other than those of England and Wales.

27.2 Notices. All notices and other communications required or permitted hereunder shall be in writing must be delivered, given or otherwise provided (a) by hand (in which case, it will be effective upon delivery if received by the recipient before 5:00 P.M. local time at the recipient's location on a business day, otherwise effective the next business day), (b) by facsimile (in which case, it will be effective upon receipt of confirmation of good transmission), so long as such notice is also delivered by mail, postage prepaid, (c) by email (in which case, it will be effective upon transmission), so long as such notice is also delivered by mail, postage prepaid or (d) by overnight delivery by a nationally recognized, reputable courier service (in which case, it will be effective on the business day after being deposited with such courier service), in each case addressed (i) if to MeiraGTx, Hologen and any other Member, at the address, facsimile number or email address, as applicable, of MeiraGTx, Hologen or such Member designated herein below or at such other address, facsimile number or email address as MeiraGTx, Hologen or such Member shall have furnished to the Company in writing as the address, facsimile number or email address to which notices are to be sent hereunder and (ii) if to the Company or to the Board of Directors, to it at:

To MeiraGTx:

[***]

To Hologen:

[***]

To Company:

[***]

27.3 Severability. If any provision of this Agreement is determined by a court to be invalid or unenforceable, that determination shall not affect the other provisions hereof, each of which shall be construed and enforced as if the invalid or unenforceable portion were not contained herein. Such invalidity or unenforceability shall not affect any valid and enforceable application thereof, and each such provision shall be deemed to be effective, operative, made, entered into or taken in the manner and to the full extent permitted by law. Notwithstanding the foregoing, if any such invalidity or unenforceability shall deprive any party hereto of a material portion of the benefits intended to be provided to such party hereby, the parties shall in good faith seek to negotiate a substitute benefit for such Person, it being understood that it is possible that no such

substitute benefit is susceptible to being negotiated or given, in which event the other provisions of this Section 27.3 shall continue to apply.

27.4 Construction. The parties agree that they have been represented by, or had the opportunity to consult with, counsel during the negotiation and execution of this Agreement and have together drafted this Agreement and, therefore, waive the application of any law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the party drafting such agreement or document.

27.5 Table of Contents, Headings. The table of contents and headings used in this Agreement are used for administrative convenience only and do not constitute substantive matter to be considered in construing this Agreement.

27.6 No Third Party Rights. Except as expressly provided herein, including with respect to the rights set forth in Section 22, the provisions of this Agreement are solely for the benefit of the Company, the Board of Directors, MeiraGTx, Hologen and any other Members, and no other Person, including creditors of the Company, shall have any right or claim against the Company, the Board of Directors, MeiraGTx, Hologen and any other Member by reason of this Agreement or any provision hereof or be entitled to enforce any provision of this Agreement.

27.7 Entire Agreement. This Agreement, the Share Purchase Agreement, the Subscription Letters, that certain guarantee letter between Hologen, MeiraGTx Holdings plc, an Affiliate of MeiraGTx, and certain investors a party thereto, and the other agreements contemplated hereby constitute the entire agreement of MeiraGTx, Hologen and any other Members and their Affiliates relating to the Company and supersede all prior meetings, communications, representations, negotiations, contracts or agreements (including any prior drafts thereof) with respect to the Company, whether oral or written, none of which shall be used as evidence of the parties' intent.

27.8 Effect of Waiver or Consent. A waiver or consent, express or implied, to or of any breach or default by any Person in the performance by that Person of its obligations with respect to the Company is not a consent or waiver to or of any other breach or default in the performance by that Person of the same or any other obligations of that Person with respect to the Company. Failure on the part of a Person to complain of any act of any Person or to declare any Person in default with respect to the Company, irrespective of how long that failure continues, does not constitute a waiver by that Person of its rights with respect to that default until the applicable statute-of-limitations period has run.

27.9 Counterparts and Electronic Delivery. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, may be executed in one or more counterparts, all of which shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a facsimile machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

27.10 Jurisdiction and Venue.

(a) Each party irrevocably agrees that the Courts of England shall have exclusive jurisdiction in relation to any dispute or claim arising out of or in connection with this Agreement or its subject matter, existence, negotiation, validity, termination or enforceability (including non-contractual disputes or claims).

(b) To the extent not prohibited by applicable law, each party hereto waives and agrees not to assert, by way of motion, as a defense or otherwise, in any such proceeding brought in the above-named court, any claim that such party is not subject personally to the jurisdiction of such court, that such party's property is exempt or immune from attachment or execution, that such proceeding is brought in an inconvenient forum, that the venue of such proceeding is improper, or that this Agreement or the subject matter thereof, may not be enforced in or by such court.

27.11 Business Days. If any time period for giving notice or taking action hereunder expires on a day which is a Saturday, Sunday, or public holiday in London, England or New York, United States of America, then the time period shall automatically be extended to the business day immediately following such Saturday, Sunday or public holiday.

27.12 Currency.

(a) In this Agreement a reference to "$", "USD" or "Dollars" is to the lawful currency of the United States of America. A reference to "£", "GBP" or "Pounds" is to the lawful currency of England.

(b) Any amount to be converted from Dollars to Pounds or vice versa for the purposes of this Agreement shall be converted into an equivalent amount of the second currency at the Barclays FX spot rate.

27.13 Survival. Section 1 (Definitions), Section 17.4 (Non-Disclosure) and Section 22 (Indemnification) shall survive and continue in full force in accordance with their terms notwithstanding any termination of this Agreement or the dissolution of the Company.

27.14 Gender. Any reference to the masculine gender shall be deemed to include the feminine and neuter genders unless the context otherwise requires.

[*Remainder of Page Left Intentionally Blank; Signature Pages Follow*]

SCHEDULE 6.2

COMPLETION ACTIONS

1. MeiraGTx shall deliver or procure the delivery of:

1.1. a copy of the Share Purchase Agreement duly executed by MeiraGTx;

1.2. a stock transfer form in respect of the Sale Shares to be transferred to Hologen pursuant to the Share Purchase Agreement duly executed by MeiraGTx;

1.3. a share certificate, or a suitable indemnity for any lost share certificate(s), in respect of the Sale Shares;

1.4. a copy of the Services Agreement duly executed by MeiraGTx UK Limited and the Company;

1.5. a copy of the MeiraGTx Subscription Letter duly executed by MeiraGTx;

1.6. a copy of the resolutions (whether in the form of minutes or written resolutions) passed by the board of MeiraGTx which approve and authorise the execution and completion of (i) this Agreement, (ii) the Share Purchase Agreement, and (iii) MeiraGTx Subscription Letter; and which approve the form of (iv) the Hologen Option Share Purchase Agreement and (v) the MeiraGTx Option Share Purchase Agreement.

2. The Company shall deliver or procure delivery of written resolutions of the board of the Company which approve the following matters:

2.1. the registration of the transfer of the Sale Shares to Hologen and the entry of Hologen in the register of members of the Company (subject in each case only to the transfer being presented duly stamped);

2.2. the appointment of the initial MeiraGTx Directors and the initial Hologen Directors and the Chairperson of the Board of Directors of the Company;

2.3. entry into the Services Agreement by the Company; and

2.4. the instruction of the secretary of the Company to (i) file with the Registrar of Companies within the prescribed time limits the resolution passed to adopt the New Articles and all other appropriate resolutions and forms relating to the matters provided for in this paragraph 2 of this Schedule 6.2 and (ii) update the company books.

3. Hologen shall deliver:

3.1. a copy of the Share Purchase Agreement duly executed by Hologen;

3.2. a copy of the Hologen Subscription Letter duly executed by Hologen;

3.3. a copy of the resolutions (whether in the form of minutes or written resolutions) passed by the board of Hologen which approve and authorise the execution and completion of (i) this Agreement and (ii) the Share Purchase Agreement.

SCHEDULE 6.2 – ANNEX A

SHARE PURCHASE AGREEMENT

[***]

SCHEDULE 6.2 – ANNEX B

SHARE SUBSCRIPTION LETTER – MEIRAGTX

[***]

SCHEDULE 6.2 – ANNEX C

SHARE SUBSCRIPTION LETTER – HOLOGEN

[***]

SCHEDULE 7

HOLOGEN OPTION SHARE PURCHASE AGREEMENT

[***]

SCHEDULE 8.1

MEIRAGTX OPTION SHARE PURCHASE AGREEMENT

[***]

SCHEDULE 9.3

SERVICES AGREEMENT

[***]

SCHEDULE 11.6

DEED OF ADHERENCE

Reference is made to the Framework Agreement (the "Agreement") dated [·] among MeiraGTx Limited, Hologen Limited and MeiraGTx Manufacturing Limited. Once executed, this deed of adherence (this "Deed") will be supplemental to and will form part of the Agreement, and at no time shall the provisions of this Deed be used to contravene, derogate or detract from the Agreement, unless to the extent otherwise expressly provided in this Deed.

Capitalized terms used but not defined in this Deed shall have the meanings given to such terms in the Agreement.

1. Adherence. For good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the undersigned (the "Adhering Party"), a transferee of Transfer Shares pursuant to the terms of the Agreement, by executing this Deed and upon the satisfaction of the conditions to the admission of the Adhering Party as a Member pursuant to Section 11.6 of the Agreement, (a) agrees to become a party to the Agreement as a Member with the same force and effect as if originally named [MeiraGTx][Hologen] in the Agreement, fully bound by, and subject to, all of the covenants, terms and conditions of the Agreement as though so originally named; and (b) without limiting the generality of the foregoing, assumes all of the rights and obligations of [MeiraGTx][Hologen] under the Agreement, in each case, as of the time of delivery of this Deed, with effect from [date][FOR PERMITTED TRANSFEREES, INCLUDE:; provided that, [MeiraGTx][Hologen] is and shall remain obligated for and will be deemed to have guaranteed, the performance by the Adhering Party of any and all of the obligations of the Adhering Party under the Agreement. The Adhering Party acknowledges that it has received and reviewed a complete copy of the Agreement and of the Articles. The Adhering Party agrees and undertakes to exercise all rights and perform all obligations in a manner consistent with the exercise of such rights (including with respect of voting) and performance of such obligations by [MeiraGTx][Hologen]].

2. Warranties. (a) Each of [MeiraGTx][Hologen] and the Adhering Party warrants to [MeiraGTx][Hologen] and the Company that the warranties made by [MeiraGTx][Hologen] in Section 23 to the Agreement are true and correct as of the date of this Deed with respect to [MeiraGTx][Hologen] and the Adhering Party (i.e., all references in such warranties to a Warranting Party will be deemed to refer to each of [MeiraGTx][Hologen] and the Adhering Party), and (b) each of [MeiraGTx][Hologen] and the Adhering Party additionally and severally warrants to [MeiraGTx][Hologen] that either the Adhering Party is a Permitted Transferee or the Transfer of Shares to the Adhering Party has complied with all applicable provisions in Section 19 of the Agreement.

3. Notices. For purposes of Section 27.2 of the Agreement, the notice information of the Adhering Party shall be (subject to the provisions of such Section 27.2):

   Name: [*Name of Adhering Party*]
   Address: [*Address*]

Attention: [*Name; Title*]

4. Governing Law. This Deed and its enforcement shall be governed by, and construed and enforced in accordance with, the laws of England and Wales, without regard to any conflicts-of-laws principles that would cause the application of laws of any jurisdiction other than those of England and Wales.

5. Counterparts. This Deed may be executed in more than one counterpart, each of which upon execution and delivery will constitute an original and all of which when taken together will constitute one agreement.

6. Other Terms and Agreements. Sections 1, 26 and 27 of the Agreement are deemed to be incorporated in this Deed and shall apply *mutatis mutandis*.

Executed as a **DEED** by
[**Adhering Party]**
acting by a director in the presence of:

_____
Director

Witness' signature: _____

Name (print): _____

Name (print): _____

Occupation: Address: _____

[*Remainder of Page Left Intentionally Blank; Signature Pages Follow*]

IN WITNESS WHEREOF, the parties intending to be bound have caused this Agreement to be executed and delivered as a DEED on the date specified at the beginning of this Agreement by their duly authorized representatives.

Executed as a **DEED** by **MEIRAGTX MANUFACTURING LIMITED** acting by a director in the presence of:	/s/ Alexandria Forbes Director
Witness' signature:	/s/ Robert Wollin
Name (print):	Robert Wollin
Occupation:	[***]
Address:	[***]

[Signature page to Framework Agreement]

Executed as a **DEED** by **MEIRAGTX LIMITED** acting by a director in the presence of:	/s/ Alexandria Forbes
	Director
Witness' signature:	/s/ Robert Wollin
Name (print):	Robert Wollin
Occupation:	[***]
Address:	[***]

[Signature page to Framework Agreement]

Executed as a **DEED** by **HOLOGEN LIMITED** acting by a director in the presence of:	/s/Andrew Henton Director
Witness' signature:	/s/ Jamie Oldfield
Name (print):	Jamie Oldfield
Occupation:	[***]
Address:	[***]

[Signature page to Framework Agreement]

MEIRAGTX HOLDINGS PLC

INSIDER TRADING COMPLIANCE POLICY

This Insider Trading Compliance Policy (this "***Policy***") consists of seven sections:

- Section I provides an overview;
- Section II sets forth the policies of the Company prohibiting insider trading;
- Section III consists of procedures that have been put in place by the Company to prevent insider trading;
- Section IV explains insider trading;
- Section V sets forth additional transactions that are prohibited by this Policy;
- Section VI explains Rule 10b5-1 trading plans and provides information about Rule 144; and
- Section VII refers to the execution and return of a certificate of compliance.

I. SUMMARY

Preventing insider trading is necessary to comply with securities laws and to preserve the reputation and integrity of MeiraGTx Holdings plc (the "***Company***") as well as that of all persons affiliated with the Company. "Insider trading" occurs when any person purchases or sells a security while in possession of inside information relating to the security. As explained in Section IV below, "inside information" is information that is both "material" and "non-public." Insider trading is a crime. The penalties for violating insider trading laws include imprisonment, disgorgement of profits, civil fines, and significant criminal fines. Insider trading is also prohibited by this Policy, and violation of this Policy may result in Company-imposed sanctions, including termination of employment or service for cause.

This Policy applies to all directors, officers and other employees of the Company and its subsidiaries, as well as those contractors and consultants of the Company and its subsidiaries that have entered into a consulting agreement with the Company or its subsidiaries (collectively, "***Company Personnel***"). Company Personnel are responsible for ensuring that members of their households also comply with this Policy. This Policy also applies to any persons' securities or any entities over which the Company Personnel has control, including any corporations, partnerships, trusts or other entities (such persons and entities, collectively "***Related Parties***" and, together with all Company Personnel, collectively "***Covered Persons***"), and transactions by these persons and entities should be treated for the purposes of this Policy and applicable securities laws as if they were for such Company Personnel's own account. This Policy extends to all activities within and outside an individual's Company duties. All Company Personnel must review this Policy and

certify that they have read and understand its provisions. Questions regarding the Policy should be directed to the Company's General Counsel.

As explained in more detail in Section III below, **all transactions in the Company's securities (including without limitation, acquisitions and dispositions of Company shares, gifts, the exercise of share options, the sale of Company shares issued upon exercise of share options or vesting of equity awards and the sale of shares acquired through the Company's employee share purchase plan) by Covered Persons must be pre-cleared** by the Company's General Counsel or his or her designee.

II. STATEMENT OF POLICIES PROHIBITING INSIDER TRADING

No Covered Person (or any other person designated as subject to this Policy) shall purchase or sell any type of security while in possession of material, non-public information relating to the issuer of such security, whether the issuer of such security is the Company or any other company. Accordingly, Company Personnel who learn of material, non-public information about the Company may not trade in the Company's securities until the information becomes public or is no longer material.

Further, no Company Personnel shall purchase or sell any security of any other company, including another company in the Company's industry, on the basis of material, non-public information obtained in the course of their employment or service with the Company. For example, if Company Personnel learns of material, non-public information about another company with which the Company does business, including a business partner or collaborator, such Company Personnel may not trade in such other company's securities until the information becomes public or is no longer material.

Additionally, certain Company Personnel are designated from time to time by the Board of Directors, the Chief Executive Officer or the General Counsel as being subject to quarterly blackout periods, which also applies to their Related Parties ("*Blackout Persons*"). Such Blackout Persons are prohibited from purchasing or selling any security of the Company during the period beginning at 11:59 p.m., Eastern time, on the seventh calendar day before the end of any fiscal quarter of the Company and ending upon the completion of the second full trading day after the public release of earnings data for such fiscal quarter or during any other trading suspension period declared by the Company. For example, if the Company's fourth fiscal quarter ends at 11:59 p.m., Eastern time, on December 31, the corresponding blackout period would begin at 11:59 p.m., Eastern time, on December 24. For the purposes of this Policy, a "trading day" is a day on which the U.S. national stock exchange on which the Company's securities are traded is open for trading.

Subject to pre-clearance by the General Counsel or his or her designee, the following transactions may be permitted during blackout periods:

- purchases of the Company's securities by a Covered Person from the Company or sales of the Company's securities by a Covered Person to the Company;

- exercises of share options or other equity awards or the surrender or withholding of shares to the Company in payment of the exercise price or in satisfaction of any tax withholding obligations in a manner permitted by the applicable equity award

agreement, or vesting of equity-based awards, that in each case do not involve a market sale of the Company's securities (the "cashless exercise" of a Company share option through a broker or a broker-assisted sale to cover any tax withholding obligations incurred in connection with such exercise or vesting does involve a market sale of the Company's securities, and therefore would not qualify under this exception);

- *bona fide* gifts of the Company's securities; or

- purchases or sales of the Company's securities made pursuant to any binding contract, specific instruction or written plan entered into outside of a blackout period and while the purchaser or seller, as applicable, was unaware of any material, non-public information and which contract, instruction or plan (i) meets all of the requirements of the affirmative defense provided by Rule 10b5-1 ("***Rule 10b5-1***") promulgated under the Securities Exchange Act of 1934, as amended (the "***1934 Act***"), (ii) was pre-cleared in advance pursuant to this Policy and (iii) has not been amended or modified in any respect after such initial pre-clearance without such amendment or modification being pre-cleared in advance pursuant to this Policy. For more information about Rule 10b5-1 trading plans, see Section VI below.

In addition, no Covered Person shall directly or indirectly communicate (or "***tip***") material, non-public information to anyone outside of the Company or to anyone within the Company other than on a need-to-know basis, provided that only designated Company Personnel may disclose material, non-public information outside the Company in connection with their duties and responsibilities as an employee of the Company and in strict accordance with the Company's policies regarding the protection or authorized external disclosure of Company information including, but not limited to, their Employee Confidentiality and Inventions Agreement and the Policy Statement containing Guidelines for Corporate Disclosure. If you are unsure whether you are authorized to disclose material, non-public information, please contact the General Counsel.

III. STATEMENT OF PROCEDURES PREVENTING INSIDER TRADING

The following procedures have been established, and will be maintained and enforced, by the Company to prevent insider trading.

A. Pre-Clearance of All Trades by Covered Persons

To provide assistance in preventing inadvertent violations of applicable securities laws and to avoid the appearance of impropriety in connection with the purchase and sale of the Company's securities, **all transactions in the Company's securities (including without limitation, acquisitions and dispositions of Company shares, gifts, the exercise of share options, the sale of Company shares issued upon exercise of share options or vesting of equity awards and the sale of shares acquired through the Company's employee share purchase plan) by Covered Persons must be pre-cleared** by the Company's General Counsel or his or her designee. Pre-clearance does not relieve anyone of his or her responsibility under SEC rules. **A Covered Person may not enter an order to trade the Company's securities without the prior written approval of the General Counsel or his or her designee.**

A request for pre-clearance must be sent by email to [***] to request approval in advance of the proposed transaction using, or providing the information in, the Pre-Clearance Request form attached hereto as "Attachment B" or as otherwise approved by the General Counsel or his or her designee. The pre-clearance request should include the identity of the Covered Person, the type of proposed transaction (for example, an open market purchase, a privately negotiated sale, an option exercise, etc.), the proposed date of the transaction and the number of shares or options to be involved. **In addition, the Covered Person must state in the e-mail that he, she or it is not aware of material, nonpublic information about the Company.** The General Counsel shall have sole discretion to decide whether to clear any contemplated transaction, provided that the Chief Executive Officer or Chief Financial Officer shall have sole discretion to decide whether to clear transactions by the General Counsel or persons or entities subject to this policy as a result of their relationship with the General Counsel.

All trades that are pre-cleared must be effected within five business days of receipt of the pre-clearance (or, if earlier, prior to the start of a blackout period if the individual is subject to it) unless a specific exception has been granted by the General Counsel (or the Chief Executive Officer or Chief Financial Officer, in the case of the General Counsel or persons or entities subject to this policy as a result of their relationship with the General Counsel). A pre-cleared trade (or any portion of a pre-cleared trade) that has not been effected during the five business day period must be pre-cleared again prior to execution following the same steps set forth above. Notwithstanding receipt of pre-clearance, if the Covered Person becomes aware of material, non-public information or becomes subject to a blackout period before the transaction is effected, the transaction may not be completed.

B. Blackout Periods

Additionally, no Blackout Persons shall purchase or sell any security of the Company during the period beginning at 11:59 p.m., Eastern time, on the seventh calendar day before the end of any fiscal quarter of the Company and ending upon the completion of the second full trading day after the public release of earnings data for such fiscal quarter or during any other trading suspension period declared by the Company, except for purchases and sales made pursuant to the permitted transactions described in Section II. For example, if the Company's fourth fiscal quarter ends at 11:59 p.m., Eastern time, on December 31, the corresponding blackout period would begin at 11:59 p.m., Eastern time, on December 24. The list of Blackout Persons may be updated from time to time by the General Counsel or his or her designee, and the list of Blackout Persons shall be maintained in the Company's records.

Exceptions to the blackout period policy may be approved only by the Company's General Counsel (or, in the case of an exception for the General Counsel or persons or entities subject to this policy as a result of their relationship with the General Counsel, the Chief Executive Officer or Chief Financial Officer or, in the case of exceptions for directors or persons or entities subject to this policy as a result of their relationship with a director, the Board of Directors).

From time to time, the Company, through the Board of Directors, the Chief Executive Officer, the Chief Financial Officer or the General Counsel, may recommend that officers, directors, employees or others suspend trading in the Company's securities because of developments that have not yet been disclosed to the public. If a special blackout period is imposed, the Company will

notify affected individuals. Subject to the exceptions noted above, all of those affected should not trade in the Company's securities while the suspension is in effect, and should not disclose to others that the Company has suspended trading.

If the Company is required to impose a "pension fund blackout period" under Regulation BTR, each director and executive officer shall not, directly or indirectly sell, purchase or otherwise transfer during such blackout period any equity securities of the Company acquired

in connection with his or her service as a director or officer of the Company, except as permitted by Regulation BTR.

C. Post-Termination Transactions

The portions of this Policy relating to trading the Company's securities or the securities of another company while in possession of material non-public information and the use or disclosure of that information continue to apply to transactions even after a Covered Person's service with the Company terminates. As a result, all transactions in the Company's securities (including without limitation, acquisitions and dispositions of Company shares, gifts, the exercise of share options, the sale of Company shares issued upon exercise of share options or vesting of equity awards and the sale of shares acquired through the Company's employee share purchase plan) by Covered Persons must be pre-cleared by the Company's General Counsel or his or her designee in accordance with the procedures set forth above for three months from the date that the Company Personnel's service terminates. If any Company Personnel continues to be in possession of material, non-public information more than three months after his or her service terminates, that individual and his or her Related Parties may not trade in the Company's securities or the securities of another company until that information has become public or is no longer material.

D. Information Relating to the Company

1. *Access to Information*

Access to material, non-public information about the Company, including the Company's business, earnings or prospects, should be limited to Company Personnel on a need-to-know basis. In addition, such information should not be communicated to anyone outside the Company under any circumstances (except in accordance with the Company's policies regarding the protection or authorized external disclosure of Company information) or to anyone within the Company on an other than need-to-know basis.

In communicating material, non-public information to Company Personnel, such Company Personnel must take care to emphasize the need for confidential treatment of such information and adherence to the Company's policies with regard to confidential information.

2. *Inquiries From Third Parties*

Company Personnel are prohibited from responding to inquiries from, or providing material, nonpublic information to, third parties, such as shareholders, industry analysts or members of the media, about the Company unless authorized by the Chief Executive Officer, Chief Financial Officer, General Counsel or unless listed as an authorized person under the Company's Policy Statement Containing Guidelines for Corporate Disclosure. Any such inquiries should be directed to the Chief Financial Officer or the General Counsel.

E. Limitations on Access to Company Information

The following procedures are designed to maintain confidentiality with respect to the Company's business operations and activities.

Company Personnel should take all steps and precautions necessary to restrict access to, and secure, material, non-public information by, among other things:

- maintaining the confidentiality of Company-related transactions;
- conducting their business and social activities so as not to risk inadvertent disclosure of confidential information. Review of confidential documents in public places should be conducted so as to prevent access by unauthorized persons;
- restricting access to documents and files (including computer files) containing material, non-public information to individuals on a need-to-know basis (including maintaining control over the distribution of documents and drafts of documents);
- promptly removing and cleaning up all confidential documents and other materials from conference rooms following the conclusion of any meetings;
- disposing of all confidential documents and other papers, after there is no longer any business or other legally required need, through shredders when appropriate;
- restricting access to areas likely to contain confidential documents or material, non-public information;
- safeguarding laptop computers, mobile devices, tablets, memory sticks, CDs and other items that contain confidential information; and
- avoiding the discussion of material, non-public information in places where the information could be overheard by others such as in elevators, restrooms, hallways, restaurants, airplanes, rideshare vehicles or taxicabs.

Personnel involved with material, non-public information, to the extent feasible, should conduct their business and activities in areas separate from other Company activities.

IV. EXPLANATION OF INSIDER TRADING

*"**Insider trading**"* refers to the purchase or sale of a security while in possession of "material," "non-public" information relating to the security or its issuer.

*"**Securities**"* includes shares, bonds, notes, debentures, options, warrants and other convertible securities, as well as derivative instruments.

*"**Purchase**"* and *"**sale**"* are defined broadly under the federal securities law. *"Purchase"* includes not only the actual purchase of a security, but any contract to purchase or otherwise acquire a security. *"Sale"* includes not only the actual sale of a security, but any contract to sell or otherwise dispose of a security. These definitions extend to a broad range of transactions, including conventional cash-for-share transactions, conversions, the exercise of share options, and acquisitions and exercises of warrants or puts, calls or other derivative securities.

It is generally understood that insider trading includes the following:

- trading by insiders while in possession of material, non-public information;
- trading by persons other than insiders while in possession of material, non-public information, if the information either was given in breach of an insider's fiduciary duty to keep it confidential or was misappropriated; and
- communicating or tipping material, non-public information to others, including recommending the purchase or sale of a security while in possession of such information.

A. What Facts are Material?

The materiality of a fact depends upon the circumstances. A fact is considered "material" if there is a substantial likelihood that a reasonable investor would consider it important in making a decision to buy, sell or hold a security, or if the fact is likely to have a significant effect on the market price of the security. Material information can be positive or negative and can relate to virtually any aspect of a company's business or to any type of security, debt or equity.

Examples of information that could be material include (but are not limited to) information about:

- financial information, including corporate earnings or earnings forecasts;
- possible mergers, acquisitions, tender offers or dispositions;
- major new products or product developments, or pricing;
- gain or loss of a material contract, customer or supplier;
- important business developments such as trial results, developments regarding strategic collaborators or the status of regulatory submissions;
- significant incidents and risks with respect to cybersecurity, data protection and personally identifiable information;
- management or control changes;
- significant financing developments including pending public sales or offerings of debt or equity securities;
- defaults on borrowings;

- bankruptcies; and

- significant litigation or regulatory actions.

Moreover, material information does not have to be related to a company's business. For example, the contents of a forthcoming newspaper column that is expected to affect the market price of a security can be material.

A good general rule of thumb: **When in doubt, do not trade.**

B. What is Non-Public?

Information is "non-public" if it is not available to the general public. In order for information to be considered public, it must be widely disseminated in a manner making it generally available to investors, including, for example, through a national news wire, a broadcast on widely available radio or television programs, publication in a widely available newspaper, magazine or news web site, a Regulation FD-compliant conference call, posting on the Company's web site or public disclosure documents filed with the U.S. Securities and Exchange Commission ("***SEC***") that are available on the SEC's web site.

The circulation of rumors, even if accurate and reported in the media, does not constitute effective public dissemination. In addition, even after a public announcement, a reasonable period of time must lapse in order for the market to react to the information. Generally, one should allow two full trading days following publication as a reasonable waiting period before such information is deemed to be public.

C. Who is an Insider?

"Insiders" include officers, directors and employees of a company and anyone else who has material non-public information about a company, for example, contractors or consultants to a company. Insiders have independent fiduciary duties to their company and its shareholders not to trade on material, non-public information relating to the company's securities. All officers, directors and employees and designated contractors and consultants of the Company should consider themselves insiders with respect to material, non-public information about the Company's business, activities and securities. Such persons may not trade in the Company's securities while in possession of material, non-public information relating to the Company, nor may they tip such information to anyone outside the Company (except in accordance with the Company's policies regarding the protection or authorized external disclosure of Company information) or to anyone within the Company other than on a need-to-know basis.

Individuals subject to this Policy are responsible for ensuring that members of their households also comply with this Policy. This Policy also applies to any entities controlled by individuals subject to the Policy, including any corporations, partnerships, trusts or other entities, and transactions by these entities should be treated for the purposes of this Policy and applicable securities laws as if they were for the individual's own account.

D. Trading by Persons Other than Insiders

Insiders may be liable for communicating or tipping material, non-public information to a third party ("***tippee***"), and insider trading violations are not limited to trading or tipping by insiders. Persons other than insiders also can be liable for insider trading, including tippees who trade on material, non-public information tipped to them or individuals who trade on material, non-public information that has been misappropriated.

Tippees inherit an insider's duties and are liable for trading on material, non-public information illegally tipped to them by an insider. Similarly, just as insiders are liable for the insider trading of their tippees, so are tippees who pass the information along to others who trade. In other words, a tippee's liability for insider trading is no different from that of an insider. Tippees can obtain material, non-public information by receiving overt tips from others or through, among other things, conversations at social, business, or other gatherings.

E. Penalties for Engaging in Insider Trading

The securities laws of the U.S. and many other countries prohibit the purchase or sale of the securities of a company while in possession of material, non-public information about the company. The laws also prohibit the tipping of material, non-public information about a company to a third party who may trade in the securities of the company. The U.S. securities laws in most cases are applicable to non-U.S. individuals subject to this Policy.

Penalties for trading on or tipping material, non-public information can extend significantly beyond any profits made or losses avoided, both for individuals engaging in such unlawful conduct and their employers. For example, the SEC and U.S. Department of Justice have made the civil and criminal prosecution of insider trading violations a top priority. Enforcement remedies available to the government or private plaintiffs under the U.S. federal securities laws include:

- SEC administrative sanctions;
- securities industry self-regulatory organization sanctions;
- civil injunctions;
- damage awards to private plaintiffs;
- disgorgement of all profits;
- civil fines for the violator of up to three times the amount of profit gained or loss avoided;
- civil fines for the employer or other controlling person of a violator (i.e., where the violator is an employee or other controlled person) of up to the greater of $2.166 million (subject to adjustment for inflation) or three times the amount of profit gained or loss avoided by the violator;
- criminal fines for individual violators of up to $5.0 million ($25.0 million for an entity); and
- jail sentences of up to 20 years.

In addition, insider trading could result in serious sanctions by the Company, including for an employee, dismissal, for a contractor or consultant, termination of service or, for a director, a request that such director resign from the Board of Directors of the Company. Insider trading violations are not limited to violations of the securities laws. Other federal, state and local civil or criminal laws, such as the laws prohibiting mail and wire fraud and the U.S. Racketeer Influenced and Corrupt Organizations Act (RICO), also may be violated in connection with insider trading.

F. Size of Transaction and Reason for Transaction Do Not Matter

The size of the transaction or the amount of profit received does not have to be significant to result in prosecution. The SEC has the ability to monitor even the smallest trades, and the SEC performs routine market surveillance. Brokers and dealers are required by law to inform the SEC of any possible violations by people who may have material, non-public information. The SEC aggressively investigates even small insider trading violations.

G. Examples of Insider Trading

Examples of insider trading cases include:

- actions brought against corporate officers, directors, and employees who traded in a company's securities after learning of significant confidential corporate developments;
- friends, business associates, family members and other tippees of such officers, directors, and employees who traded in the securities after receiving such information;
- government employees who learned of such information in the course of their employment; and
- other persons who misappropriated, and took advantage of, confidential information from their employers.

The following are illustrations of insider trading violations. These illustrations are hypothetical and, consequently, not intended to reflect on the actual activities or business of the Company or any other entity.

Trading by Insider

An officer of X Corporation learns that earnings to be reported by X Corporation will decrease dramatically. Prior to the public announcement of such earnings, the officer sells X Corporation's shares. The officer, an insider, would be liable for all losses avoided, as well as penalties of up to three times the amount of all such avoided losses. The officer also is subject to, among other things, criminal prosecution, including up to $5,000,000 in additional fines and 20 years in jail. Depending on the circumstances, X Corporation and the individual to whom the officer reports could also be liable as controlling persons.

Trading by Tippee

An officer of X Corporation tells a friend that X Corporation is about to publicly announce that it has signed an agreement for a major acquisition. This tip causes the friend to

purchase X Corporation's shares in advance of the announcement. The officer is jointly liable with his friend for all of the friend's profits, and each is liable for all civil penalties of up to three times the amount of the friend's profits. The officer and his friend are also subject to criminal prosecution and other remedies and sanctions, as described above.

V. ADDITIONAL PROHIBITED TRANSACTIONS

The Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. Therefore, Company Personnel shall comply with the following policies with respect to certain transactions in the Company securities:

A. Short Sales

Short sales of the Company's securities evidence an expectation on the part of the seller that the securities will decline in value, and therefore signal to the market that the seller has no confidence in the Company or its short-term prospects. In addition, short sales may reduce the seller's incentive to improve the Company's performance. For these reasons, short sales of the Company's securities are prohibited by this Policy. In addition, Section 16(c) of the 1934 Act absolutely prohibits Section 16 reporting persons from making short sales of the Company's equity securities, *i.e.*, sales of shares that the insider does not own at the time of sale, or sales of shares against which the insider does not deliver the shares within 20 days after the sale.

B. Publicly Traded Options

A transaction in options is, in effect, a bet on the short-term movement of the Company's shares and therefore creates the appearance that Company Personnel is trading based on inside information. Transactions in traded options, whether traded on an exchange, on any other organized market or on an over-the-counter market, also may focus the Company Personnel's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in puts, calls or other derivative securities involving the Company's equity securities, on an exchange or in any other organized market or an over-the-counter market, are prohibited by this Policy.

C. Hedging Transactions

Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow Company Personnel to lock in much of the value of his or her shareholdings, often in exchange for all or part of the potential for upside appreciation in the shares. These transactions allow Company Personnel to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, Company Personnel may no longer have the same objectives as the Company's other shareholders. Therefore, all hedging transactions involving the Company's equity securities are prohibited by this Policy.

D. Purchases of the Company's Securities on Margin; Pledging the Company's Securities to Secure Margin or Other Loans

Purchasing on margin means borrowing from a brokerage firm, bank or other entity in order to purchase the Company's securities (other than in connection with a cashless exercise of share options through a broker under the Company's equity plans). Margin purchases of the Company's securities are prohibited by this Policy. Pledging the Company's securities as collateral to secure loans is prohibited. This prohibition means, among other things, that you cannot hold the Company's securities in a "margin account" (which would allow you to borrow against your holdings to buy securities).

E. Partnership Distributions

Nothing in this Policy is intended to limit the ability of a hedge fund, private equity fund, venture capital partnership or other similar entity with which a director is affiliated to distribute Company securities to its partners, members or other similar persons. It is the responsibility of each affected director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances and applicable securities laws.

VI. RULE 10B5-1 TRADING PLANS AND RULE 144

A. Rule 10b5-1 Trading Plans

Rule 10b5-1 can help protect Covered Persons from insider trading liability under Rule 10b5-1 for transactions under a previously established contract, plan or instruction to trade in the Company's shares (a "***Trading Plan***") entered into in good faith and in accordance with the terms of Rule 10b5-1 and all applicable SEC, state and local laws, and Company policies and procedures. Such a Trading Plan will be exempt from the trading restrictions set forth in this Policy. The initiation of, and any modification to, any such Trading Plan will be deemed to be a transaction in the Company's securities, and such initiation or modification is subject to all limitations and prohibitions relating to transactions in the Company's securities. Each such Trading Plan, and any modification or revocation thereof, must be submitted to and pre-approved by the Company's General Counsel, or such other person as the Board of Directors may designate from time to time (the "***Authorizing Officer***"), who may impose such conditions on the implementation and operation of the Trading Plan as the Authorizing Officer deems necessary or advisable. However, compliance of the Trading Plan to the terms of Rule 10b5-1 and the execution of transactions pursuant to the Trading Plan are the sole responsibility of the person initiating the Trading Plan, not the Company or the Authorizing Officer.

Trading Plans do not exempt individuals from complying with Section 16 short-swing profit rules or liability.

Rule 10b5-1 presents an opportunity for insiders to establish arrangements to sell (or purchase) Company shares without the restrictions of trading windows and blackout periods, even when there is undisclosed material information. A Covered Person may enter into a Trading Plan only when he or she is not in possession of material, non-public information, and only during a

trading window period outside of the trading blackout period. Although transactions effected under a Trading Plan will not require further pre-clearance at the time of the trade, any transaction (including the quantity and price) made pursuant to a Trading Plan of a Section 16 reporting person must be reported to the Company promptly on the day of each trade to permit the Company's filing coordinator to assist in the preparation and filing of a required Form 4. Such reporting should be in writing (including by e-mail) and should include the identity of the reporting person, the type of transaction, the date of the transaction, the number of shares involved and the purchase or sale price. However, the ultimate responsibility, and liability, for timely filing remains with the Section 16 reporting person.

The Company reserves the right from time to time to suspend, discontinue or otherwise prohibit any transaction in the Company's securities, including revocation of the Trading Plan, even pursuant to a previously approved Trading Plan, if the Authorizing Officer or the Board of Directors, in its discretion, determines that such suspension, discontinuation, revocation or other prohibition is in the best interests of the Company. Any Trading Plan submitted for approval hereunder should explicitly acknowledge the Company's right to prohibit transactions in the Company's securities. Failure to discontinue purchases and sales as directed shall constitute a violation of the terms of this Section VI.A and result in a loss of the exemption set forth herein.

For clarity, the requirements of this Section VI.A do not apply to any Trading Plan entered into by a hedge fund, private equity fund, venture capital partnership or other similar entity with which a director is affiliated. It is the responsibility of each such entity, in consultation with their own counsel (as appropriate), to comply with applicable securities laws in connection with any Trading Plan.

None of the Company, the General Counsel, the Authorizing Officer, the Company's other employees or any other person will have any liability for any delay in reviewing, or refusal of, a Trading Plan submitted pursuant to this Section VI.A or a request for pre-clearance submitted pursuant to Section III of this Policy. Notwithstanding any review of a Trading Plan pursuant to this Section VI.A or pre-clearance of a transaction pursuant to Section III of this Policy, none of the Company, the General Counsel, the Authorizing Officer, the Company's other employees or any other person assumes any liability for the legality or consequences of such Trading Plan or transaction to the person engaging in or adopting such Trading Plan or transaction.

Ultimately, the responsibility for determining whether an individual is in possession of material, non-public information and avoiding unlawful transactions rests with that individual, and any action on the part of the Company, the General Counsel or any other employee or director pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. Accordingly, you should use your best judgment and consult your personal legal and financial advisors as needed. Anyone looking at your transactions will be doing so with the benefit of hindsight. As a practical matter, you should carefully consider how enforcement authorities and others might view a particular transaction in hindsight before you engage in that transaction.

B. Rule 144

Rule 144 provides a safe harbor exemption to the registration requirements of the Securities Act of 1933, as amended, for certain resales of "restricted securities" and "control securities." "Restricted securities" are securities acquired from an issuer, or an affiliate of an issuer, in a transaction or chain of transactions not involving a public offering. "Control securities" are *any* securities owned by directors, executive officers or other "affiliates" of the issuer, including shares purchased in the open market and shares received upon exercise of share options. Sales of Company restricted and control securities must comply with the requirements of Rule 144, which are summarized below:

- ***Holding Period***. Restricted securities must be held for at least six months before they may be sold in the market.

- ***Current Public Information.*** The Company must have filed all SEC-required reports during the last 12 months or such shorter period that the Company was required to file such reports.

- ***Volume Limitations.*** For affiliates, total sales of the Company's common shares for any three-month period may not exceed the *greater* of: (i) 1% of the total number of outstanding common shares of the Company, as reflected in the most recent report or statement published by the Company, or (ii) the average weekly reported volume of such shares traded during the four calendar weeks preceding the filing of the requisite Form 144.

- ***Method of Sale.*** For affiliates, the shares must be sold either in a "broker's transaction" or in a transaction directly with a "market maker." A "broker's transaction" is one in which the broker does no more than execute the sale order and receive the usual and customary commission. Neither the broker nor the selling person can solicit or arrange for the sale order. In addition, the selling person or Board member must not pay any fee or commission other than to the broker. A "market maker" includes a specialist permitted to act as a dealer, a dealer acting in the position of a block positioner, and a dealer who holds himself out as being willing to buy and sell the Company's common shares for his own account on a regular and continuous basis.

- ***Notice of Proposed Sale.*** For affiliates, a notice of the sale (a Form 144) may be required to be filed with the SEC at the time of the sale. Brokers generally have internal procedures for executing sales under Rule 144 and will assist you in completing the Form 144 and in complying with the other requirements of Rule 144.

If you are subject to Rule 144, you must instruct your broker who handles trades in Company securities to follow the brokerage firm's Rule 144 compliance procedures in connection with all trades.

VII. CERTIFICATION OF COMPLIANCE

After reading this Policy, all officers and employees should certify that they received,

reviewed, understand and will comply with the Policy through the Company's compliance portal (e.g., MasterControl) or, if you are a director, contractor or consultant or you do not otherwise have access to the Company's compliance portal, execute and submit the Certification of Compliance form attached hereto as "Attachment A" and return it to the Company's General Counsel.

* * * * *

Effective Date: December 31, 2022

ATTACHMENT A

MEIRAGTX HOLDINGS PLC

CERTIFICATE OF COMPLIANCE
FOR INSIDER TRADING COMPLIANCE POLICY

CHECK ONE BOX BELOW ONLY

☐

NEW COMPANY PERSONNEL COMPLETING FOR THE FIRST TIME

I have received, reviewed and understand the MeiraGTx Holdings plc Insider Trading Compliance Policy and undertake, as a condition to my present and continued employment with (or, if I am not an employee, affiliation with) MeiraGTx Holdings plc, to comply fully with the policies and procedures contained therein.

☐

CURRENT COMPANY PERSONNEL – ANNUAL RECERTIFICATION

I have received, reviewed and understand the MeiraGTx Holdings plc Insider Trading Compliance Policy and undertake, as a condition to my present and continued employment with (or, if I am not an employee, affiliation with) MeiraGTx Holdings plc, to comply fully with the policies and procedures contained therein.

I hereby certify, to the best of my knowledge, that during the previous calendar year, I have complied fully with all policies and procedures set forth in the above-referenced Insider Trading Compliance Policy.

ATTACHMENT B

MEIRAGTX HOLDINGS PLC

PRE-CLEARANCE REQUEST FORM
INSIDER TRADING COMPLIANCE POLICY

Please complete and return this form (or provide the information called for in this form) via email to [***]

Note – You must pre-clear transactions involving Company securities by you, your spouse, children and relatives sharing your household, as well as transactions involving other entities such as trusts, corporations and partnerships in which you have or share control.

Name of Person Requesting Pre-Clearance _____

I wish to ___buy ____ sell (choose one) _____ ordinary shares of MeiraGTx Holdings plc (the "Company") on _____, 20__ pursuant to:

____ an open market transaction (e.g., on the Nasdaq Stock Market)

____ a privately negotiated transaction

____ a broker-assisted cashless exercise of an employee stock option

____ Other: _____

I confirm that I am not aware of any material, non-public information regarding the Company.

Exhibit 21

SUBSIDIARIES OF MEIRAGTX HOLDINGS PLC

Legal Name of Subsidiary	**Jurisdiction of Organization**
BRI-Alzan, Inc.	Delaware
MeiraGTx B.V.	Netherlands
MeiraGTx Netherlands B.V.	Netherlands
MeiraGTx Limited	England and Wales
MeiraGTx, LLC	Delaware
MeiraGTx UK Limited	England and Wales
MeiraGTx UK II Limited	England and Wales
MeiraGTx Ireland DAC	Ireland
MeiraGTx Neurosciences, Inc.	Delaware
MeiraGTx Bio Inc.	Delaware
MeiraGTx Belgium	Belgium
MeiraGTx Therapeutics, Inc.	Delaware
MeiraGTx Neuro I, LLC	Delaware
MeiraGTx Neuro II, LLC	Delaware
MeiraGTx Manufacturing Limited	England and Wales
MeiraGTx Ocular UK Limited	England and Wales
MeiraGTx Gene Regulation Limited	England and Wales
MeiraGTx Neuro UK Limited	England and Wales

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-276183) of MeiraGTx Holdings plc,

(2) Registration Statement (Form S-3 No. 333-273675) of MeiraGTx Holdings plc,

(3) Registration Statement (Form S-3 No. 333-273672) of MeiraGTx Holdings plc,

(4) Registration Statement (Form S-3 No. 333-232527) of MeiraGTx Holdings plc,

(5) Registration Statement (Form S-3 No. 333-232677) of MeiraGTx Holdings plc,

(6) Registration Statement (Form S-8 No. 333-225535) pertaining to the 2016 Equity Incentive Plan, 2018 Incentive Award Plan and 2018 Employee Share Purchase Plan of MeiraGTx Holdings plc, and

(7) Registration Statement (Form S-8 No. 333-257164) pertaining to the 2018 Incentive Award Plan and 2018 Employee Share Purchase Plan of MeiraGTx Holdings plc;

of our report dated March 13, 2025, with respect to the consolidated financial statements of MeiraGTx Holdings plc included in this Annual Report (Form 10-K) of MeiraGTx Holdings plc for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Jericho, New York
March 13, 2025

Exhibit 31.1

CERTIFICATION

I, Alexandria Forbes, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2024 of MeiraGTx Holdings plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2025

By: /s/ Alexandria Forbes

Alexandria Forbes
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Richard Giroux, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2024 of MeiraGTx Holdings plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2025

By: /s/ Richard Giroux

Richard Giroux
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of MeiraGTx Holdings plc (the "Company") for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 13, 2025

By: /s/ Alexandria Forbes

Alexandria Forbes
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of MeiraGTx Holdings plc (the "Company") for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 13, 2025

By: /s/ Richard Giroux

Richard Giroux
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)