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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2022

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)**

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

Not Applicable
(Former name, former address, and former fiscal year, if changed since last report)

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

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

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, 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 ☒	Small 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2022, the registrant had 44,725,678 ordinary shares, $0.00003881 par value per share, outstanding.

Forward-Looking Statements

This Quarterly Report on Form 10-Q (the "Form 10-Q") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 10-Q that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding expectations regarding meetings with global regulatory authorities and the FDA, product pipeline, anticipated product benefits, goals and strategic priorities, product candidate development and status and expectations relating to clinical trials, growth expectations or targets, pre-clinical and clinical data expectations in respect of collaborations and expectations related to financing arrangements and the intended use of proceeds thereunder, including, in each case, in light of the COVID-19 pandemic, as well as statements that include the words "expect," "will," "intend," "plan," "believe," "project," "forecast," "estimate," "may," "could," "should," "would," "continue," "anticipate" and similar statements of a future or forward-looking nature. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed under "Item 1A. Risk Factors" in this Form 10-Q. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Form 10-Q. Any such forward-looking statements represent management's estimates as of the date of this Form 10-Q. While we may elect to update such forward-looking statements at some point in the future, unless required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. 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. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Form 10-Q.

Risk Factor Summary

We are providing the following summary of the principal risk factors contained in this Form 10-Q 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-Q 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.
- 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.
- We are heavily dependent on the success of our Most Advanced Product Candidates (as defined in "Item 1A. Risk Factors"), which are still in development, and if none of them receive regulatory approval or are successfully commercialized, our business may be harmed.
- The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies, clinical trials, manufacturing capabilities and regulatory approvals.
- It is difficult to predict the time and cost of product candidate development on our novel gene therapy platform. Very few 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 government regulation and other legal obligations relating to privacy and data protection. Compliance with these requirements is complex and costly. Failure to comply 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 will need to expand our organization, and we may experience difficulties in managing this growth, 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.

Preliminary Notes

Unless the context otherwise requires, references in this Form 10-Q to “Meira,” “we,” “us”, “our” and “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-Q that are important to our business. Solely for convenience, the trademarks, trade names and service marks may appear in this Form 10-Q 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-Q are the property of their respective owners.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 114,706	$ 137,703
Accounts receivable - related party	23,701	22,384
Prepaid expenses	10,171	8,102
Tax incentive receivable	4,897	12,634
Other current assets	1,561	2,420
Total Current Assets	155,036	183,243
Property, plant and equipment, net	93,620	75,860
Intangible assets, net	1,293	1,791
In-process research and development	682	783
Other assets	1,322	1,404
Equity method and other investments	6,656	6,656
Right-of-use assets - operating leases, net	19,913	22,782
Right-of-use assets - finance leases, net	22,890	27,645
TOTAL ASSETS	$ 301,412	$ 320,164
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 21,693	$ 15,348
Accrued expenses	24,774	27,586
Lease obligations, current	3,659	3,374
Deferred revenue - related party, current	18,878	21,820
Other current liabilities	3,359	—
Total Current Liabilities	72,363	68,128
Deferred revenue - related party	15,486	43,046
Lease obligations	17,458	20,359
Asset retirement obligations	2,081	2,081
Deferred income tax liability	171	196
Note payable, net	70,845	—
Other long-term liabilities	338	953
TOTAL LIABILITIES	178,742	134,763
COMMITMENTS (Note 10)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 44,725,678 and 44,548,925 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	2	2
Capital in excess of par value	550,168	528,659
Accumulated other comprehensive income (loss)	15,391	(2,671)
Accumulated deficit	(442,891)	(340,589)
Total Shareholders' Equity	122,670	185,401
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 301,412	$ 320,164

See Notes to Condensed Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share amounts)

	For the Three-Month Period Ended September 30,		For the Nine-Month Period Ended September 30,	
	2022	2021	2022	2021
License revenue - related party	$ 4,816	$ 6,948	$ 21,208	$ 16,658
Operating expenses:				
General and administrative	10,762	7,887	32,548	28,214
Research and development	16,862	21,613	63,960	53,512
Total operating expenses	27,624	29,500	96,508	81,726
Loss from operations	(22,808)	(22,552)	(75,300)	(65,068)
Other non-operating income (expense):				
Foreign currency loss	(12,838)	(3,367)	(25,911)	(4,600)
Interest income	288	33	345	188
Interest expense	(1,892)	(59)	(2,051)	(169)
Fair value adjustment	(34)	—	615	—
Net loss	(37,284)	(25,945)	(102,302)	(69,649)
Other comprehensive income:				
Foreign currency translation gain	8,772	2,669	18,062	1,991
Comprehensive loss	$ (28,512)	$ (23,276)	$ (84,240)	$ (67,658)
Net loss	$ (37,284)	$ (25,945)	$ (102,302)	$ (69,649)
Basic and diluted net loss per ordinary share	$ (0.83)	$ (0.59)	$ (2.29)	$ (1.58)
Weighted-average number of ordinary shares outstanding	44,687,635	44,170,299	44,620,900	44,094,873

See Notes to Condensed Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY
FOR THE PERIOD ENDED SEPTEMBER 30, 2022
(unaudited)
(in thousands, except share amounts)

	Ordinary Shares	Amount	Capital in Excess of Par Value	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
Balance at December 31, 2021	44,548,925	$ 2	$ 528,659	$ (2,671)	$ (340,589)	$ 185,401
Share-based compensation activity	161,753	—	4,996	—	—	4,996
Other comprehensive income	—	—	—	1,933	—	1,933
Net loss for the three-month period ended March 31, 2022	—	—	—	—	(31,045)	(31,045)
Balance at March 31, 2022	44,710,678	2	533,655	(738)	(371,634)	161,285
Share-based compensation activity	—	—	7,303	—	—	7,303
Other comprehensive income	—	—	—	7,357	—	7,357
Net loss for the three-month period ended June 30, 2022	—	—	—	—	(33,973)	(33,973)
Balance at June 30, 2022	44,710,678	$ 2	$ 540,958	$ 6,619	$ (405,607)	$ 141,972
Share based compensation activity	15,000	—	6,937	—	—	6,937
Other comprehensive income	—	—	—	8,772	—	8,772
Warrants issued in connection with note payable	—	—	2,273	—	—	2,273
Net loss for the three-month period ended September 30, 2022	—	—	—	—	(37,284)	(37,284)
Balance at September 30, 2022	44,725,678	$ 2	$ 550,168	$ 15,391	$ (442,891)	$ 122,670

See Notes to Condensed Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY
FOR THE PERIOD ENDED SEPTEMBER 30, 2021
(unaudited)
(in thousands, except share amounts)

	Ordinary Shares	Amount	Capital in Excess of Par Value	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Shareholders' Equity
Balance at December 31, 2020	44,189,150	$ 2	$ 504,482	$ (4,897)	$ (261,028)	$ 238,559
Share-based compensation activity	17,923	—	4,958	—	—	4,958
Issuance of shares in connection with equity method and other investments	75,000	—	1,165	—	—	1,165
Other comprehensive loss	—	—	—	(271)	—	(271)
Net loss for the three-month period ended March 31, 2021	—	—	—	—	(23,618)	(23,618)
Balance at March 31, 2021	44,282,073	2	510,605	(5,168)	(284,646)	220,793
Share-based compensation activity	27,380	—	5,422	—	—	5,422
Other comprehensive loss	—	—	—	(407)	—	(407)
Net loss for the three-month period ended June 30, 2021	—	—	—	—	(20,086)	(20,086)
Balance at June 30, 2021	44,309,453	$ 2	$ 516,027	$ (5,575)	$ (304,732)	$ 205,722
Share-based compensation activity	6,932	—	5,393	—	—	5,393
Other comprehensive income	—	—	—	2,669	—	2,669
Net loss for the three-month period ended September 30, 2021	—	—	—	—	(25,945)	(25,945)
Balance at September 30, 2021	44,316,385	$ 2	$ 521,420	$ (2,906)	$ (330,677)	$ 187,839

See Notes to Condensed Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	For the Nine-Month Period Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (102,302)	$ (69,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	21,818	15,359
Foreign currency loss	25,911	4,600
Depreciation and amortization	6,231	5,811
Net change in right-of-use assets and liabilities	(85)	161
Gain on disposal of equipment, furniture and fixtures	(38)	—
Amortization of interest on asset retirement obligations	125	112
Amortization of debt discount	170	—
Fair value adjustment	(615)	—
(Increase) decrease in operating assets:		
Accounts receivable - related party	(2,150)	21,484
Prepaid expenses	(2,838)	(1,827)
Tax incentive receivable	6,518	7,518
Other current assets	578	2,387
Other assets	(111)	(519)
Increase (decrease) in operating liabilities:		
Accounts payable	8,628	3,898
Accrued expenses	944	(2,012)
Other current liabilities	1,593	(23)
Deferred revenue - related party	(21,208)	(16,658)
Net cash used in operating activities	(56,831)	(29,358)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(36,471)	(21,982)
Payment for right-of-use asset	—	(8,866)
Equity method and other investments	—	(5,500)
Net cash used in investing activities	(36,471)	(36,348)
Cash flows from financing activities:		
Exercise of share options	192	414
Payments of withholdings on shares withheld for income taxes	(2,774)	—
Payments on lease obligations - financing leases	—	(1)
Proceeds from Issuance of note payable	75,000	—
Payment of financing fees	(2,051)	—
Net cash provided by financing activities	70,367	413
Net decrease in cash and cash equivalents	(22,935)	(65,293)
Effect of exchange rate changes on cash	(62)	(593)
Cash and cash equivalents at beginning of the period	137,703	209,520
Cash and cash equivalents at end of the period	$ 114,706	$ 143,634
Supplemental disclosure of non-cash transactions:		
Issuance of shares in connection with equity method and other investments	$ —	$ 1,165
Fixed asset acquisition included in accounts payable and accrued expenses at end of the period	$ 7,598	$ 4,027
Right-of-use assets obtained in exchange for lease liabilities	$ 1,793	$ 4,424
Asset retirement obligations incurred in connection with leases	$ 8	$ —
Warrants issued in connection with note payable	$ 2,273	$ —
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 165	$ 57

See Notes to Condensed Consolidated Financial Statements

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation:

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 gene therapy company with six programs in clinical development and a broad pipeline of preclinical and research programs. The Company has core capabilities in viral vector design and optimization and gene therapy manufacturing, as well as a potentially transformative gene regulation technology. Led by an experienced management team, the Company has taken a portfolio approach by licensing, acquiring and developing technologies that give depth across both product candidates and indications. The Company's initial focus is on three distinct areas of unmet medical need: ocular, including both inherited retinal diseases as well as large degenerative ocular diseases, neurodegenerative diseases and severe forms of xerostomia. Though initially focusing on the eye, central nervous system and salivary gland, the Company intends to expand its focus in the future to develop additional gene therapy treatments for patients suffering from a range of serious diseases. The Company also owns and operates a current good manufacturing practices, or cGMP, multi-product, multi-viral vector manufacturing facility in London, United Kingdom ("UK"), which includes fill and finish capabilities and can supply the Company's clinical and potential commercial material. Additionally, the Company expanded its manufacturing and supply chain capabilities by acquiring a second cGMP viral vector manufacturing facility and its first cGMP plasmid and DNA production facility in Shannon, Ireland. The Company completed the acquisition of these facilities in January 2021.

Basis of Presentation

The accompanying condensed 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 Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Interim Financial Statements

The accompanying condensed consolidated financial statements have been prepared in accordance with GAAP for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete consolidated financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary in order to make the condensed consolidated financial statements not misleading. Operating results for the nine-month period ended September 30, 2022 are not necessarily indicative of the final results that may be expected for the year ending December 31, 2022. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Form 10-K").

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 September 30, 2022 totaled $442.9 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, dependence on key personnel and the COVID-19 pandemic and mitigation measures. For the nine-months ended September 30, 2022, the Company used $56.8 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 September 30, 2022, the Company had cash and cash equivalents in the amount of $114.7 million, which consisted of depository accounts and money market accounts. 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 milestone payment of $30.0 million in December 2021. The Company also receives funding for certain research, manufacturing, clinical development and commercialization costs, potential additional milestone payments upon the achievement of such milestones and royalties on future net sales of products. The Company estimates that its cash and cash equivalents on-hand and accounts receivable – related party at September 30, 2022, will be sufficient to cover its expenses for at least the next twelve months from the date of issuance of these condensed 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.

There are also many uncertainties regarding the pandemic caused by the novel coronavirus, or COVID-19, and the Company continues to closely monitor the impact of the pandemic on all aspects of its business, including how the pandemic will impact its financial condition, liquidity, operations, clinical studies, employees, vendors, and industry. While the pandemic did not materially affect the Company's financial results and business operations during the nine-month period ended September 30, 2022, the Company is unable to predict the impact that COVID-19 will have on its financial position and operating results in future periods due to numerous uncertainties. The Company will continue to assess the evolving impact of the COVID-19 pandemic and will make adjustments to its operations as necessary.

The Company's capital resources and operations to date have been funded primarily with the proceeds from the Collaboration Agreement and private and public equity offerings, as well as the proceeds from the financing described in Note 9. 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. The COVID-19 outbreak and mitigation measures also have had, and may continue to have, an adverse impact on global economic conditions, which could have an adverse effect on the Company's ability to raise capital when needed.

2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements:

Certain of the Company's significant accounting policies are described below. All of the Company's significant accounting policies are disclosed in the notes to the audited consolidated financial statements as of and for the year ended December 31, 2021 included in the Company's Form 10-K.

Consolidation

The accompanying condensed 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 ("BRI-Alzan");

MeiraGTx Bio, Inc., a Delaware corporation ("Meira Bio");

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 ("Meira Neuro");

MeiraGTx Therapeutics, Inc., a Delaware corporation ("Meira Therapeutics"); and

MeiraGTx UK Limited, a limited company incorporated under the laws of England and Wales ("Meira UK").

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 condensed 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 condensed consolidated financial statements, management used significant estimates in the following areas, among others: collaboration revenue, the accounting for research and development costs, share-based compensation, valuation of warrants, leases, asset retirement obligations and tax incentive receivable.

Additionally, the Company has made estimates of the impact of the COVID-19 pandemic within the condensed consolidated financial statements and there may be changes to those estimates in future periods. Actual results may differ from these estimates.

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 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	September 30, 2022	Significant Observable Inputs (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable (Level 3)
Cash and cash equivalents	$ 77,907	$ 77,907	$ —	$ —
Other long-term liabilities	$ 338	$ 338	$ —	$ —

		Fair Value Measurement Using:		
Description	December 31, 2021	Significant Observable Inputs (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable (Level 3)
Cash and cash equivalents	$ 66,585	$ 66,585	$ —	$ —
Other long-term liabilities	$ 953	$ 953	$ —	$ —

At September 30, 2022, the Company's financial instruments included cash and cash equivalents, accounts receivable - related party, and accounts payable. The carrying amounts reported in the Company's consolidated financial statements for these instruments approximates their respective fair values because of the short-term nature of these instruments. In addition, at September 30, 2022, the Company believed the carrying value of its Initial Loan (as defined in Note 9) 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 condensed 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.

Leases

The Company accounts for leases in accordance with 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 and lease obligations are included on the Company’s condensed 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 and lease obligations on the Company’s condensed 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 a lease term 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 as other liabilities on the condensed consolidated balance sheet 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 condensed consolidated statements of operations and comprehensive loss.

The change in asset retirement obligations is as follows (in thousands):

	For the Nine-Month Period Ended September 30,	
	2022	2021
Balance at beginning of period	$ 2,081	$ 1,814
Additional asset retirement obligations during the period	8	—
Amortization of interest	125	112
Effects of exchange rate changes	(133)	(10)
Balance at end of period	$ 2,081	$ 1,916

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. To date, the Company has entered into two separate collaboration agreements, both of which are with Janssen, which were determined to be within the scope of 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 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 7 for further information related to the accounting for the Collaboration Agreement.

Revenue Recognition

Arrangements with collaborators may include licenses to intellectual property, research and development services, manufacturing services for clinical and commercial supply, and participation on joint steering committees. 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.

The Collaboration Agreement with Janssen is accounted for under ASC 808, however, as ASC 808 does not address recognition or measurement matters such as determining the appropriate unit of accounting or when the recognition criteria are met, the Company accounts for the consideration received from Janssen in accordance with ASC 606. In accordance with 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 for arrangements that the Company determines are within the scope of ASC 606, it 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, once the contract is determined to be by analogy within the scope of ASC 606, 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.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. 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 condensed 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 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: The Company is incurring research and development costs, with Janssen responsible for up to 100% of the costs, depending on the type of research and development services being performed. The Company records costs associated with the development activities as research and development expenses in the condensed consolidated statements of operations and comprehensive loss consistent with ASC 730, *Research and Development*. The reimbursement of the research and development costs by Janssen is representative of the joint risk sharing nature of the arrangement. The Company considered the guidance in ASC 808 and recognizes the payments received from Janssen as a reduction to research and development expense when the related costs are incurred.

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 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 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 condensed consolidated financial statements as prepaid expenses or accrued expenses, as the case may be.

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 shares 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:

	September 30, 2022	September 30, 2021
Share options	6,968,181	6,141,510
Restricted share units	2,182,500	1,415,000
Restricted ordinary shares subject to forfeiture	28,097	145,000
	9,178,778	7,701,510

Segment Information

Management has concluded it has a single reporting segment for purposes of reporting financial condition and results of operations.

The Company's license revenue, research funding and deferred revenue from its Collaboration Agreement are generated in the United Kingdom.

The following table summarizes long-lived assets by geographical area (in thousands):

	September 30, 2022	December 31, 2021
United States	$ 21,802	$ 23,636
United Kingdom	35,529	43,349
European Union	89,045	69,936
	$ 146,376	$ 136,921

Recent Accounting Pronouncements Adopted

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. The guidance is effective for fiscal years beginning on or after December 15, 2021, with early adoption permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company adopted the new standard as of January 1, 2022. The adoption of the standard had no material impact.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which adds a new Topic 326 to the Codification and removes the thresholds that companies apply to measure credit losses on financial instruments measured at amortized cost, such as loans, receivables, and held-to-maturity debt securities. Under current GAAP, companies generally recognize credit losses when it is probable that the loss has been incurred. The revised guidance will remove all recognition thresholds and will require companies to recognize an allowance for credit losses for the difference between the amortized cost basis of a financial instrument and the amount of amortized cost that the Company expects to collect over the instrument's contractual life. ASU 2016-13 also amends the credit loss measurement guidance for available-for-sale debt securities and beneficial interests in securitized financial assets. The guidance is applicable for fiscal years beginning after December 15, 2019 and interim periods within those years, however, the FASB extended the effective date for smaller reporting companies to fiscal years beginning after December 15, 2022. The Company is currently evaluating the potential impact of the adoption of this standard on its related disclosures.

3. Equity Method and Other Investments

The Company's investments consist of the following (in thousands):

		September 30, 2022		
Investee	Investment Type	Ownership Percentage	Carrying Value	Cost Basis
Visiogene LLC	Equity Method Investment	25 %	$ 5,156	$ 5,165
Other	Equity Investment	3 %	1,500	1,500
Total equity method and other investments			$ 6,656	$ 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.

4. Accrued Expenses

Accrued expenses for the periods presented are comprised of the following (in thousands):

	September 30, 2022	December 31, 2021
Clinical trial costs	$ 17,627	$ 12,524
Manufacturing costs	1,471	2,889
Fixed assets	1,304	2,077
Compensation and benefits	1,516	6,029
Professional fees	1,156	1,018
Consulting	1,120	858
Research and development	180	1,735
Other	400	456
	$ 24,774	$ 27,586

5. 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 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.

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 December 31, 2021 and for the nine-month period ended September 30, 2022 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, 2021	5,924,690	$ 13.16	7.40 years
Granted	1,443,400	$ 18.92	
Exercised	(18,065)	$ 10.61	
Forfeited	(381,844)	$ 17.90	
Outstanding at September 30, 2022	6,968,181	$ 14.12	7.08 years
Options exercisable at September 30, 2022	4,388,802	$ 12.02	6.15 years
Aggregate intrinsic value of options outstanding as of September 30, 2022	$ 3,825		
Aggregate intrinsic value of options exercisable as of September 30, 2022	$ 3,712		

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 annual meeting of shareholders after the date of grant.

The total share-based compensation expense recorded in connection with the options was $3.8 million and $3.6 million, of which $1.3 million and $1.4 million was recorded as general and administrative expense and $2.5 million and $2.2 million was recorded as research and development expense during the three-month periods ended September 30, 2022 and 2021, respectively.

The total share-based compensation expense recorded in connection with the options was $12.3 million and $11.3 million, of which $4.3 million and $4.6 million was recorded as general and administrative expense and $8.0 million and $6.7 million was recorded as research and development expense during the nine-month periods ended September 30, 2022 and 2021, respectively.

The total fair value of options vested during the three-month periods ended September 30, 2022 and 2021 was $2.6 million and $2.5 million, respectively.

The total fair value of options vested during the nine-month periods ended September 30, 2022 and 2021 was $13.6 million and $12.2 million, respectively.

The weighted-average grant date fair value of options granted during the nine-month periods ended September 30, 2022 and 2021 was $13.07 per share and $11.54 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:

	2022	2021
Risk-free interest rate	1.56 - 3.37%	0.62 - 1.14%
Expected volatility	80%	90%
Expected dividend yield	0%	0%
Expected term (in years)	5.5 - 6.1	5.5 - 6.1

As of September 30, 2022, the total compensation expense relating to unvested options granted that had not yet been recognized was $28.9 million, which is expected to be realized over a period of 3.94 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 as of December 31, 2021 and for the nine-month period ended September 30, 2022 is as follows:

	Number of Restricted Share Units		Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2021	1,415,000	$	17.16
Granted	1,180,000	$	20.12
Vested	(397,500)	$	18.40
Forfeited	(15,000)	$	8.25
Outstanding at September 30, 2022	2,182,500	$	18.59

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 June 2022 and future years, the directors may annually elect whether to defer the payment of their annual RSU awards under the Deferred Compensation Plan for Non-Employee Directors. 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 condensed consolidated statements of operations and comprehensive loss.

Total share-based compensation expense recorded in connection with the RSUs was $3.2 million and $1.7 million, of which $2.2 million and $1.5 million was recorded as general and administrative expense and $1.0 million and $0.2 million was recorded as research and development expense during the three-month periods ended September 30, 2022 and 2021, respectively.

Total share-based compensation expense recorded in connection with the RSUs was $9.5 million and $4.1 million, of which $6.7 million and $3.5 million was recorded as general and administrative expense and $2.8 million and $0.6 million was recorded as research and development expense during the nine-month periods ended September 30, 2022 and 2021, respectively.

As of September 30, 2022, the total compensation expense relating to unvested RSUs granted that had not yet been recognized was $29.9 million, which is expected to be realized 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 nine months ended September 30, 2022, the Company withheld 128,812 ordinary shares with a total value of approximately $2.8 million. No shares were withheld during the nine months ended September 30, 2021. These amounts are presented as a cash outflow from financing activities in the accompanying consolidated statement of cash flows.

During the nine-month period ended September 30, 2022 and 2021, the Company recognized total share-based compensation expense in the accompanying condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three-Month Period Ended September 30,	
	2022	2021
Research and development	$ 3,482	$ 2,436
General and administrative	3,455	2,903
Total share-based compensation	$ 6,937	$ 5,339

	Nine-Month Period Ended September 30,	
	2022	2021
Research and development	$ 10,780	$ 7,273
General and administrative	11,038	8,086
Total share-based compensation	$ 21,818	$ 15,359

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 nine-month periods ended September 30, 2022 and 2021.

6. Income Taxes

The Company did not record a provision for income taxes for the three-month and nine-month periods ended September 30, 2022 and 2021, as the Company has generated losses for all periods.

The Company periodically evaluates the realizability of its deferred tax assets based on all available evidence, both positive and negative. The realization of deferred tax assets is dependent on the Company's ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. The Company weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on its deferred tax assets (after consideration of the reversal of the deferred tax liabilities for the ROU assets and fixed assets) in the United States, United Kingdom, Ireland and Netherlands as of September 30, 2022. Should the Company determine that it would be able to realize its remaining deferred tax assets in the foreseeable future, an adjustment to its remaining deferred tax assets would cause a material increase to income in the period such determination is made.

7. Related-Party Transactions

Collaboration and License Agreements

Janssen Pharmaceuticals, Inc.

On January 30, 2019, the Company entered into a Collaboration Agreement with Janssen for the research, development and commercialization of gene therapies for the treatment of IRDs. Under the agreement, Janssen paid the Company a non-refundable upfront fee of $100.0 million. Janssen and the Company will collaborate to develop the Company's current clinical programs in retinitis pigmentosa and two genetic forms of achromatopsia, and

Janssen has the exclusive right to commercialize these three product candidates ("Clinical IRD Product Candidates") globally.

Pursuant to the Collaboration Agreement, the Company and Janssen also agreed on a research collaboration to develop a pipeline of preclinical inherited retinal disease gene therapy candidates ("Research IRD Product Candidates"). The parties will select and prioritize the Research IRD Product Candidates and Janssen has 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 will continue in effect, on a product-by-product and country-by-country basis, until such time as the royalty terms expire in such country. The Company has determined enforceable rights exist in the Collaboration Agreement as the termination clauses are substantive termination penalties by way of the non-refundable upfront fee and the reversion of any licensed intellectual property granted to Janssen upon the termination of the agreement.

On February 27, 2019, in connection with a private placement, the Company issued 2,898,550 ordinary shares to Johnson & Johnson Innovation – JJDC, Inc. ("JJDC"), the investment arm of Johnson and Johnson and owner of Janssen, on the same terms and conditions as the other investors in the offering. After the offering, JJDC became a related party.

Clinical IRD Product Candidates

Under the Collaboration Agreement, the Company and Janssen will jointly develop Clinical IRD Product Candidates to permit Janssen to commercialize such Clinical IRD Product Candidates under an exclusive license from the Company. In general, the Company will have 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 will manufacture these products in its cGMP manufacturing facility for both clinical and commercial supply. Janssen will pay 100% of the clinical and commercialization costs of the products and the Company is eligible to receive untiered 20% royalties on net sales of products and additional development and commercialization milestones up to $340.0 million.

Research IRD Product Candidates

Under the Collaboration Agreement, the Company and Janssen will collaborate to develop Research IRD Product Candidates, with Janssen paying for the majority of the research costs. Janssen has the right to exclusively license any product coming out of the collaboration at the time of an investigational new drug application ("IND") for an additional fee for each Research IRD Product Candidate. Janssen will then pay 100% of the clinical and commercialization costs for these Research IRD Product Candidates and the Company will receive an untiered royalty on net sales in the high teens as well as development milestones for each Research IRD Product Candidate.

Revenue Recognition under the Collaboration Agreement

The Collaboration Agreement is accounted for under ASC 808, however, ASC 808 does not address recognition or measurement matters. Therefore, the Company will account for the recognition and measurement of consideration under ASC 606. In determining the appropriate amount of revenue to be recognized under ASC 606, the Company performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company evaluated the potential performance obligations in the contract, 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 have been excluded from the initial allocation of transaction price and the Company will account for these options as separate contracts when and if Janssen elects 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 to be included in the transaction price will be updated at each reporting date as a change in estimate. The amount related to the unsatisfied portion will be recognized as that portion is 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 Janssen on a product candidate basis. Janssen's right to purchase exclusive options to obtain certain development, manufacturing and commercialization rights are accounted for separately as they do not represent material rights, based on the criteria of ASC 606. Upon the exercise of any purchased option by Janssen, the contract promises associated with an Option Target would use 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 Janssen and during the year ended December 31, 2021, 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.

During the three-month periods ended September 30, 2022 and 2021, the Company recognized $4.8 million and $6.9 million, respectively, of the deferred revenue – related party as license revenue.

During the nine-month periods ended September 30, 2022 and 2021, the Company recognized $21.2 million and $16.7 million, respectively, of the deferred revenue – related party as license revenue.

The Company also recognized $24.1 million and $16.9 million during the three-month periods ended September 30, 2022 and 2021, respectively, related to the reimbursement of research and development expenses, which were recorded as an offset to research and development expenses.

The Company also recognized $53.4 million and $47.1 million during the nine-month periods ended September 30, 2022 and 2021, respectively, related to the reimbursement of research and development expenses, which were recorded as an offset to research and development expenses.

As of September 30, 2022, the Company expects to recognize the remaining $34.4 million in deferred revenue associated with the non-refundable upfront fee and milestone payment over the estimated research and development period using the cost-to-cost input method over an estimated period of approximately 3.2 years.

A summary of the deferred revenue recognition is as follows (in thousands):

Deferred revenue at December 31, 2020	$ 72,842
Milestone payment from Janssen	30,000
Deferred revenue recognized as license revenue during the year ended December 31, 2021	(37,701)
Effects of exchange rate changes	(275)
Deferred revenue at December 31, 2021	64,866
Deferred revenue recognized as license revenue during the nine-month period ended September 30, 2022	(21,208)
Effects of exchange rate changes	(9,294)
Deferred revenue at September 30, 2022	$ 34,364

Financing Agreement

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"). Perceptive Advisors, LLC is a 15.6% 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, an affiliate of Perceptive. Refer to the discussion in Note 9 for further information related to the accounting for the Financing Agreement.

Leases

ARE Vivarium Lease

Effective May 1, 2019, the Company entered into an operating lease for vivarium space with ARE-East River Science Park, LLC ("ARE"), which was subsequently amended to add additional space within the vivarium. The initial lease had a term of twelve months which automatically renews on an annual basis.

The rent expense under this operating lease was $0.04 million and $0.03 million for the three-month periods ended September 30, 2022 and 2021, respectively, which are included in loss from operations.

The rent expense under this operating lease was $0.1 million and $0.05 million for the nine-month periods ended September 30, 2022 and 2021, respectively.

The Company made cash payments to ARE in connection with this operating lease in the amount of $0.04 million and $0.01 million during the three-month periods ended September 30, 2022 and 2021, respectively.

The Company made cash payments to ARE in connection with this operating lease in the amount of $0.1 million and $0.05 million during the nine-month period ended September 30, 2022 and 2021, respectively.

There were no amounts due to ARE under this operating lease at September 30, 2022 and December 31, 2021.

Kadmon Lease

The Company leased office space on a month-to-month basis from Kadmon Corporation, LLC ("Kadmon").

During the three-month periods ended September 30, 2022 and 2021, the Company incurred and paid rent charges from Kadmon in the amount of $0 and $0.2 million, respectively, which are included in loss from operations.

During the nine-month periods ended September 30, 2022 and 2021, the Company incurred and paid rent charges from Kadmon in the amount of $0 and $0.5 million, respectively, which are included in loss from operations.

This lease has been terminated effective November 12, 2021.

8. 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 under these leases was $1.3 million and $1.3 million for the three-month periods ended September 30, 2022 and 2021, respectively.

Total rent expense under these leases was $4.0 million and $3.7 million for the nine-month periods ended September 30, 2022 and 2021, respectively.

As of September 30, 2022, the Company has short term lease commitments amounting to approximately $0.01 million on a monthly basis for one lease for vivarium space that is on a one-year lease.

During the nine-month period ended September 30, 2022, the Company recognized three operating leases for locations in connection with its clinical trials for its IRD product candidates and office and warehouse space, with initial lease terms between 3 years and 9 years. Certain lease agreements contain provisions for tenant allowances and future rent increases. Payments due under the lease contracts include fixed payments. In conjunction with these operating leases, the Company recognized initial operating lease right-of-use assets in the amount of $1.8 million and corresponding lease liabilities in the amount of $1.8 million which are included in the right-of-use assets and lease obligations in the condensed consolidated balance sheets as of September 30, 2022.

The components of lease cost for the three-month and nine-month periods ended September 30, 2022 and 2021 are as follows (in thousands):

	Three-Month Period Ended September 30,	
	2022	2021
Finance lease cost		
Amortization of right-of-use assets	$ 257	$ 305
Interest on lease liabilities	—	—
Total finance lease cost	257	305
Operating lease cost	1,311	1,293
Short-term lease cost	39	182
Total lease cost	$ 1,607	$ 1,780

	Nine-Month Period Ended September 30,	
	2022	2021
Finance lease cost		
Amortization of right-of-use assets	$ 825	$ 927
Interest on lease liabilities	1	1
Total finance lease cost	826	928
Operating lease cost	3,986	3,715
Short-term lease cost	115	640
Total lease cost	$ 4,927	$ 5,283

Amounts reported in the condensed consolidated balance sheets for leases where the Company is the lessee as of September 30, 2022 and December 31, 2021 were as follows (in thousands):

	September 30, 2022	December 31, 2021
Operating leases		
Right-of-use asset	$ 19,913	$ 22,782
Capitalized lease obligations	$ 21,117	$ 23,721
Finance leases		
Right-of-use asset	$ 22,890	$ 27,645
Capitalized lease obligations	$ —	$ 12
Weighted-average remaining lease term		
Operating leases	5.9 years	6.5 years
Finance leases	176.0 years	176.7 years
Weighted-average discount rate		
Operating leases	8.5 %	8.5 %
Finance leases	8.0 %	8.0 %

Other information related to leases for the three-month and nine-month periods ended September 30, 2022 and 2021 are as follows (in thousands):

	Three-Month Period Ended September 30, 2022	2021
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from finance leases	$ 4	$ 4
Operating cash flows from operating leases	$ 1,309	$ 1,234
Financing cash flows from finance leases	$ —	$ —
Right-of-use assets obtained in exchange for lease liabilities		
Operating leases	$ —	$ —
Finance leases	$ —	$ —

	Nine-month periods ended September 30, 2022	2021
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from finance leases	$ 11	$ 12
Operating cash flows from operating leases	$ 4,044	$ 3,678
Financing cash flows from finance leases	$ —	$ 1
Right-of-use assets obtained in exchange for lease liabilities		
Operating leases	$ 1,793	$ 4,424
Finance leases	$ —	$ —

Future minimum lease payments under non-cancellable leases as of September 30, 2022 are as follows (in thousands):

	Operating Leases	Finance Leases
2022	$ 1,311	$ —
2023	5,353	—
2024	5,237	—
2025	5,207	—
2026	4,912	—
Thereafter	4,313	—
Total undiscounted lease payments	$ 26,333	$ —
Less: Imputed interest	(5,216)	—
Total lease liabilities	$ 21,117	$ —

9. Financing Agreement

On August 2, 2022 the Company, as borrower, and the Subsidiary Guarantors, entered into the Financing Agreement by and among the Company, the Subsidiary Guarantors, the lenders and other parties from time to time party thereto and Perceptive, as administrative agent and lender.

The Financing Agreement provides for an initial $75.0 million term loan (the “Initial Loan”), and the Company may request an additional $25.0 million term loan tranche to be made available at Perceptive’s sole discretion before August 2, 2024. The Financing Agreement matures on August 2, 2026 and is interest-only during the term. The Company has the option to prepay outstanding principal borrowings at any time along with an applicable early prepayment fee. Outstanding borrowings under the Financing 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 13.04% at September 30, 2022. As of September 30, 2022, the outstanding balance of the term loan was $75.0 million plus accrued interest of $1.6 million.

The Company’s obligations under the Financing 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 Financing Agreement imposes covenants that include, among other things, enrolling in a Phase III trial for AAV-RPGR on or before June 30, 2023, and ensuring the Company’s Shannon manufacturing facility meets or satisfies all applicable good manufacturing practice requirements on or before December 31, 2023, as well as various 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.

In connection with 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 Financing Agreement totaling $2.1 million, which were recorded as a discount to the loan. The aggregate discount of $4.3 million is being amortized to interest expense over the term of the Financing Agreement. The Company amortized $0.2 million of the discount to

interest expense during the three and nine months ended September 30, 2022. At September 30, 2022, the remaining unamortized discount was $4.2 million.

10. Commitments

There were no new material commitments entered into during the nine-month period ended September 30, 2022.

11. Subsequent Event

On November 9, 2022, the Company entered into a securities purchase agreement with JJDC pursuant to which the Company, in a private placement, agreed to issue and sell to JJDC an aggregate of 3,742,514 ordinary shares at a purchase price of $6.68 per share, for gross proceeds of approximately $25.0 million (the “Private Placement”).

In connection with the Private Placement, the Company intends to enter into a registration rights agreement whereby the Company will be obligated to prepare and file with the Securities and Exchange Commission a registration statement to register for resale the shares within 180 days of executing the registration rights agreement. The Company shall use reasonable best efforts to have the registration statement declared effective as soon as practicable.

Item 2. 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 related notes appearing in this Quarterly Report on Form 10-Q ("Form 10-Q") and those included in our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-Q, 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 "Risk Factors" section of this Form 10-Q, 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. Unless the context requires otherwise, references in this Management's Discussion and Analysis of Financial Condition and Results of Operations to the "Company," "we," "us" and "our" refer to MeiraGTx Holdings plc and its subsidiaries.

Overview

We are a vertically integrated, clinical-stage gene therapy company with six programs in clinical development and a broad pipeline of preclinical and research programs. We have core capabilities in viral vector design and optimization, gene therapy manufacturing, as well as a potentially transformative gene regulation technology. Led by an experienced management team, we have taken a portfolio approach by licensing, acquiring and developing technologies that give us depth across both product candidates and indications. Our initial focus is on three distinct areas of unmet medical need: ocular, including both inherited retinal diseases as well as large degenerative ocular diseases, neurodegenerative diseases, and severe forms of xerostomia. Though initially focusing on the eye, central nervous system and salivary gland, we intend to expand our focus in the future to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

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 cGMP 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, 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, option and license agreement with Janssen Pharmaceuticals, Inc. ("Janssen"), one of the Janssen Pharmaceuticals Companies of Johnson & Johnson (the "Collaboration Agreement"), which also provides us with research funding. Through September 30, 2022, we received gross proceeds of approximately $446.0 million from sales of our ordinary shares, Series A ordinary shares and convertible preferred C shares, $130.0 million from the Collaboration Agreement, and $75.0 million from the debt financing further described under "Liquidity and Capital Resources." As of September 30, 2022, we had cash and cash equivalents of $114.7 million, as well as $23.7 million in receivables due from Janssen that we expect to collect in the fourth quarter of 2022, in connection with the Collaboration Agreement.

We are a clinical stage company and have not generated any product revenues to date. We have six clinical programs and a pipeline of preclinical programs. Since inception, we have incurred significant operating losses. Our net losses for the three-month periods ended September 30, 2022 and 2021 were $37.3 million and $25.9 million, respectively. For the nine-month periods ended September 30, 2022 and 2021, our net losses were $102.3 million and $69.6 million, respectively. As of September 30, 2022, we had an accumulated deficit of $442.9 million. We do not expect to generate revenue from sales of any products for several years, if at all. 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 are eligible to receive research and development funding and additional potential milestone payments and royalties.

Our total operating expenses for the three-month periods ended September 30, 2022 and 2021 were $27.6 million and $29.5 million, respectively. For the nine-month periods ended September 30, 2022 and 2021, our total operating expenses were $96.5 million and $81.7 million, respectively. While we expect our operating expenses to increase in connection with our ongoing development activities related to our product candidates, including the ongoing Phase 3 Lumeos clinical trial of botaretigene sparoparvovec, formerly referred to as AAV-RPGR, for the treatment of patients with X-linked retinitis pigmentosa (XLRP) and the initiation of a Phase 3 clinical trial of AAV-RPE65 for the treatment of retinal dystrophy associated with mutations in the *RPE65* gene, we believe that certain of these increases will be partially offset by the research funding in connection with the Collaboration Agreement. In addition, 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, as well as for AAV-GAD for the treatment of Parkinson's disease. We also incurred expenses during the nine-month period ended September 30, 2022 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 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 November 9, 2022, we entered into a securities purchase agreement with Johnson and Johnson Innovation – JJDC, Inc., the investment arm of Johnson and Johnson ("JJDC"), pursuant to which we, in a private placement, agreed to issue and sell to JJDC an aggregate of 3,742,514 ordinary shares at a purchase price of $6.68 per share for gross proceeds of approximately $25.0 million (the "Private Placement").

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 and cash equivalents at September 30, 2022 and the research funding and milestone payments we expect to receive under the Collaboration Agreement, together with the proceeds from the Private Placement, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. 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 additional future debt financing or preferred equity or other 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 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 further development of our manufacturing facilities or processes, 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.

Recent Development Highlights and Anticipated Milestones

Botaretigene Sparoparvovec for the Treatment of XLRP:

- In October 2022, we presented positive data from the MGT009 Phase 1/2 clinical trial of the investigational gene therapy botaretigene sparoparvovec (formerly referred to as AAV-RPGR) for the treatment of patients with XLRP with disease-causing variants in the RPGR gene at the American Academy of Ophthalmology (AAO) 2022 Annual Meeting.
- Treatment with botaretigene sparoparvovec was found to have an acceptable safety profile and was well-tolerated, with no dose-limiting events.[1]
- Adverse events (AE) profile was anticipated and manageable, with most AEs related to the surgical delivery procedure, transient and resolved without intervention.[1] A total of three serious adverse events (SAEs) were observed in the overall Phase 1/2 MGT009 clinical study; two SAEs, which were previously reported, were observed in the dose-escalation phase of the study (n=10; one retinal detachment and one panuveitis in the low dose cohort), and a single additional SAE of increased intraocular pressure was observed in the dose escalation phase and resolved with treatment.[1]
- Sustained or increased functional improvements were demonstrated at six months post-treatment in multiple endpoints across each of the three domains of vision -- retinal function, visual function, and functional vision -- in patients treated with botaretigene sparoparvovec when compared to the randomized untreated control arm of the study.[1]
- Further sensitivity analysis was conducted on study participants by applying the Phase 3 LUMEOS (NCT04671433) study eligibility criteria that corroborated the endpoints selected for the Phase 3 study.[1] Currently, the LUMEOS study of botaretigene sparoparvovec for the treatment of patients with XLRP with disease-causing variants in the RPGR gene is actively dosing patients.

[1] Michaelides, M et al. Ph1/2 AAV5-RPGR (Botaretigene Sparoparvovec) Gene Therapy Trial in RPGR-associated X-linked Retinitis Pigmentosa (XLRP). Abstract #30071754. Presented at the 2022 American Academy of Ophthalmology Annual Meeting.

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

- We plan to present data from all four cohorts (n=12) in the unilateral dose escalation Phase 1 AQUAx trial (NCT04043104) as well as data from the bilateral cohorts (n=12) in the fourth quarter of 2022.
- We have met with regulatory agencies and are incorporating their feedback as we plan to initiate a randomized, double-blind, placebo-controlled Phase 2 study in the coming months with material manufactured in our cGMP facility in London, United Kingdom.

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

- We are now dosing patients in the AAV-GAD Phase 1 study under a new IND using material manufactured in our cGMP facility in London, United Kingdom.
- The objective of the AAV-GAD trial (NCT05603312) is to evaluate the safety and tolerability of AAV-mediated delivery of glutamic acid decarboxylase (GAD) gene transfer into the subthalamic nuclei (STN) of participants with Parkinson's disease.

Riboswitch Gene Control Platform:

- We presented new data from our gene control platforms at the European Society of Gene and Cell Therapy (ESGCT) Annual Congress in October 2022, including our gene regulation technology applied to cell therapy for the first time, in this case the regulation of CAR-Ts.
- Our next generation riboswitch-based gene regulation platform can be used to precisely control gene expression with an unprecedented dynamic range using novel, synthetic and orally delivered small molecules.

Gene Therapy Manufacturing:

- Our wholly-owned facilities have now produced GMP clinical trial material for 6 different indications, using multiple AAV serotypes, including administration into the eye, salivary gland and central nervous system.
- We believe that bringing all aspects of testing and vector production in-house reduces regulatory risk, ensures the highest quality of products, lowers costs, and helps avoid bottlenecks in clinical development.
- In addition to our 30,000-square-foot facility in London, we now have a 150,000-square-foot plant in Shannon, Ireland which contains three facilities: one built to be flexible and scalable for viral vector production, another to manufacture plasmid DNA – the critical starting material for producing gene therapy products – and third, a Quality Control (QC) hub performing advanced biochemical quality control testing appropriate for commercialization.

Investment by JJDC:

- On November 9, 2022, JJDC purchased $25 million of our ordinary shares in the Private Placement at the closing price of $6.68 per share.

Components of Our Results of Operations

License Revenue

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.

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 expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support increased research and development activities. We have also 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; 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 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 that our research and development expenses will continue to increase substantially for the foreseeable future as we initiate additional preclinical and clinical trials of our existing product candidates, including the ongoing Phase 3 Lumeos trial of botaretigene sparoparvovec for the treatment of patients with XLRP and the initiation of a Phase 3 clinical trial of AAV-RPE65 for the treatment of retinal dystrophy associated with mutations in the *RPE65* gene, and continue to discover and develop additional product candidates. Certain of these increases in research and development costs will be partially offset by the research funding provided in connection with the Collaboration Agreement we entered into in January 2019. In addition, 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.

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;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

- business interruption from the COVID-19 pandemic that may affect any of the foregoing.

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 condensed consolidated financial statements are presented in U.S. dollars, which is our reporting currency. The financial position and results of operations of our subsidiaries MeiraGTx UK II Limited, MeiraGTx Ireland DAC, MeiraGTx Netherlands B.V., MeiraGTx Belgium and MeiraGTx B.V. 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 condensed consolidated statements of operations and comprehensive loss. The Company also has gains and losses on foreign currency exchanges which is also included as part of the foreign currency gains and losses on the condensed consolidated statements of operations and comprehensive loss.

Other comprehensive income (loss)

Other comprehensive income (loss) includes the following:

Foreign currency translation gain (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 condensed consolidated balance sheet date. The resulting translation gain and loss adjustments are recorded directly as a separate component of shareholders' equity and as other comprehensive loss on the condensed 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 condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgements that affect the reporting amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed 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.

The Company's critical accounting policies, significant judgements and estimates are included in the Company's Form 10-K for the year ended December 31, 2021 and Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q.

Results of Operations

Comparison of Three Months Ended September 30, 2022 and 2021

	2022	2021	Change
		(in thousands)	
License revenue - related party	$ 4,816	$ 6,948	$ (2,132)
Operating expenses:			
General and administrative	10,762	7,887	2,875
Research and development	16,862	21,613	(4,751)
Total operating expenses	27,624	29,500	(1,876)
Loss from operations	(22,808)	(22,552)	(256)
Other non-operating income (expense)			
Foreign currency loss	(12,838)	(3,367)	(9,471)
Interest income	288	33	255
Interest expense	(1,892)	(59)	(1,833)
Fair value adjustment	(34)	—	(34)
Net loss	(37,284)	(25,945)	(11,339)
Other comprehensive income:			
Foreign currency translation gain	8,772	2,669	6,103
Total comprehensive loss	$ (28,512)	$ (23,276)	$ (5,236)

License Revenue

License revenue was $4.8 million for the three months ended September 30, 2022, compared to $6.9 million for the three months ended September 30, 2021. This decrease represents decreased amortization of the $100.0 million upfront payment as well as amortization of the $30.0 million milestone payment received in connection with the Collaboration Agreement.

General and Administrative Expenses

General and administrative expenses were $10.8 million for the three months ended September 30, 2022, compared to $7.9 million for the three months ended September 30, 2021. The increase of $2.9 million was primarily due to an increase of $0.9 million in consulting fees, $0.7 million in rent and facilities costs due to additional allocations to research and development, $0.6 million in legal and accounting fees, $0.6 million in share-based compensation, $0.3 million in payroll and payroll-related costs and $0.1 million in depreciation. These increases were partially offset by a decrease of $0.3 million in insurance costs.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2022 were $16.9 million, compared to $21.6 million for the three months ended September 30, 2021. The decrease of $4.7 million was primarily due to a decrease of $0.6 million in license fees, $0.4 million in rent and facilities costs, $0.9 million reduction of the estimated research and development tax credit refund and an increase of $7.1 million in research funding provided under our Collaboration Agreement with Janssen. These decreases were partially offset by an increase of $1.3 million in payroll and payroll-related costs, $1.0 million in share-based compensation, $1.0 million in costs related to the manufacture of material for our clinical trials and $1.0 million in costs related to our pre-clinical research and clinical trials.

Foreign Currency Loss

Foreign currency loss was $12.8 million for the three months ended September 30, 2022 compared to a loss of $3.4 million for the three months ended September 30, 2021. The increase in the loss of $9.4 million was primarily due to

an unrealized loss on the quarterly valuation of our intercompany payables and receivables due to the strengthening of the U.S. dollar against the pound sterling and euro during the three months ended September 30, 2022.

Interest Expense

Interest expense was $1.9 million for the three months ended September 30, 2022 compared to $0.1 million for the three months ended September 30, 2021. The increase of $1.8 million was primarily due to the interest accrued and amortization of the debt discount in connection with the Initial Loan entered into on August 2, 2022.

Fair Value Adjustments

Fair value adjustment was $0.03 million for the three months ended September 30, 2022. There was no fair value adjustment for the three months ended September 30, 2021. The adjustment relates to 40,138 ordinary shares that are to be issued 18 months following our acquisition of Bullseye Therapeutics, Inc. on October 4, 2021, provided that we do not submit certain indemnification claims under the merger agreement. The 40,138 ordinary shares were valued as a liability at a fair value of $0.3 million on June 30, 2022. The liability was revalued to $0.33 million based upon the closing price of the Company's ordinary shares of $8.41 per share on September 30, 2022.

Other Comprehensive Income – Foreign Currency Translation Gain

Foreign currency translation adjustments resulted in a translation gain of $8.8 million for the three months ended September 30, 2022 compared to a translation gain of $2.7 million for the three months ended September 30, 2021. The increase in the gain of $6.1 million was primarily due to a strengthening of the U.S. dollar against the pound sterling and euro during the three months ended September 30, 2022.

Comparison of Nine Months Ended September 30, 2022 and 2021

	2022	2021	Change
		(in thousands)	
License revenue - related party	$ 21,208	$ 16,658	$ 4,550
Operating expenses:			
General and administrative	32,548	28,214	4,334
Research and development	63,960	53,512	10,448
Total operating expenses	96,508	81,726	14,782
Loss from operations	(75,300)	(65,068)	(10,232)
Other non-operating income (expense)			
Foreign currency loss	(25,911)	(4,600)	(21,311)
Interest income	345	188	157
Interest expense	(2,051)	(169)	(1,882)
Fair value adjustment	615	—	615
Net loss	(102,302)	(69,649)	(32,653)
Other comprehensive income:			
Foreign currency translation gain	18,062	1,991	16,071
Total comprehensive loss	$ (84,240)	$ (67,658)	$ (16,582)

License Revenue

License revenue was $21.2 million for the nine months ended September 30, 2022, compared to $16.7 million for the nine months ended September 30, 2021. This increase represents increased amortization of the $100.0 million upfront payment received as well as amortization of the $30.0 million milestone payment received in connection with the Collaboration Agreement.

General and Administrative Expenses

General and administrative expenses were $32.5 million for the nine months ended September 30, 2022, compared to $28.2 million for the nine months ended September 30, 2021. The increase of $4.3 million was primarily due to increases of $3.0 million in share-based compensation, $1.3 million in consulting fees, $0.8 million in legal and accounting fees, $0.6 million in payroll and payroll-related costs, $0.3 million in depreciation and $0.1 million in other office related costs. These increases were partially offset by decreases of $1.0 million in insurance and $0.8 million in rent and facilities costs due to additional allocations to research and development during the nine months ended September 30, 2021.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2022 were $64 million, compared to $53.5 million for the nine months ended September 30, 2021. The increase of $10.5 million was primarily due to an increase of $6.2 million in costs related to our pre-clinical research and clinical trials, $5.1 million in payroll and payroll-related costs, $3.5 million in share-based compensation, $2.9 million of costs related to the manufacture of material for our clinical trials, $1.9 million in rent and facilities costs, $0.2 million in depreciation and $0.3 million in other research and development costs. These increases were partially offset by decreases of $2.3 million in license fees, $0.9 million reduction of the estimated research and development tax credit refund, and an increase of $6.4 million in research funding provided under our Collaboration Agreement with Janssen.

Interest Expense

Interest expense was $2.1 million for the nine months ended September 30, 2022 compared to $0.2 million for the nine months ended September 30, 2021. The increase of $1.9 million was primarily due to the interest accrued and amortization of the debt discount in connection with the Initial Loan entered into on August 2, 2022.

Foreign Currency Loss

Foreign currency loss was $25.9 million for the nine months ended September 30, 2022 compared to a loss of $4.6 million for the nine months ended September 30, 2021. The increase in the loss of $21.3 million was primarily due to an unrealized loss on the quarterly valuation of our intercompany payables and receivables due to the strengthening of the U.S. dollar against the pound sterling and euro during the nine months ended September 30, 2022.

Other Comprehensive Income – Foreign Currency Translation Gain

Foreign currency translation adjustments resulted in a translation gain of $18.1 million for the nine months ended September 30, 2022 compared to a translation gain of $2.0 million for the nine months ended September 30, 2021. The increase in the gain of $16.1 million was due to a strengthening of the U.S. dollar against the pound sterling and euro during the nine months ended September 30, 2022.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. For the nine months ended September 30, 2022, we used $56.8 million in cash flows from operations. We did not generate positive cash flows from operations during the period 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, expanding our intellectual property portfolio, and providing general and administrative support for our operations. In addition, on August 4, 2020 we entered into agreements to acquire our second cGMP viral vector manufacturing facility and our first cGMP plasmid and DNA production facility in Shannon, Ireland

to expand our manufacturing and supply chain capabilities. We closed on the acquisition of the first building in August 2020 and on the second building in January 2021. As a result of these incurred and expected costs, 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. In March 2019 and December 2021, we received a $100.0 million upfront payment and a $30.0 million milestone payment, respectively, in connection with the Collaboration Agreement, which also provides us with research funding, and we are eligible to receive potential milestone payments and royalties.

Additionally, 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").

The Financing Agreement provides for an initial $75.0 million term loan (the "Initial Loan"), and we may request an additional $25.0 million term loan tranche to be made available at Perceptive's sole discretion before August 2, 2024 (the "Discretionary Loan", together with the Initial Loan, the "Loans"). The Financing Agreement matures on August 2, 2026 and is interest-only during the term. We have the option to prepay outstanding principal borrowings at any time along with an applicable early prepayment fee. Outstanding borrowings under the Financing 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 Financing Agreement are secured by our London, UK and Shannon, Ireland manufacturing facilities, $3 million of our cash and the bank accounts of the Subsidiary Guarantors, and the issued and outstanding equity interests of the Subsidiary Guarantors.

The Financing Agreement imposes covenants that include, among other things, enrolling in a Phase III trial for AAV-RPGR on or before June 30, 2023, and ensuring the Company's Shannon manufacturing facility meets or satisfies all applicable good manufacturing practice requirements on or before December 31, 2023, as well as various 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 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 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 and cash equivalents at September 30, 2022 and the research funding we expect to receive under the Collaboration Agreement, together with the proceeds from the Private Placement, we estimate that we will be able to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. 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

As of September 30, 2022, we had $114.7 million of cash and cash equivalents.

The following table summarizes our sources and uses of cash and cash equivalents for the period presented:

	For the Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (56,831)	$ (29,358)
Net cash used in investing activities	(36,471)	(36,348)
Net cash provided by financing activities	70,367	413
Net decrease in cash and cash equivalents	$ (22,935)	$ (65,293)

Operating Activities

During the nine months ended September 30, 2022, our cash used in operating activities of $56.8 million was primarily due to a net loss of $102.3 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 non-cash charges of $53.5 million, which consisted primarily of $21.8 million of share-based compensation, $25.9 million of a foreign currency loss, $6.4 million of depreciation and amortization, which was partially offset by a decrease of $0.6 million of a fair value adjustment. Additionally, operating assets, consisting of accounts receivable-related party, prepaid expenses, tax incentive receivable, other current assets and other assets, decreased by $2.0 million and operating liabilities, consisting of accounts payable, accrued expenses, other current liabilities and deferred revenue – related party, decreased by $10.0 million.

During the nine months ended September 30, 2021, our cash used in operating activities of $29.4 million was primarily due to a net loss of $69.6 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 non-cash charges of $26.0 million, which consisted primarily of $15.4 million of share-based compensation, $4.6 million of a foreign currency loss and $5.8 million of depreciation and amortization. Additionally, operating assets, consisting of accounts receivable-related party, prepaid expenses, tax incentive receivable, other current assets, security deposits and other assets, decreased by $29.0 million and operating liabilities, consisting of accounts payable, accrued expenses, deferred revenue – related party and other current liabilities, decreased by $14.8 million.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 of $36.5 million consisted of purchases of property and equipment for our manufacturing, laboratory and process development facilities and buildout costs of our new facilities.

Net cash used in investing activities for the nine months ended September 30, 2021 of $36.3 million consisted primarily of $8.8 million in payments for the acquisition of the second building and long-term lease for our manufacturing facility in Ireland, $5.5 million in connection with equity method and other investments and $22.0 million for purchases of property and equipment for our manufacturing, laboratory and process development facilities and buildout costs of our new facilities.

Financing Activities

Net cash provided by financing activities was $70.4 million for the nine months ended September 30, 2022, which consisted primarily of $73.0 million from the net proceeds from the Initial Loan, and $0.2 million in proceeds from the exercise of share options, which was partially offset by the payment of $2.8 million to cover tax withholding obligations upon the vesting of restricted share unit awards.

Net cash provided by financing activities was $0.4 million for the nine months ended September 30, 2021, which consisted primarily of proceeds from the exercise of share options.

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.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, (the "JOBS Act"), permits an "emerging growth company," which we are, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The following section updates "Item 7A. Quantitative and Qualitative Disclosures of Market Risk" in the Annual Report on Form 10 K for the fiscal year ended December 31, 2021 and should be read in conjunction with that report as well as our condensed consolidated financial statements included in "Part 1, Item 1. Financial Statements" of this Quarterly Report on Form 10-Q.

Foreign Currency Exchange Risk

We currently operate in the United States, the United Kingdom, the Netherlands, Ireland and Belgium. Our activities in these countries 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 September 30, 2022, we did not hold any foreign currency forward contracts. With respect to our foreign currency exposures as of September 30, 2022, we estimate a 10% unfavorable movement in foreign currency exchange rates would have the effect of creating an additional foreign currency loss of approximately $21.3 million within other non-operating income (expense) for the nine months ended September 30, 2022.

Interest Rate Risk

We are exposed to market risk as a result of changes in interest rates applicable to borrowings under our Financing Agreement. Borrowings under the Financing 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 9 to our unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q. 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 September 30, 2022, the annual interest rate was 13.04% and the outstanding balance of the term loan was $75.0 million. Assuming no change in the outstanding borrowings under the Financing Agreement, we estimate that a hypothetical 1% increase in the SOFR would increase our annual interest expense by approximately $0.8 million as of September 30, 2022.

Item 4. 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 our Chief Financial Officer (principal financial officer), evaluated, as of the end of the period covered by this Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15I 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-Q.

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 September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

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-Q. 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, particularly in light of the continually evolving nature of the COVID-19 pandemic, containment measures, vaccine distribution, vaccination rates, new variants and the related impacts to economic and operating conditions.

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 $102.3 million and $69.6 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of approximately $442.9 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, 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, 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 3 Lumeos clinical trial of botaretigene sparoparvovec for the treatment of patients with XLRP and the initiation of a Phase 3 clinical trial of AAV-RPE65 for the treatment of retinal dystrophy associated with mutations in the RPE65 gene, although we believe that certain of these increases will be partially offset by the research funding in connection with the Collaboration Agreement. In addition, 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. 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. Our expenses have and will continue to increase substantially as a public company and as we continue to add clinical, scientific, operational, financial,

manufacturing, compliance and management information systems and personnel, including personnel to support our product development, manufacturing and planned future commercialization efforts.

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 U.S. Food and Drug Administration (the "FDA"), UK Medicines and Healthcare Regulatory Agency (the "MHRA"), European Medicines Agency, (the "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.

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, strategic alliances and licensing arrangements, and the COVID-19 outbreak and mitigation measures. Furthermore, we expect to continue to incur costs associated with operating as 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 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 September 30, 2022, our cash and cash equivalents were $114.7 million. In addition, we expect to receive $23.7 million in receivables which we expect to collect in the fourth quarter of 2022 from Janssen in connection with the Collaboration Agreement. Based on our cash and cash equivalents at September 30, 2022 and the research funding and milestone payments we expect to receive under the Collaboration Agreement, together with the proceeds from the Private Placement, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. 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 ongoing clinical development for our X-linked retinitis pigmentosa product candidate, botaretigene sparoparvovec, including the ongoing Phase 3 Lumeos clinical trial of botaretigene sparoparvovec for the treatment of patients with XLRP, for our CNGB3 achromatopsia gene therapy product candidate, AAV-CNGB3, for our CNGA3 achromatopsia gene therapy product candidate, AAV-CNGA3, for our RPE65-associated retinal dystrophy product candidate, AAV-RPE65, including the initiation of a Phase 3 clinical trial of AAV-RPE65 for the treatment of retinal dystrophy associated with mutations in the RPE65 gene, for our radiation induced xerostomia product candidate, AAV-hAQP1, and to continue to conduct our ongoing natural history studies for inherited retinal diseases, or IRDs;

- the progress, timing, costs and results of our clinical development program for our product candidate for the treatment of Parkinson's disease, AAV-GAD;

- 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 potentially transformative gene regulation technology designed to precisely and specifically control gene therapy expression levels via dose-response to orally delivered small molecules;

- 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 the Financing Agreement, we issued warrants to Perceptive 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 and the Subsidiary Guarantors entered into the Financing Agreement with Perceptive for the Initial Loan of $75 million, with an additional Discretionary Loan of $25 million available at our request and at Perceptive's sole discretion before August 2, 2024. The Loans 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 Financing Agreement matures on August 2, 2026 and is interest-only during the term. The Financing 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 Financing Agreement are secured by our London, UK and Shannon, Ireland manufacturing facilities, $3 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 Perceptive will elect to make the Discretionary Loan available to us or that our cash and cash equivalents available under the Financing 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 Financing 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 Loans 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**.**

We are heavily dependent on the success of our Most Advanced 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, 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 botaretigene sparoparvovec, AAV-GAD, AAV-CNGB3, AAV-CNGA3, AAV-RPE65 and AAV-hAQP1 (the "Most Advanced Product Candidates"), 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. While we have entered into a Collaboration Agreement with Janssen with respect to AAV-CNGB3, AAV-CNGA3 and botaretigene sparoparvovec, pursuant to which we received a $100 million upfront payment and will also receive funding for certain research, manufacturing, clinical development and commercialization costs, potential additional milestone payments upon the achievement of such milestones and royalties on future net sales of products, there can be no assurance that these three product candidates will be successfully developed and commercialized by us and Janssen. We cannot be certain that our Most Advanced 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 Most Advanced 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 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 Most Advanced Product Candidates in the United States until they receive approval of a biologics license application, or BLA, from the FDA, we cannot market them in the United Kingdom, or UK, or European Union, or EU, until we receive approval for a marketing authorization, or 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 other product candidates are based on similar technology as our Most Advanced Product Candidates, 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

The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies, clinical trials, manufacturing capabilities and regulatory approvals.

The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce globally, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; demand for certain goods and services has spiked or fallen; and travel and transport have been restricted.

As a result of the COVID-19 pandemic, we have at times restricted onsite activities, and may continue to restrict onsite activities, to manufacturing functions, laboratory research and certain support activities. We have also experienced some delays in enrolling, treating and monitoring patients in our clinical trials, as well as limited supply chain disruptions. We may experience other disruptions from the COVID-19 pandemic or other pandemic, epidemic or outbreak of an infectious disease that could severely impact our business, preclinical studies, clinical trials and laboratory and manufacturing activities, including:

- 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, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, state, local or foreign governments, employers and others, or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA, MHRA, EMA or other regulatory authorities, which may impact review and approval timelines;

- interruption of, or delays in, the manufacturing of our product candidates due to staffing shortages, governmental restrictions relating to on-site activities, production slowdowns or stoppages and supply chain disruptions;

- slowdowns or problems with the development and completion of our new manufacturing facilities in Shannon, Ireland;

- 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, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and

- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic continues to impact businesses globally and new and more contagious variations of the virus have emerged or may emerge in the future. The extent to which the outbreak may further 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 the 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 the 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. The pandemic and public and private responses to the pandemic may continue to affect economic conditions and may lead to an economic downturn, significant inflation and/or a recession, at a global scale, 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 Financing Agreement.

In addition, we expect the COVID-19 pandemic will continue to affect our employees, our vendors and their employees or the employees of companies with which we do business, which may ultimately disrupt our business operations. We have and will continue to adhere to applicable guidelines and safety measures including work-from-home policies and restricting onsite activities to manufacturing functions, laboratory research and certain support activities as necessary. Employees who are working in our offices are required to quarantine if they are diagnosed with, show symptoms of, or are exposed to someone with, the coronavirus. We may also have to reinstitute a broader work-from-home policy for an undetermined amount of time if COVID-19 cases increase in the jurisdictions where we have offices. An extended period of remote working, whether by our employees, our vendors and their employees or the employees of companies with which we do business may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk due to increases in malware campaigns and phishing attacks exploiting remote workers and preying on the uncertainties surrounding COVID-19, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with regulators, laboratory and manufacturing sites, research or clinical trial sites and other important agencies and contractors.

It is difficult to predict the time and cost of product candidate development on our novel gene therapy platform. Very few 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, very few 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, very few therapeutic products have received marketing authorization from the FDA, 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 Tissues and Advanced Therapies 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 are also subject to review and oversight by an institutional biosafety committee, or IBC, 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 advanced therapy medicinal products, or 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 marketing authorization 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 marketing authorization 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, marketing authorization applications, or MAAs, for ATMPs in Great Britain 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. In Northern Ireland, ATMPs will continue to be authorized according to the EU's centralized procedure. Definitions for individual classes of ATMPs remain unchanged and classification of ATMPs are undertaken by the MHRA in accordance with EU legislation and current guidance from CAT. 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 in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, MHRA, EMA or other regulatory bodies may not consider the clinical trial endpoints 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 agreement with the FDA, MHRA, EMA or other regulatory authorities as to the design or implementation of our clinical trials and obtaining regulatory 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 at each site;
- inability to recruit suitable patients to participate in a clinical trial;
- inability to develop and validate the companion diagnostic to be used in a clinical trial, if applicable;
- delays in sufficiently developing, designing and manufacturing equipment or medical devices used in our clinical trials;
- 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;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements, or applicable regulatory guidelines in other countries;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- having an insufficient number of clinical trial sites; or
- inability to manufacture sufficient quantities of our product candidates for use in clinical trials.

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, such as the COVID-19 pandemic, 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, EMA or other 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, EMA 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 Most Advanced 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.

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 recently evolved. The EU Clinical Trials Regulation, or CTR, adopted in April 2014 became applicable on January 31, 2022 and repeals the EU Clinical Trials Directive. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. 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 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 foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CRO, 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 existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK

chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek an MA in the EU for our product candidates on the basis of clinical trials conducted in the UK.

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.

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, in 2003, trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. Although none of our current product candidates utilize murine gamma-retroviral vectors, 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 new 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 new products that meet certain criteria. Specifically, new drugs and biological products 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. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. For product candidates with Fast Track designation, sponsors may be eligible for more frequent meetings with the FDA to discuss the candidate's development plan and more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers. In addition, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted if relevant criteria are satisfied, including an agreement with FDA on the proposed schedule for the submission of portions of the BLA, and the payment of applicable user fees before FDA may initiate a review. Even if Fast Track designation is granted, it may be rescinded if the product no longer meets the qualifying criteria. In April 2018, botaretigene sparoparvovec was issued Fast Track designation by the FDA for the treatment of X-linked retinitis pigmentosa owing to defects in RPGR. 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. In February 2020, botaretigene sparoparvovec for the treatment of X-linked retinitis pigmentosa owing to defects in RPGR was admitted to the PRIME scheme of the EMA.

A sponsor may also seek a Regenerative Medicine Advanced Therapy, or 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. 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.

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 designed to

accelerate the review and approval of new drugs 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.

We have received orphan drug designation from the FDA and European Commission for AAV-CNGB3, AAV-CNGA3, AAV-RPE65, botaretigene sparoparvovec, AAV-AIPL1, AAV-RDH12 and from the FDA for AAV-hAQP1, and we may seek orphan drug designation for additional product candidates in the future, but any orphan drug 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 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 drug 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 indication for which it has orphan 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 drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following approval for the approved therapeutic indication. This period may be reduced to six years if, at the end of the fifth year, the orphan drug designation criteria are no longer met, including where it is shown that the drug is sufficiently profitable not to justify maintenance of market exclusivity. In the EU, an MA for an orphan designated product will not be granted if a similar drug has been approved in the EU for the same therapeutic indication, unless the applicant can establish that its product is safer, more effective or otherwise clinically superior. A similar drug 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.

Products with an orphan designation in the EU may be considered for a Great Britain orphan marketing authorization. However, where centrally authorized MAs have an existing EU orphan designation, these have been converted into Great Britain MAs and shall continue in effect with the remaining period of orphan market exclusivity. Since the end of the Brexit transition period, there has been no route to obtain pre-MA orphan designation in Great Britain, however, as a result of the implementation of the Protocol on Ireland and Northern Ireland, EU orphan drug designation and time periods of market exclusivity still remain valid for marketing products in Northern Ireland. Instead, the MHRA

now reviews applications for Great Britain orphan designation in parallel with the corresponding MA application. Market exclusivity periods between those approved by the MHRA may vary to products which already have an EU orphan designation.

We have obtained orphan drug designation from the FDA and 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 botaretigene sparoparvovec for the treatment of X-linked retinitis pigmentosa, 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. We may seek orphan drug designation for other current and future product candidates. Even with orphan drug 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 an indication broader than the orphan-designated indication 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 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 condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Likewise, in the EU and Great Britain, the European Commission or MHRA, respectively, can approve a similar product for the same therapeutic indication, if it concludes that the later product is safer, more effective or clinically superior. Orphan drug designation neither 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 for other existing and future product candidates, we may never receive such designations. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded our product candidates in ways that are difficult to predict. It is uncertain how ongoing and future challenges might affect our business.

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 completed the fit-out of our first cGMP manufacturing facility in early 2018 and we completed the acquisition of the buildings for our second cGMP viral vector manufacturing facility and our first cGMP plasmid and DNA production facility in Shannon, Ireland in January 2021 to expand our manufacturing and supply chain capabilities. However, if we experience slowdowns or problems with our completed facility or the development and completion of our new facilities and 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 cGMP. 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. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA, MHRA or other regulatory approval of the products 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. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for 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 facility in London, United Kingdom, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or other related activities in the future. In January 2021, we completed the acquisition of the buildings for our second cGMP viral vector manufacturing facility and our first cGMP plasmid and DNA production facility in Shannon, Ireland. Expanding our manufacturing capacity to produce the preclinical, clinical and commercial supply of our products and their components will require completing the development

and completion of our new facilities in Ireland, substantial additional expenditures, time, and various regulatory approvals and permits, all of which may be impacted by the COVID-19 pandemic. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, including in our new facilities in Ireland. 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 or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMP 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. The natural history studies may 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. 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, such as the COVID-19 pandemic, 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.

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, 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. A proposal for revision of several legislative instruments related to medicinal products (potentially revising the duration of regulatory exclusivity, eligibility for expedited pathways, etc.) is expected to be adopted by the European Commission by the end of 2022. The proposed revisions, once they are agreed and adopted by the European Parliament and European Council (not expected before the end of 2024) may 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 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 foreign regulatory agencies, that such product candidates are safe and effective 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 and / or our collaboration partners, as applicable, obtain FDA, MHRA or European Commission approval for AAV-GAD, botaretigene sparoparvovec, AAV-CNGB3, AAV-CNGA3, AAV-RPE65, AAV-hAQP1 or our other 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 cGMP 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 health care 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 lose any marketing approval that we may have obtained 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, 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, over the last several 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.

Separately, in response to the COVID-19 pandemic, in March 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products and also temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it is safest to conduct prioritized domestic inspections.

Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the U.S. have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 Centers for Medicare & Medicaid Services, or 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. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health

insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payment varies from 1% from April 1, 2022 through June 30, 2022, to up to 3% in the final year of this sequester, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 health care 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.

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 government laws, regulations, standards and other legal obligations relating to data privacy and security. Compliance with these requirements is complex and costly and our actual or perceived failures to comply could materially harm our business.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention and security of personal information.

In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care 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 patient health 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 California Consumer Privacy Act, or CCPA, confers individual privacy rights for California consumers (as such term is defined in the law) and places increased privacy and security obligations on entities handling personal information of consumers or households. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or the CPRA, was passed in California in November 2020. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA, the CPRA 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 General Data Protection Regulation, or GDPR, imposes stringent requirements for processing the personal data of individuals within the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Lichtenstein and Iceland. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or up to 4% of the total worldwide annual turnover of 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. In July 2020, the Court of Justice of the European Union, or CJEU, limited how organizations could lawfully transfer personal data from the EEA to the U.S. by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), or SCCs. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021. Arrangements using the existing standard contractual clauses must be migrated to the revised clauses by December 27,

2022. Upon introduction, the new SCCs were intended to apply only to the transfer of personal data outside of the EEA and not the UK. However, following a public consultation by the UK's Information Commission's Office, revised data transfer mechanisms came into force in March 2022. The revised mechanism provides greater flexibility for international transfers of personal data, and allows for incorporation of EEA SCCs as required. The resultant text permit EEA and UK personal data transfers to be made under one single set of SCCs. For UK transfers, companies are permitted to use legacy SCCs if agreed prior to September 22, 2022, which can remain in place until March 2024. The subject of international transfers continues to be a contentious, complex and mercurial matter globally, and to date regulatory guidance has been correspondingly fluid. There are no certainties for the future stability of international personal data transfer requirements, as global privacy laws continue to develop. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines. 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, since the beginning of 2021, after the end of the transition period following the UK's departure from the EU, we are also subject to the UK data protection regime, 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 company's global annual revenue for the preceding financial year, whichever is greater. 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 and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business 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, Biogen, Inc. 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., Axovant Gene Therapies Ltd. and Prevail Therapeutics Inc. (which was purchased by 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 health care, 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. For example, Janssen will be solely responsible for the commercialization of botaretigene sparoparvovec, AAV-CNGB3 and AAV-CNGA3 pursuant to our Collaboration Agreement with them. 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-GAD, AAV-RPE65, AAV-hAQP1 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, such as under our Collaboration Agreement with Janssen. 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 privacy 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, such as the COVID-19 pandemic, 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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. 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 cGMP and GMP manufacturing facilities are unable to supply our product candidates for all of our current preclinical, clinical and potential commercial needs, we will be forced to seek out third-party manufacturers. We currently contract with third parties for the manufacture of plasmid used in producing our 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 cGMP viral vector manufacturing facility completed in early 2018 and we completed the acquisition of the buildings for our second cGMP viral vector manufacturing facility and our first cGMP plasmid and DNA production facility in Shannon, Ireland in January 2021 to expand our manufacturing and supply chain capabilities. However, if our current facility is damaged, suffers any form of delay or regulatory challenges, we experience slowdowns or problems with the development and completion of our new 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. While we now have our own plasmid manufacturing capabilities in our Shannon, Ireland facilities, we may also rely on third-party manufacturers from time to time for the manufacture of plasmid used in the production of some of our 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, such as the COVID-19 pandemic, 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 cGMP 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 cGMP 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 our Collaboration Agreement with Janssen for the development and commercialization of AAV-CNGB3, AAV-CNGA3 and botaretigene sparoparvovec. We have also entered into a manufacturing research collaboration agreement with Janssen to further develop processes for manufacturing AAV viral vectors. 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 the applicable protocol, legal, quality, regulatory and scientific standards. Our reliance on

these third parties does not relieve us of our regulatory responsibilities. For example, we are conducting the Phase 3 Lumeos clinical trial of botaretigene sparoparvovec for the treatment of patients with XLRP caused by mutations in the RPGR gene at multiple clinical trial sites in North America and Europe. 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, including as a result of the impact of the COVID-19 pandemic, 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.

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 has been registered 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 will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2022, we had 361 employees. We expect to continue to significantly expand our organization, including hiring and training significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations in our new facilities in Ireland. 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, loss of employees and reduced productivity among remaining employees. Our expected 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 expected 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 expected 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.

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, health care 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 trial liability, employment practices liability, property, 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, we intend to acquire insurance coverage to include the sale 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 director and officer 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, 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 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. 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 liability 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. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups, governments and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working 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 information technology 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). 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 information technology 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.

The UK's withdrawal from the EU has resulted in changes to regulatory requirements and has had and may continue to have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our shares.

Following a national referendum and enactment of legislation by the government of the UK, the UK formally withdrew from the EU on January 31, 2020, commonly referred to as "Brexit" and, following the expiry of the Brexit transitional period on December 31, 2020, the UK now operates under a distinct regulatory regime and certain EU laws now only apply to the UK in respect of Northern Ireland (as laid out in the Protocol on Ireland and Northern Ireland, including but not limited to MAs). The MHRA is now the UK's standalone regulator. Although the UK and EU have reached an agreement on their future trading relationship pursuant to the EU-UK Trade and Cooperation Agreement, or TCA, which has been provisionally applicable from January 1, 2021, the agreement does not cover all regulatory areas regarding supply of medicinal product, which will likely be subject to future bilateral discussions going forward and could further change the relationship between the UK and the EU in this regard.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new legislation such as the CTR or in relation to orphan medicines will not be applicable. In addition, as there is no general power to amend the "retained EU law", the UK government adopted the Medicines and Medical Devices Act 2021 in February 2021 which introduces delegated powers in favor of the Secretary of State or an "appropriate authority" to amend or supplement existing regulations in the area of medicinal products. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines and clinical trials of human medicines. The new UK legislation may diverge from EU law and require that we comply with separate procedures and standards, which may lead to additional costs and increase our overall risk exposure.

Brexit has created additional administrative burdens that are likely to result in disruptions to and uncertainty surrounding our planned clinical trials and activities in the UK and the EU, which may impact relationships with our existing and prospective customers, partners, vendors and employees. Already, various benefits of membership no longer apply to the UK for clinical trials, such that, for example, UK sponsored trials that span several EU countries now need to have an individual or organization in the EU to act as a legal representative, or sponsor and it is unclear whether the UK will have access to new EU clinical trial databases such as the Clinical Trial Information System (the centralized EU Portal for clinical trial information storage) going forward. Additionally, new rules apply to the import of investigational medicinal products from the EU and EEA to Great Britain.

While agreement on the terms of the TCA has avoided a "no deal" Brexit scenario, and provides in principle for quota and tariff free trading of goods, it is nevertheless expected that the TCA will result in the creation of non-tariff barriers (such as increased shipping and regulatory costs and complexities) to the trade in goods between the UK and EU. Further, the TCA does not provide for the continued free movement of services between the UK and EU and also grants each of the UK and EU the ability, in certain circumstances, to unilaterally impose tariffs on one another. The TCA does provide for the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued. However, it is important to note that significant regulatory gaps still exist and the TCA does not contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards between the parties, for example, in relation to batch testing and pharmacovigilance, which remain subject to further discussions.

For MAs, an applicant for a centralized procedure MA must be established in the EU. After 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 (such as the Access Consortium) to obtain an MA to market products in the UK. The MHRA may rely on a decision taken by the European Commission on the approval of a new (centralized procedure) MA when determining an application for a Great Britain MA; or use the MHRA's decentralized or mutual recognition procedures which enable MAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in Great Britain. Additionally, the 'Unfettered Access Procedure' enables a marketing authorization holder in Northern Ireland to seek recognition in Great Britain.

The full impact of these new arrangements and requirements, both on our existing processes and our ability to adjust our business and operations to operate successfully in the UK and EU, as well as more broadly on UK-EU cross-border trade and the economy, are expected to become clearer in the coming years. In particular, it remains to be seen whether the initial implementation of, and adjustment of UK-EU trading processes for, the TCA could disrupt or otherwise negatively impact our business and operations. These negative impacts could include amongst others a decrease in foreign direct investment in the UK, an increase of our costs, disruption of our supply chains, restrictions on our ability to access capital and depression on economic activity or economic instability, which could in turn lead to a reduction in asset valuations, currency exchange rates and credit ratings.

In addition, the TCA has imposed additional restrictions on the free movement of people between the UK and the EU, which could have a material adverse effect on us, since we compete in these jurisdictions for well qualified employees in all aspects of our business. Any impact on our ability to attract new employees and to retain existing employees in their current jurisdictions could decrease our competitiveness. Any of these factors could have an adverse effect on our business, financial condition, results of operations, and prospects.

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. Additionally, the trading prices for our ordinary shares and the shares of other smaller biopharmaceutical companies have been and continue to be highly volatile as a result of the COVID-19 pandemic. 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;
- 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-Q.

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 and during the COVID-19 pandemic. 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.

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 September 30, 2022, 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 43.0% of our outstanding ordinary shares. In addition, in connection with the Financing Agreement, we issued to Perceptive, our largest shareholder that has 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 an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- reduced disclosure obligations relating to the presentation of financial statements in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in our periodic reports filed with the SEC;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

We are also 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. Similar to emerging growth companies, 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 emerging growth companies and 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, 2021, 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, 2021 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 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, 2021, we had federal and state NOL carryforwards in the United States of $73.6 million and $73.3 million, respectively, and cumulative carryforward tax losses in the UK of $164.3 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). The U.S. federal and state NOLs incurred prior to January 1, 2018 in the amount of approximately $6.8 million and $6.7 million, respectively, will begin to expire in 2036. 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. As of December 31, 2021, we also had orphan drug and research and development credits in the U.S. in the amount of $6.7 million and research and development credits in the UK of $1.5 million. The UK carryforward tax losses will continue indefinitely, subject to relevant restrictions, under current UK legislation.

The NOLs and carryforward tax losses are subject to review and possible adjustment by the applicable tax authorities. Additionally, NOLs and UK 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. 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 December 31, 2020, there were no limitations in the UK. However, for U.S. federal tax purposes, we have determined that ownership changes occurred in August 2016 and June 2018. We are still in the process of determining the annual limitation on NOLs as a result of such ownership changes. 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. 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, the loan proceeds provided under our Financing Agreement may be used for working capital and general corporate purposes. 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 compliance initiatives and corporate governance practices.

As a public company, and particularly if we no longer qualify as an emerging growth company and smaller reporting company in the future, we incur and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. 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 remain an emerging growth company, 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 an emerging growth company, 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, stock exchanges, certain investors and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance factors. The SEC is considering and in some cases has proposed rules regarding new disclosure requirements relating to environmental, social and governance factors, and the SEC approved in 2021 new Nasdaq listing and disclosure requirements relating to board diversity that are applicable to us. Some investors may use these 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 Financing 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 our Form 10-K for the year ended December 31, 2021 previously filed with the SEC for additional information.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
4.1	Form of Warrant Agreement, dated August 2, 2022, issued by MeiraGTx Holdings plc to certain warrant holders.					*
10.1†	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.					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
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 Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (Formatted in Inline XBRL and contained in exhibit 101)					*

* Filed herewith.
** Furnished herewith.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of 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: November 10, 2022

By: /s/ Alexandria Forbes

Alexandria Forbes
Chief Executive Officer
(*principal executive officer and authorized signatory*)

Date: November 10, 2022

By: /s/ Richard Giroux

Richard Giroux
Chief Financial Officer and Chief Operating Officer
(*principal financial officer and principal accounting officer*)

Exhibit 4.1

SCHEDULE OF WARRANT HOLDERS

In accordance with Instruction 2 to Item 601 of Regulation S-K, below is a schedule setting forth details in which the omitted executed warrants differ from the form of warrant that follows:

Holder	Exercise Price Per Share	Number of Ordinary Shares
Perceptive Credit Holdings III, LP	$15.00	400,000
Perceptive Credit Holdings III, LP	$20.00	300,000
Total		**700,000**

WARRANT CERTIFICATE

THIS WARRANT CERTIFICATE AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS WARRANT CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR QUALIFIED UNDER ANY STATE OR FOREIGN SECURITIES LAWS AND MAY NOT BE OFFERED FOR SALE, SOLD, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED OR ASSIGNED UNLESS (I) A REGISTRATION STATEMENT COVERING SUCH SHARES IS EFFECTIVE UNDER THE SECURITIES ACT AND IS QUALIFIED UNDER APPLICABLE STATE AND FOREIGN LAW OR (II) THE TRANSACTION IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS UNDER THE SECURITIES ACT AND THE QUALIFICATION REQUIREMENTS UNDER APPLICABLE STATE AND FOREIGN LAW AND, IN EACH CASE, IF THE COMPANY REQUESTS, AN OPINION SATISFACTORY TO THE COMPANY TO SUCH EFFECT HAS BEEN RENDERED BY COUNSEL.

Issuer: MeiraGTx Holdings plc

Warrant Shares Issuable: [●] ordinary shares

Warrant Certificate No.: [●]

Issue Date: August 2, 2022 (the "***Issue Date***")

FOR VALUE RECEIVED, MeiraGTx Holdings plc, an exempted company incorporated with limited liability under the laws of the Cayman Islands with registration number 336306 (the "***Company***"), hereby certifies that for good and valuable consideration, PERCEPTIVE CREDIT HOLDINGS III, LP, a Delaware limited partnership (the "***Initial Holder***" and, together with its successors and permitted transferees and assigns, a "***Holder***") is entitled to purchase, at the per share Exercise Price (defined below), up to [●] ([●]) fully paid and nonassessable Warrant Shares (defined below), all subject to the terms, conditions and adjustments set forth below in this Warrant Certificate and subject further to the rules or regulations of the Trading Market and terms of the Articles.

This Warrant Certificate has been issued as a condition precedent to the making of the loans under and pursuant to that certain Credit Agreement and Guaranty, dated as of August 2, 2022 (as amended or otherwise modified from time to time, the "***Credit Agreement***"), among the

Company, as the borrower, certain Subsidiaries of the Company from time to time party thereto, as guarantors, the lenders from time to time party thereto, and the Initial Holder, acting in its capacity as the administrative agent for the lenders.

Section 1. Definitions. Capitalized terms used in this Warrant Certificate but not otherwise defined herein have the meanings ascribed thereto in the Credit Agreement as in effect on the Issue Date. The following terms when used herein have the following meanings:

"***Aggregate Exercise Price***" means, with respect to any exercise of this Warrant Certificate for Warrant Shares pursuant to **Section 3**, an amount equal to the product of (i) the number of Warrant Shares in respect of which this Warrant Certificate is then being exercised pursuant to **Section 3**, multiplied by (ii) the Exercise Price.

"***Articles***" means the Amended and Restated Articles of Association of the Company adopted by special resolution dated June 19, 2019.

"***Assignment***" has the meaning set forth in **Section 6**.

"***Bloomberg***" means Bloomberg Financial Markets or an equivalent, reliable reporting service reasonably acceptable to the Holder and the Company.

"***Cashless Exercise***" has the meaning set forth in **Section 3(b)(ii)**.

"***Company***" has the meaning set forth in the preamble.

"***Convertible Securities***" means any Equity Interests that, directly or indirectly, are convertible into or exchangeable for Ordinary Shares.

"***Credit Agreement***" has the meaning set forth in the preamble.

"***Determination Date***" has the meaning set forth in the definition of "Fair Market Value".

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Exercise Certificate***" has the meaning set forth in **Section 3(a)(i)**.

"***Exercise Date***" means, for any given exercise of this Warrant Certificate, whether in whole or in part, a Business Day on which the conditions to such exercise as set forth in **Section 3** shall have been satisfied at or prior to 5:00 p.m., New York City time, including, without limitation, the receipt by the Company of the Exercise Certificate.

"***Exercise Period***" means the period from (and including) the Issue Date to (and including) 5:00 p.m., New York City time, on the Expiration Date.

"***Exercise Price***" means $20.00 per Warrant Share.

"***Expiration Date***" means August 2, 2027.

"***Fair Market Value***" means, as of any date of determination (a "***Determination Date***"), if the Ordinary Shares are traded on a Trading Market, (i) the VWAP for such date, (ii) if there is no VWAP on such date, the per share closing price for such Ordinary Shares on such Determination Date on the primary Trading Market for such shares, or (iii) if there have been no sales of the Ordinary Shares on such Determination Date on the primary Trading Market for such shares, the per share closing price for the Ordinary Shares on the immediately preceding day on which the Ordinary Shares were sold on its primary Trading Market; provided that if at any time the Ordinary Shares are not listed, quoted or otherwise available for trading on any Trading Market (so that no Trading Date shall have occurred), the "***Fair Market Value***" of such Warrant Shares shall be the fair market value per share of such Warrant Shares as determined by the Board of the Company acting reasonably and in good faith; provided further, that, in the event the Holder, in the exercise of its reasonable good faith judgment, disagrees with such determination, "***Fair Market Value***" shall be determined pursuant to **Section 9(a)** or **Section 9(b)**, as applicable.

"***Holder***" has the meaning set forth in the preamble.

"***Independent Advisor***" has the meaning set forth in **Section 9(a)**.

"***Initial Holder***" has the meaning set forth in the preamble.

"***Issue Date***" means the date designated as such on the first page of this Warrant Certificate.

"***Marketable Securities***" means Equity Interests meeting each of the following requirements: (i) the issuer thereof is subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act, and is current in its filing of all required reports and other information under the Securities Act and the Exchange Act; (ii) such Equity Interests are traded on a Trading Market; and (iii) if delivered (or to be delivered) as payment or compensation to a Holder in connection with an automatic Cashless Exercise resulting from a Sale of the Company pursuant to **Section 3(c)**, following the closing of such Sale of the Company the Holder would not be restricted from publicly re-selling any or all of such Equity Interests delivered to it, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, or (y) does not extend beyond six (6) months from the closing of such Sale of the Company to the extent such restrictions may be lifted at such time under the applicable federal or state securities laws, rules or regulations.

"***Nasdaq***" means The Nasdaq Stock Market, LLC

"***NYSE***" means the New York Stock Exchange.

"***Options***" means any warrants, options or similar rights to subscribe for or purchase Equity Interests of the Company, including its Ordinary Shares or Convertible Securities.

"***Ordinary Shares***" means the Company's ordinary shares, par value $0.00003881 per share, having ordinary voting rights, as provided in the Articles.

"***OTC Bulletin Board***" means the National Association of Securities Dealers, Inc. OTC Bulletin Board.

"***Registration Statement***" means, in connection with any Public Offering of securities, any registration statement required pursuant to the Securities Act that covers the offer and sale of any such securities, including any prospectus, amendments or supplements to such Registration Statement, including post-effective amendments and all exhibits and all materials incorporated by reference in such Registration Statement.

"***Rule 144***" means Rule 144 promulgated under the Securities Act.

"***Sale of the Company***" means an event or transaction or series of related events or transactions pursuant to which, directly or indirectly, either (i) any Person or group of Persons acting jointly or otherwise in concert acquires ownership, directly or indirectly, beneficially or of record, of Equity Interests of the Company having more than fifty percent (50%) of the aggregate ordinary voting power, determined on a fully-diluted, as-if-converted or exercised basis, whether such right is exercisable immediately or only after the passage of time, or (ii) all or substantially all of the assets or businesses of the Company and its Subsidiaries, taken as a whole, are transferred or sold, including by way of lease, transfer, conveyance or other disposition.

"***SEC***" means the Securities and Exchange Commission or any successor thereto.

"***Securities Act***" means the Securities Act of 1933, as amended.

"***Share Reorganization***" has the meaning set forth in **Section 4(a)**.

"***Trading Market***" means, with respect to the Ordinary Shares or any other Marketable Securities, the principal US exchange or market on which such securities are quoted or available for trading, including the Nasdaq, the NYSE, the OTC Bulletin Board or otherwise.

"***Unrestricted Conditions***" has the meaning set forth in **Section 10(a)(ii)**.

"***VWAP***" means volume weighted average sale price of the Ordinary Shares on Trading Market as reported by Bloomberg for the preceding five (5) Business Days.

"***Warrant Certificate***" means this Warrant Certificate and all subsequent warrant certificates issued upon division, combination or transfer of, or in substitution for, this Warrant Certificate.

"***Warrant Register***" has the meaning set forth in **Section 5**.

"***Warrant Shares***" means the Ordinary Shares purchasable upon exercise of this Warrant Certificate in accordance with the terms of this Warrant Certificate and the Articles and any other Equity Interests into which such Ordinary Shares may be converted, exchanged or otherwise reclassified or modified pursuant to any Share Reorganization or otherwise.

Section 2. Term of Warrant Certificate. Subject to the terms and conditions hereof, from time to time during the Exercise Period, the Holder of this Warrant Certificate may exercise this

Warrant Certificate for all or any part of the Warrant Shares purchasable hereunder (subject to adjustment as provided herein).

Section 3. Exercise of Warrant Certificate.

(a) **Exercise Procedure**. This Warrant Certificate may be exercised from time to time on any Business Day during the Exercise Period, for all or any part of the unexercised Warrant Shares, upon:

(i) delivery to the Company of a duly completed and executed Exercise Certificate in the form attached hereto as **Exhibit A** (each, an "***Exercise Certificate***"), which certificate will specify the number of Warrant Shares to be purchased and the Aggregate Exercise Price; and

(ii) substantially contemporaneously with the delivery of the Exercise Certificate, payment to the Company of the Aggregate Exercise Price in accordance with **Section 3(b)**; provided that, notwithstanding anything to the contrary herein, in no event shall the Exercise Price be lower than the par value of a Warrant Share.

(b) **Payment of the Aggregate Exercise Price**. Payment of the Aggregate Exercise Price shall be made, at the option of the Holder as expressed in the Exercise Certificate, by any of the following methods:

(i) by wire transfer of immediately available funds to an account designated in writing by the Company, in the amount of such Aggregate Exercise Price;

(ii) by instructing the Company to withhold a number of Warrant Shares then issuable upon exercise of this Warrant Certificate with an aggregate Fair Market Value as of the Exercise Date equal to such Aggregate Exercise Price; or

(iii) any combination of the foregoing.

In the event of any withholding of Warrant Shares pursuant to **Section 3(b)(ii)** or **(iii)** (such method of payment is herein referred to as "***Cashless Exercise***") where the number of such shares whose value is equal to the Aggregate Exercise Price is not a whole number, the number of such shares withheld by the Company shall be rounded up to the nearest whole share and the Company shall make a cash payment to the Holder (by wire transfer of immediately available funds to an account designated by the Holder) in an amount calculated as provided pursuant to **Section 3(e)** below.

To the extent permitted by applicable Law, for purposes of Rule 144, it is acknowledged and agreed that (i) the Warrant Shares issuable upon any exercise of this Warrant Certificate in any Cashless Exercise transaction shall be deemed to have been acquired on the Issue Date, and (ii) the holding period for any Warrant Shares issuable upon the exercise of this Warrant Certificate in any Cashless Exercise transaction shall be deemed to have commenced on the Issue Date; provided that the Company makes no representation or warranty regarding the commencement of the holding period of any Warrant Share.

(c) **Automatic Cashless Exercise**. To the extent this Warrant Certificate has not been exercised in full by the Holder prior to the date of any of the following events or circumstances, any portion of this Warrant that remains unexercised on such date shall be deemed to have been exercised automatically pursuant to a Cashless Exercise, in whole (and not in part), on the Business Day immediately preceding the earlier of (i) the occurrence of the Expiration Date and (ii) the consummation of a Sale of the Company in which the consideration to be received by the Company or its shareholders consists solely of cash, Marketable Securities or a combination thereof; provided that, unless the Holder otherwise notifies the Company in writing, the automatic Cashless Exercise contemplated by this **Section 3(c)** shall not occur, and this Warrant Certificate shall automatically terminate without additional cost to the Borrower, in the event that, as of the Business Day immediately preceding any event described in the preceding **clauses (i)** or **(ii)** above, the Fair Market Value of a Warrant Share is less than the Exercise Price then in effect.

(d) **Delivery of Stock Certificates**. With respect to any exercise of this Warrant Certificate by the Holder, upon receipt by the Company of the Exercise Certificate and delivery of the Aggregate Exercise Price, the Company shall, within three (3) Business Days, deliver in accordance with the terms hereof to or upon the order of the Holder that number of Warrant Shares for the portion of this Warrant Certificate so exercised on such date, together with cash in lieu of any fraction of a share, as provided in **Section 3(e)** below. If such Warrant Shares are issued in certificated form, the Company shall deliver a certificate or certificates representing the number of Warrant Shares purchased pursuant to the applicable Exercise Certificate to the address provided by the Holder. If such Warrant Shares are issued in uncertificated form, the Company shall deliver upon request an extract of the register of members of the Company evidencing such issuance to the account designated by the Holder. Unless as otherwise provided herein, upon any exercise hereof this Warrant Certificate shall be deemed to have been exercised and such certificate or certificates of Warrant Shares shall be deemed to have been issued (if applicable), and the Holder shall be deemed to have become a holder of record of such Warrant Shares for all purposes, as of the Exercise Date.

(e) **Fractional Shares**. The Company shall not be required to issue a fractional Warrant Share upon exercise of any Warrant Certificate. As to any fraction of a Warrant Share that the Holder would otherwise be entitled upon such exercise, including pursuant to a Cashless Exercise, the Company shall pay to such Holder an amount in cash (by wire transfer of immediately available funds to an account designated by the Holder) equal to the product of (i) such fraction multiplied by (ii) the Fair Market Value of one Warrant Share on the Exercise Date.

(f) **Surrender of this Warrant; Delivery of New Warrant Certificate**

(i) The Holder shall not be required to physically surrender this Warrant to the Company until this Warrant has been exercised in full by the Holder, in which case, the Holder shall, at the written request of the Company, surrender this Warrant to the Company for cancellation within three (3) Business Days after the date the final Exercise Certificate is delivered to the Company and the Warrant Shares issuable in connection with such Exercise Certificate have been issued and delivered by the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder

shall have the effect of lowering the outstanding number of Warrant Shares issuable hereunder by an amount equal to the applicable number of Warrant Shares that have been issued hereunder as a result of previous exercises and withheld in connection with Cashless Exercises. Pursuant to **Section 5** hereof the Company shall maintain the Warrant Register which will, among other things, record the number of Warrant Shares issued and purchased, the date of such issuances and purchases and the number of Warrant Shares withheld in connection with Cashless Exercises. The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this **Section 3(f)**, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be fewer than the amount stated on the face hereof.

(ii) Notwithstanding the foregoing, to the extent that there are unexpired and unexercised Warrant Shares remaining under the Warrant Certificate, the Holder may request that the Company (and the Company shall), at the time of issuance of any Warrant Shares in accordance with **Section 3(d)** and the surrender of this Warrant Certificate, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unexpired, unexercised and not withheld (in connection with Cashless Exercises) Warrant Shares called for by this Warrant Certificate. Unless otherwise agreed upon by the Holder such new Warrant Certificate shall in all other respects be identical to this Warrant Certificate.

(g) **Valid Issuance of Warrant Certificate and Warrant Shares; Payment of Taxes**. With respect to the exercise of this Warrant Certificate, the Company hereby represents, warrants, covenants and agrees as follows:

(i) This Warrant Certificate is, and any Warrant Certificate issued in substitution for or replacement of this Warrant Certificate shall be, upon issuance, duly authorized.

(ii) All Warrant Shares issuable upon the exercise of this Warrant Certificate (or any substitute or replacement Warrant Certificate) shall be, upon issuance, and the Company shall take all such actions as may be necessary or appropriate in order that such Warrant Shares are, validly issued, fully paid and non-assessable, issued without violation of any pre-emptive or similar rights of any shareholder of the Company and free and clear of all liens and charges.

(iii) The Company shall take all such actions as may be necessary to (x) comply with **Section 3(i)** below and (y) ensure that all such Warrant Shares are issued without violation by the Company of any Organic Document to which it is subject or any applicable Law or any requirements of any U.S. or non-U.S. securities exchange upon which Warrant Shares may be listed at the time of such exercise.

(iv) The Company shall pay all expenses in connection with, and all governmental charges that may be imposed with respect to, the issuance or delivery of Warrant Shares issuable upon exercise of this Warrant Certificate.

(v) The Company is an exempted company duly organized and validly existing under the Laws of the Cayman Islands and has the capacity and corporate power and authority to enter into, deliver and perform this Warrant Certificate.

(vi) The Company has taken or caused to be taken all action required to be taken to authorize the execution, delivery and performance of this Warrant Certificate and the issuance of the Warrant Shares.

(vii) This Warrant Certificate has been duly executed and delivered by the Company.

(viii) The obligations of the Company under this Warrant Certificate are legal, valid and binding obligations, enforceable against the Company in accordance with the terms hereof and thereof, as applicable.

(ix) The Company has complied with all obligations set forth in **Section 3(i)** and **3(j)**, below.

(h) **Conditional Exercise.** Notwithstanding any other provision hereof, if an exercise of all or any portion of this Warrant Certificate is to be made in connection with a Sale of the Company or other possible liquidity transaction or event, such exercise may, at the election of the Holder, be conditioned upon the consummation of such transaction, in which case such exercise shall not be deemed to be effective until immediately prior to the consummation of such transaction or event.

(i) **Reservation of Shares**. The Company shall at all times during the Exercise Period reserve and keep available out of its authorized but unissued Ordinary Shares or (if applicable) other Equity Interests constituting Warrant Shares, the maximum number of Warrant Shares or other Equity Interests issuable upon the exercise of this Warrant Certificate or the conversion or exchange of Warrant Shares issuable upon such exercise. The Company shall not increase the par value of any Warrant Shares receivable upon the exercise of this Warrant Certificate above the Exercise Price then in effect, and shall take all such actions within its power as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant Certificate.

(j) **Rule 144 Compliance**. With a view to making available to the Holder the benefits of Rule 144 and any other rule or regulation of the SEC that may at any time permit a holder to sell securities of the Company to the public without registration or pursuant to a Registration Statement, the Company shall:

(i) use reasonable commercial efforts to make and keep adequate public information available, as required by clause (c) of Rule 144;

(ii) use reasonable commercial efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and

(iii) furnish, or otherwise make available to the Holder so long as the Holder owns Warrant Shares, promptly upon request, a written statement by the Company as to its compliance with the reporting requirements of Rule 144 and the Exchange Act, a copy of the most recent annual or quarterly report of the Company to the extent not otherwise publicly available on the SEC website, and such other reports and documents so filed or furnished by the

Company as such holder may reasonably request in connection with the sale of Warrant Shares without registration.

(k) **Ownership Cap**. The Company shall not knowingly effect the exercise of this Warrant Certificate, and the Initial Holder shall not have the right to exercise this Warrant Certificate to the extent that, after giving effect to such exercise, the Initial Holder (together with its Affiliates) would beneficially own in excess of 19.99% of the Ordinary Shares of the Company immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of such voting Equity Interests beneficially owned by the Initial Holder and its Affiliates shall include the number of Warrant Shares issuable upon exercise of this Warrant Certificate with respect to which the determination of such aggregate number is being made, but shall exclude Warrant Shares (if any) that do not have ordinary voting rights, if any, or that would be issuable upon (i) exercise of the remaining, unexercised portion of this Warrant Certificate beneficially owned by the Initial Holder and its Affiliates and (ii) exercise or conversion of the unexercised or unconverted portion of any other Equity Interests of the Company beneficially owned by the Initial Holder and its Affiliates (including, without limitation, any Convertible Securities) subject to a limitation on conversion or exercise analogous to the limitations contained herein. Except as set forth in the preceding sentence, for purposes of this **Section 3(k)**, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act. For purposes of this Warrant Certificate, in determining the number of outstanding Ordinary Shares, the Initial Holder of this Warrant Certificate may rely on the number of such outstanding Equity Interests as reflected in the most recent of (i) if available, the Company's Form 10-K, Form 10-Q or other public filing with the SEC, as the case may be, (ii) a more recent public announcement by the Company, or (iii) any other written notice or statement by the Company or its transfer agent setting forth the number of outstanding Ordinary Shares. In addition, upon the written request of the Initial Holder, the Company shall, within three (3) Business Days, confirm to the Initial Holder the number of the Company's outstanding Ordinary Shares.

Section 4. Adjustment to Number of Warrant Shares, Exercise Price, etc. The number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be subject to adjustment from time to time as provided in this **Section 4**.

(a) **Adjustment to Number of Warrant Shares Upon Reorganizations, Reclassifications, etc.** In the event of any changes in the aggregate number of outstanding Ordinary Shares of the Company by reason of redemptions, recapitalizations, reclassifications, combinations or exchanges of shares, splits or reverse splits, separations, reorganizations, liquidations, substitutions, replacements or the like (any of the foregoing or combination thereof being a "**Share Reorganization**"), the Exercise Price and the aggregate number of Warrant Shares then available upon exercise of this Warrant Certificate shall be correspondingly adjusted, such that the Exercise Price shall be adjusted by multiplying the Exercise Price in effect immediately prior to the record date for the determination of such Share Reorganization by a fraction, the numerator of which shall be the number of Ordinary Shares outstanding immediately before such event and the denominator of which shall be the number of Ordinary Shares outstanding immediately after such event, and the number of Warrant Shares issuable upon exercise of this Warrant Certificate shall be proportionately adjusted such that (i) the Aggregate Exercise Price shall remain unchanged and (ii) the Holder shall be entitled to receive,

upon exercise of this Warrant Certificate, the total number of Ordinary Shares it would have owned as a result of exercising this Warrant Certificate had this Warrant Certificate been exercised immediately prior to such Share Reorganization and had the Holder continued to hold such Ordinary Shares until after giving effect to such Share Reorganization and the resulting adjustment.

(b) **Effect of Dividends, Distributions, Etc**. If the Company declares or pays a dividend or distribution on the outstanding shares of its Ordinary Shares payable in cash, Equity Interests or other property (or prior to the exercise of this Warrant Certificate in full the holders of the Company's Ordinary Shares become entitled to receive any such dividend or distribution), then upon exercise of this Warrant Certificate, for each Warrant Share acquired, the Holder shall receive, without additional cost to the Holder, the total amount, number and kind of cash, Equity Interests or other property which the Holder would have received had the Holder owned the Warrant Shares of record as of the date such dividend or distribution was paid.

(c) **Certificate as to Adjustment**.

(i) As promptly as reasonably practicable upon the request of the Holder following any change or adjustment of the type described above in this **Section 4**, but in any event not later than three (3) Business Days thereafter, the Company shall furnish to the Holder a certificate of a Responsible Officer setting forth in reasonable detail such change or adjustment and the facts upon which it is based and certifying the calculation thereof.

(ii) As promptly as reasonably practicable following the receipt by the Company of a written request by the Holder, but in any event not later than three (3) Business Days thereafter, the Company shall furnish to the Holder a certificate of a Responsible Officer certifying the number of Warrant Shares or the amount, if any, of other Equity Interests, securities or assets then issuable upon exercise of the Warrant Certificate.

(d) **Notices**. In the event that, at any time during the Exercise Period the Company shall take a record of the holders of its outstanding shares (or other Equity Interests at the time issuable upon exercise of this Warrant Certificate) for the purpose of:

(i) entitling or enabling such holders to receive any dividend or other distribution, to receive any right to subscribe for or purchase any shares of any class or any other securities, or to receive any other security;

(ii) (x) any capital reorganization of the Company, any reclassification of any outstanding securities, any consolidation or merger of the Company with or into another Person, any Public Offering of the Company's Equity Interests, or (y) a Sale of the Company; or

(iii) the voluntary or involuntary dissolution, liquidation or winding-up of the Company (including by way of a bankruptcy or similar event involving the Company);

then, and in each such case, the Company shall send or cause to be sent to the Holder at least ten (10) Business Days prior to the applicable record date or the applicable expected effective date, as the case may be, for the event, a written notice prepared in reasonable detail specifying, as the case may be, (A) the record date for such dividend, distribution or other right or action, and a

description of such dividend, distribution or other right or action, or (B) the effective date on which such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up is proposed to take place, and the date, if any is to be fixed, as of which the books of the Company shall close or a record shall be taken with respect to which the holders of record of its shares (or such other Equity Interests at the time issuable upon exercise of the Warrant Certificate) shall be entitled to exchange their shares (or such other Equity Interests), for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Warrant Certificate and the Warrant Shares.

Section 5. Warrant Register. The Company shall keep and properly maintain at its principal executive offices a register (the "***Warrant Register***") for the registration of this Warrant Certificate and any transfers thereof. The Company may deem and treat the Person in whose name this Warrant Certificate is registered on such register as the Holder thereof for all purposes, and the Company shall not be affected by any notice to the contrary, except any assignment, division, combination or other transfer of this Warrant Certificate effected in accordance with the provisions of this Warrant Certificate.

Section 6. Transfer of Warrant Certificate. Subject to **Section 10** hereof, this Warrant Certificate and all rights hereunder are assignable and transferable, in whole or in part, by the Holder without charge to the Holder, upon surrender of this Warrant Certificate to the Company at its then principal executive offices with a properly completed and duly executed instrument of assignment in the form attached hereto as **Exhibit B** (an "***Assignment***"). Upon such compliance, surrender and delivery, the Company shall execute and deliver a new Warrant Certificate or Warrant Certificates in the name of the assignee or assignees and in the denominations specified in such Assignment, and shall issue to the assignor a new Warrant Certificate evidencing the portion of this Warrant Certificate, if any, not so assigned, and this Warrant Certificate shall promptly be cancelled.

Section 7. The Holder Not Deemed a Shareholder; Limitations on Liability. Except as otherwise specifically provided herein (including in **Section 4(b)** above), (i) prior to the Exercise Date, the Holder shall not be entitled to receive dividends, nor shall anything contained in this Warrant Certificate be construed to confer upon the Holder, as such, any of the rights of a shareholder of the Company or any right to receive dividends or subscription rights, and (ii) prior to due exercise of this Warrant Certificate, the Holder shall not be entitled to vote, nor shall anything contained in this Warrant Certificate be construed to confer upon the Holder, as such, any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of shares, reclassification of shares, consolidation, merger, conveyance or otherwise) or receive notice of meetings. In addition, nothing contained in this Warrant Certificate shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant Certificate or otherwise) or as a shareholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company. Notwithstanding this **Section 7**, the Company shall provide the Holder with copies of the same notices and other information given to all shareholders of the Company generally, contemporaneously with the giving thereof to such shareholders.

Section 8. Replacement on Loss; Division and Combination.

(a) **Replacement of Warrant Certificate on Loss**. Subject to any further requirements in relation to the cancellation of this Warrant Certificate pursuant to applicable Law, upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant Certificate and upon delivery of an indemnity reasonably satisfactory to it (it being understood that a written indemnification agreement or affidavit of loss of the Holder, in customary form, shall be a sufficient indemnity) and, in case of mutilation, upon surrender of such Warrant Certificate for cancellation to the Company, the Company at its own expense shall execute and deliver to the Holder, in lieu hereof, a new Warrant Certificate of like tenor and exercisable for an equivalent number of Warrant Shares as this Warrant Certificate so lost, stolen, mutilated or destroyed; provided that, in the case of mutilation, no indemnity shall be required if this Warrant Certificate in identifiable form is surrendered to the Company for cancellation.

(b) **Division and Combination of Warrant Certificate**. Subject to compliance with the applicable provisions of this Warrant Certificate as to any transfer or other assignment which may be involved in such division or combination, this Warrant Certificate may be divided or, following any such division of this Warrant Certificate, subsequently combined with other Warrant Certificates, upon the surrender of this Warrant Certificate or Warrant Certificates to the Company at its then principal executive offices, together with a written notice specifying the names and denominations in which new Warrant Certificates are to be issued, signed by each applicable Holder or its agents or attorneys. Subject to compliance with the applicable provisions of this Warrant Certificate as to any transfer or assignment which may be involved in such division or combination, the Company shall at its own expense execute and deliver a new Warrant Certificate or Warrant Certificates in exchange for this Warrant Certificate or Warrant Certificates so surrendered in accordance with such notice. Such new Warrant Certificate or Warrant Certificates shall be of like tenor to the surrendered Warrant Certificate or Warrant Certificates and shall be exercisable in the aggregate for an equivalent number of Warrant Shares as this Warrant Certificate or Warrant Certificates so surrendered in accordance with such notice.

Section 9. Disputes; No Impairment, etc. The parties hereto agree as follows:

(a) **Disputes**. In the event of any dispute which arises between the Holder and the Company (including the Board of the Company) with respect to the calculation or determination of Fair Market Value, the adjusted Exercise Price, the number of Warrant Shares, other Equity Interests, cash or other property issuable upon exercise of this Warrant Certificate, the amount or type of consideration due to the Holder in connection with any event, transaction or other matter described in **Section 4** above or any other matter involving this Warrant Certificate or the Warrant Shares that is not resolved by the parties after good faith discussions and efforts to reach resolution, upon the request of the Holder, the disputed issue(s) shall be submitted to a firm of independent investment bankers or public accountants of recognized national standing, which (i) shall be chosen by the Company and be reasonably satisfactory to the Holder and (ii) shall be completely independent of the Company (an "***Independent Advisor***"), for determination, and such determination by the Independent Advisor shall be binding upon the Company and the Holder with respect to this Warrant Certificate, any Warrant Shares issued or issuable in connection herewith, the Exercise Price therefor, or any other matter in dispute, as the case may

be, absent manifest error. Costs and expenses of the Independent Advisor shall be shared 50/50 by the Company and the Holder.

(b) **Equitable Equivalent**. In case any event shall occur as to which the provisions of **Section 9(a)** above are not strictly applicable but the failure to make any adjustment would not, in the reasonable, good faith opinion of the Holder, fairly protect the rights and benefits of the Holder represented by this Warrant Certificate in accordance with the essential intent and principles of **Sections 4** and **9(a)**, then, in any such case, at the request of the Holder, the Company shall submit the matter and issues raised by the Holder to an Independent Advisor, which shall give its opinion upon the adjustment, if any, on a basis consistent with the essential intent and principles established in **Sections 4** and **9(a)**, to the extent necessary to preserve, without dilution, the rights and benefits represented by this Warrant Certificate. Upon receipt of such opinion, the Company will promptly mail a copy thereof to the Holder and shall make the adjustments described therein, if any. Costs and expenses of the Independent Advisor shall be shared 50/50 by the Company and the Holder.

(c) **No Avoidance**. The Company shall not, by way of amendment of any of its Organic Documents or through any consolidation, merger, reorganization, transfer of assets, dissolution, issue or sale of securities or any other voluntary action or transaction, avoid or seek to avoid the observance, performance or intended results of any of the terms of this Warrant Certificate, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the Holder against dilution or other impairment as if the Holder was a shareholder of the Company entitled to the benefit of fiduciary duties afforded to shareholders under the Laws of the Cayman Islands.

Section 10. Compliance with the Securities Act.

(a) **Agreement to Comply with the Securities Act, etc.**

(i) **Legend**. The Holder, by acceptance of this Warrant Certificate, agrees to comply in all respects with the provisions of this **Section 10** and the restrictive legend requirements set forth on the face of this Warrant Certificate and further agrees that it shall not offer, sell or otherwise dispose of this Warrant Certificate or any Warrant Shares to be issued upon exercise hereof except under circumstances that will not result in a violation of the Securities Act. Subject to **clause (ii)** below, this Warrant Certificate and all Warrant Shares issued upon exercise of this Warrant Certificate (unless registered under the Securities Act) shall be stamped or imprinted with a legend in substantially the form as set forth on the face hereof.

(ii) **Removal of Restrictive Legends**. Neither this Warrant Certificate nor any certificates evidencing Warrant Shares issuable or deliverable under or in connection with this Warrant Certificate shall contain any legend restricting the transfer of such Warrant Certificate or Warrant Shares as applicable (including the legend required above in **clause (i)**) in any of the following circumstances: (A) following any sale to a non-Affiliate of the Company of this Warrant Certificate or any Warrant Shares issued or delivered to the Holder under or in connection herewith pursuant to Rule 144 or (B) if, in the opinion of counsel to the Company, such legend is not required under applicable requirements of the Securities Act (including

judicial interpretations and pronouncements issued by the staff of the SEC), including clause (b)(1) of Rule 144 (collectively, the "***Unrestricted Conditions***"). If the Unrestricted Conditions are met at the time of issuance of this Warrant Certificate or Warrant Shares, as the case may be, this Warrant Certificate or Warrant Shares, as the case may be, shall be issued free of all legends.

(iii) **Replacement Warrant Certificate**. The Company agrees that at such time as the Unrestricted Conditions have been satisfied it shall promptly (but in any event within five (5) Business Days) following written request from the Holder issue a replacement Warrant Certificate or replacement Warrant Shares, as the case may be, free of all restrictive legends.

(iv) **Sale of Unlegended Shares**. The Holder agrees that the removal of the restrictive legend from this Warrant Certificate and any certificates representing securities as set forth in **Section 10(a)(ii)** above is predicated upon the Company's receipt of a certification from such Holder confirming that the Holder will sell this Warrant Certificate or any such securities pursuant to either an effective Registration Statement or otherwise pursuant to the requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and that if such securities are sold pursuant to a Registration Statement, they will be sold in compliance with the plan of distribution set forth therein, and any other matters reasonably requested by the Company.

(b) **Representations of the Holder**. In connection with the issuance of this Warrant Certificate, the Holder represents, as of the Issue Date, to the Company by acceptance of this Warrant Certificate as follows:

(i) The Holder is an "accredited investor" as defined in Rule 501 of Regulation D promulgated under the Securities Act. The Holder is acquiring this Warrant Certificate and the Warrant Shares to be issued upon exercise hereof for investment for its own account and not with a view towards, or for resale in connection with, the public sale or distribution of this Warrant Certificate or the Warrant Shares, except pursuant to sales registered or exempted under the Securities Act.

(ii) The Holder understands and acknowledges that this Warrant Certificate and the Warrant Shares to be issued upon exercise hereof are "restricted securities" under the Securities Act inasmuch as they are being acquired from the Company in a transaction not involving a Public Offering and that, under such Laws and applicable regulations, such securities may be resold without registration under the Securities Act only in certain limited circumstances. In addition, the Holder represents that it is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

(iii) The Holder acknowledges that it can bear the economic and financial risk of its investment for an indefinite period and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in this Warrant Certificate and the Warrant Shares. The Holder has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant Certificate and the business, properties, prospects and financial condition of the Company.

Section 11. **Notices**. All notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing and shall be deemed to have been given: (i) when delivered by hand (with written confirmation of receipt); (ii) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (iii) on the date sent by e-mail of a PDF document (with confirmation of transmission) if sent during normal business hours of the recipient, and on the next Business Day if sent after normal business hours of the recipient; or (iv) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective parties at the addresses indicated below (or at such other address for a party as shall be specified in a notice given in accordance with this **Section 11**).

If to the Company: MeiraGTx Holdings plc
450 East 29th Street, 14th Floor
New York, NY 10016
Attention: Rich Giroux
Email: rich@meiragtx.com

with a copy to (which shall not qualify as notice to any party hereto):

legalnotices@meiragtx.com

and

Latham and Watkins LLP
200 Clarendon Street
Boston, MA 02116
Attention: Peter N. Handrinos and Keith L. Halverstam
E-mail: Peter.Handrinos@lw.com; Keith.Halverstam@lw.com

If to the Holder: Perceptive Credit Holdings III, LP
c/o Perceptive Advisors LLC
51 Astor Place, 10th Floor
New York, NY 10003
Attention: Sandeep Dixit
Email: Sandeep@perceptivelife.com;
PCOFReporting@perceptivelife.com

with a copy to (which shall not qualify as notice to any party hereto):

Morrison & Foerster LLP
250 West 55th Street
New York, NY 10019
Attention: Mark Wojciechowski, Esq.
E-mail: mwojciechowski@mofo.com

Section 12. **Cumulative Remedies**. The rights and remedies provided in this Warrant Certificate are cumulative and are not exclusive of, and are in addition to and not in substitution for, any other rights or remedies available at Law, in equity or otherwise.

Section 13. Entire Agreement. This Warrant Certificate constitutes the sole and entire agreement of the parties to this Warrant Certificate with respect to the subject matter contained herein and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter.

Section 14. Successor and Assigns. This Warrant Certificate and the rights evidenced hereby shall be binding upon and shall inure to the benefit of the parties hereto and the successors of the Company and the successors and permitted assigns of the Holder. Such successor or permitted assign of the Holder shall be deemed to be the "Holder" for all purposes hereunder.

Section 15. No Third-Party Beneficiaries. This Warrant Certificate is for the sole benefit of the Company and the Holder and their respective successors and, in the case of the Holder, permitted assigns, and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever, under or by reason of this Warrant Certificate.

Section 16. Headings. The headings in this Warrant Certificate are for reference only and shall not affect the interpretation of this Warrant Certificate.

Section 17. Amendment and Modification; Waiver. Except as otherwise provided herein, this Warrant Certificate may only be amended, modified or supplemented by an agreement in writing signed by each party hereto. No waiver by the Company or the Holder of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the party so waiving. No waiver by any party shall operate or be construed as a waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any rights, remedy, power or privilege arising from this Warrant Certificate shall operate or be construed as a waiver thereof, nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

Section 18. Severability. If any term or provision of this Warrant Certificate is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Warrant Certificate or invalidate or render unenforceable such term or provision in any other jurisdiction.

Section 19. Governing Law. This Warrant Certificate shall be governed by and construed in accordance with the internal Laws of the State of New York without effect to any choice or conflict of Law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of Laws of any jurisdiction other than those of the State of New York.

Section 20. Submission to Jurisdiction. Any legal suit, action or proceeding arising out of or based on this Warrant Certificate or the transactions contemplated hereby may be instituted in the federal courts of the United States or the courts of the State of New York, in each case located in the city and county of New York. Each party irrevocably submits to the exclusive jurisdiction of such courts in any such suit, action or proceeding. Service of process, summons,

notice or other document by certified or registered mail to such party's address set forth in **Section 11** shall be effective service of process for any suit, action or other proceeding, and the parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in such courts and irrevocably waive and agree not to plead or claim in any such court that any such suit, action or proceeding has been brought in an inconvenient forum.

Section 21. Counterparts. This Warrant Certificate may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Warrant Certificate delivered by e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Warrant Certificate.

Section 22. No Strict Construction. This Warrant Certificate shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted.

Section 23. TO THE FULLEST EXTENT PERMITTED BY LAW, EACH PARTY HERETO IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS WARRANT.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Company has duly executed this Warrant Certificate on the Issue Date.

MEIRAGTX HOLDINGS PLC

By _____
Name:
Title:

[Signature Page to Warrant Certificate]

Accepted and agreed,

PERCEPTIVE CREDIT HOLDINGS III, LP

By: PERCEPTIVE CREDIT OPPORTUNITIES GP, LLC**,** its general partner

By: _____
Name: Sandeep Dixit
Title: Chief Credit Officer

By: _____
Name: Sam Chawla
Title: Portfolio Manager

[Signature Page to Warrant Certificate]

Exhibit A
to Warrant Certificate

FORM OF EXERCISE CERTIFICATE

(To be signed only upon exercise of Warrant Certificate)

To: MeiraGTx Holdings plc
450 East 29th Street, 14th Floor
New York, NY 10016
Attention: Rich Giroux

Reference is made to that certain Warrant Certificate, having an issue date of August 2, 2022 and bearing Warrant Certificate No. [●] (the "***Warrant Certificate***"), issued by MeiraGTx Holdings plc (the "***Company***") to the undersigned (the "***Holder***"), a true and correct copy of which is attached to this Exercise Certificate. Unless otherwise defined, capitalized terms used herein have the meanings ascribed thereto in the Warrant Certificate.

The undersigned represents and warrants that it is the Holder of the Warrant Certificate. Pursuant to the terms of the Warrant Certificate, the undersigned hereby elects to exercise its purchase right represented by such Warrant Certificate for, and to purchase thereunder, [_____ (_____)] Warrant Shares of the Company and herewith makes payment with respect to this Exercise Certificate of [_____ Dollars ($_____)] therefor by the following method.

(Check all that apply):

☐ The undersigned hereby elects to make payment of the Aggregate Exercise Price of [_____Dollars ($_____)] for [(_____)] shares of Ordinary Shares using the method described in **Section 3(b)(i)**.

☐ The undersigned hereby elects to make payment of the Aggregate Exercise Price of [_____Dollars ($_____)] for [(_____)] shares of Ordinary Shares using the method described in **Section 3(b)(ii)**.

☐ The undersigned hereby elects to make payment of the Aggregate Exercise Price of [_____Dollars ($_____)] for [(_____)] shares of Ordinary Shares using the method described in **Section 3(b)(iii)**.

DATED: _____

[NAME OF HOLDER]

By _____
Name:
Title:

Exhibit B
to Warrant Certificate

FORM OF ASSIGNMENT

[DATE OF ASSIGNMENT]

Reference is made to that certain Warrant Certificate, having an issue date of August 2, 2022 and bearing Warrant Certificate No. [●] (the "***Warrant Certificate***"), issued by MeiraGTx Holdings plc (the "***Company***") to the undersigned (the "***Holder***"), a true and correct copy of which is attached to this Assignment. Unless otherwise defined herein, capitalized terms used herein have the meanings ascribed thereto in the Warrant Certificate.

Pursuant to the terms of the Warrant Certificate, the Holder is entitled to purchase up to [●]Warrant Shares.

FOR VALUE RECEIVED, the Holder hereby sells, assigns and transfers to [NAME OF ASSIGNEE] (the "***Assignee***") the right to acquire [all Warrant Shares entitled to be purchased upon exercise of the Warrant Certificate] [_____ of the Warrant Shares entitled to be purchased upon exercise of the Warrant Certificate]. In furtherance of the foregoing assignment, the Holder hereby irrevocably instructs the Company to (i) memorialize such assignment in the Warrant Register as required pursuant to **Section 5** of the Warrant Certificate, and (ii) pursuant to **Section 6** of the Warrant Certificate, execute and deliver to [each of] the Assignee [and the Holder][a new Warrant Certificate][new Warrant Certificates] reflecting the foregoing assignment (each, a "***Substitute Warrant Certificate***").

The Assignee acknowledges and agrees that it is (and will be) bound by the terms and provisions of its Substitute Warrant Certificate, and further acknowledges and agrees that its Substitute Warrant Certificate and the Warrant Shares to be issued upon exercise thereof are being acquired for investment and that the Assignee will not offer, sell or otherwise dispose of its Substitute Warrant Certificate or any Warrant Shares to be issued upon exercise or conversion thereof except under circumstances which will not result in a violation of the Securities Act or any applicable state securities Laws. The Assignee represents and warrants for the benefit of the Company that the Assignee is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Securities Act.

To the extent (and for so long as) required pursuant to **Section 10(a)** of the Warrant Certificate, the Assignee acknowledges and agrees that restrictive legends shall be applied to the Assignee's Substitute Warrant and the Warrant Shares issuable upon exercise of such certificate substantially consistent with the legends required pursuant to **Section 10(a)** of the Warrant Certificate.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto agree as set forth above as of the date first written above.

[NAME OF HOLDER]

By _____
Name:
Title:

Accepted and agreed,

[NAME OF ASSIGNEE]

By _____
Name:
Title:

[_____]

By _____
Name:
Title:

Exhibit 10.1

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.

CREDIT AGREEMENT AND GUARANTY

dated as of

August 2, 2022

by and among

MEIRAGTX HOLDINGS PLC,
as the Borrower,

THE SUBSIDIARY GUARANTORS FROM TIME TO TIME PARTY HERETO,

as the Subsidiary Guarantors,

THE LENDERS FROM TIME TO TIME PARTY HERETO,

as the Lenders,

and

PERCEPTIVE CREDIT HOLDINGS III, LP
as the Administrative Agent

U.S. $100,000,000

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SCHEDULES AND EXHIBITS

CREDIT AGREEMENT AND GUARANTY

CREDIT AGREEMENT AND GUARANTY, dated as of August 2, 2022 (this "***Agreement***"), by and among MeiraGTx Holdings plc, an exempted company with limited liability incorporated under the laws of the Cayman Islands with registration number 336306 (the "***Borrower***"), certain Subsidiaries of the Borrower required to provide Guarantees from time to time hereunder, Perceptive Credit Holdings III, LP and each other lender that may from time to time become a party hereto (each, together with their permitted successors and assigns, a "***Lender***" and collectively, the "***Lenders***"), and Perceptive Credit Holdings III, LP, as administrative agent for the Lenders (in such capacity, together with its permitted successors and assigns, the "***Administrative Agent***").

WITNESSETH:

WHEREAS, the Borrower has requested that the Lenders provide a senior secured term loan facility to the Borrower in an aggregate principal amount of $100,000,000, with (i) $75,000,000 in aggregate principal amount of Loans to be available on the Closing Date (the "***Tranche 1 Loan***") and (ii) $25,000,000 in aggregate principal amount of Loans (the "***Tranche 2 Loan***") to be available after the Tranche 1 Borrowing Date but prior to August 2, 2024 (the "***Tranche 2 Draw Period***"), in each case, subject to the terms and conditions set forth herein, including the applicable terms and conditions set forth in **Section 6** hereof and, with respect to the Tranche 2 Loan, at the sole discretion of the Majority Lenders; and

WHEREAS, the Lenders are willing, on the terms and subject to the conditions set forth herein, to provide such senior secured term loan facility.

NOW, THEREFORE, the parties hereto agree as follows:

SECTION 1
DEFINITIONS

1.01 Certain Defined Terms. As used herein (including the preamble and recitals), the following terms have the following respective meanings:

"***Account Pledge Agreement***" means the Account Pledge Agreement, dated as of the date hereof, by and between the Borrower and the Administrative Agent.

"***Acquisition***" means any transaction, or any series of related transactions, by which any Person directly or indirectly, by means of an amalgamation, consolidation, merger, tender offer, purchase of Equity Interests or other assets or properties, or similar transaction having the same effect as any of the foregoing, (i) acquires all or substantially all of the assets of another Person including substantially all of a business line, business unit or business division of any other Person, (ii) acquires control of Equity Interests of another Person representing more than fifty percent (50%) of the ordinary voting power (as determined on a fully-diluted, as-if-converted or exercised basis) for the election of directors or other governing body if the business affairs of such Person are managed by a Board of directors, or (iii) acquires control of more than fifty percent (50%) of the Equity Interests (as determined on a fully-diluted, as-if-converted or exercised basis) of another Person engaged in any business that is not managed by a Board.

"***Administrative Agent***" has the meaning set forth in the preamble hereto.

"***Affected Financial Institution***" means (a) any EEA Financial Institution, or (b) any UK Financial Institution.

"***Affiliate***" means, with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified; provided that with respect to any Lender, an Affiliate of such Lender shall include, without limitation, all of such Lender's Related Funds so long as such entities are Controlled by such Lender.

"***Agreement***" has the meaning set forth in the preamble hereto.

"***Applicable Margin***" means ten percent (10.00%), as such percentage may be increased pursuant to **Section 3.02(b)**.

"***Asset Sale***" has the meaning set forth in **Section 9.09**.

"***Assignment and Assumption***" means an assignment and assumption entered into by a Lender and an assignee of such Lender in substantially the form of **Exhibit F**.

"***Authorisation***" means an authorisation, consent, approval, resolution, licence, exemption, filing, notarisation, certificate or registration.

"***Bail-In Action***" means the exercise of any Write-Down and Conversion Powers by the applicable Resolution Authority in respect of any liability of an Affected Financial Institution.

"***Bail-In Legislation***" means (a) with respect to any EEA Member Country implementing Article 55 of Directive 2014/59/EU of the European Parliament and of the Council of the European Union, the implementing law, regulation, rule or requirement for such EEA Member Country from time to time which is described in the EU Bail-In Legislation Schedule, and (b) with respect to the United Kingdom, Part I of the United Kingdom Banking Act 2009 (as amended from time to time) and any other law, regulation or rule applicable in the United Kingdom relating to the resolution of unsound or failing banks, investment firms or other financial institutions or their affiliates (other than through liquidation, administration or other insolvency proceedings).

"***Bank Levy***" means (i) any amount payable by any Recipient or any of its Affiliates on the basis of, or in relation to, its balance sheet or capital base or any part of that person's liabilities or minimum regulatory capital or any combination thereof (including, without limitation, the UK bank levy as set out in the Finance Act 2011) and any other levy or tax in any jurisdiction levied on a similar basis or for a similar purpose, (ii) any financial activities taxes (or other taxes) of a kind contemplated in the European Commission consultation paper on financial sector taxation dated 22 February 2011), and (iii) any bank surcharge or banking corporation tax surcharge as set out in United Kingdom Finance (No. 2) Act 2015 and any other surcharge or tax of a similar nature implemented in any other jurisdiction, in each case, as amended from time to time.

"***Bankruptcy Code***" means Title 11 of the United States Code entitled "Bankruptcy."

"***Benefit Plan***" means any employee benefit plan as defined in Section 3(3) of ERISA (whether governed by the laws of the United States or otherwise) to which any Obligor or Subsidiary thereof incurs or otherwise has any obligation or liability, contingent or otherwise.

"***Board***" means, with respect to any Person, the board of directors (or equivalent management or oversight body) of such Person or any committee thereof duly authorized to act on behalf of such board or equivalent body.

"***Borrower***" has the meaning set forth in the preamble hereto.

"***Borrower DTTP Filing***" means a HMRC Form DTTP2 duly completed and filed by the Borrower, which:

(a) where it relates to a UK Treaty Lender (or a Lender which would be a UK Treaty Lender upon the completion of any necessary procedural formalities) that is a party hereto as at the date of this Agreement, contains the UK DTTP Scheme reference number and jurisdiction of tax residence stated opposite that Lender's name in **Schedule 1** (*Commitments*), and is filed with HMRC within 30 days of the date of this Agreement; or

(b) where it relates to a UK Treaty Lender (or a Lender which would be a UK Treaty Lender upon the completion of any necessary procedural formalities) that becomes a party hereto after the date of this Agreement, contains the UK DTTP Scheme reference number and jurisdiction of tax residence stated in respect of that Lender in the relevant documentation which it executes on becoming a party hereto, and is filed with HMRC within 30 days of that date.

"***Borrower Party***" has the meaning set forth in **Section 14.03(b)**.

"***Borrowing***" means, as the context may require, the borrowing of the Tranche 1 Loan on the Closing Date or the borrowing of Tranche 2 Loan on the Tranche 2 Borrowing Date.

"***Borrowing Notice***" means a written notice substantially in the form of **Exhibit B**.

"***Business Day***" means a day (other than a Saturday, Sunday or other day that is a legal holiday under the laws of the State of New York, or under the laws of England) on which commercial banks are not authorized or required by Law to close in New York, New York and in London, England; provided that if such day relates to any document governed by the laws of Ireland or the performance of any obligations under the Loan Documents by any Obligor incorporated under the laws of Ireland, the term "Business Day" shall exclude any day on which commercial banks are authorized to close under the laws of, or are in fact closed in, Ireland.

"***Capital Lease Obligations***" means, as to any Person, the obligations of such Person to pay rent or other amounts under a lease of (or other agreement conveying the right to use) real and/or personal property which obligations are required to be classified and accounted for as a capital lease on a balance sheet of such Person under GAAP and, for purposes of this Agreement, the amount of such obligations shall be the capitalized amount thereof without giving effect to any change in accounting for leases pursuant to GAAP, including, without limitation, resulting from changes to (x) Accounting Standards Codification Topic 840, *Leases*, or the implementation of (y) Accounting Standards Codification Topic 842, *Leases*).

"***Casualty Event***" means the damage, destruction or condemnation, as the case may be, of any property of any Person.

"***Certificate of Title***" means a certificate of or report on title in respect of the London Manufacturing Facility and Shannon Manufacturing Facility (as applicable) prepared by the Borrower's solicitors and supplied to the Administrative Agent in accordance with **Section 8.17** dated as at the date of this Agreement.

"***cGMP***" means (i) the FDA's current good manufacturing practice, (ii) any similar or functionally equivalent guidelines or requirements applicable to, or required by, any non-U.S. jurisdiction or Governmental Authority and (iii) all supplements, amendments, or regulatory filings related to any of the foregoing.

"***Change of Control***" means (i) any transaction, or any series of related transactions, by which any Person directly or indirectly, by means of a tender offer, amalgamation, consolidation, merger, purchase of assets, or similar transaction having the same effect as any of the foregoing, acquires ownership, directly or indirectly, beneficially or of record, by any Person or group of Persons acting jointly or otherwise in concert of Equity Interests of the Borrower having more than thirty-five percent (35%) of the aggregate ordinary voting power, determined on a fully diluted, as-if converted or exercised, basis, (ii) the Borrower shall cease to own, directly or indirectly, beneficially and of record, one hundred percent (100%) of the issued and outstanding Equity Interests of each of the Subsidiary Guarantors or (iii) the sale of all or substantially all of the property of the business of the Borrower and its Subsidiaries, taken as a whole.

"***Change of Law***" means any change after the date of this Agreement or, if later, after the date on which the relevant Lender became a Lender under this Agreement (as applicable) in any law, regulation or Treaty (or in the published interpretation, administration or application of any law, regulation or Treaty) or any published practice or published concession of any relevant tax authority, other than any change that occurs pursuant to, or in connection with, the adoption, ratification, approval or acceptance of, the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting of 24 November 2016 in or by any jurisdiction.

"***Claim***" means any claim, demand, complaint, grievance, action, application, suit, cause of action, order, charge, indictment, prosecution, final judgment or other similar process, assessment or reassessment, whether made, converted or assessed in connection with a debt, liability, dispute, breach, failure or otherwise.

"***Closing Date***" means August 2, 2022.

"***Code***" means the U.S. Internal Revenue Code of 1986.

"***Collateral***" means any asset or property in which a Lien is purported to be granted under any Security Documents.

"***Commitment***" means, with respect to each Lender, the obligation of such Lender to make the Loan to the Borrower on the Closing Date in accordance with the terms and conditions of this Agreement, which commitments are in the amounts set forth opposite such Lender's name on

Schedule 1 hereto, as such Schedule may be amended from time to time pursuant to an Assignment and Assumption or otherwise; provided that with respect to the Loan, the aggregate Commitments of all Lenders on the Closing Date equal $75,000,000.

"***Commodity Account***" means any commodity account, as such term is defined in Section 9-102 of the NY UCC.

"***Competitor***" means any Person that is (i) listed as a competitor in the Borrower's most recent public filings made with the SEC as may be supplemented from time to time with the SEC or (ii) listed on **Schedule A**.

"***Compliance Certificate***" has the meaning set forth in **Section 8.01(c)**.

"***Conforming Changes***" means, with respect to either the use or administration of One-Month Term SOFR, any technical, administrative or operational changes (including changes to the definition of "Business Day," the definition of "U.S. Government Securities Business Day," the definition of "Interest Period" or any similar or analogous definition (or the addition of a concept of "interest period"), with respect to the timing and frequency of determining rates and making payments of interest, the timing of borrowing requests or prepayments, conversion or continuation notices, the applicability and length of lookback periods, the applicability of **Section 3.02(e)** and other technical, administrative or operational matters) that the Administrative Agent reasonably decides may be appropriate to reflect the adoption and implementation of any such rate or to permit the use and administration thereof by the Administrative Agent in a manner substantially consistent with market practice (or, if the Administrative Agent decides that adoption of any portion of such market practice is not administratively feasible or if the Administrative Agent determines that no market practice for the administration of any such rate exists, in such other manner of administration as the Administrative Agent decides is reasonably necessary in connection with the administration of this Agreement and the other Loan Documents).

"***Connection Income Taxes***" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

"***Contingent Acquisition Obligations***" has the meaning set forth in **clause (v)** of the definition of "***Indebtedness***".

"***Contract***" means any contract, license, lease, agreement, obligation, promise, undertaking, understanding, arrangement, document, commitment, entitlement, indenture, instrument, or engagement under which a Person has, or will have, any liability or contingent liability (in each case, whether written or oral, express or implied, and whether in respect of monetary or payment obligations, performance obligations or otherwise).

"***Control***" means, in respect of a particular Person, the possession, by one or more other Persons, directly or indirectly, of the power to direct or cause the direction of the management or policies of such particular Person, whether through the ability to exercise voting power, by contract or otherwise. "***Controlling***" and "***Controlled***" (and similar derivatives) have meanings correlative thereto.

"***Controlled Account***" has the meaning set forth in **Section 8.16(a)**.

"***Copyright***" means all copyrights, copyright registrations and applications for copyright registrations, including all renewals and extensions thereof, all rights to recover for past, present or future infringements thereof, and all other rights whatsoever accruing thereunder or pertaining thereto.

"***Default***" means any Event of Default and any event that, upon the giving of notice, the lapse of time or both, would constitute an Event of Default.

"***Default Rate***" has the meaning set forth in **Section 3.02(b)**.

"***Deposit Account***" means any deposit account, as such term is defined in Section 9-102 of the NY UCC.

"***Designated Jurisdiction***" means any country or territory that is itself the target of comprehensive Sanctions (as of the date of this Agreement, Cuba, Iran, North Korea, Syria, the Crimea region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic).

"***Disqualified Equity Interests***" means, with respect to any Person, any Equity Interest of such Person that, by its terms (or by the terms of any security or other Equity Interest into which it is convertible or for which it is exchangeable upon exercise or otherwise), or upon the happening of any event or condition (i) matures or is mandatorily redeemable (other than solely for Qualified Equity Interests), including pursuant to a sinking fund obligation or otherwise, (ii) is redeemable at the option of the holder thereof (other than solely for Qualified Equity Interests), in whole or in part, (iii) provides for the scheduled payments of dividends or other distributions in cash or other securities that would constitute Disqualified Equity Interests, or (iv) is or becomes convertible into or exchangeable for Indebtedness or any other Equity Interests that would constitute Disqualified Equity Interests, in each case, prior to the date that is ninety-one (91) days after the scheduled Maturity Date; provided that, if such Equity Interests are issued pursuant to any plan for the benefit of directors, officers, employees or consultants of such Person or by any such plan to such directors, officers, employees or consultants, such Equity Interests shall not constitute Disqualified Equity Interests solely because they may be required to be repurchased by such Person upon the death, disability, retirement or termination of employment or service of such director, officer, employee or consultant.

"***Disqualified Institution***" means (i) those Persons that are Competitors, (ii) those Persons separately identified by name by the Borrower to the Administrative Agent in writing on or before the Closing Date, or (iii) in the case of **clauses (i)** or **(ii)**, any of their respective Affiliates (other than Affiliates that are bona fide debt funds engaged in, or that advise funds or other investment vehicles that are engaged in, making, purchasing, holding or otherwise investing in commercial loans, notes, bonds or similar extensions of credit or securities in the ordinary course of its business except such funds that primarily invest in distressed debt or other distressed financial assets) that are (x) clearly identifiable as Affiliates solely on the basis of their name (provided that the Administrative Agent shall not have any obligation to carry out due diligence in order to identify such Affiliates) or (y) identified by name by the Borrower to the Administrative Agent in writing

from time to time; provided that the foregoing shall not apply retroactively to disqualify any Person that previously acquired an assignment or participation interest to the extent such Person was not a Disqualified Institution at the time of the applicable assignment or participation, as the case may be.

"***Dollars***" and "***$***" means lawful money of the United States of America.

"***Early Prepayment Fee***" means, with respect to any prepayment of all or any portion of the outstanding principal amount of the Loans on any Prepayment Date, whether pursuant to **clause (a)** or **(b)** of **Section 3.03** or otherwise, occurring (i) on or prior to the first anniversary of the Closing Date, an amount equal to the sum of five percent (5.0%) of the aggregate outstanding principal amount of the Loan being prepaid; (ii) at any time after the first anniversary of the Closing Date and on or prior to the second anniversary of the Closing Date, an amount equal to four percent (4.0%) of the aggregate outstanding principal amount of the Loans being prepaid; (iii) at any time after the second anniversary of the Closing Date and on or prior to the third anniversary of the Closing Date, an amount equal to one percent (1.0%) of the aggregate outstanding principal amount of the Loans being prepaid and (iv) thereafter, zero percent (0%) of the aggregate outstanding principal amount of the Loans being prepaid.

"***EEA Financial Institution***" means (i) any credit institution or investment firm established in any EEA Member Country which is subject to the supervision of an EEA Resolution Authority, (ii) any entity established in an EEA Member Country which is a parent of an institution described in **clause (i)** of this definition, or (iii) any financial institution established in an EEA Member Country which is a subsidiary of an institution described in **clauses (i)** or **(ii)** of this definition and is subject to consolidated supervision with its parent.

"***EEA Member Country***" means any of the member states of the European Union, Iceland, Liechtenstein, and Norway.

"***EEA Resolution Authority***" means any public administrative authority or any person entrusted with public administrative authority of any EEA Member Country (including any delegee) having responsibility for the resolution of any EEA Financial Institution.

"***Eligible Transferee***" means and includes (i) any commercial bank, (ii) any insurance company, (iii) any finance company, (iv) any financial institution, (v) any investment fund that invests in loans or other obligations for borrowed money, (vi) with respect to any Lender, any of its Affiliates, and (vii) any other "accredited investor" (as defined in Regulation D of the Securities Act) that is principally in the business of managing investments or holding assets for investment purposes; provided that, in each case, "Eligible Transferee" shall not include any Disqualified Institution.

"***English Guarantor***" means MeiraGTx UK II Limited incorporated in England and Wales with company registration number 09348737.

"***English Law Security Agreement***" means the English law governed security agreement dated on or about the date of this Agreement and made between the English Guarantor and the Irish Subsidiary Guarantor as chargor and the Administrative Agent as security trustee.

"***English Law Share Charge***" means the English law governed share charge in respect of the shares MeiraGTx Limited owns in the English Guarantor dated on or about the date of this Agreement and made between the Borrower as charger and the Administrative Agent as security trustee.

"***English Obligor***" means any Obligor incorporated in England and Wales.

"***Environmental Law***" means any Law or Governmental Approval relating to pollution or protection of the environment or the treatment, storage, disposal, release, threatened release or handling of hazardous materials, and all local laws and regulations, whether U.S. or non-U.S., related to environmental matters and any specific agreements entered into with any competent authorities which include commitments related to environmental matters.

"***Equity Interests***" means, with respect to any Person (for purposes of this defined term, an "***issuer***"), all shares of, interests or participations in, or other equivalents in respect of such issuer's capital stock, including all membership interests, partnership interests or equivalent, and all debt or other securities (including warrants, options and similar rights) directly or indirectly exchangeable, exercisable or otherwise convertible into, such issuer's capital stock, whether now outstanding or issued after the Closing Date, and in each case, however classified or designated and whether voting or non-voting.

"***Equivalent Amount***" means, with respect to an amount denominated in a single currency, the amount in another currency that could be purchased by the amount in the former currency determined by reference to the Exchange Rate at the time of determination.

"***ERISA***" means the United States Employee Retirement Income Security Act of 1974, as amended.

"***ERISA Affiliate***" means, collectively, any Obligor, Subsidiary thereof, and any Person under common control, or treated as a single employer, with any Obligor or Subsidiary thereof, within the meaning of Section 414(b), (c), (m) or (o) of the Code.

"***ERISA Event***" means (i) a reportable event as defined in Section 4043 of ERISA with respect to a Title IV Plan, excluding, however, such events as to which the PBGC by regulation has waived the requirement of Section 4043(a) of ERISA that it be notified within thirty (30) days of the occurrence of such event; (ii) a withdrawal by any Obligor or any ERISA Affiliate thereof from a Title IV Plan or the termination of any Title IV Plan resulting in liability under Sections 4063 or 4064 of ERISA; (iii) the withdrawal of any Obligor or any ERISA Affiliate thereof in a complete or partial withdrawal (within the meaning of Section 4203 and 4205 of ERISA) of any ERISA Affiliate from any Multiemployer Plan if there is any potential liability therefor, or the receipt by any Obligor or any ERISA Affiliate thereof of notice from any Multiemployer Plan that it is insolvent pursuant to Section 4245 of ERISA; (iv) the filing of a notice of intent to terminate, the treatment of a plan amendment as a termination under Section 4041 or 4041A of ERISA, or the commencement of proceedings by the PBGC to terminate a Title IV Plan or Multiemployer Plan; (v) the imposition of liability on any Obligor or any ERISA Affiliate thereof pursuant to Sections 4062(e) or 4069 of ERISA or by reason of the application of Section 4212(c) of ERISA; (vi) the failure by any Obligor or any ERISA Affiliate thereof to make any required contribution

to a Plan, or the failure to meet the minimum funding standard of Section 412 of the Code with respect to any Title IV Plan (whether or not waived in accordance with Section 412(c) of the Code) or the failure to make by its due date a required installment under Section 430 of the Code with respect to any Title IV Plan or the failure to make any required contribution to a Multiemployer Plan; (vii) the determination that any Title IV Plan is considered an at-risk plan or a plan in endangered to critical status within the meaning of Sections 430, 431 and 432 of the Code or Sections 303, 304 and 305 of ERISA; (viii) an event or condition which could reasonably be expected to constitute grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Title IV Plan or Multiemployer Plan; (ix) the imposition of any liability under Title I or Title IV of ERISA, other than PBGC premiums due but not delinquent under Section 4007 of ERISA, upon any Obligor or any ERISA Affiliate thereof; (x) an application for a funding waiver under Section 303 of ERISA or an extension of any amortization period pursuant to Section 412 of the Code with respect to any Title IV Plan; (xi) the occurrence of a non-exempt prohibited transaction under Sections 406 or 407 of ERISA for which any Obligor or any Subsidiary thereof may be directly or indirectly materially liable; (xii) receipt from the IRS of notice of the failure of any Qualified Plan to qualify under Section 401(a) of the Code, or the failure of any trust forming part of any Qualified Plan to fail to qualify for exemption from taxation under Section 501(a) of the Code; (xiii) the imposition of any Lien (or the fulfillment of the conditions for the imposition of any Lien) on any of the rights, properties or assets of any Obligor or any ERISA Affiliate thereof, in either case pursuant to Title I or Title IV of ERISA, including Section 302(f) or 303(k) of ERISA or to Section 401(a)(29) or 430(k) of the Code; or (xiv) any Foreign Benefit Event.

"***ERISA Funding Rules***" means the rules regarding minimum required contributions (including any installment payment thereof) to Title IV Plans, as set forth in Sections 412, 430, 431, 432 and 436 of the Code and Sections 302, 303, 304 and 305 of ERISA.

"***EU Bail-In Legislation Schedule***" means the EU Bail-In Legislation Schedule published by the Loan Market Association (or any successor Person), as in effect from time to time.

"***Euros***" or "**€**" means the single currency of the member states of the European Union that have the euro as their lawful currency in accordance with legislation of the European Union relating to the Economic and Monetary Union.

"***Event of Default***" has the meaning set forth in **Section 11.01**.

"***Exchange Rate***" means, as of any date of determination, the rate at which any currency may be exchanged into another currency, as set forth on the relevant Reuters screen at or about 11:00 a.m. (New York City time) on such date. In the event that such rate does not appear on the Reuters screen, the "***Exchange Rate***" shall be determined by reference to such other publicly available service for displaying exchange rates as may be reasonably agreed upon by the Borrower and the Administrative Agent (each acting in good faith) or, in the absence of such agreement within two (2) Business Days, such Exchange Rate shall instead be reasonably designated by the Administrative Agent.

"***Excluded Taxes***" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient: (i) Taxes imposed

on or measured by net income (however denominated), franchise Taxes and branch profits Taxes, in each case, (x) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivisions thereof) or (y) that are Other Connection Taxes (ii) any withholding Taxes imposed under FATCA, or (iii) in the case of any successor or assignee of Perceptive Credit Holdings III, LP, any UK Tax Deduction that qualifies as a UK Excluded Tax.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"***Exclusive License***" means any outbound license of Intellectual Property that is exclusive (whether as to use, field, geography or otherwise) and (i) has a term that is longer than twelve (12) months from the date of the original effective date of such license or (ii) is not subject to any automatic renewal right or obligation by the parties thereto.

"***FATCA***" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

"***FD&C Act***" means the U.S. Food, Drug and Cosmetic Act of 1938 (21 U.S.C. §§ 301), as amended from time to time, and the regulations promulgated thereunder.

"***FDA***" means the U.S. Food and Drug Administration and any successor entity.

"***Federal Funds Effective Rate***" means, for any day, the greater of (i) the rate calculated by the Federal Reserve Bank of New York based on such day's federal funds transactions by depositary institutions (as determined in such manner as the Federal Reserve Bank of New York sets forth on its public website from time to time) and published on the next succeeding Business Day by the Federal Reserve Bank of New York as the federal funds effective rate and (ii) zero percent (0%).

"***Foreign Benefit Event***" means, with respect to any Foreign Pension Plan, (a) the existence of unfunded liabilities in excess of the amount permitted under any material applicable Law, or in excess of the amount that would be permitted absent a waiver from a Governmental Authority, (b) the failure to make the required contributions or payments, under any material applicable Law, on or before the due date for such contributions or payments, (c) the receipt of a written notice by a Governmental Authority relating to the termination of any such Foreign Pension Plan or to appoint a trustee or similar official to administer any such Foreign Pension Plan, or alleging the insolvency of any such Foreign Pension Plan, (d) the incurrence of any liability the Borrower or any of its Subsidiaries under applicable Law on account of the complete or partial termination of such Foreign Pension Plan or the complete or partial withdrawal of any participating employer therein, or (e) the occurrence of any transaction that is prohibited under any applicable Law and that could reasonably be expected to result in the incurrence of any liability by the

Borrower or any of its Subsidiaries, or the imposition on the Borrower or any of its Subsidiaries of any fine, excise tax or penalty resulting from any noncompliance with any applicable Law.

"***Foreign Pension Plan***" means any benefit plan that under applicable Law, other than the Laws of the United States or any political subdivision thereof, is required to be funded through a trust or other funding vehicle other than a trust or funding vehicle maintained exclusively by a Governmental Authority.

"***Foreign Collateral Security Documents***" means (i) the English Law Security Agreement, (ii) the English Law Share Charge, (iii) the Irish Security Agreement, (iv) the Irish Share Charge, and (v) any other document evidencing or creating a Lien over any asset to secure any obligation of any Obligor to the Secured Parties under the Loan Documents.

"***Foreign Real Property Security Document***" means any Contract evidencing or creating a Lien over any Manufacturing Facility entered into in accordance with **Section 8.17**.

"***GAAP***" means generally accepted accounting principles in the United States, as in effect from time to time, set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants, in the statements and pronouncements of the Financial Accounting Standards Board and in such other statements by such other entity as may be in general use by significant segments of the accounting profession that are applicable to the circumstances as of the date of determination. Unless otherwise mutually agreed upon by the Borrower and the Administrative Agent pursuant to **Section 1.02(b)**, all references to "GAAP" used herein shall be to GAAP applied consistently with the principles used in the preparation of the financial statements delivered pursuant to **Section 6.01(e)(i)**.

"***Governmental Approval***" means any consent, authorization, approval, order, license, franchise, permit (including any Healthcare Permit), certification, accreditation, registration, clearance, exemption, filing or notice that is issued or granted by or from (or pursuant to any act of) any Governmental Authority pursuant to or in connection with any Law (including any Healthcare Law).

"***Governmental Authority***" means any nation, government, branch of power (whether executive, legislative or judicial), state, province or municipality or other political subdivision thereof and any entity exercising executive, legislative, judicial, monetary, regulatory or administrative functions of or pertaining to government, including without limitation regulatory authorities, governmental departments, agencies, commissions, bureaus, officials, ministers, courts, bodies, boards, tribunals and dispute settlement panels, and other law-, rule- or regulation-making organizations or entities of any state, territory, county, city or other political subdivision of any country, in each case whether U.S. or non-U.S., including the FDA and any other agency, branch or other governmental body that has regulatory, supervisory or administrative authority or oversight over, or is charged with the responsibility or vested with the authority to administer or enforce, any Healthcare Laws or issue or approve any Healthcare Permits under or in connection with any such Healthcare Laws.

"***Guarantee***" of or by any Person (the "***guarantor***") means any obligation, contingent or otherwise, of the guarantor guaranteeing or having the economic effect of guaranteeing any

Indebtedness or other monetary obligation of any other Person (the "***primary obligor***") in any manner, whether directly or indirectly, and including any obligation of the guarantor, direct or indirect, (i) to purchase or pay (or advance or supply funds for the purchase or payment of) such Indebtedness or other monetary obligation or to purchase (or to advance or supply funds for the purchase of) any security for the payment thereof, (ii) to purchase or lease property, securities or services for the purpose of assuring the owner of such Indebtedness or other monetary obligation of the payment thereof, (iii) to maintain working capital, equity capital or any other financial statement condition or liquidity of the primary obligor so as to enable the primary obligor to pay such Indebtedness or other monetary obligation or (iv) as an account party in respect of any letter of credit or letter of guaranty issued to support such Indebtedness or monetary obligation; provided, that the term "Guarantee" shall not include endorsements for collection or deposit in the ordinary course of business.

"***Guarantee Assumption Agreement***" means a Guarantee Assumption Agreement substantially in the form of **Exhibit C**, executed by any entity that, pursuant to **Section 8.12** is required to become a "Subsidiary Guarantor".

"***Guaranteed Obligations***" has the meaning set forth in **Section 13.01**.

"***Hazardous Material***" means any substance, element, chemical, compound, product, solid, gas, liquid, waste, by-product, pollutant, contaminant or material which is hazardous or toxic, and includes, without limitation, (i) asbestos, polychlorinated biphenyls and petroleum (including crude oil or any fraction thereof) and (ii) any material classified or regulated as "hazardous" or "toxic" or words of like import pursuant to an Environmental Law.

"***Headlease***" means a lease under which an Obligor holds title to all or any part of a Manufacturing Facility.

"***Healthcare Laws***" means all applicable healthcare Laws, whether U.S. or non-U.S., the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)) (the "***Federal Anti-Kickback Statute***"), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Act (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1035, 1347 and 1349, the exclusion law (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §§ 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the FD&C Act, the statutes, regulations and binding directives of applicable federal healthcare programs, including but not limited to Medicare (Title XVIII of the Social Security Act) and Medicaid (Title XIX of the Social Security Act), any rules and regulations promulgated pursuant to the statutes listed herein and any and all comparable U.S. and non-U.S. Laws and other applicable healthcare laws and regulations.

"***Healthcare Permit***" means, with respect to any Person and with respect to its ordinary course business or commercial activities (including the commercialization and development of its products), any Governmental Approval (i) issued or required under any Healthcare Laws applicable to such activities of such Person, or (ii) issued to such Person or required to be held by

such Person under any Healthcare Laws with respect to its ordinary course business or commercial activities (including the commercialization and development of its products).

"***Hedging Agreement***" means any interest rate exchange agreement, foreign currency exchange agreement, commodity price protection agreement or other interest or currency exchange rate or commodity price hedging arrangement. For the avoidance of doubt, no Permitted Bond Hedge Transaction or Permitted Warrant Transaction shall constitute Hedging Agreements.

"***HMRC***" means HM Revenue & Customs.

"***IDA Grant***" means the transactions and grant awarded by the Industrial Development Agency (Ireland) to the Irish Subsidiary Guarantor pursuant to the IDA Grant Agreement.

"***IDA Grant Agreement***" means the IDA Grant Agreement, dated as of August 27, 2021, by and between the Industrial Development Agency (Ireland) and the Irish Subsidiary Guarantor, as amended, restated, supplemented or otherwise modified from time to time.

"***Immaterial Subsidiary***" means, as of any date of determination, any Subsidiary of an Obligor (i) the unconsolidated assets of which does not exceed 5.0% of the consolidated assets of the Borrower and its consolidated Subsidiaries as set forth in the financial statements most recently delivered pursuant to **Sections 6.01**, **8.1(a)** or **8.1(b)**, as applicable, and (ii) the unconsolidated revenues of which does not exceed 5.0% of the consolidated revenues of the Borrower and its consolidated Subsidiaries as set forth in the financial statements most recently delivered pursuant to **Sections 6.01**, **8.1(a)** or **8.1(b)**, as applicable; provided that no Subsidiary of the Obligors shall qualify as an Immaterial Subsidiary if the assets or revenue of such Subsidiary taken together with the consolidated assets or revenue of all then existing Immaterial Subsidiaries exceeds 10.0% of the consolidated assets or revenue, as applicable, of the Borrower and its consolidated Subsidiaries.

"***Impermissible Specified Assets Exclusive License***" means any outbound license (or similar transaction or arrangement) of any Specified Asset, in whole or in part, to a Person that is not an Affiliate that (i) qualifies as an Exclusive License, and (ii) is not terminable by its terms (or automatically terminates) or by the licensor within twenty (20) years from either (x) the original date of such outbound license or (y) if the term of such outbound license is extended and so long as such extension does not result from an automatic renewal right or equivalent, the date of such extension.

"***Indebtedness***" of any Person means, without duplication, (i) all obligations of such Person for borrowed money, (ii) all obligations of such Person evidenced by bonds, debentures, notes, loan agreements, or similar instruments, (iii) all obligations of such Person upon which interest charges are customarily paid (excluding trade account payables), (iv) all obligations of such Person under conditional sale or other title retention agreements relating to property acquired by such Person, (v) all obligations of such Person in respect of the deferred purchase price of property or services ((A) excluding accounts payable incurred in the ordinary course of business, but (B) including earn-out payments, purchase price adjustments and similar contingent payment obligations relating to any Acquisition (such obligations arising pursuant to **clause (B)**, collectively, "***Contingent Acquisition Obligations***")), (vi) all Indebtedness of others secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be

secured by) any Lien on property owned or acquired by such Person, whether or not the Indebtedness secured thereby has been assumed, (vii) all Guarantees by such Person of Indebtedness of others, (viii) all Capital Lease Obligations of such Person, (ix) all obligations, contingent or otherwise, of such Person as an account party in respect of letters of credit and letters of guaranty, (x) obligations under any Hedging Agreement, currency swaps, forwards, futures or derivatives transactions, (xi) all obligations, contingent or otherwise, of such Person in respect of bankers' acceptances, (xii) all obligations of such Person under license or other agreements containing a guaranteed minimum payment or purchase by such Person other than operating leases entered into in the ordinary course of business and any such license or other agreement for the purchase of goods, software and other intangibles, services or supplies in the ordinary course of business, (xiii) any Disqualified Equity Interests of such Person, and (xiv) all other obligations required to be classified as indebtedness of such Person under GAAP, excluding any of the foregoing to the extent comprised of an obligation in respect of a trade payable, a commercial letter of credit supporting one or more trade payables or similar obligations to a trade creditor, in each case in the ordinary course of business. The Indebtedness of any Person shall include the Indebtedness of any other entity (including any partnership in which such Person is a general partner) to the extent such Person is liable therefor as a result of such Person's ownership interest in or other relationship with such entity, except to the extent the terms of such Indebtedness provide that such Person is not liable therefor. Notwithstanding the foregoing, no Permitted Bond Hedge Transaction or Permitted Warrant Transaction shall constitute Indebtedness.

"***Indemnified Party***" has the meaning set forth in **Section 14.03(b)**.

"***Indemnified Taxes***" means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any Obligation and (ii) to the extent not otherwise described in **clause (i)**, Other Taxes.

"***Independent Appraiser***" has the meaning set forth in **Section 6.01(p)**.

"***Information Certificate***" means an Information and Collateral Certificate, in substantially the form set forth in **Exhibit G**.

"***Insolvency Proceeding***" means (i) any case, action or proceeding before any court or other Governmental Authority relating to bankruptcy, reorganization, insolvency, liquidation, receivership, examinership, dissolution, winding-up or relief of debtors, or (ii) any general assignment for the benefit of creditors, composition, marshaling of assets for creditors, or other, similar arrangement in respect of any Person's creditors generally or any substantial portion of such Person's creditors, in each case undertaken under U.S. federal, state or foreign Law, including the Bankruptcy Code, or similar laws of Ireland or other applicable jurisdictions from time to time.

"***Intellectual Property***" means all Patents, Trademarks, Copyrights, and Technical Information, whether registered or not, U.S. or non-U.S., including (without limitation) all of the following:

(i) applications, registrations, amendments and extensions relating to such Intellectual Property;

(ii) rights and privileges arising under any applicable Laws with respect to such Intellectual Property;

(iii) rights to sue for or collect any damages for any past, present or future infringements of such Intellectual Property; and

(iv) rights of the same or similar effect or nature in any jurisdiction corresponding to such Intellectual Property throughout the world.

"***Intercompany Subordination Agreement***" means a subordination agreement to be executed and delivered by the Borrower and each of its Subsidiaries, pursuant to which all obligations in respect of any Indebtedness owing to any such Person by the Borrower or any of its Subsidiaries shall be subordinated to the prior payment in full in cash of all Obligations, such agreement to be substantially in the form attached hereto as **Exhibit H**.

"***Interest Period***" means (i) initially, the period commencing on (and including) the Closing Date and ending on (and including) the last day of the calendar quarter in which the Closing Date occurred, and (ii) thereafter, the period beginning on (and including) the first day of each succeeding calendar quarter and ending on the earlier of (and including) (x) the last day of such calendar quarter and (y) the Maturity Date.

"***Interest Rate***" means, for any Interest Period, the sum of (i) the Applicable Margin plus (ii) the greater of (x) the Reference Rate as of the second Business Day immediately preceding the first day of such Interest Period and (y) one percent (1.00%).

"***Invention***" means any novel, inventive or useful art, apparatus, method, process, machine (including any article or device), manufacture or composition of matter, or any novel, inventive and useful improvement in any art, method, process, machine (including article or device), manufacture or composition of matter.

"***Investment***" means, for any Person: (i) the acquisition (whether for cash, property, services or securities or otherwise) of Equity Interests, bonds, notes, debentures, partnership or other ownership interests or other securities of any other Person or any agreement to make any such acquisition (including any "short sale" or any sale of any securities at a time when such securities are not owned by the Person entering into such sale); (ii) the making of any deposit with, or advance, loan, assumption of debt, or other extension of credit to, or capital contribution in any other Person (including the purchase of property from another Person subject to an understanding or agreement, contingent or otherwise, to resell such property to such Person), but excluding any such advance, loan or extension of credit having a term not exceeding one hundred eighty (180) days arising in connection with the sale of inventory, services or supplies by such Person in the ordinary course of business; (iii) the entering into of any Guarantee of, or other contingent obligation with respect to, Indebtedness or other liability of any other Person and (without duplication) any amount committed to be advanced, lent or extended to such Person; or (iv) the entering into of any Hedging Agreement. The amount of an Investment will be determined at the time the Investment is made without giving effect to any subsequent changes in value.

"***Irish Companies Act***" means the Companies Act of Ireland, 2014 (as amended).

"***Irish Security Agreement***" means the Irish law debenture to be executed and delivered by the Irish Subsidiary Guarantor and the Administrative Agent, as amended, restated, amended and restated, supplemented or otherwise modified from time to time.

"***Irish Share Charge***" means an Irish law share charge over the shares of MeiraGTx Ireland DAC, to be executed and delivered by MeiraGTx Limited and the Administrative Agent, as amended, restated, amended and restated, supplemented or otherwise modified from time to time.

"***Irish Subsidiary Guarantor***" means MeiraGTx Ireland DAC, a designated activity company limited by shares incorporated in Ireland under registration number 672472 and with its registered address at 25-28 North Wall Quay, Dublin 1, D01 H104 and any other company incorporated in Ireland who accedes to this Agreement as a Subsidiary Guarantor from time to time.

"***IRS***" means the U.S. Internal Revenue Service.

"***Janssen Collaboration Agreement***" means that certain Collaboration, Option and License Agreement, dated January 30, 2019, by and between Janssen Pharmaceuticals, Inc. and Borrower, as may be amended, restated, supplemented or otherwise modified from time to time.

"***Law***" means any U.S. or non-U.S. federal, state, provincial, territorial, municipal or local statute, treaty, rule, regulation, ordinance, code or administrative or judicial precedent or authority, including any interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority, in each case having the force of law.

"***Legal Reservations***" means, solely in respect of the English Guarantor and the Irish Subsidiary Guarantor, (i) the principle that equitable or discretionary remedies may be granted or refused at the discretion of a court and the limitation of enforcement by laws relating to insolvency, reorganisation and other laws generally affecting the rights of creditors; (ii) the time barring of claims under the UK Limitation Acts or the Statute of Limitations 1957 (Ireland) (as applicable), the possibility that an undertaking to assume liability for or indemnify a person against non-payment of stamp duty may be void and defences of set-off or counterclaim; (iii) the limitation of the enforcement of the terms of leases of real property by laws of general application to those leases; (iv) similar principles, rights and remedies under the laws of any Relevant Jurisdiction; and (v) any other matters which are set out as qualifications or reservations as to matters of law of general application in any legal opinions supplied to the Lender under this Agreement.

"***Lenders***" has the meaning set forth in the preamble hereto.

"***Lien***" means any mortgage, lien, pledge, charge, assignment by way of security or other security interest, or any lease, title retention agreement, mortgage, restriction, easement, right-of-way, option or adverse claim (of ownership or possession) or other encumbrance of any kind or character whatsoever or any preferential arrangement that has the practical effect of creating a security interest.

"***Loan***" means, as the context may require, any of the Tranche 1 Loan and the Tranche 2 Loan, and "Loans" means, collectively, any combination of the foregoing, as the case may be.

"***Loan Documents***" means, collectively, this Agreement, the Notes, the Security Documents, any Guarantee, any Warrant Certificate, the Intercompany Subordination Agreement, and any other guaranty, security agreement, subordination agreement, intercreditor agreement or other present or future document, instrument, agreement, certificate or other amendment, waiver or modification of the foregoing, delivered to the Administrative Agent or any Lender in connection with this Agreement or any of the other Loan Documents, in each case, as amended or otherwise modified.

"***London Manufacturing Facility***" means the leasehold interest held by the UK Subsidiary Guarantor with Land Registry title number EGL434767 and known as Pharmacy Manufacturing Unit, Britannia Walk, London (N1 7LU) and located at 92 Britannia Walk, London, United Kingdom.

"***Loss***" means judgments, debts, liabilities, expenses, costs, damages or losses, contingent or otherwise, whether liquidated or unliquidated, matured or unmatured, disputed or undisputed, contractual, legal or equitable, including loss of value, professional fees, including fees and disbursements of legal counsel on a full indemnity basis, and all costs incurred in investigating or pursuing any Claim or any proceeding relating to any Claim.

"***Majority Lenders***" means, at any time, Lenders having at such time in excess of fifty percent (50%) of the aggregate Commitments (or, if such Commitments are terminated, the outstanding principal amount of the Loans) then in effect, ignoring, in such calculation, the Commitments of and outstanding Loans owing to any Lender that has failed to perform its funding obligations in respect of its Commitment to make Loans hereunder.

"***Manufacturing Facility***" means (i) the Shannon Manufacturing Facility and (ii) the London Manufacturing Facility.

"***Margin Stock***" means "margin stock" within the meaning of Regulation U and Regulation X.

"***Material Adverse Change***" and "***Material Adverse Effect***" mean a material adverse change in or effect on (i) the business, assets, operations or condition (financial or otherwise) of the Borrower and its Subsidiaries, taken as a whole, (ii) the ability of any Obligor to perform its obligations under the Loan Documents, as and when due, or (iii) the legality, validity, binding effect or enforceability of the Loan Documents or the rights and remedies of the Administrative Agent or the Lenders under any of the Loan Documents.

"***Material Agreement***" means (i) any Contract to which the Borrower or any of its Subsidiaries is a party or a beneficiary from time to time, the absence or termination of which could reasonably be expected to result in a Material Adverse Effect, and (ii) without duplication, any other Contract to which the Borrower or any of its Subsidiaries is a party or a guarantor (or equivalent) that, during any period of twelve (12) consecutive months is reasonably expected to (1) result in payments or receipts (including royalty, licensing or similar payments) made to the Borrower or any of its Subsidiaries in an aggregate amount in excess of $5,000,000, or (2) require

payments or expenditures (including royalty, licensing or similar payments) to be made by the Borrower or any of its Subsidiaries in an aggregate amount in excess of $5,000,000.

"***Material Indebtedness***" means, at any time, any Indebtedness of any Obligor or any Subsidiary thereof (excluding any intercompany Indebtedness by and among the Obligors and their respective Subsidiaries that is permitted hereunder), the outstanding principal amount of which, individually or in the aggregate, exceeds $5,000,000 (or the Equivalent Amount in other currencies).

"***Material Intellectual Property***" means any Intellectual Property of the Obligors, whether currently owned or licensed, or acquired, developed or otherwise licensed or obtained after the date hereof the loss of which could reasonably be expected to result in a Material Adverse Effect.

"***Maturity Date***" means August 2, 2026.

"***MD&A***" has the meaning set forth in Section 8.01(c).

"***Medicaid***" means that government-sponsored entitlement program under Title XIX, P.L. 89-97 of the Social Security Act, which provides federal grants to states for medical assistance based on specific eligibility criteria, as set forth on Section 1396, et seq. of Title 42 of the United States Code.

"***Medicare***" means that government-sponsored insurance program under Title XVIII, P.L. 89-97, of the Social Security Act, which provides for a health insurance system for eligible elderly and disabled individuals, as set forth at Section 1395, et seq. of Title 42 of the United States Code.

"***Minimum Liquidity Account***" has the meaning set forth in **Section 10.01**.

"***Multiemployer Plan***" means any multiemployer plan, as defined in Section 400l(a)(3) of ERISA, to which any ERISA Affiliate incurs or otherwise has any obligation or liability, contingent or otherwise.

"***Net Cash Proceeds***", means, (i) with respect to any Casualty Event experienced or suffered by the Borrower or any of its Subsidiaries, the amount of cash proceeds received (directly or indirectly) including, without limitation, in the form of insurance proceeds or condemnation awards in respect of such Casualty Event, from time to time by or on behalf of such Person after deducting therefrom only (x) reasonable fees, costs and expenses related thereto incurred by the Borrower or such Subsidiary in connection therewith, (y) amounts required to be repaid on account of any Permitted Indebtedness (other than the Obligations) required to be repaid as a result of such Casualty Event, (y) amounts required to be reserved in accordance with GAAP for indemnities and against liabilities associated with the property damaged, destructed or condemned in such Casualty Event, and (z) Taxes (including transfer Taxes or net income Taxes) paid or payable in connection therewith; and (ii) with respect to any Asset Sale by the Borrower or any of its Subsidiaries, the amount of cash proceeds received (directly or indirectly) from time to time by or on behalf of such Person after deducting therefrom only (x) reasonable fees, costs and expenses related thereto incurred by the Borrower or such Subsidiary in connection therewith, (y) amounts required to be repaid on account of any Permitted Indebtedness (other than the Obligations) required to be repaid as a result of such Asset Sale, and (z) Taxes (including transfer Taxes or net

income Taxes) paid or payable in connection therewith; provided that, in each case of **clauses (i)** and **(ii)**, costs and expenses shall only be deducted to the extent, that the amounts so deducted are (x) actually paid to a Person that is not an Affiliate of the Borrower or any of its Subsidiaries and (y) properly attributable to such Casualty Event or Asset Sale, as the case may be.

"***Note***" means a promissory note, in substantially the form of **Exhibit A** hereto, executed and delivered by the Borrower to any Lender in accordance with **Section 2.03**.

"***NY UCC***" means the UCC as in effect from time to time in New York.

"***Obligations***" means, with respect to any Obligor, all amounts, obligations, liabilities, covenants and duties of every type and description (including all Guaranteed Obligations) owing by such Obligor to any Secured Party, any indemnitee hereunder or any participant, arising out of, under, or in connection with, any Loan Document, whether direct or indirect (regardless of whether acquired by assignment), absolute or contingent, due or to become due, whether liquidated or not, now existing or hereafter arising and however acquired, and whether or not evidenced by any instrument or for the payment of money, including, without duplication, (i) if such Obligor is the Borrower, all Loans, (ii) all interest, whether or not accruing after the filing of any petition in bankruptcy or after the commencement of any insolvency, reorganization or similar proceeding, and whether or not a claim for post-filing or post-petition interest is allowed in any such proceeding, and (iii) all other fees, expenses (including fees, charges and disbursement of counsel), interest, commissions, charges, costs, disbursements, indemnities and reimbursement of amounts paid and other sums chargeable to such Obligor under any Loan Document. Notwithstanding the foregoing, the "Obligations" shall not include the Warrant Obligations and any obligations under any other warrant or other instrument or any equity or other investment.

"***Obligors***" means, collectively, the Borrower, the Subsidiary Guarantors and their respective successors and permitted assigns.

"***OFAC***" means the U.S. Department of the Treasury's Office of Foreign Assets Control.

"***One-Month Term SOFR***" means, the Term SOFR Reference Rate (expressed, as a decimal, rounded upwards, if necessary, to the nearest 1/100th of 1%) for a one month tenor on the day (such day, the "***Periodic Term SOFR Determination Day***") that is two (2) U.S. Government Securities Business Days prior to the first day of the Interest Period, as such rate is published by the Term SOFR Administrator; provided, however, that if as of 5:00 p.m. (New York City time) on any Periodic Term SOFR Determination Day the Term SOFR Reference Rate for the one month tenor has not been published by the Term SOFR Administrator, then Term SOFR will be the Term SOFR Reference Rate for a one month tenor as published by the Term SOFR Administrator on the first preceding U.S. Government Securities Business Day for which such Term SOFR Reference Rate for such tenor was published by the Term SOFR Administrator so long as such first preceding U.S. Government Securities Business Day is not more than three (3) U.S. Government Securities Business Days prior to such Periodic Term SOFR Determination Day.

"***Organic Document***" means, for any Person, such Person's formation documents, including, as applicable its certificate of incorporation, by-laws, constitution, memorandum and articles of association, certificate of partnership, partnership agreement, certificate of formation,

limited liability agreement, constitution, operating agreement and all shareholder agreements, voting trusts and similar arrangements applicable to such Person's Equity Interests, or any equivalent document of any of the foregoing.

"***Other Connection Taxes***" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

"***Other Taxes***" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment (other than an assignment made pursuant to **Section 5.03(h)**).

"***Overage Deed***" means an overage deed relating to the London Manufacturing Facility made between (1) the English Guarantor and (2) Moorfields Eye Hospital NHS Foundation Trust dated 14 December 2018.

"***Participant***" has the meaning set forth in **Section 14.05(e)**.

"***Participant Register***" has the meaning set forth in **Section 14.05(g)**.

"***Patents***" means all patents and patent applications, including (i) the reissues, divisions, continuations, renewals, extensions, and continuations in part thereof, (ii) all rights to recover for all past, present and future infringements thereof and all rights to sue therefor, and (iii) all rights whatsoever accruing thereunder or pertaining thereto throughout the world.

"***Patriot Act***" has the meaning set forth in **Section 14.20.**

"***Payment Date***" means (i) the last day of each Interest Period; provided that if such last day of any Interest Period is not a Business Day, then the Payment Date shall be the next succeeding Business Day, and (ii) the Maturity Date.

"***PBGC***" means the United States Pension Benefit Guaranty Corporation referred to and defined in ERISA and any successor entity performing similar functions.

"***Perfection Requirements***" means, solely in respect of the English Guarantor and the Irish Subsidiary Guarantor, the making or the procuring of filings, stampings, registrations, notarisations, endorsements, translations and/or notifications of any Loan Document (and/or any Liens created under it) necessary for the validity, enforceability (as against the relevant Obligor or any relevant third party) and/or perfection of that Loan Document.

"***Periodic Term SOFR Determination Day***" has the meaning set forth in the definition of "One-Month Term SOFR".

"***Permitted Acquisition***" means any Acquisition by the Borrower or any of its Subsidiaries that satisfies each of the following conditions:

(a) immediately prior to, and after giving effect to such Acquisition, (i) all representations and warranties contained in this Agreement and the other Loan Documents that are qualified by materiality, Material Adverse Effect or the like are, in each case, true and correct, (ii) all representations and warranties contained in this Agreement and the other Loan Documents that are not qualified by materiality, Material Adverse Effect or the like are, in each case, true and correct in all material respects, and (iii) no Event of Default shall have occurred and be continuing or could reasonably be expected to result therefrom;

(b) all transactions in connection therewith shall be consummated in accordance with all applicable Laws and in conformity with all applicable Governmental Approvals, in each case, in all material respects;

(c) in the case of an Acquisition of Equity Interests of any Person, all of such Equity Interests (except for any such securities in the nature of directors' qualifying shares required pursuant to any applicable Law) acquired, or otherwise issued by such Person or any newly formed Subsidiary of the Borrower in connection with such acquisition, shall be owned by an Obligor or a wholly-owned Subsidiary of an Obligor, and the Borrower shall have taken, or caused to be taken, as of the date such Person becomes a Subsidiary of the Borrower, each of the actions set forth in **Section 8.12(a)**, if applicable;

(d) the Person (in the case of an Acquisition of Equity Interests), business, property, or assets that is the subject of such Acquisition shall be engaged or used, as the case may be, in substantially the same business or lines of business in which the Borrower and its Subsidiaries are engaged as of the Closing Date;

(e) on a *pro forma* basis after giving effect to such Acquisition, the Borrower and its Subsidiaries shall be in compliance with the financial covenant set forth in **Section 10.01**;

(f) with respect to any Acquisition, the consideration paid for such Acquisition (i) when taken together with consideration paid for all other Acquisitions consummated or effected during the prior period of twelve (12) consecutive months ending on the date such Acquisition becomes effective, does not exceed $20,000,000 in the aggregate (which amount shall include the aggregate amount of outstanding principal and unpaid interest (or equivalent if an equivalent concept exists in its jurisdiction of organization or incorporation) in respect of any Indebtedness assumed, incurred or otherwise created in connection with any such applicable Acquisitions, including all related Contingent Acquisition Obligations), and (ii) when taken together with consideration paid for all other Acquisitions consummated or effected since the Closing Date, does not exceed $50,000,000 in the aggregate (which amount shall also include, without duplication, the aggregate amount of outstanding principal and unpaid interest (or equivalent) in respect of any Indebtedness assumed, incurred or otherwise created in connection with any such applicable Acquisitions, including all related Contingent Acquisition Obligations); provided that for purposes of determining amounts to be calculated for purposes of this

clause (f), non-cash consideration shall be determined on the basis of fair market value as determined by the Borrower's Board acting in good faith;

(g) the Borrower shall have provided the Administrative Agent with at least ten (10) calendar days' prior written notice of any such Acquisition, together with any available summaries, prepared in reasonable detail, of all material non-confidential due diligence conducted by or on behalf of the Borrower or the applicable Subsidiary, as applicable, prior to such Acquisition;

(h) at least three (3) Business Days prior to the proposed date of the Acquisition, the Administrative Agent shall have received a certificate of a Responsible Officer of the Borrower (prepared in reasonable detail), certifying that the Acquisition complies with the requirements of this definition;

(i) to the extent that the purchase price for any such Acquisition is paid in Equity Interests, all such Equity Interests shall be Qualified Equity Interests;

(j) promptly upon request by the Administrative Agent in the case of any Acquisition that has a purchase price in excess of $25,000,000, the Borrower shall provide (i) a copy of the draft purchase agreement related to the proposed Acquisition (and any related documents reasonably requested by the Administrative Agent), (ii) any available quarterly and annual financial statements of the Person whose Equity Interests or assets are being acquired for the twelve (12) month period ending forty-five (45) days immediately prior to such Acquisition, including any audited financial statements that are available, and (iii) any other information reasonably requested by the Administrative Agent and available to the Obligors; and

(k) neither the Borrower nor any of its Subsidiaries shall, in connection with any such Acquisition, assume or remain subject to or liable with respect to (x) any Indebtedness of the related seller or the business, Person or properties acquired, except to the extent permitted pursuant to **Section 9.01**, (y) any Lien on any business, Person or assets acquired, except to the extent permitted pursuant to **Section 9.02**, or (z) any other liability (including Tax, ERISA and environmental liabilities), except (with respect to liabilities under this **clause (k))**, to the extent the assumption of any such liability could not reasonably be expected to result in a Material Adverse Effect; provided that any other such Indebtedness, liabilities or Liens not permitted to be assumed, continued or otherwise supported by the Borrower or any of its Subsidiaries hereunder shall be paid in full or released as to the business, Persons or properties being so acquired substantially on or before the consummation of such Acquisition.

"***Permitted Bond Hedge Transaction***" means any bond hedge, capped call or similar option transaction entered into by the Borrower in respect of the Borrower's ordinary shares and entered into in connection with the issuance of Permitted Convertible Indebtedness; provided that (i) the terms, conditions and covenants of each such transaction shall be customary for transactions of such type, as determined in good faith by the Borrower, (ii) such transaction is consummated substantially concurrently with the issuance of such Permitted Convertible Indebtedness, and (iii) the purchase price for such Permitted Bond Hedge Transaction (net of any proceeds to Borrower

from the sale of any related Permitted Warrant Transaction) (x) does not exceed the Net Cash Proceeds received by the Borrower from the issuance of Permitted Convertible Indebtedness and (y) is financed with the proceeds of such issuance.

"***Permitted Cash Equivalent Investments***" means (i) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any state thereof having maturities of not more than one year from the date of acquisition, (ii) commercial paper maturing no more than one year after the date of its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., (iii) certificates of deposit, or bankers' acceptance maturing no more than one year after issue provided that the account in which any such certificate of deposit is maintained is subject to an account control agreement in favor of the Administrative Agent, (iv) money market funds at least ninety five percent (95%) of the assets of which constitute Permitted Cash Equivalent Investments of the kinds described in **clauses (i)** through **(iii)** of this definition, (v) fully collateralized repurchase agreements with a term of not more than 30 days for securities described in **clause (i)** above, and (vi) investments permitted pursuant to an investment policy approved by the Borrower's Board, as amended from time to time, provided that such investment policy (and any such amendment thereto) shall have been approved in advance in writing by the Administrative Agent.

"***Permitted Convertible Indebtedness***" means unsecured Indebtedness in the form of notes issued by the Borrower that (i) as of the date of issuance thereof contains terms, conditions, covenants, conversion or exchange rights, redemption rights and offer to repurchase rights, in each case, as are typical and customary for notes of such type, as determined by the Borrower, (ii) is convertible or exchangeable into a fixed number of shares of ordinary shares of the Borrower (or Qualified Equity Interests following a merger event or other conversion or exchange of ordinary shares of the Borrower), cash or a combination thereof (such amount of cash determined by reference to the price of the Borrower's ordinary shares or such Qualified Equity Interests), and cash in lieu of fractional shares of ordinary shares of the Borrower or such Qualified Equity Interests, (iii) has a stated final maturity date that is no earlier than the date that is one hundred eighty (180) days after the Maturity Date (the "***Earliest Date***"), (iv) shall not be required to be repaid, prepaid, redeemed, repurchased or defeased (whether through scheduled amortization, principal payments, mandatory redemptions, payments of principal or otherwise), whether on one or more fixed dates, prior to the Earliest Date, except (x) upon the occurrence of an event of default, "fundamental change" or equivalent or (y) following the Borrower's election to redeem such notes; provided that the right to convert such Indebtedness into Qualified Equity Interests, cash or any combination thereof shall not be deemed to violate this **clause (iv)**, and (v) is not supported by a Guarantee made or issued by any Subsidiary of the Borrower that is not an Obligor.

"***Permitted Indebtedness***" means any Indebtedness permitted under **Section 9.01**.

"***Permitted Liens***" means any Liens permitted under **Section 9.02**.

"***Permitted Refinancing***" means, with respect to any Indebtedness permitted to be refinanced, extended, renewed or replaced hereunder, any refinancings, extensions, renewals and replacements of such Indebtedness; provided that such refinancing, extension, renewal or replacement shall not (i) increase the outstanding principal amount of the Indebtedness being refinanced, extended, renewed or replaced, (ii) contain terms relating to outstanding principal

amount, amortization, maturity, collateral security (if any) or subordination (if any), or other material terms that, taken as a whole, are less favorable in any material respect to the Borrower and its Subsidiaries or the Secured Parties than the terms of any agreement or instrument governing the Indebtedness being refinanced, (iii) have an applicable interest rate or equivalent yield that exceeds the interest rate or equivalent yield of the Indebtedness being refinanced, (iv) contain any new requirement to grant any Lien or to give any Guarantee that was not an existing requirement of the Indebtedness being refinanced and (v) after giving effect to such refinancing, extension, renewal or replacement, no Event of Default shall have occurred (or could reasonably be expected to occur) as a result thereof.

"***Permitted Warrant Transaction***" means any call option, warrant or right to purchase (or substantively equivalent derivative transaction) relating to ordinary shares (or other securities or property following a merger event or other change of the ordinary shares) and/or cash (in an amount determined by reference to the price of such ordinary shares) sold by Borrower substantially concurrently with any purchase by Borrower of a related Permitted Bond Hedge Transaction and as may be amended in accordance with its terms; provided that (x) that the terms, conditions and covenants of each such call option transaction are customary for agreements of such type, as determined in good faith by Borrower and (y) such call option transaction would be classified as an equity instrument in accordance with GAAP.

"***Person***" means any individual, corporation, company, voluntary association, partnership, limited liability company, exempted company, joint venture, trust, unincorporated organization or Governmental Authority or other entity of whatever nature.

"***Plan***" means any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the Code or Section 302 of ERISA, and in respect of which the Borrower or any ERISA Affiliate is (or, if such plan were terminated, would under Section 4069 of ERISA be deemed to be) an "employer" as defined in Section 3(5) of ERISA.

"***Prepayment Date***" has the meaning set forth in **Section 3.03(a)(i)**.

"***Prepayment Price***" has the meaning set forth in **Section 3.03(a)(i)**.

"***Proceeding***" has the meaning set forth in **Section 14.03(b)**.

"***Prohibited Payment***" means any bribe, rebate, payoff, influence payment, kickback or other payment or gift of money or anything of value (including meals or entertainment) to any officer, employee or ceremonial office holder of any government or instrumentality thereof, political party or supra-national organization (such as the United Nations), any political candidate, any royal family member or any other person who is connected or associated personally with any of the foregoing for the purpose of influencing any act or decision of such payee in his official capacity, inducing such payee to do or omit to do any act in violation of his lawful duty, securing any improper advantage or inducing such payee to use his influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in each case that is prohibited under any applicable Law.

"***Proportionate Share***" means, with respect to each Lender, the percentage obtained by dividing (i) the sum of all Commitments (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of such Lender then in effect by (ii) the sum of all Commitments (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of all Lenders then in effect.

"***Proposal Letter***" means the Proposal Letter, dated July 7, 2022, between the Borrower and Perceptive Advisors LLC (as supplemented by the outline of proposed terms and conditions attached thereto).

"***Qualified Equity Interest***" means, with respect to any Person, any Equity Interest of such Person that is not a Disqualified Equity Interest.

"***Qualified Plan***" means an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time maintained or sponsored by any Obligor or any ERISA Affiliate thereof or to which any Obligor or any ERISA Affiliate thereof has ever made, or was ever obligated to make, contributions, and (ii) that is intended to be tax qualified under Section 401(a) of the Code.

"***Real Property Collateral Security Documents***" means any mortgage or deed of trust or any other real property security document executed or required hereunder to be executed by the applicable Obligors and granting a security interest in real property owned or leased (as tenant) by such Obligor in favor of the Secured Parties for purposes of securing the Obligations.

"***Recipient***" means any Lender, the Administrative Agent or any other recipient of any payment to be made by or on account of any Obligation, as applicable.

"***Recognised Stock Exchange***" has the meaning given to that term in section 1005 of the UK ITA.

"***Reference Rate***" means One-Month Term SOFR; provided that if the Administrative Agent determines (which determination shall be conclusive absent manifest or demonstrable error) that One-Month Term SOFR cannot be determined pursuant to the definition thereof or a Reference Rate Transition Event has occurred with respect to One-Month Term SOFR or the then-current Reference Rate, then "Reference Rate" means the applicable "Reference Rate Replacement" to the extent that such Reference Rate Replacement has replaced such prior reference rate pursuant to **Section 1.05**.

"***Reference Rate Replacement***" means, with respect to any Reference Rate Transition Event, an alternate reference rate that has been selected by the Administrative Agent and the Borrower, each of which agree, in good faith, to establish an alternate reference rate of interest to One-Month Term SOFR that gives due consideration to the then prevailing market convention for determining a rate of interest for middle-market loans in the United States at such time, and shall enter into an amendment to this Agreement to reflect such alternate rate of interest and such other related changes to this Agreement as may be applicable; provided, further that, until such alternate rate of interest is agreed upon by the Administrative Agent and the Borrower, the Reference Rate for purposes hereof and of each other Loan Document shall be the Wall Street Journal Prime Rate.

"***Reference Rate Transition Event***" means the occurrence of one or more of the following events with respect to the Reference Rate then in effect:

(a) a public statement or publication of information by or on behalf of the administrator of such Reference Rate announcing that such administrator has ceased or will cease to provide such Reference Rate, permanently or indefinitely; provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Reference Rate;

(b) a public statement or publication of information by the Governmental Authority governing or regulating the administrator of such Reference Rate, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the then-current administrator for such Reference Rate, a resolution authority with jurisdiction over the then-current administrator for such Reference Rate or a court or an entity with similar insolvency or resolution authority over the administrator for such Reference Rate, which in any case states that the then-current administrator of such Reference Rate has ceased or will cease to provide such Reference Rate permanently or indefinitely; provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Reference Rate; or

(c) a public statement or publication of information by the Governmental Authority governing or regulating the then-current administrator of such Reference Rate announcing that such Reference Rate is no longer representative.

For the avoidance of doubt, a "***Reference Rate Transition Event***" will be deemed to have occurred with respect to any Reference Rate if a public statement or publication of information set forth above has occurred with respect to each then-current available tenor of such Reference Rate (or the published component used in the calculation thereof).

"***Register***" has the meaning set forth in **Section 14.05(d)**.

"***Regulation T***" means Regulation T of the Board of Governors of the Federal Reserve System, as amended.

"***Regulation U***" means Regulation U of the Board of Governors of the Federal Reserve System, as amended.

"***Regulation X***" means Regulation X of the Board of Governors of the Federal Reserve System, as amended.

"***Related Fund***" means, with respect to any Lender, a fund which is managed or advised by the same investment manager or investment adviser as such Lender or, if it is managed by a different investment manager or investment adviser, a fund whose investment manager or investment adviser is an Affiliate of the investment manager or investment adviser of such Lender.

"***Related Parties***" has the meaning set forth in **Section 14.16**.

"***Requisite Consents***" has the meaning set forth in **Section 8.19(c)(ii)**.

"***Resolution Authority***" means an EEA Resolution Authority or, with respect to any UK Financial Institution, a UK Resolution Authority.

"***Responsible Officer***" of any Person means each of the president, chief executive officer, chief financial officer, chief accounting officer, director, secretary, treasurer, general counsel and similar officer of such Person.

"***Restricted Payment***" means any dividend or other distribution (whether in cash, Equity Interests or other property) with respect to any Equity Interests of the Borrower or any of its Subsidiaries, any payment of interest, principal or fees in respect of any Indebtedness owed by the Borrower or any of its Subsidiaries to any holder of any Equity Interests of the Borrower or any of its Subsidiaries, or any payment (whether in cash, Equity Interests or other property), including any sinking fund or similar deposit, on account of the purchase, redemption, retirement, acquisition, cancellation or termination of any such Equity Interests of the Borrower or any of its Subsidiaries, or any option, warrant or other right to acquire any such Equity Interests of the Borrower or any of its Subsidiaries.

"***Restrictive Agreement***" means any Contract or other arrangement that prohibits, restricts or imposes any condition upon (i) the ability of the Borrower or any of its Subsidiaries to create, incur or permit to exist any Lien upon any of its properties or assets (other than (x) customary provisions in Contracts (including without limitation anti-assignment clauses, leases and licenses of Intellectual Property) restricting the assignment thereof and (y) restrictions or conditions imposed by any Contract governing secured Permitted Indebtedness permitted under **Section 9.01(g)**, to the extent that such restrictions or conditions apply only to the property or assets securing such Indebtedness), or (ii) the ability of the Borrower or any of its Subsidiaries to make Restricted Payments with respect to any of their respective Equity Interests or to make or repay loans or advances to the Borrower or any of its Subsidiaries or such other Obligor or to Guarantee Indebtedness of the Borrower or any of its Subsidiaries thereof or such other Obligor.

"***Sanction***" means any international economic sanction administered or enforced by the United States government (including, without limitation, OFAC), the United Nations Security Council, the European Union or its Member States, Her Majesty's Treasury or other relevant sanctions authority.

"***Secured Party***" means each Lender, the Administrative Agent, each other Indemnified Party, any other holder of any Obligation, and any of their respective permitted transferees or assigns.

"***Securities Account***" means any securities account, as such term is defined in Section 8-501 of the NY UCC.

"***Securities Act***" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"***Security Documents***" means, collectively, the Account Pledge Agreement, each Real Property Collateral Security Document (if any), each Foreign Collateral Security Document, each Foreign Real Property Security Document and each other security agreement, control agreement or financing statement, registration, recordation, filing, instrument or approval required, entered

into or recommended to grant, perfect and otherwise render enforceable Liens in favor of the Secured Parties for purposes of securing the Obligations, including (without limitation) pursuant to **Section 8.12**.

"***Shannon Manufacturing Facility"*** means Buildings 2 & 3, Block K, Shannon Free Zone, Shannon, Co. Clare.

"***SOFR***" means a rate equal to the secured overnight financing rate as administered by the SOFR Administrator.

"***SOFR Administrator***" means the Federal Reserve Bank of New York (or a successor administrator of the secured overnight financing rate).

"***Solvent***" means, at any time of determination and with respect to any Person and its Subsidiaries, taken as a whole, that (i) the present fair saleable value of the property of such Person and its Subsidiaries is greater than the total amount of liabilities (including contingent liabilities) of such Person and its Subsidiaries, (ii) the present fair saleable value of the property of such Person and its Subsidiaries is not less than the amount that will be required to pay the probable aggregate liabilities of such Person and its Subsidiaries on their collective debts as they become absolute and matured, (iii) such Person and its Subsidiaries have not incurred and does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's and its Subsidiaries' ability to pay as such aggregate debts and liabilities mature.

"***Specified Assets***" means any of the Borrower's (i) gene regulation platform technologies, (ii) AAV-AQP1 program, or (iii) AAV-GAD program, as further described in reasonable detail on **Schedule B** hereto, and all assets and properties of the Borrower and its Subsidiaries reasonably related thereto (including Intellectual Property); provided that the Specified Assets shall not at any time include any assets or property of the Borrower or any of its Subsidiaries that constitutes Collateral.

"***Specified Assets Conditions***" means with respect to any Specified Asset, in whole or in part, (i) no Event of Default has occurred and is continuing, or could reasonably be expected to occur, as a result of the entry into such transaction, (ii) such transaction does not result in, nor could it reasonably be expected to result in, the outright sale or disposition of any Specified Asset, in whole or in part, (iii) such transaction does not constitute, nor could it reasonably be expected to constitute, an Impermissible Specified Assets Exclusive License and (iv) such transaction does not interfere with or adversely affect, nor could it reasonably be expected to interfere with or adversely affect, the Secured Parties' Liens on any Collateral or its rights or remedies in respect thereof.

"***Sterling***" or "**£**" means lawful money of the United Kingdom.

"***Subsidiary***" means, with respect to any Person (for purposes of this definition, the "***parent***") at any date, any corporation, limited liability company, exempted company, partnership, association or other entity the accounts of which would be consolidated with those of the parent in the parent's consolidated financial statements if such financial statements were prepared in accordance with GAAP as of such date, as well as any other corporation, limited liability company, exempted company, partnership, association or other entity (i) of which securities or other

ownership interests representing more than fifty percent (50%) of the equity or more than fifty percent (50%) of the ordinary voting power or, in the case of a partnership, more than fifty percent (50%) of the general partnership interests are, as of such date, owned, controlled or held, directly or indirectly or (ii) that is, as of such date, otherwise Controlled, by the parent or one or more direct or indirect subsidiaries of the parent or by the parent and one or more direct or indirect subsidiaries of the parent. Unless otherwise specified, all references herein to a "Subsidiary" or to "Subsidiaries" shall refer to a Subsidiary or Subsidiaries of the Borrower.

"***Subsidiary Guarantor***" means, initially as of the Closing Date, each Subsidiary of the Borrower identified under the caption "SUBSIDIARY GUARANTORS" on the signature pages hereto and, thereafter, each Subsidiary of such Subsidiary Guarantors (i.e. the Subsidiary Guarantors as of the Closing Date) that becomes, or is required to become, a "Subsidiary Guarantor" after the Closing Date pursuant to **Section 8.12**.

"***Taxes***" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"***Technical Information***" means all trade secrets and other proprietary or confidential information, public information, non-proprietary know-how, any information of a scientific, technical, or business nature in any form or medium, standards and specifications, conceptions, ideas, innovations, discoveries, Invention disclosures, all documented research, developmental, demonstration or engineering work and all other information, data, plans, specifications, reports, summaries, experimental data, manuals, models, samples, know-how, technical information, systems, methodologies, computer programs, information technology and any other information.

"***Term SOFR Administrator***" means CME Group Benchmark Administration Limited (CBA) (or a successor administrator of the Term SOFR Reference Rate selected by the Administrative Agent in its reasonable discretion).

"***Term SOFR Reference Rate***" means the forward-looking term rate based on SOFR.

"***Title IV Plan***" means an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time maintained or sponsored by any Obligor or any ERISA Affiliate thereof or to which any Obligor or any ERISA Affiliate thereof has ever made, or was obligated to make, contributions, and (ii) that is or was subject to Section 412 of the Code, Section 302 of ERISA or Title IV of ERISA.

"***Trademarks***" means all trade names, trademarks and service marks, logos, trademark and service mark registrations, and applications for trademark and service mark registrations, including (i) all renewals of trademark and service mark registrations, (ii) all rights to recover for all past, present and future infringements thereof and all rights to sue therefor, and (iii) all rights whatsoever accruing thereunder or pertaining thereto throughout the world, together, in each case, with the goodwill of the business connected with the use thereof.

"***Tranche 1 Borrowing Date***" means the date on which the Tranche 1 Loan is made pursuant to the terms and conditions hereof.

"***Tranche 1 Loan***" has the meaning set forth in the first recital hereto.

"***Tranche 1 Facility Fee***" has the meaning set forth in **Section 3.04**.

"***Tranche 2 Borrowing Date***" means the date on which the Tranche 2 Loan is made pursuant to the terms and conditions hereof.

"***Tranche 2 Borrowing Date Certificate***" has the meaning set forth in **Section 6.02(c)**.

"***Tranche 2 Draw Period***" has the meaning set forth in the first recital hereto,

"***Tranche 2 Facility Fee***" has the meaning set forth in **Section 3.04**.

"***Tranche 2 Loan***" has the meaning set forth in the first recital hereto.

"***Tranche 2 Loan Commitment Amount***" means the Commitment of the Lenders, subject to the terms and conditions set forth herein, to make the Tranche 2 Loan in the amount of $25,000,000.

"***Transactions***" means the negotiation, preparation, execution, delivery and performance by each Obligor of this Agreement and the other Loan Documents to which such Obligor is (or is intended to be) a party, the making of the Loans hereunder, and all other transactions contemplated pursuant to this Agreement and the other Loan Documents.

"***UCC***" means, with respect to any applicable jurisdictions, the Uniform Commercial Code as in effect in such jurisdiction, as may be modified from time to time.

"***UCL Licenses***" means each stand alone license agreement entered into from January to February 2019, by and between the English Guarantor and UCL Business plc, in each case, as may be amended, restated, supplemented or otherwise modified from time to time.

"***UK CTA***" means the Corporation Tax Act 2009 of the United Kingdom (as amended).

"***UK DTTP Scheme***" means HMRC's Double Taxation Treaty Passport scheme, as modified from time to time.

"***UK Excluded Taxes***" means any UK Tax Deduction from a payment by a Withholding Agent under a Loan Document, if on the date on which the payment falls due:

(i) the payment could have been made to the relevant Lender without a UK Tax Deduction if that Lender had been a UK Qualifying Lender, but on that date that Lender is not or has ceased to be a UK Qualifying Lender other than as a result of any Change of Law; or

(ii) the relevant Lender is a UK Qualifying Lender solely by virtue of sub-paragraph (a)(ii) of the definition of UK Qualifying Lender and (i) that relevant Lender has not given a UK Tax Confirmation to the Administrative Agent, and (ii) the payment could have been made to the relevant Lender without a UK Tax Deduction if that Lender had given a UK Tax Confirmation to the Administrative Agent, on the basis that the UK Tax Confirmation would have enabled the

Withholding Agent making the payment to have formed a reasonable belief that the payment was an "excepted payment" for the purpose of section 930 of the UK ITA; or

(iii) the relevant Lender is a UK Qualifying Lender solely under sub-paragraph (a)(ii) of the definition of UK Qualifying Lender and (i) an officer of HMRC has given (and not revoked) a direction (a "***UK Direction***") under section 931 of the UK ITA which relates to that payment and that Lender has received from the Borrower a certified copy of that UK Direction, and (ii) the payment could have been made to the Lender without any UK Tax Deduction if that UK Direction had not been made; or

(iv) the relevant Lender is a UK Treaty Lender (or a Lender which would be a UK Treaty Lender upon the completion of any necessary procedural formalities) and the payment could have been made to the Lender without a UK Tax Deduction had that Lender complied with its obligations under **paragraphs (i) or (j)** of **Section 5.03**; provided that any UK Tax Deduction from a payment by a Withholding Agent to Perceptive Credit Holdings III, LP (but not its any of its successors or assigns) shall not be treated as UK Excluded Taxes for the purposes of this Agreement.

"***UK ITA***" means the Income Tax Act 2007 of the United Kingdom (as amended).

"***UK Financial Institution***" means any BRRD Undertaking (as such term is defined under the PRA Rulebook (as amended from time to time) promulgated by the United Kingdom Prudential Regulation Authority) or any Person falling within IFPRU 11.6 of the FCA Handbook (as amended from time to time) promulgated by the United Kingdom Financial Conduct Authority, which includes certain credit institutions and investment firms, and certain affiliates of such credit institutions or investment firms.

"***UK Limitation Acts***" means the Limitation Act 1980 and the Foreign Limitation Periods Act 1984.

"***UK Non-Bank Lender***" means a Lender which falls within **clause (a)(ii)** of the definition of "UK Qualifying Lender" and: (a) where such Lender is a party hereto as at the date of this Agreement, is described as such in **Schedule 1 (*Commitments*)**; or (b) where such a Lender becomes a party hereto after the date of this Agreement, gives a UK Tax Confirmation in the documentation which it executes on becoming a party hereto.

"***UK Qualifying Lender***" means a successor or assignee of Perceptive Credit Holdings III, LP and is:

(a) a Lender which is beneficially entitled to interest payable to that Lender in respect of an advance under a Loan Document and is:

(i) a Lender:

(A) which is a bank (as defined for the purpose of section 879 of the UK ITA) making an advance under a Loan Document and is within the charge to United Kingdom corporation tax as respects any payments of interest made in respect of

that advance or would be within such charge as respects such payments apart from section 18A of the UK CTA; or

(B) in respect of an advance made under a Loan Document by a person that was a bank (as defined for the purpose of section 879 of the UK ITA) at the time that such advance was made and is within the charge to United Kingdom corporation tax as respects any payments of interest made in respect of that advance; or

(ii) a Lender which is:

(A) a company resident in the United Kingdom for United Kingdom tax purposes;

(B) a partnership, each member of which is:

(1) a company so resident in the United Kingdom; or

(2) a company not so resident in the United Kingdom which carries on a trade in the United Kingdom through a permanent establishment and which brings into account in computing its chargeable profits (within the meaning of section 19 of the UK CTA) the whole of any share of interest payable in respect of that advance that falls to it by reason of Part 17 of the UK CTA; or

(C) a company not so resident in the United Kingdom which carries on a trade in the United Kingdom through a permanent establishment and which brings into account interest payable in respect of that advance in computing the chargeable profits (within the meaning of section 19 of the UK CTA) of that company; or

(iii) a UK Treaty Lender; or

(b) a Lender which is a building society (as defined for the purposes of section 880 of the UK ITA) making an advance under a Loan Document.

"***UK Resolution Authority***" means the Bank of England or any other public administrative authority having responsibility for the resolution of any UK Financial Institution.

"***UK Shareholder***" means MeiraGTx Limited, a private limited company incorporated in England and Wales with registration number 09501998 and whose registered office address is at 92 Britannia Walk, London, England, N1 7NQ.

"***UK Subsidiary Guarantor***" means MeiraGTx UK II Limited, a private limited company incorporated in England and Wales with registration number 09348737 and whose registered office address is at 92 Britannia Walk, London, England, N1 7NQ.

"***UK Tax Confirmation***" means a confirmation in writing by a Lender that the person beneficially entitled to interest payable to that Lender in respect of an advance under a Loan Document is either:

(i) a company resident in the UK for UK tax purposes;

(ii) a partnership each member of which is: (A) a company so resident in the UK; or (B) a company not so resident in the UK which carries on a trade in the UK through a permanent establishment and which brings into account in computing its chargeable profits (within the meaning of section 19 of the UK CTA) the whole of any share of interest payable in respect of that advance that falls to it by reason of Part 17 of the UK CTA; or

(iii) a company not so resident in the UK which carries on a trade in the UK through a permanent establishment and which brings into account interest payable in respect of that advance in computing the chargeable profits (within the meaning of section 19 of the UK CTA) of that company.

"***UK Tax Deduction***" means a deduction or withholding from a payment under any Loan Document for and on account of any Taxes imposed by the United Kingdom.

"***UK Treaty Lender***" means a Lender which is a successor or assignee of Perceptive Credit Holdings III, LP and: (i) is treated as a resident of a UK Treaty State for the purposes of the relevant Treaty; (ii) does not carry on a business in the United Kingdom through a permanent establishment with which that Lender's participation in any advance is effectively connected; and (iii) meets all other conditions applicable to that Lender in the relevant Treaty in order to obtain full exemption from Tax imposed by the United Kingdom on payments of interest, including the completion of any necessary procedural formalities.

"***UK Treaty State***" means a jurisdiction having a double taxation agreement (a "***Treaty***") with the United Kingdom which makes provision for full exemption from tax imposed by the United Kingdom on payments of interest.

"***United Kingdom***" and "***UK***" each means the United Kingdom of Great Britain and Northern Ireland.

"***United States***" or "***U.S.***" means the United States of America, its fifty (50) states and the District of Columbia.

"***U.S. Government Securities Business Day***" means any day except for (a) a Saturday, (b) a Sunday or (c) a day on which the Securities Industry and Financial Markets Association recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities.

"***Valuation Report***" has the meaning set forth in **Section 8.19(a)**.

"***VAT***" means: (i) any value added tax imposed by the UK Value Added Tax Act 1994 (as amended); (ii) any tax imposed in compliance with the Council Directive of 28 November 2006 on the common system of value added tax (EC Directive 2006/112); and (iii) any other tax of a

similar nature, whether imposed in the UK or in a member state of the European Union in substitution for, or levied in addition to, such tax referred to in paragraph (i) or (ii) above, or imposed elsewhere.

"***Wall Street Journal Prime Rate***" means the Wall Street Journal Prime Rate, as published and defined in The Wall Street Journal.

"***Warrant Certificate***" means a Warrant Certificate in substantially the form of **Exhibit J** hereto, to be delivered pursuant to **Section 6.01(g)**, as amended or otherwise modified pursuant to the terms thereof.

"***Warrant Obligations***" means all Obligations of the Borrower arising out of, under or in connection with the Warrant Certificates.

"***Withdrawal Liability***" means, at any time, any liability incurred (whether or not assessed) by any ERISA Affiliate and not yet satisfied or paid in full at such time with respect to any Multiemployer Plan pursuant to Section 4201 of ERISA.

"***Withholding Agent***" means the Borrower, any other Obligor and the Administrative Agent.

"***Works***" means means the fit out and other construction works currently being carried out, on the instruction of the Borrower, to the Shannon Manufacturing Facility to include works carried out pursuant to planning permissions references 20/840, 20/841, 21/45, 21/58, 21/222, 21/426, 21/488, 21/1242, 21/1356, 22/134 and 22/204.

"***Write-Down and Conversion Powers***" means (a) with respect to any EEA Resolution Authority, the write-down and conversion powers of such EEA Resolution Authority from time to time under the Bail-In Legislation for the applicable EEA Member Country, which write-down and conversion powers are described in the EU Bail-In Legislation Schedule and (b) with respect to the United Kingdom, any powers of the applicable Resolution Authority under the Bail-In Legislation to cancel, reduce, modify or change the form of a liability of any UK Financial Institution or any contract or instrument under which that liability arises, to convert all or part of that liability into shares, securities or obligations of that Person or any other Person, to provide that any such contract or instrument is to have effect as if a right had been exercised under it or to suspend any obligation in respect of that liability or any of the powers under that Bail-In Legislation that are related to or ancillary to any of those powers.

1.02 Accounting Terms and Principles.

(a) Unless otherwise specified, all accounting terms used in each Loan Document shall be interpreted, and all accounting determinations and computations thereunder (including under **Section 10** and any definitions used in such calculations) shall be made, in accordance with GAAP. Unless otherwise expressly provided, all financial covenants and defined financial terms shall be computed on a consolidated basis for the Borrower and its Subsidiaries, in each case without duplication. Notwithstanding the foregoing, the representations and warranties made in Section 7.08 and the covenants made in Section 8.04 shall be construed in accordance with UK GAAP, as applicable.

(b) If at any time any change in GAAP or the application thereof would affect the computation of any financial term, covenant, ratio or requirement set forth in any Loan Document, and either the Borrower or the Administrative Agent shall so request, the Administrative Agent and the Borrower shall negotiate in good faith to amend such term, covenant, ratio or requirement to preserve the original intent thereof set forth in the applicable Loan Document in light of such change in GAAP or application thereof; provided that, until so amended, such term, covenant, ratio or requirement shall continue to be computed in accordance with GAAP prior to such change therein for all purposes hereof.

1.03 Interpretation. For all purposes of this Agreement, except as otherwise expressly provided herein or unless the context otherwise requires,

(a) the terms defined in this Agreement include the plural as well as the singular and vice versa;

(b) words importing gender include all genders;

(c) any reference to a Section, Annex, Schedule or Exhibit refers to a Section of, or Annex, Schedule or Exhibit to, this Agreement;

(d) any reference to "this Agreement" refers to this Agreement, including all Annexes, Schedules and Exhibits hereto, and the words herein, hereof, hereto and hereunder and words of similar import refer to this Agreement and its Annexes, Schedules and Exhibits as a whole and not to any particular Section, Annex, Schedule, Exhibit or any other subdivision;

(e) references to days, months and years refer to calendar days, months and years, respectively;

(f) all references herein to "include" or "including" shall be deemed to be followed by the words "without limitation";

(g) the word "from" when used in connection with a period of time means "from and including" and the word "until" means "to but not including";

(h) the words "asset" and "property" shall be construed to have the same meaning and effect and to refer broadly to any and all assets and properties, whether tangible or intangible, real or personal, including cash, securities, rights under contractual obligations and permits and any right or interest in any such assets or property;

(i) accounting terms not specifically defined herein (other than "property" and "asset") shall be construed in accordance with GAAP;

(j) the word "will" shall have the same meaning as the word "shall";

(k) where any provision in this Agreement or any other Loan Document refers to an action to be taken by any Person, or an action which such Person is prohibited from taking, such provision shall be applicable whether such action is taken directly or indirectly; and

(l) references to any Lien granted or created hereunder or pursuant to any other Loan Document securing any Obligations shall be deemed to be a Lien for the benefit of the Secured Parties; and

(m) references to any Law will include all statutory and regulatory provisions amending, consolidating, replacing, supplementing or interpreting such Law from time to time.

Unless otherwise expressly provided herein, references to organizational documents, agreements (including the Loan Documents) and other contractual instruments shall be deemed to include all subsequent amendments, restatements, extensions, supplements and other modifications thereto permitted by the Loan Documents.

If any obligation to pay any amount pursuant to the terms and conditions of any Loan Document falls due on a day which is not a Business Day, then such required payment date shall be extended to the immediately following Business Day. For the purposes of calculations made pursuant to the terms of this Agreement or otherwise for purposes of compliance herewith, GAAP will be deemed to treat operating leases as set forth in the definition of Capitalized Lease Obligations. For the avoidance of doubt, any lease that would have been characterized as an operating lease under Accounting Standards Codification Topic No. 840, *Leases*, shall be accounted for as an operating lease (and not as a capital lease or otherwise reflected on the Borrower's consolidated balance sheet) for purposes of this Agreement regardless of the implementation of Accounting Standards Codification Topic No. 842, *Leases*, or any change in GAAP following the Closing Date that would otherwise require such lease to be characterized or re-characterized (on a prospective or retroactive basis or otherwise) as a capital lease.

1.04 Divisions. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws): (i) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person, and (ii) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time.

1.05 Reference Rate Replacement. Upon the occurrence of an event of the type described in the definition of "Reference Rate Transition Event", the Administrative Agent will promptly notify the Borrower thereof and as set forth in the definition of "Reference Rate Replacement", the Administrative Agent and the Borrower shall endeavor, in good faith, to establish an alternate rate of interest to One-Month Term SOFR.

1.06 Times of Day; Times of Performance.

(a) Unless otherwise specified, all references herein to times of day shall be references to New York City time (daylight or standard, as applicable).

(b) If any delivery or other performance obligation hereunder (other than payments) falls due on a day which is not a Business Day, then such due date shall be extended to the immediately following Business Day.

1.07 Rates. The Administrative Agent does not warrant or accept responsibility for, and shall not have any liability with respect to (a) the continuation of, administration of, submission of, calculation of or any other matter related to the Term SOFR Reference Rate or One-Month Term SOFR, or any component definition thereof or rates referred to in the definition thereof, or any alternative, successor or replacement rate thereto, including whether the composition or characteristics of any such alternative, successor or replacement rate will be similar to, or produce the same value or economic equivalence of, or have the same volume or liquidity as, the Term SOFR Reference Rate or One-Month Term SOFR prior to its discontinuance or unavailability, or (b) the effect, implementation or composition of any Conforming Changes. There is no assurance that the composition or characteristics of any such alternative, successor or replacement Reference Rate will be similar to or produce the same value or economic equivalence as One-Month Term SOFR or that it will have the same volume or liquidity as did One-Month Term SOFR prior to its discontinuance or unavailability. The Administrative Agent and its affiliates or other related entities may engage in transactions that affect the calculation of the Term SOFR Reference Rate or One-Month Term SOFR, any alternative, successor or replacement rate or any relevant adjustments thereto, in each case, in a manner that is adverse to the Borrower. The Administrative Agent may select information sources or services in its reasonable discretion to ascertain the Term SOFR Reference Rate or One-Month Term SOFR, in each case pursuant to the terms of this Agreement, and shall have no liability to the Borrower, any Lender or any other Person for damages of any kind, including direct or indirect, special, punitive, incidental or consequential damages, costs, losses or expenses (whether in tort, contract or otherwise and whether at law or in equity), for any error or calculation of any such rate (or component thereof) provided by any such information source or service.

SECTION 2
THE COMMITMENTS AND THE LOANS

2.01 Loans.

(a) On the terms and subject to the conditions of this Agreement, (i) each Lender shall make its Tranche 1 Loan on the Closing Date to the Borrower, in an aggregate principal amount for all Lenders not to exceed $75,000,000 and (ii) in the sole discretion of the Majority Lenders, during the Tranche 2 Draw Period, Borrower may request the Tranche 2 Loan in an aggregate amount not to exceed the Tranche 2 Loan Commitment Amount.

(b) No amounts repaid or prepaid with respect to any Loan may be reborrowed.

(c) Any term or provision hereof (or of any other Loan Document) to the contrary notwithstanding, Loans made to the Borrower will be denominated solely in Dollars and no other currency.

2.02 Borrowing Procedures. Unless the Administrative Agent otherwise agrees in writing, at least one (1) Business Day, but not more than five (5) Business Days, prior to any proposed Closing Date, the Borrower shall deliver to the Administrative Agent a Borrowing Notice, which notice, if received by the Administrative Agent on a day that is not a Business Day or after 1:00 P.M. (New York City time) on a Business Day, shall be deemed to have been delivered on the next Business Day.

2.03 Notes. If requested by any Lender, any Loan of such Lender shall be evidenced by one or more Notes. The Borrower shall prepare, execute and deliver to the Lender such Notes in the form attached hereto as **Exhibit A**.

2.04 Use of Proceeds. The Borrower shall use the proceeds of the Loans for working capital and general corporate purposes, including the payment of fees and expenses associated with this Agreement and the other Loan Documents and the transactions contemplated hereby and thereby.

SECTION 3
PAYMENTS OF PRINCIPAL AND INTEREST

3.01 Repayments and Prepayments Generally; Application.

(a) There will be no scheduled repayments of principal on the Loans prior to the Maturity Date.

(b) On the Maturity Date, the Borrower shall repay the entire remaining outstanding principal balance of the Loans in full and in cash.

(c) The Borrower agrees that all amounts payable hereunder or under any other Loan Document, whether in respect of any Loans, fees or interest accrued or accruing thereon, or any other Obligations, shall be paid, repaid and prepaid, as the case may be, solely in Dollars and no other currency pursuant to the terms of this **Section 3**. Except as otherwise provided in this Agreement, proceeds of each payment (including each repayment and prepayment of Loans) by the Borrower shall be deemed to be made ratably to the Lenders in accordance with their respective Proportionate Shares.

3.02 Interest.

(a) **Interest Generally**. The outstanding principal amount of the Loans, as well as the amount of all other outstanding Obligations, shall accrue interest at the Interest Rate on and from the Closing Date. The Administrative Agent's determination of the Interest Rate shall be binding on the Borrower, its Subsidiaries and the Lenders in the absence of manifest error.

(b) **Default Interest**. Notwithstanding the foregoing, unless the Administrative Agent otherwise agrees in writing, upon the occurrence and during the continuance of any Event of Default, the Applicable Margin shall increase automatically by three percent (3.0%) per annum (the Interest Rate, as increased pursuant to this **Section 3.02(b)**, being the "***Default Rate***"). If any Obligation is not paid when due under any applicable Loan Document, the amount thereof shall accrue interest at the Default Rate. For the avoidance of doubt, the Default Rate shall not be cumulative and no more than three percent (3.00%) per annum can be applicable to the Loan or any past due Obligation at any time, and further for the avoidance of doubt, once an Event of Default is waived by the Administrative Agent or the Majority Lenders, the Default Rate shall cease to apply.

(c) **Interest Payment Dates**. Accrued interest on the Loans shall be payable in cash, in arrears, on each Payment Date with respect to the most recently completed Interest Period, and upon the payment or prepayment of the Loans (on the principal amount being so paid or prepaid);

provided that interest payable at the Default Rate, or any accrued interest not paid on or before the Maturity Date, shall be payable from time to time in cash on the Administrative Agent's demand until paid in full.

(d) **Conforming Changes**. In connection with the use or administration of One-Month Term SOFR, the Administrative Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document. The Administrative Agent will promptly notify the Borrower and the Lenders of the effectiveness of any Conforming Changes in connection with the use or administration of One-Month Term SOFR.

(e) **Compensation for Loss**. In the event of the payment of any principal of any Loan other than on the last day of the Interest Period applicable thereto (including as a result of an Event of Default), then, in any such event, the Borrower shall compensate each Lender for any reasonable and documented loss, cost and expense attributable to such event, including any reasonable and documented loss, cost or expense arising from the liquidation or redeployment of funds. A certificate of any Lender including documentary evidence of any amount or amounts that such Lender is entitled to receive pursuant to this Section shall be delivered to the Borrower and shall be conclusive absent manifest error. The Borrower shall pay such Lender the amount shown as due on any such certificate within 30 days after receipt thereof.

(f) **Conversion of Loans into Listed Notes**. Following the execution of this Agreement, the parties agree to co-operate in good faith promptly to amend and restate this Agreement in order to convert the Loans into loan notes capable of being listed on a Recognised Stock Exchange, and to use commercially reasonable best efforts to assist the Borrower to obtain and maintain a listing of such loan notes on a Recognised Stock Exchange by no later than six months after the date of this Agreement so that the exemption from UK withholding tax under section 882 of the UK ITA applies; provided, however, that notwithstanding anything to the contrary in this Agreement, no Lender shall be obligated to take any actions that would disclose the identity of its partners. Any such conversion or equivalent transaction will be conducted pursuant to a valid exemption from the registration and prospectus delivery requirements under the Securities Act and the qualification requirements under applicable state and foreign Law and otherwise in compliance with the securities Laws of the United States. Any costs arising in connection with the listing shall be borne by the Borrower.

(g) **Interest Deferral**. Notwithstanding any other provision of this Agreement, the payment of any interest in respect of a Loan shall automatically be deferred, at no additional cost to the Obligors, in respect of all Payment Dates, until the first Payment Date following the earlier of:

(i) the conversion of the Loans under this Agreement into loan notes and confirmation that such loan notes have been listed on a Recognised Stock Exchange; and

(ii) the date that is six months after the date of this Agreement.

(h) **Additional obligations**. If the Loans are not converted into loan notes and listed on a Recognised Stock Exchange within six months after the date of this Agreement, or if the exemption from UK withholding tax under section 882 of the UK ITA is otherwise unavailable, the Lender shall use all commercially reasonable efforts to ensure that the Borrower is able to make payments to that Lender, to the maximum extent possible, without a UK Tax Deduction, including the completion of any procedural formalities necessary for the Borrower to obtain authorization to make such payments without a UK Tax Deduction; provided, however, that notwithstanding anything to the contrary in this Agreement, no Lender shall be obligated to take any actions that would disclose the identity of its partners.

3.03 Prepayments; Prepayment Premium.

(a) **Optional Prepayments**.

(i) Subject to prior written notice pursuant to **clause (a)(ii)** below and the applicable portion of the payment of the Early Prepayment Fee pursuant to **clause (c)** below, the Borrower shall have the right to optionally prepay, in whole or in part, the outstanding principal amount of the Loans on any Business Day (a "***Prepayment Date***"); provided that in addition to such prepaid principal amount and the Early Prepayment Fee applicable to such prepaid principal amount, the Borrower shall also make payment in full in cash on such Prepayment Date the applicable portion of all accrued but unpaid interest on the principal amount of the Loans being prepaid (such aggregate amount of Early Prepayment Fee, prepaid principal and accrued interest being herein referred to as the "***Prepayment Price***").

(ii) A notice of optional prepayment shall be effective only if received by the Administrative Agent not later than 2:00 p.m. (New York City time) on a date at least three (3) (but not more than five (5)) Business Days prior to the proposed Prepayment Date. Each notice of optional prepayment shall specify the proposed Prepayment Date (and may be revocable), the principal amount of the Loans to be prepaid, the amount of accrued and unpaid interest that will be paid on the Prepayment Date, and, in reasonable detail, a calculation of the Early Prepayment Fee payable on such Prepayment Date in connection with such proposed prepayment.

(b) **Mandatory Prepayments**. Within ten (10) Business Days of the receipt of Net Cash Proceeds from the occurrence of any Casualty Event or Asset Sale (other than any Asset Sale permitted pursuant to **Sections 9.09 (a)**, **(b)**, **(c)**, **(d)**, **(e)**, **(g)**, **(j)** and **(k)**), to the extent that the aggregate amount of Net Cash Proceeds received by Borrower and its Subsidiaries (and not paid to the Administrative Agent as a prepayment of the Loans) in respect of all such Casualty Events or Asset Sales, when taken together, exceeds $2,500,000 in any fiscal year, the Borrower shall apply an amount equal to one hundred percent (100%) of the Net Cash Proceeds received by the Borrower or any of its Subsidiaries with respect to such Casualty Event or Asset Sale, as the case may be with such amount of Net Cash Proceeds being allocated, to (i) the prepayment of principal outstanding Loans, and (ii) the payment of accrued and unpaid interest on such principal amount of the Loans being prepaid and the payment of the applicable portion of the Early Prepayment Fee being paid. Such Net Cash Proceeds shall be allocated to such prepayment and payments such that the full amount of the applicable Prepayment Price shall be paid with such Net Cash Proceeds. Notwithstanding the foregoing, so long as no Event of Default has occurred and is continuing or shall immediately result therefrom, if, within seven (7) Business Days following the occurrence of

any such Casualty Event or Asset Sale, a Responsible Officer of the Borrower delivers to the Administrative Agent a notice to the effect that the Borrower or the applicable Subsidiary intends to apply the Net Cash Proceeds from such Casualty Event or Asset Sale to repair, refurbish, restore, replace or rebuild the asset subject to such Casualty Event or Asset Sale, then such Net Cash Proceeds of such Casualty Event or Asset Sale may be applied for such purpose in lieu of such mandatory prepayment otherwise required pursuant to this **clause (b)** to the extent such Net Cash Proceeds of such Casualty Event or Asset Sale are actually applied for such purpose; provided that, in the event that Net Cash Proceeds have not been so applied within one hundred eighty (180) days following the occurrence of such Casualty Event or Asset Sale, the Borrower shall make a mandatory prepayment of the Loans in an aggregate amount equal to one hundred percent (100%) of the unused balance of such Net Cash Proceeds received by the Borrower or any of its Subsidiaries with respect to such Casualty Event or Asset Sale, as the case may be, together with payment of accrued and unpaid interest on the principal amount of the Loans being so prepaid and the applicable Early Prepayment Fee, with such amount of Net Cash Proceeds being allocated to the prepayment of principal, the payment of accrued and unpaid interest on such principal amount of the Loans being prepaid and the payment of the applicable portion of the Early Prepayment Fee being paid such that the full payable with respect to such mandatory prepayment is paid with such unused balance of Net Cash Proceeds. Notwithstanding the foregoing, in respect of a Casualty Event relating to a Manufacturing Facility, to the extent required by the basis of settlement under any policy of insurance relating to that Manufacturing Facility or pursuant to the terms of any lease under which the Borrower or any of its Subsidiaries holds an interest in that Manufacturing Facility, the Borrower or the applicable Subsidiary shall apply moneys received under any policy of insurance in respect of that Manufacturing Facility towards replacing, restoring or reinstating that Manufacturing Facility.

(c) **Early Prepayment Fee**. Without limiting the foregoing, whenever any prepayment of Loans is made hereunder pursuant to **Section 3.03(a)** or **Section 3.03(b)**, acceleration or otherwise, the applicable portion of the Early Prepayment Fee being paid shall be due and payable in full in cash on the applicable Prepayment Date for such prepayment.

(d) **Application**. Proceeds of any prepayment made pursuant to **clauses (a)** or **(b)** above shall be applied in the following order of priority, with proceeds being applied to a succeeding level of priority only if amounts owing pursuant to the immediately preceding level of priority have been paid in full in cash; provided that all such prepayments made to Lenders shall be applied pro rata in accordance with their respective Proportionate Shares:

(i) first, to the payment of that portion of the Obligations payable to the Administrative Agent constituting fees, indemnities, costs, expenses, and other amounts then due and owing (including fees and disbursements and other charges of counsel payable under **Section 14.03**);

(ii) second, to the payment of that portion of the Obligations payable to the Lenders constituting fees (other than any Early Prepayment Fee), indemnities, expenses, and other amounts then due and owing (including fees and disbursements and other charges of counsel payable under **Section 14.03**) ratably among them in proportion to the respective amounts described in this **clause (ii)** payable to them;

(iii) third, to the payment of any accrued and unpaid interest and any fees then due and owing;

(iv) fourth, to the payment of unpaid principal of the Loans;

(v) fifth, to the payment of any Early Prepayment Fee then due and payable;

(vi) sixth, to the payment in full of all other Obligations then due and payable to the Administrative Agent and the Lenders, ratably among them in proportion to the respective amounts described in this **clause (vi)** payable to them; and

(vii) seventh, to the Borrower or such other Persons as may lawfully be entitled to or directed by the Borrower to receive the remainder.

3.04 Facility Fees. The Borrower shall pay (i) on the Closing Date, to the Administrative Agent (for the pro rata benefit of the Lenders) a fee equal to [***] (the "***Tranche 1 Facility Fee***") by way of deduction from the proceeds of the Loans advanced to the Borrower by the Lenders and (ii) on the Tranche 2 Borrowing Date, to the Administrative Agent (for the pro rata benefit of the Lenders) a fee equal to 0.75% of the aggregate principal amount of the Tranche 2 Loan (the "***Tranche 2 Facility Fee***" and together with the Tranche 1 Facility Fee, the "***Facility Fees***"). Upon receipt of payment from the Borrower, the Administrative Agent will promptly thereafter distribute like funds relating to any such payment to the Lenders pro rata on the basis of each Lender's Proportionate Share. Once paid by the Borrower, such Facility Fees shall be non-refundable.

SECTION 4
PAYMENTS, ETC.

4.01 Payments.

(a) **Payments Generally**. Each payment of principal, interest and other amounts to be made by the Obligors under this Agreement or any other Loan Document shall be made (i) in Dollars, in immediately available funds, without deduction, set off or counterclaim, to the Administrative Agent, for the account of the respective Lenders to which such payment is owed, to the deposit account of the Administrative Agent designated by the Administrative Agent by notice to the Borrower, and (ii) not later than 2:00 p.m. (New York City time) on the date on which such payment is due (each such payment made after such time on such due date shall be deemed to have been made on the next succeeding Business Day).

(b) **Application of Payments**. All such payments referenced in **clause (a)** above shall be applied as set forth in **Section 3.03(d)** above.

(c) **Non-Business Days**. If the due date of any payment under this Agreement (whether in respect of principal, interest, fees, costs or otherwise) would otherwise fall on a day that is not a Business Day, such date shall be extended to the next succeeding Business Day; provided that if such next succeeding Business Day would fall after the Maturity Date, payment shall be made on the immediately preceding Business Day.

4.02 Computations. All computations of interest and fees hereunder shall be computed on the basis of a year of three hundred and sixty (360) days and actual days elapsed during the period for which payable.

4.03 Set-Off.

(a) **Set-Off Generally**. Upon the occurrence and during the continuance of any Event of Default, the Administrative Agent, each of the Lenders is hereby authorized at any time and from time to time, to the fullest extent permitted by Law, to set off and apply any and all deposits (general or special, time or demand, provisional or final, in whatever currency) at any time held and other obligations (in whatever currency) at any time owing by the Administrative Agent, any Lender to or for the credit or the account of any Obligor against any and all of the Obligations, whether or not such Person shall have made any demand and although such obligations may be unmatured. Any Person exercising rights of set off hereunder agrees to promptly notify the Borrower after any such set-off and application; provided that the failure to give such notice shall not affect the validity of such set-off and application. The rights of the Administrative Agent, the Lenders under this **Section 4.03** are in addition to other rights and remedies (including other rights of set-off) that such Persons may have.

(b) **Exercise of Rights Not Required**. Nothing contained in **Section 4.03(a)** shall require the Administrative Agent, any Lender to exercise any such right or shall affect the right of such Persons to exercise, and retain the benefits of exercising, any such right with respect to any other indebtedness or obligation of any Obligor.

(c) **Payments Set Aside**. To the extent that any payment by or on behalf of any Obligor is made to the Administrative Agent or any Lender, or the Administrative Agent, any Lender or any Affiliate of the foregoing exercises its right of setoff, and such payment or the proceeds of such setoff or any part thereof is subsequently invalidated, declared to be fraudulent, or preferential, set aside or required (including pursuant to any settlement entered into by the Administrative Agent, such Lender or such Affiliate in its discretion) to be repaid to a trustee, receiver, examiner or any other party, in connection with any Insolvency Proceeding or otherwise, then to the extent of such recovery, the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such setoff had not occurred.

(d) To the extent permitted under applicable Law, any Participant acquiring a participation pursuant to **Section 14.05(e)** hereof (as well as any Lender acquiring a participation pursuant to **Section 3.03(e)** hereof) may exercise against the Obligors rights of setoff and counterclaim with respect to such participation as fully as if such Participant was a direct creditor of the Obligor in the amount of such participation.

SECTION 5
YIELD PROTECTION, ETC.

5.01 Additional Costs.

(a) **Changes in Law Generally**. If, on or after the Closing Date (or, with respect to any Lender, such later date on which such Lender becomes party to this Agreement), the adoption

of any Law, or any change in any applicable Law, or any change in the interpretation or administration thereof by any court or other Governmental Authority charged with the interpretation or administration thereof, or compliance by the Administrative Agent or any of the Lenders (or its lending office) with any request or directive (whether or not having the force of Law) of any such Governmental Authority, shall impose, modify or deem applicable any reserve (including any such requirement imposed by the Board of Governors of the Federal Reserve System), special deposit, contribution, insurance assessment or similar requirement, in each case that becomes effective after the Closing Date (or, with respect to any Lender, such later date on which such Lender becomes party to this Agreement) against assets of, deposits with or for the account of, or credit extended by, a Lender (or its lending office) or other Recipient or shall impose on a Lender (or its lending office) or other Recipient any other condition affecting the Loans or the Commitment, and the result of any of the foregoing is to increase the cost to such Lender or such other Recipient of making or maintaining the Loans, or to reduce the amount of any sum received or receivable by such Lender or other Recipient under this Agreement or any other Loan Document, or subject any Lender to any Taxes on its Loan, Commitment or other obligations, or its deposits, reserves, other liabilities or capital (if any) attributable thereto by an amount reasonably deemed by such Lender in good faith to be material (other than (i) Indemnified Taxes, (ii) Taxes described in **clauses (ii)** through **(iv)** of the definition of "**Excluded Taxes**", (iii) Connection Income Taxes and (iv) any Bank Levy or any payment attributable to, or liability arising as a consequence of, a Bank Levy), then the Borrower shall pay to such Lender within three (3) Business Days after written demand such additional amount or amounts as will compensate such Lender for such increased cost or reduction.

(b) **Change in Capital Requirements**. If a Lender shall have determined that, on or after the Closing Date (or, with respect to any Lender, such later date on which such Lender becomes party to this Agreement), the adoption of any applicable Law regarding capital adequacy, or any change therein, or any change in the interpretation or administration thereof by any Governmental Authority charged with the interpretation or administration thereof, or any request or directive regarding capital adequacy (whether or not having the force of Law) of any such Governmental Authority, in each case that becomes effective after the Closing Date (or, with respect to any Lender, such later date on which such Lender becomes party to this Agreement), has or would have the effect of reducing the rate of return on capital of a Lender (or its parent) as a consequence of a Lender's obligations hereunder or the Loans to a level below that which a Lender (or its parent) could have achieved but for such adoption, change, request or directive by an amount reasonably deemed by it to be material, then the Borrower shall pay to such Lender on demand such additional amount or amounts as will compensate such Lender (or its parent) for such reduction.

(c) **Notification by Lender**. Each Lender shall promptly notify the Borrower of any event of which it has knowledge, occurring after the Closing Date (or, with respect to any Lender, such later date on which such Lender becomes party to this Agreement), which will entitle such Lender to compensation pursuant to this **Section 5.01**. Before giving any such notice pursuant to this **Section 5.01(c)** such Lender shall designate a different lending office if such designation (x) will, in the reasonable judgment of such Lender, avoid the need for, or reduce the amount of, such compensation and (y) will not, in the reasonable judgment of such Lender, be materially disadvantageous to such Lender. A certificate of such Lender claiming compensation under this **Section 5.01**, setting forth in reasonable detail the additional amount or amounts to be paid to it

hereunder and also setting forth in reasonable detail the basis for calculating the additional amounts claimed to be owed to such Lender, shall be conclusive and binding on the Borrower in the absence of manifest error.

(d) **Delays in Requests**. Failure or delay on the part of any Lender to demand compensation pursuant to the foregoing provisions of this Section shall not constitute a waiver of such Lender's right to demand such compensation; provided that the Borrower shall not be required to compensate a Lender pursuant to the foregoing provisions of this Section for any increased costs unless the Lender notifies the Borrower within ninety (90) days following the receipt by such Lender of its audited annual financial statements of the change in Law giving rise to such increased costs or reductions and of such Lender's intention to claim compensation therefor.

(e) **Other Changes**. Notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to constitute a change in Law for all purposes of this **Section 5.01**, regardless of the date enacted, adopted or issued.

5.02 Illegality. Notwithstanding any other provision of this Agreement, in the event that on or after the Closing Date (or, with respect to any Lender, such later date on which such Lender becomes party to this Agreement), the adoption of or any change in any applicable Law or in the interpretation or application thereof by any competent Governmental Authority shall make it unlawful for a Lender or its lending office to make or maintain the Loans (and, in the opinion of such Lender, the designation of a different lending office would either not avoid such unlawfulness or would be disadvantageous to such Lender), then such Lender shall promptly notify the Borrower thereof, following which (i) such Lender's Commitment shall be suspended until such time as such Lender may again make and maintain the Loans hereunder and (ii) if such Law shall so mandate, the Loans shall be prepaid by the Borrower on or before such date as shall be mandated by such Law in an amount equal to the Prepayment Price applicable on such Prepayment Date in accordance with **Section 3.03(a)**.

5.03 Taxes.

(a) **Payments Free of Taxes**. Any and all payments by or on account of any Obligation shall be made without deduction or withholding for any Taxes, except as required by applicable Law. If any applicable Law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable Law and, if such Tax is an Indemnified Tax, then the sum payable by such Obligor shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this **Section 5.03**) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b) **Payment of Other Taxes by the Borrower**. The Borrower shall timely pay to the relevant Governmental Authority in accordance with applicable Law, or at the option of the Administrative Agent or each Lender, timely reimburse it for the payment of any Other Taxes.

(c) **Evidence of Payments**. As soon as reasonably practicable after any payment of Taxes by the Borrower to a Governmental Authority pursuant to this **Section 5**, the Borrower shall deliver to the Administrative Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to the Administrative Agent.

(d) **Indemnification by the Borrower**. The Borrower shall reimburse and indemnify each Recipient, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this **Section 5**) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority, but excluding, for the avoidance of doubt, any Indemnified Tax which is suffered or incurred in respect of any Bank Levy, or any payment attributable to, or liability arising as a consequence of, a Bank Levy. A certificate as to the amount of such payment or liability delivered to the Borrower by a Lender (with a copy to the Administrative Agent), or by the Administrative Agent on its own behalf or on behalf of a Lender shall be conclusive absent manifest error.

(e) **Indemnification by the Lenders**. Each Lender shall severally indemnify the Administrative Agent, within ten (10) days after demand therefor, for (i) any Indemnified Taxes attributable to such Lender (but only to the extent that the Borrower has not already indemnified the Administrative Agent for such Indemnified Taxes and without limiting the obligation of the Borrower to do so), (ii) any Taxes attributable to such Lender's failure to comply with the provisions of **Section 14.05(g)** relating to the maintenance of a Participant Register, and (iii) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by (or withheld from payments to) the Administrative Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by the Administrative Agent shall be conclusive absent manifest error. Each Lender hereby authorizes the Administrative Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by the Administrative Agent to the Lender from any other source against any amount due to the Administrative Agent under this **clause (e)**.

(f) **Status of Successors and Assignees**.

(i) Any Lender that is a successor or assignee of Perceptive Credit Holdings III, LP and that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to the Borrower and the Administrative Agent at the time or times reasonably requested by the Borrower or the Administrative Agent, such properly completed and executed documentation reasonably requested by the Borrower or the Administrative Agent as will permit such payments to be made without withholding or at a reduced

rate of withholding. Notwithstanding anything to the contrary in the preceding sentence, the completion, execution and submission of such documentation (other than such documentation set forth in **Section 5.03(f)(ii)(A)**) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or could materially prejudice the legal or commercial position of such Lender. For the avoidance of doubt, notwithstanding anything to the contrary in this Agreement, no Lender shall be obligated to take any actions that would disclose the identity of its partners.

(ii) If a payment made to any Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall deliver to the Borrower and the Administrative Agent at the time or times prescribed by Law and at such time or times reasonably requested by the Borrower or the Administrative Agent such documentation prescribed by applicable Law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by the Borrower or the Administrative Agent as may be necessary for the Borrower and the Administrative Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this **clause (ii)**, "***FATCA***" shall include any amendments made to FATCA after the date of this Agreement.

Each Recipient agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify the Borrower and the Administrative Agent in writing of its legal inability to do so.

(g) **Treatment of Certain Tax Benefits**. If any party to this Agreement determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this **Section 5.03** (including by the payment of additional amounts pursuant to this **Section 5.03**), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this **Section 5.03** with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this **Section 5.03** (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this **Section 5.03(g)**, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this **Section 5.03(g)** the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This **Section 5.03(g)** shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(h) **Mitigation Obligations**. If the Borrower is required to pay any Indemnified Taxes or additional amounts to any Lender or to any Governmental Authority for the account of any Lender pursuant to **Section 5.01**, then such Lender shall (at the request of the Borrower) use reasonable efforts to designate a different lending office for funding or booking its Loans hereunder or to assign and delegate its rights and obligations hereunder to another of its offices, branches or Affiliates if, in the sole, reasonable judgment of such Lender, such designation or assignment and delegation would (i) eliminate or reduce amounts payable pursuant to **Section 5.01**, as the case may be, in the future, (ii) not subject such Lender to any unreimbursed cost or expense and (iii) not otherwise be disadvantageous to such Lender. The Borrower hereby agrees to pay all reasonable costs and expenses incurred by any Lender in connection with any such designation or assignment and delegation.

(i) **United Kingdom Requirements**.

(i) Subject to sub-paragraph (ii) below, a UK Treaty Lender (or a Lender which would be a UK Treaty Lender upon the completion of any necessary procedural formalities) and each Withholding Agent which makes a payment to which that Lender is entitled shall co-operate in completing any procedural formalities necessary for that Withholding Agent to obtain authorization to make that payment without a UK Tax Deduction.

(ii) Each UK Treaty Lender (or a Lender which would be a UK Treaty Lender upon the completion of any necessary procedural formalities): (A) which is a Lender as at the date of this Agreement and that holds a passport under the UK DTTP Scheme, and which wishes that scheme to apply to this Agreement, shall confirm its UK DTTP Scheme reference number and its jurisdiction of tax residence opposite its name on **Schedule 1**; and (B) that becomes a Lender after the date of this Agreement and that holds a passport under the UK DTTP Scheme, and which wishes that scheme apply to such Lender's participation in this Agreement, shall confirm its UK DTTP Scheme reference number and its jurisdiction of tax residence in the documentation which it executes on becoming a party hereto as a Lender, and in each case under (A) and (B) above, having done so, that Lender shall be under no further obligation pursuant to sub-paragraph (i) above.

(iii) If a Lender has confirmed its UK DTTP Scheme reference number and its jurisdiction of tax residence in accordance with sub-paragraph (i)(ii) above and:

(A) the Borrower making a payment to that Lender has not made a Borrower DTTP Filing in respect of that Lender; or

(B) the Borrower making a payment to that Lender has made a Borrower DTTP Filing in respect of that Lender but (1) that Borrower DTTP Filing has been rejected by HMRC, (2) HMRC has not given the Borrower authority to make payments to that Lender without a UK Tax Deduction within 60 days of the date of the Borrower DTTP Filing, or (3) HMRC has given authority for the Borrower to make payments to that Lender without a UK Tax Deduction but such authority has subsequently been revoked, suspended or expired,

and in each case, the Borrower has notified that Lender in writing, then the applicable Lender shall co-operate with the Borrower in completing any additional procedural

formalities necessary for that Borrower to obtain authorization to make that payment without a UK Tax Deduction.

(iv) If a Lender has not confirmed its UK DTTP Scheme reference number and

(v) jurisdiction of tax residence in accordance with sub-paragraph (i)(ii) above, no Withholding Agent shall make a Borrower DTTP Filing or file any other form relating to the UK DTTP Scheme in respect of a Commitment by such Lender or its participation in any advance unless the Lender otherwise agrees.

(vi) The Borrower shall, promptly on making any Borrower DTTP Filing, deliver a copy of that Borrower DTTP Filing to the Administrative Agent for delivery to the relevant Lender.

(vii) A UK Non-Bank Lender shall promptly notify the Administrative Agent if there is any change in the position from that set out in the applicable UK Tax Confirmation.

(viii) If the Administrative Agent receives a UK Tax Confirmation from a UK Non-Bank Lender it shall promptly provide a copy of such UK Tax Confirmation to the Borrower.

(ix) The Borrower shall upon becoming aware that the Borrower must make a UK Tax Deduction (or that there is any change in the rate or the basis of a UK Tax Deduction) notify the Administrative Agent accordingly. Similarly, a Lender shall notify the Administrative Agent on becoming aware that a Withholding Agent must make a UK Tax Deduction (or that there is any change in the rate or the basis of a UK Tax Deduction). If the Administrative Agent receives such notification from a Lender, it shall promptly notify the Borrower.

(j) **Lender Status Confirmation**.

(i) Each Lender which becomes a party after the date of this Agreement shall indicate in the documentation which it executes on becoming a party which of the following categories it falls into: (A) not a UK Qualifying Lender; (B) a UK Qualifying Lender (other than a UK Treaty Lender); or (C) a UK Treaty Lender (or a Lender which would be a UK Treaty Lender upon the completion of any necessary procedural formalities).

(ii) If a Lender fails to indicate its status in respect of a Borrower in accordance with paragraph (j)(i) above, then such Lender shall be treated for the purposes of this Agreement (including by each Withholding Agent) as if it is not a UK Qualifying Lender until such time as it notifies the Administrative Agent which categories apply (and the Administrative Agent, upon receipt of such notification, shall promptly inform the Borrower). For the avoidance of doubt, the documentation which a Lender executes on becoming a Party as a Lender shall not be invalidated by any failure of such Lender to comply with this clause 5.03(j).

(iii) Where a Lender will become be a UK Treaty Lender only upon the completion of certain procedural formalities, it shall be treated for the purposes of this Agreement (including by each Withholding Agent) as if it is not a UK Qualifying Lender until such time as it notifies the Administrative Agent that such procedural formalities are complete (and the Administrative Agent, upon receipt of such notification, shall promptly inform the Borrower).

(k) **VAT**.

(i) All amounts expressed to be payable under a Loan Document by any party to any Secured Party which (in whole or in part) constitute the consideration for a supply or supplies for VAT purposes shall be deemed to be exclusive of any VAT which is chargeable on such supply or supplies, and accordingly, subject to paragraph (ii) below, if VAT is or becomes chargeable on any supply made by any Secured Party to any party under a Loan Document and:

(A) such Secured Party is required to account to the relevant tax authority for the VAT, that party shall pay to the Secured Party (in addition to and at the same time as paying any other consideration for such supply) an amount equal to the amount of such VAT (and such Secured Party shall promptly provide an appropriate VAT invoice to such party); or

(B) if such party is required to directly account for such VAT under the reverse charge procedure provided for by article 44 of the Council Directive 2006/112/EC, or section 7A of the Value Added Tax Act 1994 of the United Kingdom, in each case, as amended, or any relevant VAT provisions of the jurisdiction in which such party received such supply, then such party shall account for the VAT at the appropriate rate (and the relevant Secured Party must promptly provide an appropriate VAT invoice to such party stating that the amount is charged in respect of a supply that is subject to VAT but that the reverse charge procedure applies).

(ii) If VAT is or becomes chargeable on any supply made by any Secured Party (the "***VAT Supplier***") to any other Secured Party (the "***VAT Recipient***") under a Loan Document, and any party other than the VAT Recipient (the "***Relevant Party***") is required by the terms of any Loan Document to pay an amount equal to the consideration for that supply to the VAT Supplier (rather than being required to reimburse or indemnify the VAT Recipient in respect of that consideration):

(iii) where the VAT Supplier is the person required to account to the relevant tax authority for the VAT, the Relevant Party must also pay to the VAT Supplier (at the same time as paying that amount) an additional amount equal to the amount of VAT. The VAT Recipient must (where this sub-paragraph (ii)(A) applies) promptly pay to the Relevant Party an amount equal to any credit or repayment the VAT Recipient receives from the relevant tax authority which the VAT Recipient reasonably determines relates to the VAT chargeable on that supply; and

(iv) where the VAT Recipient is the person required to account to the relevant tax authority for the VAT, the Relevant Party must promptly, following demand from the VAT Recipient, pay to the VAT Recipient an amount equal to the VAT chargeable on that supply but only to the extent that the VAT Recipient reasonably determines that it is not entitled to credit or repayment from the relevant tax authority in respect of that VAT.

(v) Where a Loan Document requires any party to reimburse or indemnify a Secured Party for any cost or expense in connection with such Loan Document, the reimbursement or indemnity (as the case may be) shall be for the full amount of such cost or expense, including such part thereof as represents VAT, save to the extent that such Secured Party reasonably determines that it is entitled to credit or repayment in respect of such VAT from the relevant tax authority.

(vi) Any reference in this clause 11.1(i) to any party shall, at any time when such party is treated as a member of a group or unity (or fiscal unity) for VAT purposes, include (where appropriate and unless the context otherwise requires) a reference to the representative member of such group at such time as making the supply, or (as appropriate) receiving the supply, under the grouping rules (as provided for in Article 11 of Council Directive 2006/112/EC (or as implemented by the relevant member state of the European Union) or any other similar provision in any jurisdiction which is not a member state of the European Union, including, for the avoidance of doubt, in accordance with section 43 of the UK Value Added Tax Act 1994) so that a reference to a party shall be construed as a reference to that party or the relevant group or unity (or fiscal unity) of which that party is a member for VAT purposes at the relevant time or the relevant representative member (or head) of that group or unity (or fiscal unity) at the relevant time (as the case may be).

(vii) In relation to any supply made by a Secured Party to any party under a Loan Document, if reasonably requested by such Secured Party, that party must as promptly as reasonably practicable provide such Secured Party with details of that party's VAT registration and such other information as is reasonably requested in connection with such Secured Party's VAT reporting requirements in relation to such supply.

(l) **Hybrid Mismatch Rules**. The Lender agrees to use commercially reasonable efforts to assist the Borrower in preparing an analysis of available interest deductions to the Borrower under the UK hybrid mismatch rules contained in Part 6A of the Taxation (International and Other Provisions) Act 2010 at Borrower's cost; provided, however, that notwithstanding anything to the contrary in this Agreement, the Lender shall not be obligated to take any actions that would disclose the identity of its partners.

(m) **Survival**. Each party's obligations under this **Section 5.03** shall survive the resignation or replacement of the Administrative Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Commitments and the repayment, satisfaction or discharge of all Obligations under any Loan Document.

SECTION 6
CONDITIONS PRECEDENT

6.01 Conditions to the Borrowing of the Tranche 1 Loan on the Closing Date. The obligation of the Lenders to make the Tranche 1 Loan on the Closing Date shall be subject to the execution and delivery of this Agreement by the parties hereto, the delivery of a Borrowing Notice as required pursuant to **Section 2.02**, the delivery of a funds flow memorandum summarizing, in reasonable detail, the use of proceeds of the Tranche 1 Loan, and the prior or concurrent satisfaction (or waiver thereof by the Administrative Agent) of each of the conditions precedent set forth below in this **Section 6.01**.

(a) **Secretary's Certificate, Etc.** The Administrative Agent shall have received from each Obligor party to a Loan Document on the Closing Date:

(i) a copy of a good standing certificate or the equivalent thereof, dated a date reasonably close to the Closing Date, for each such Person; and

(ii) a certificate, dated as of the Closing Date, duly executed and delivered by such Person's director, secretary or assistant secretary, managing member, general partner, authorized signatory or equivalent, as to:

(A) resolutions of each such Person's Board then in full force and effect authorizing the execution, delivery and performance of each Loan Document and the Transactions, to be executed and delivered by such Person;

(B) the incumbency and signatures of those of its officers, directors, managing member or general partner or equivalent authorized to act with respect to each Loan Document to be executed and delivered by such Person; and

(C) true and complete copies of each Organic Document of such Person and, in relation to any Person that is a Cayman Islands exempted company or limited liability company, its register of directors and officers and register of mortgages and charges;

(iii) solely with respect to the Irish Subsidiary Guarantor:

(A) evidence that the constitution of such Irish Subsidiary Guarantor does not restrict the registration of the transfer of secured shares and does not apply any company lien over shares; and

(B) a certificate from such Irish Subsidiary Guarantor certifying that entry into the Loan Documents by it will not breach Sections 82 and 239 of the Irish Companies Act;

which certificates shall be in form and substance reasonably satisfactory to the Administrative Agent and upon which the Administrative Agent and the Lenders may conclusively rely until they shall have received a further certificate of the director, secretary, assistant secretary, managing member, general partner or equivalent of any such Person cancelling or amending the prior certificate of such Person.

(b) **Information Certificate**. The Administrative Agent shall have received a fully completed Information Certificate, in form and substance reasonably satisfactory to the Administrative Agent, dated as of the Closing Date, duly executed and delivered by a Responsible Officer of the Borrower, which shall be true and correct in all material respects as of the Closing Date. All documents and agreements required to be appended to the Information Certificate, if any, shall be in form and substance reasonably satisfactory to the Administrative Agent, shall have been executed and delivered by the requisite parties and shall be in full force and effect.

(c) **Closing Date Certificate**. The following statements shall be true and correct, and the Administrative Agent shall have received a certificate, dated as of the Closing Date in form and substance reasonably satisfactory to the Administrative Agent, duly executed and delivered by a Responsible Officer of the Borrower certifying that: (i) both immediately before and after giving effect to the Borrowing on the Closing Date, (x) the representations and warranties set forth in each Loan Document that are qualified by materiality, Material Adverse Effect or the like are, in each case, true and correct, (y) the representations and warranties set forth in each Loan Document that are not qualified by materiality, Material Adverse Effect or the like are, in each

case, true and correct in all material respects, and (z) no Event of Default has occurred and is continuing, or could reasonably be expected to result from the making of the Tranche 1 Loan being advanced, or the consummation of any Transactions contemplated to occur on the Closing Date, and (ii) all of the conditions set forth in this **Section 6.01** have been satisfied (except to the extent waived in writing by the Administrative Agent). All documents and agreements required to be appended to the certificate delivered pursuant to this **Section 6.01(c)**, if any, shall be in form and substance reasonably satisfactory to the Administrative Agent, shall have been executed (if applicable) and delivered by the requisite parties, and shall be in full force and effect.

(d) **[Reserved].**

(e) **Financial Information, Etc.** The Administrative Agent shall have received:

(i) audited consolidated financial statements of the Borrower and its Subsidiaries for the fiscal year ended December 31, 2021; and

(ii) unaudited consolidated balance sheets of the Borrower and its Subsidiaries for each fiscal quarter ended after December 31, 2021 and at least thirty (30) Business Days prior to the Closing Date, together with the related consolidated statement of operations, shareholder's equity and cash flows for each such fiscal quarter.

(f) **Minimum Liquidity Compliance**. The Administrative Agent shall have received evidence reasonably satisfactory to it that, immediately after giving effect to the Borrowing on the Closing Date, the Borrower will be in compliance with the covenant set forth in **Section 10.01**.

(g) **Closing Date Warrant Certificates**. The Administrative Agent shall have received (i) an executed counterpart of a Warrant Certificate, exercisable into 400,000 shares of the Borrower's ordinary shares with a per share exercise price of $15.00 and (ii) an executed counterpart of a Warrant Certificate, exercisable into 300,000 shares of the Borrower's ordinary shares with a per share exercise price of $20.00, in each case duly executed and delivered by the Borrower.

(h) **Insurance**. The Administrative Agent shall have received certificates of insurance evidencing that the insurance required to be maintained pursuant to **Section 8.05** is in full force and effect, together with endorsements naming the Administrative Agent, for the benefit of the Lenders, as additional insured and loss payee thereunder, in each case, in form and substance reasonably satisfactory to the Administrative Agent.

(i) **Solvency**. The Administrative Agent shall have received a solvency certificate substantially in the form of **Exhibit I**, duly executed and delivered by the chief financial or other Responsible Officer of the Borrower, dated as of the Closing Date, in form and substance reasonably satisfactory to the Administrative Agent.

(j) **Security Documents**. The Administrative Agent shall have received executed counterparts of all Security Documents, each dated as of the date hereof, duly executed and delivered by the applicable Obligors, together with:

(i) The delivery of all certificates (in the case of Equity Interests that are securities (as defined in the UCC)) evidencing the issued and outstanding capital securities of the Subsidiary Guarantors that are required to be pledged under any Security Document, which certificates in each case shall be accompanied by undated instruments of transfer duly executed in blank, or, in the case of Equity Interests that are uncertificated securities (as defined in the UCC), confirmation and evidence satisfactory to the Administrative Agent and the Lenders that the security interest required to be pledged therein under any Security Document has been transferred to and perfected by the Administrative Agent for the benefit of the Secured Parties in accordance with Articles 8 and 9 of the NY UCC and all Laws otherwise applicable to the perfection of the pledge of such Equity Interests;

(ii) financing statements naming each Obligor as a debtor and the Administrative Agent as the secured party, or other similar instruments, registrations, or documents, in each case suitable for filing, filed under the UCC (or equivalent Law) of all jurisdictions as may be reasonably necessary to perfect the Liens of the Secured Parties pursuant to any Security Document;

(iii) evidence that the Minimum Liquidity Account and all deposit accounts, lockboxes, disbursement accounts, investment accounts (or other similar cash or bank accounts) of the Subsidiary Guarantors are Controlled Accounts;

(iv) evidence that all such Controlled Accounts are subject to one or more account control agreements, or the equivalent in a foreign law jurisdiction, in favor of, and satisfactory in form and substance to, the Administrative Agent; and

(v) all notices of assignment, share deliverables and other ancillary documents necessary to perfect the Liens of the Secured Parties pursuant to any Foreign Collateral Security Document.

(k) **Lien Searches**. The Administrative Agent shall be satisfied with scope and results of Lien searches (or equivalents) regarding the Collateral made within thirty (30) days prior to the Closing Date.

(l) **Opinions of Counsel**. The Administrative Agent shall have received one or more legal opinions, dated the Closing Date and addressed to the Administrative Agent and the Lenders, from independent legal counsel to the Borrower and, if necessary, other legal counsel satisfactory to the Administrative Agent, in each case, in form and substance reasonably acceptable to the Administrative Agent.

(m) **Material Adverse Change**. No Material Adverse Change shall have occurred since December 31, 2021.

(n) **Anti-Terrorism Laws**. The Administrative Agent shall have received, as applicable, all documentation and other information required by bank regulatory authorities requested by the Administrative Agent at least three (3) Business Days prior to the Closing Date with respect to applicable "know your customer" and anti-money laundering rules and regulations, including the Patriot Act.

(o) **Fees, Expenses, Etc**. The Administrative Agent shall have received for its account and the account of each Lender, the Tranche 1 Facility Fee, together with payment and reimbursement of all other fees, costs and expenses due and payable pursuant to the Proposal Letter and **Section 14.03**, including all closing costs and fees and all unpaid reasonable expenses of the Administrative Agent and the Lenders incurred as of the Closing Date in connection with the Transactions in excess of the Expense Deposit (as defined in the Proposal Letter) (including the Administrative Agent's and the Lenders' legal fees and expenses); provided that (i) the Borrower's obligation to pay and reimburse for such closing costs, fees and unpaid reasonable expenses incurred as of the Closing Date shall not exceed [***] (inclusive of the Expense Deposit) unless otherwise agreed to by the Obligors and the Administrative Agent and (ii) the foregoing expense cap shall be exclusive of all fees, costs and expenses of the Independent Appraiser, which shall be paid and reimbursed in full by the Borrower as provided above.

(p) **Independent Appraisal of Manufacturing Facilities**. The Administrative Agent shall have received a satisfactory initial draft valuation and appraisal report, prepared by a reputable independent appraiser (the "***Independent Appraiser***") instructed and appointed by the Administrative Agent, which report shall be in scope and substance reasonably satisfactory to the Administrative Agent.

(q) **Certificates of Title and Foreign Real Property Security Documents**. The Borrower shall have delivered to the Administrative Agent:

(i) a duly executed Foreign Real Property Security Document in respect of each of the London Manufacturing Facility and the Shannon Manufacturing Facility;

(ii) copies of all lease and title documents for the London Manufacturing Facility in electronic format;

(iii) a clear (save in respect of pending applications which have been disclosed in the Certificate of Title) Land Registry Priority Search (OS1) in favour of the Administrative Agent against the title number of the London Manufacturing Facility and: (A) giving not less than 20 Business Days' priority beyond the date of the relevant Security Document; and (B) showing no adverse entries (save in respect of pending applications which have been disclosed in the relevant Certificate of Title);

(iv) the Certificates of Title;

(v) an overview report prepared by the Administrative Agent's solicitors on the Certificates of Title addressed to the Secured Parties;

(vi) all necessary HM Land Registry application forms in relation to the charging of the London Manufacturing Facility in favour of the Administrative Agent (including a form to note the obligation to make further advances and a form to register the restriction contained in the relevant Security Document), duly completed, accompanied by payment of the applicable HM Land Registry fees or an acceptable undertaking in relation to the same;

(vii) copies of all Authorisations (if any) required in connection with the charging of the London Manufacturing Facility and the Shannon Manufacturing Facility in favour of the Administrative Agent;

(viii) all title documents relating to the Shannon Manufacturing Facility or an acceptable undertaking to hold the same to the order of the Secured Parties;

(ix) all necessary Property Registration Authority forms in relation to the charging of the Shannon Manufacturing Facility in favour of the Administrative Agent;

(x) an acceptable undertaking to assist with Property Registration Authority queries relating to the registration of the Shannon Manufacturing Facility in the name of the Irish Subsidiary Guarantor and the registration of the charge over the Shannon Manufacturing Facility in favour of the Administrative Agent;

(xi) undertaking from of the Irish Subsidiary Guarantor to assist with Property Registration Authority queries relating to the registration of the Shannon Manufacturing Facility in the name of the Irish Subsidiary Guarantor and the registration of the charge over the Shannon Manufacturing Facility in favour of the Administrative Agent

(xii) Clear or duly explained and certified Land Registry / Registry of Deeds and planning searches in respect of the Shannon Manufacturing Facility and showing no adverse acts appearing;

(xiii) Sworn Family Home Declaration in relation to the Shannon Manufacturing Facility;

(xiv) Sworn Declaration re compliance with leasehold covenants in relation to the Shannon Manufacturing Facility; and

(xv) Letter from ALG addressed to the Land Registry authorising William Fry to take control over dealing D2022LR029852T.

In this Section, an "acceptable undertaking" means a solicitor's undertaking from a firm of solicitors regulated by the Solicitors Regulation Authority or the Irish Law Society (as applicable) and approved for this purpose by the Administrative Agent and in form and substance reasonably satisfactory to the Administrative Agent.

(r) **Process Agent**. Evidence that any process agent referred to in clause 21 (Service of process) of the English Law Security Agreement has accepted its appointment.

6.02 Conditions to the Borrowing of the Tranche 2 Loan. During the Tranche 2 Draw Period, the Borrower may request that the Lenders make the Tranche 2 Loan in an aggregate principal amount of $25,000,000; provided that the making of the Tranche 2 Loan shall be subject to the prior consent of the Majority Lenders in their sole discretion after receiving such request from the Borrower, and no Lender shall have any commitment to make or participate in the making of the Tranche 2 Loan unless the Majority Lenders have provided such consent in writing to the Borrower, the Administrative Agent and the other Lenders hereunder. In the event (and only in

the event) the Majority Lenders so consent to make the requested Tranche 2 Loan, in whole or in part, as provided above, the obligation of the Lenders to fund their respective Proportionate Shares of the Tranche 2 Loan at their sole discretion shall be subject to the delivery of a Borrowing Notice by the Borrower, the delivery of a funds flow memorandum by the Borrower summarizing, in reasonable detail, the use of proceeds of the Tranche 2 Loan, and the prior or concurrent satisfaction (or waiver thereof by the Administrative Agent) of such customary additional conditions as the Majority Lenders may reasonably request (including some or all conditions of the type set forth in **Section 6.01**).

SECTION 7
REPRESENTATIONS AND WARRANTIES

The Borrower and each other Obligor hereby jointly and severally represent and warrant to the Administrative Agent and each Lender that:

7.01 Power and Authority. The Borrower and each of its Subsidiaries (i) is duly organized or incorporated, as applicable, and validly existing under the laws of its jurisdiction of organization or incorporation, as applicable, (ii) has all requisite corporate or other power, and has all Governmental Approvals necessary to own or lease its assets and carry on its business as now being or as proposed to be conducted, including all Healthcare Permits, other than could not reasonably be expected to result in a Material Adverse Effect, (iii) is qualified to do business and is in good standing (or equivalent) in all jurisdictions in which the nature of the business conducted by it makes such qualification necessary and where failure so to qualify, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect, and (iv) has full power, authority and legal right to execute, deliver and perform its obligations under each of the Loan Documents to which it is a party and, in the case of the Borrower, to borrow the Loans hereunder.

7.02 Authorization; Enforceability. Each Transaction to which an Obligor is a party (or to which it or any of its assets or properties is subject) are within such Obligor's corporate or other powers and have been duly authorized by all necessary corporate action including, if required, approval by all necessary holders of Equity Interests. This Agreement has been duly executed and delivered by each Obligor and constitutes, and each of the other Loan Documents to which it is a party when executed and delivered by such Obligor, will constitute, a legal, valid and binding obligation of such Obligor, enforceable against such Obligor in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights; (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law); and (iii) solely in respect of the English Guarantor and the Irish Subsidiary Guarantor, the Legal Reservations or the Perfection Requirements.

7.03 Governmental and Other Approvals for Execution and Delivery of the Loan Documents, etc.; No Conflicts. No authorization or approval or other action by, and no notice to or filing with, any Governmental Authority or any other Person (other than those that have been duly obtained or made and which are in full force and effect) is required in connection with the due execution, delivery or performance by, any Obligor of any Loan Document to which it is a party, except for such approvals, consents, exemptions, authorizations, actions or notices

(including such filings and recordings that have been or will be made on the Closing Date in respect of perfecting or recording the Liens created pursuant to the Security Documents) that have been duly obtained, taken or made and that are in full force and effect. None of the Transactions will (i) violate or conflict with any Law, other than any such violation that could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (ii) violate or conflict with any Organic Document of the Borrower or any of its Subsidiaries, (iii) violate or conflict with any Governmental Approval of any Governmental Authority binding upon the Borrower or any of its Subsidiaries other than any such violation that could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (iv) violate or result in a default under any Material Agreement other than any such violation that could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, or (v) result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of such Obligor. The Borrower, its Subsidiaries and their respective properties and businesses are in compliance in all material respects with all applicable Laws (including Healthcare Laws) and Governmental Approvals applicable to such Person and its properties or businesses, as the case may be.

7.04 Financial Statements; Material Adverse Change.

(a) **Financial Statements**. The Borrower has heretofore furnished to the Administrative Agent and the Lenders certain consolidated financial statements as provided for in **Section 6.01(e)**. Such financial statements, and all other financial statements delivered by the Borrower pursuant hereto (including **Section 6.01**) present fairly, in all material respects, the consolidated financial position and results of operations and cash flows of the Borrower and its Subsidiaries as of such dates and for such periods in accordance with GAAP, subject to year-end audit adjustments and the absence of footnotes in the case of the statements of the type described in **Sections 8.01(a)** and **8.01(b)**. Neither the Borrower nor any of its Subsidiaries has any material contingent liabilities or unusual forward or long-term commitments required to be disclosed in the aforementioned financial statements and related footnotes in accordance with GAAP that are not disclosed therein.

(b) **No Material Adverse Change**. Since December 31, 2021, there has been no Material Adverse Change.

7.05 Properties.

(a) **Property Generally**. With respect to all real and personal assets and properties of the Borrower and each of its Subsidiaries (other than Intellectual Property which is covered in **clause (b)** below), the Borrower and each of its Subsidiaries has good and marketable fee simple title to, valid leasehold interests or other equivalent rights in, all such real and personal assets and property, whether tangible or intangible, material to its respective business and except as disclosed in a Certificate of Title, subject only to Permitted Liens and except for defects in title that do not, and are not reasonably anticipated to materially interfere with the ability of the Borrower or any such Subsidiaries, as the case may be, to utilize such assets and properties in the ordinary course of business as currently conducted and anticipated to be conducted.

(b) **Intellectual Property.**

(i) **Schedule 7.05(b)** contains, with respect to the Obligors and their respective Material Intellectual Property (set forth on an Obligor-by-Obligor basis and designated as to whether such Material Intellectual Property is owned or in-licensed):

(A) a complete and accurate list of all applied for, issued, or registered Patents owned by or licensed to the Obligors, including the jurisdiction and patent number, which would qualify as Material Intellectual Property;

(B) a complete and accurate list of all material applied for, or registered active Trademarks owned by or licensed to the Obligors, including the jurisdiction, trademark application or registration number and the application or registration date, which would qualify as Material Intellectual Property; and

(C) a complete and accurate list of all applied for or registered Copyrights owned by or licensed to the Obligors, which would qualify as Material Intellectual Property.

(ii) With respect to any such Intellectual Property listed on **Schedule 7.05(b)** that is designated as being in-licensed by the Obligors from a third party, there are no unpaid fees or royalties (or similar payment obligations) currently due and payable under or in respect of any such in-licensed Material Intellectual Property (or any license or other Contract related thereto) and, to the knowledge of the Borrower, such license is legal, valid, binding, enforceable, and in full force and effect. No Obligor is in material breach or default of any such license and, to the knowledge of the Borrower, no third party (including the licensor of any such licensed Material Intellectual Property) is in material breach or default of any such license that, in either case, could reasonably be expected to give rise to a right of rescission, termination, revision or amendment of any of any such license.

(iii) With respect to any such Material Intellectual Property listed on **Schedule 7.05(b)** that is designated as being owned by the Obligors, each Obligor, as the case may be, is the beneficial owner of all right, title and interest in and to such Person's Material Intellectual Property that it owns, with no breaks in chain of title and with good and marketable title, free and clear of any Liens or Claims of any kind whatsoever (other than Permitted Liens), and the Borrower or the applicable Obligor, as the case may be, has the right to use such Material Intellectual Property in the ordinary course of its respective business as currently conducted and as anticipated to be conducted. Without limiting the foregoing, and except as set forth on **Schedule 7.05(b)**:

(A) other than as permitted by **Section 9.09**, neither the Borrower nor any Subsidiary Guarantor, has transferred ownership of any such Material Intellectual Property, in whole or in part, to any Person who is not an Obligor;

(B) other than (1) customary restrictions in in-bound licenses of Intellectual Property and non-disclosure agreements, in each case as permitted pursuant to **Section 9.19** or (2) licenses granted to the Borrower's or any of its Subsidiaries' customers or development partners in the ordinary course of business, there are no judgments, covenants not to sue, permits, grants, licenses, Liens (other than Permitted Liens), Claims, or other agreements or arrangements relating to any such Material Intellectual Property, including any development, submission,

services, research, license or support agreements, which bind, obligate or otherwise restrict the Borrower or any of its Subsidiaries with respect to any such Material Intellectual Property in any material respect;

(C) the use by the Borrower or any of its Subsidiaries of any such Material Intellectual Property in the ordinary course of such Person's businesses does not breach, violate, infringe or interfere with or constitute a misappropriation of any valid rights arising under any Intellectual Property of any other Person that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect;

(D) (1) there are no pending or, to the Borrower's knowledge, threatened in writing Claims against the Borrower or any of its Subsidiaries asserted by any other Person relating to any such Material Intellectual Property, including any Claims of adverse ownership, invalidity, infringement, misappropriation, violation or other opposition to or conflict with such Material Intellectual Property; and (2) neither the Borrower nor any of its Subsidiaries has received any written notice from, or Claim by, any other Person that the business of the Borrower or any of its Subsidiaries, the use of any such Material Intellectual Property by the Borrower or any of its Subsidiaries materially infringes upon, violates or constitutes a misappropriation of, or may infringe upon, violate or constitute a misappropriation of, or otherwise interfere with, or otherwise offer a license with respect to any Intellectual Property of any such other Person; and

(E) to the Borrower's knowledge, no such Material Intellectual Property is being infringed, violated, misappropriated or otherwise used by any other Person without the express authorization of the Borrower; and, without limiting the foregoing, neither the Borrower nor any of its Subsidiaries has put any other Person on notice of actual or potential infringement, violation or misappropriation of any such Material Intellectual Property, and neither the Borrower nor any of its Subsidiaries has initiated the enforcement of any Claim with respect to any such Material Intellectual Property.

(iv) With respect to the owned Material Intellectual Property of the Obligors consisting of Patents listed on **Schedule 7.05(b)**, except as set forth on **Schedule 7.05(b)**, and without limiting the representations and warranties in **Section 7.05(b)(iii)**:

(A) each of the issued claims in such Patents is valid and enforceable;

(B) each inventor named in such Patents has executed written Contracts with the Borrower or one of its Subsidiaries (or a predecessor-in-interest) that properly and irrevocably assigns to the Borrower or such Subsidiary (or such predecessor-in-interest) all of such inventor's rights, title and interest to any of the Inventions claimed in such Patents;

(C) all such Patents are in good standing and none of the Patents, or the Inventions claimed in any such Patent, have been dedicated to the public;

(D) all prior art material to such Patents was adequately disclosed, to the extent such disclosure is required, to the relevant patent office or, to the Borrower's knowledge, considered by the respective patent offices during prosecution of such Patents;

(E) subsequent to the issuance of such Patents, none of the Borrower, any of its Subsidiaries or any of their respective predecessors-in-interest, has filed any disclaimer or made or permitted any other voluntary reduction in the scope of the Inventions claimed in such Patents;

(F) no subject matter designated allowable or allowed by the U.S. Patent and Trademark Office of such Patents is subject to any competing conception claims of allowable or allowed subject matter of any patent applications or patents of any third party and have not been the subject of any interference, and such Patents are not and have not been the subject of any re-examination, opposition or any other post-grant proceedings, and neither the Borrower nor any of its Subsidiaries has knowledge of any basis for any such interference, re-examination, opposition, *inter partes* review, post grant review, or any other post-grant proceedings;

(G) no such Patents have ever been finally adjudicated to be invalid, unpatentable or unenforceable for any reason in any administrative, arbitration, judicial or other proceeding, and, with the exception of publicly available documents in the applicable patent office recorded with respect to any Patents, neither the Borrower nor any of its Subsidiaries has received any written, or to its knowledge, other notice asserting that such Patents are invalid, unpatentable or unenforceable; if any of such Patents is terminally disclaimed to another patent or patent application, all patents and patent applications subject to such terminal disclaimer are included in the Collateral;

(H) neither the Borrower nor any of its Subsidiaries has received an opinion, whether preliminary in nature or qualified in any manner, which concludes that a challenge to the validity or enforceability of any such Patents is more likely than not to succeed;

(I) (i) neither the Borrower nor any of its Subsidiaries, nor, any of their respective agents or representatives, have engaged in any conduct, or omitted to perform any necessary act, the result of which would invalidate or render unpatentable or unenforceable any such Patent and (ii) to the Borrower's knowledge, no prior owner of any such Patent of the Borrower or any of its Subsidiaries, nor any of such prior owner's agents or representatives, have engaged in any conduct, or omitted to perform any necessary act, the result of which would invalidate or render unpatentable or unenforceable any such Patent; and

(J) all maintenance fees, annuities, and the like due or payable on or with respect to any such Patents have been timely paid or the failure to so pay could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(v) The Material Intellectual Property listed on **Schedule 7.05(b)**, together with the Borrower's and its Subsidiaries' lawful use of open source, freeware, is all the Intellectual Property necessary for the operation of the business of the Borrower and its Subsidiaries as it is currently conducted or as currently contemplated to be conducted. Borrower and each of its Subsidiaries have taken commercially reasonable precautions to protect the secrecy, confidentiality and value of its Material Intellectual Property consisting of trade secrets and confidential information, including unregistered Intellectual Property that is material to their respective businesses.

7.06 No Actions or Proceedings.

(a) **Litigation**. Except as set forth on **Schedule 7.06(a)**, there is no litigation, investigation or proceeding pending or, to the knowledge of the Borrower, threatened in writing, with respect to the Borrower or any of its Subsidiaries by or before any Governmental Authority or arbitrator that (i) could, individually or in the aggregate, reasonably be expected to result in an Event of Default or (ii) involves this Agreement, any other Loan Document, the Transactions or any Material Intellectual Property.

(b) **Environmental Matters**. The operations and property of the Borrower and each of its Subsidiaries comply with all applicable Environmental Laws, except to the extent the failure to so comply (either individually or in the aggregate) could not reasonably be expected to result in Material Adverse Effect.

(c) **Labor Matters**. There are no strikes, lockouts or other material labor disputes against the Borrower or any of its Subsidiaries or, to the Borrower's knowledge, threatened in writing against or directly affecting the Borrower or any of its Subsidiaries, and no material unfair labor practice complaint is pending against the Borrower or any Subsidiary or, to the knowledge of the Borrower, threatened in writing against any of them before any Governmental Authority, in each case, that could reasonably be expected to result in a Material Adverse Effect. Except as set forth on **Schedule 7.06(c)**, neither the Borrower nor any of its Subsidiaries is a party to any collective bargaining agreements or similar Contracts, no union representation exists on any facilities of the Borrower or any of its Subsidiaries and the Borrower and its Subsidiaries do not have any knowledge of any union organizing activities that are taking place.

7.07 Compliance with Laws and Agreements.

(a) Each of the Borrower and its Subsidiaries is in compliance with all applicable Laws and all Contracts binding upon it or its property, except (other than with respect to Material Intellectual Property) where the failure to do so, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect. No Default has occurred and is continuing, or will occur as a result of the making of any Loan hereunder.

(b) Without limiting the generality of the foregoing, (i) each of the Borrower and its Subsidiaries is in material compliance with all applicable Healthcare Laws and Healthcare Permits, and (ii) during the past four (4) years neither the Borrower nor any of its Subsidiaries has received written notice by a Governmental Authority of any material violation (or of any investigation, audit, or other proceeding involving allegations of any violation) of any Healthcare Laws, and no such investigation, inspection, audit or other proceeding involving allegations of any such violation has been, to the knowledge of the Borrower, threatened in writing.

7.08 Taxes. Except as set forth on **Schedule 7.08**, the Borrower and each of its Subsidiaries has timely filed or caused to be filed all federal and state income tax returns and other material tax returns and reports required to have been filed and has paid or caused to be paid all material Taxes required to have been paid by it, except for Taxes that are being contested in good faith by appropriate proceedings and for which, in each case, the Borrower or such Subsidiary, as

applicable, has set aside on its books adequate reserves with respect thereto in accordance with GAAP.

7.09 Full Disclosure. None of the reports, financial statements, certificates (other than the Certificates of Title) or other information furnished by or on behalf of the Obligors to the Administrative Agent or any Lender in connection with the negotiation of this Agreement and the other Loan Documents or delivered hereunder or thereunder (as modified or supplemented by other information so furnished) contains any material misstatement of material fact or omits to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that, with respect to projected financial information, the Borrower represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood by the Administrative Agent and the Lenders that such projected financial information is not to be viewed as facts, and that no assurances can be given that any particular projections will be realized and that actual results during the period or periods covered by any such projections may differ from the projected results and such differences may be material). In respect of the Certificates of Title, the information supplied by or on behalf of the Obligors to the lawyers who prepared any Certificate of Title for the purpose of that Certificate of Title was true, complete and accurate as at the date of the Certificate of Title or (if appropriate) as at the date (if any) at which it is stated to be given and did not omit any information which, if disclosed, would make that information untrue or misleading in any material respect.

7.10 Investment Company Act and Margin Stock Regulation.

(a) **Investment Company Act**. Neither the Borrower nor any of its Subsidiaries is an "investment company" as defined in, or subject to regulation under, the Investment Company Act of 1940, as amended.

(b) **Margin Stock**. Neither the Borrower nor any of its Subsidiaries is engaged principally, or as one of its important activities, in the business of extending credit for the purpose, whether immediate, incidental or ultimate, of buying or carrying Margin Stock, and no part of the proceeds of the Loans will be used to buy or carry any Margin Stock in violation of Regulation T, Regulation U or Regulation X.

7.11 Solvency. The Borrower and its Subsidiaries, on a consolidated basis, are, and, immediately after giving effect to the Loan and the use of proceeds thereof, will be Solvent.

7.12 Equity Holders, Subsidiaries and Other Investments.

(a) Set forth on **Schedule 7.12(a)** is a complete and correct list of all direct and indirect Subsidiaries of the Borrower. Each such Subsidiary is duly organized or incorporated, as applicable and validly existing under the jurisdiction of its organization or incorporation, as applicable shown in **Schedule 7.12(a)**, and the percentage ownership by the Borrower of each such Subsidiary thereof is as shown in **Schedule 7.12(a)**.

(b) Set forth on **Schedule 7.12(b)** is a complete and correct list of all other Equity Interests owned or held by the Borrower or any of its direct or indirect Subsidiaries in any Person that does not qualify as a direct or indirect Subsidiary of the Borrower. **Schedule 7.12(b)** also sets

forth, in reasonable detail, the type of Equity Interest held by each Obligor in such other Person and the fully-diluted percentage ownership held beneficially by the Borrower or one or more of its Subsidiaries, as the case may be, such other Person.

7.13 Continuing Secured Indebtedness. Set forth on **Schedule 7.13** is a complete and correct list of all Indebtedness of the Borrower and each of its Subsidiaries outstanding as of the date hereof that (i) will remain outstanding immediately after the making of the Loans and the application of proceeds therefrom on the Closing Date and (ii) is secured by a Lien on assets or property of the Borrower or any of its Subsidiaries.

7.14 Material Agreements. Except as set forth on **Schedule 7.14**, as of the Closing Date, all Material Agreements have been publically disclosed. Neither the Borrower nor any of its Subsidiaries is in default under any such Material Agreement, and the Borrower does not have knowledge of any material default by any counterparty to any such Material Agreement and there are no pending or, to the Borrower's knowledge, threatened material adverse Claims against the Borrower or any of its Subsidiaries asserted by any other Person relating to any such Material Agreements, including any such Claims of breach or default thereunder.

7.15 Restrictive Agreements. Except as set forth on **Schedule 7.15**, neither the Borrower nor any of its Subsidiaries is subject to any Restrictive Agreement, except those permitted under **Section 9.11**.

7.16 Real Property. Except as set forth on **Schedule 7.16**, neither the Borrower nor any of its Subsidiaries owns or leases (as a tenant) any real property.

7.17 Pension Matters. Except as, in the aggregate, could not reasonably be expected to result in a Material Adverse Effect, (a) each Benefit Plan, and each trust thereunder, intended to qualify for tax-exempt status under Section 401 or 501 of the Code or other applicable Law so qualifies, (b) each Benefit Plan and Foreign Pension Plan is in compliance with all applicable provisions of ERISA, the Code or other applicable Law, (c) no ERISA Event has occurred or is reasonably expected to occur, (d) the Borrower and each of its ERISA Affiliates has met all applicable requirements under the ERISA Funding Rules with respect to each Title IV Plan, and no waiver of the minimum funding standards under the ERISA Funding Rules has been applied for or obtained, (e) as of the most recent valuation date for any Title IV Plan, the funding target attainment percentage (as defined in Section 430(d)(2) of the Code) is at least sixty percent (60%), and none of the Borrower, any of its Subsidiaries nor any of their ERISA Affiliates knows of any facts or circumstances that could reasonably be expected to cause the funding target attainment percentage to fall below sixty percent (60%) as of the most recent valuation date and (f) neither the Borrower nor any of its ERISA Affiliates has or would have any Withdrawal Liability as a result of a complete withdrawal from any Multiemployer Plan on the date this representation is made.

7.18 Priority of Obligations; Collateral; Security Interest. No monetary Obligation arising hereunder or under any Loan Document, or arising in connection herewith or therewith, is contractually subordinated to any other Indebtedness of the Obligors. Subject to the Legal Reservations and Perfection Requirements solely in respect of the English Guarantor and the Irish Subsidiary Guarantor, each Security Document is effective to create in favor of the Secured Parties

a legal, valid and enforceable security interest in the Collateral subject to such Security Document, each such security interest is legal, valid and enforceable, and each such security interest is perfected to the extent required by the applicable Security Document on a first-priority basis (subject to Permitted Liens that may apply to specific items of Collateral permitted pursuant to **Section 9.02**) and secures the Obligations.

7.19 Governmental Approvals in Respect of Ordinary Course Activities, Etc. The Borrower and each of its Subsidiaries hold, and will continue to hold, either directly or through licensees or agents, all Governmental Approvals, including all Healthcare Permits, necessary or required for the Borrower and each of its Subsidiaries to engage in and otherwise conduct their respective operations and businesses in the ordinary course, including their commercialization and development of products.

7.20 Transactions with Affiliates. Except as set forth on **Schedule 7.20**, neither the Borrower nor any of its Subsidiaries is a party to any transaction with any Affiliate that would be prohibited pursuant to **Section 9.10** hereof.

7.21 Sanctions. Neither the Borrower nor any of its Subsidiaries, any of their respective directors, officers, or employees nor, to the knowledge of the Borrower, agents or other Persons acting on behalf of any of the foregoing (i) is currently the target of any Sanctions, (ii) is operating, organized or resident in any Designated Jurisdiction, (iii) is engaged in any transactions with, or for the benefit of, any Person who is the target of Sanctions or who is operating, organized or resident in any Designated Jurisdiction in violation of Sanctions or (iv) is in violation of Sanctions. No Loan, nor the proceeds from any Loan, will be used, directly or indirectly, to lend, contribute or provide to, or has been or will be otherwise made available to fund, any activity or business in any Designated Jurisdiction or any activity or business of any Person located, organized or residing in any Designated Jurisdiction, in violation of Sanctions or who is the subject of any Sanctions, or in any other manner that will result in any violation by any Person (including the Administrative Agent, the Lenders and their Affiliates) of Sanctions.

7.22 Anti-Corruption. Neither the Borrower nor any of its Subsidiaries, any of their respective directors, officers or employees nor, to the knowledge of the Borrower, any agents or other Persons acting on behalf of any of the foregoing, directly or indirectly, has (i) violated or is in violation of any applicable anti-corruption Law or (ii) made, offered to make, promised to make or authorized the payment or giving of, directly or indirectly, any Prohibited Payment.

7.23 Deposit and Disbursement Accounts and Investment Accounts. **Schedule 7.23** contains a list of all banks and other financial institutions at which the Obligors maintain deposit accounts, lockboxes, disbursement accounts, investment accounts or other similar accounts, and such Schedule correctly identifies the name and address of each bank or financial institution, the name in which the account is held, the type of account, and the complete account number therefor.

7.24 Centre of Main Interests. For the purposes of Regulation (EU) 2015/848 of 20 May 2015 on insolvency proceedings (recast) (the Regulation), the Borrower’s centre of main interest (as that term is used in Article 3(1) of the Regulation) is situated in its jurisdiction of organization and it has no "establishment" (as that term is used in Article 2(10) of the Regulations) in any other jurisdiction.

SECTION 8
AFFIRMATIVE COVENANTS

The Obligors jointly and severally covenant and agree with the Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations (other than inchoate indemnification and expense reimbursement obligations for which no Claim has been made) have been paid in full in cash:

8.01 Financial Statements and Other Information. The Borrower shall furnish to the Administrative Agent (with sufficient copies for each Lender***:***

(a) As soon as available and in any event within (i) forty five (45) days after the end of each of the first three fiscal quarters of each fiscal year and (ii) ninety (90) days after the end of the last fiscal quarter of each fiscal year, (i) a consolidated balance sheet of the Borrower and its Subsidiaries as of the end of such fiscal quarter, and (ii) the related consolidated statements of income, shareholders' equity and cash flows of the Borrower and its Subsidiaries for such quarter and the portion of the fiscal year through the end of such fiscal quarter, in each case, prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the corresponding period in the preceding fiscal year, together with (iii) a certificate of a Responsible Officer of the Borrower stating that (x) such financial statements fairly present in all material respects the financial condition of the Borrower and its Subsidiaries as at such date and (y) the results of operations of the Borrower and its Subsidiaries for the period ended on such date have been prepared in accordance with GAAP consistently applied, subject to changes resulting from normal, year-end audit adjustments and except for the absence of notes; provided that documents required to be furnished pursuant to this **Section 8.01(a)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR" (with the related certificate separately delivered).

(b) As soon as available and in any event within ninety (90) days after the end of each fiscal year, (i) the consolidated balance sheets of the Borrower and its Subsidiaries as of the end of such fiscal year, and (ii) the related consolidated statements of income, shareholders' equity and cash flows of the Borrower and its Subsidiaries for such fiscal year, in each case prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the previous fiscal year, accompanied by a report and opinion thereon of independent certified public accountants of recognized national standing reasonably acceptable to the Administrative Agent, which report and opinion shall be prepared in accordance with Public Company Accounting Oversight Board standards and shall not be subject to (x) with respect to any such reports or opinions prepared for any fiscal year ending after December 31, 2022, any " going concern" or similar qualification or exception (other than any such qualification or exception in respect of the Borrower's failure to have access to sufficient cash to pay the Obligations in full on the Maturity Date) or (y) any qualification or exception as to the scope of such audit, and in the case of such consolidating financial statements, certified by a Responsible Officer of the Borrower; provided that documents required to be furnished pursuant to this **Section 8.01(b)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR".

(c) Together with the financial statements required pursuant to **Sections 8.01(a)** and **8.01(b)**, (i) a management discussion and analysis ("***MD&A***"), prepared in writing and in reasonable detail in a manner consistent with the requirements of Item 303 of Regulation S–K of the Securities Act, discussing the Borrower's financial condition and results of operations as set forth in such financial statements; provided that for so long as Borrower remains (A) a "smaller reporting company" as defined in the Securities Act and Exchange Act and/or (B) an emerging growth company (as defined in the Jumpstart Our Business Startups Act of 2012) through the end of an applicable reporting period, any reduced disclosure obligations under SEC rules relating to the MD&A applicable to smaller reporting companies and/or emerging growth companies shall apply and (ii) a compliance certificate of a Responsible Officer, substantially in the form of **Exhibit E** (a "***Compliance Certificate***"), as of the end of the applicable accounting period, including, with respect to the financial statement delivered pursuant to **Section 8.01(b)**, details of any issues that are material that are raised by the Borrower's auditors. In addition, promptly following the Administrative Agent's reasonable request, reasonable proof of the Borrower's compliance with **Section 10.01**.

(d) [Reserved].

(e) Promptly after the same are released, copies of all press releases; provided that documents required to be furnished pursuant to this **Section 8.01(e)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR" or on the Borrower's website.

(f) Promptly, and in any event within five (5) Business Days after receipt, by an Obligor thereof, copies of each material notice or other material correspondence received from any securities regulator or exchange to the authority of which the Borrower or any Obligor may become subject from time to time concerning any investigation or possible investigation or other inquiry by such agency regarding financial or other operational results of the Borrower or any Obligor; provided that documents required to be furnished pursuant to this **Section 8.01(f)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR".

(g) Promptly (and in any event within five (5) Business Days of delivery) after the same are available, copies of each annual report, proxy or financial statement and any other statements, reports, communications and notices (including board kits) made available to the Borrower's Board or holders of the Equity Interests of the Borrower or any of its Subsidiaries (including copies of all annual, regular, periodic and special reports and registration statements which the Borrower or any its Subsidiaries may file or be required to file with any securities regulator or exchange to the authority of which the Borrower or such Subsidiary, as applicable, may become subject from time to time); provided that documents required to be furnished pursuant to this **Section 8.01(g)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR". Notwithstanding the foregoing, any materials delivered to a member of the Board of Borrower that is a representative of Administrative Agent or its Affiliates shall satisfy the requirements of this **clause (g)** so long as such member is permitted to provide such materials to the Administrative Agent.

(h) Promptly following Administrative Agent's reasonable request, the information regarding insurance maintained by the Borrower and its Subsidiaries as required under **Section 8.05**.

(i) Within thirty (30) days following the end of each calendar month, evidence satisfactory to the Administrative Agent, based upon the Borrower's bank account statements, that the Borrower has met its minimum liquidity requirement set forth in **Section 10.01**.

(j) Such other information respecting the operations, properties, business, liabilities or condition (financial or otherwise) of the Obligors (including with respect to the Collateral) as the Administrative Agent may from time to time reasonably request.

The Borrower hereby acknowledges that the Administrative Agent or the Lenders may not wish to receive material non-public information with respect to the Borrower or its Affiliates, or the respective securities of any of the foregoing, and the Administrative Agent, the Lenders or their respective personnel may be engaged in investment and other market-related activities with respect to such Persons' securities. In order to avoid disclosing material non-public information, the parties hereto covenant and agree that Borrower will not become obligated to provide the Administrative Agent, any Lender or their respective representatives or agents with any information pursuant to this **Section 8.01** other than information that is required to be publicly disclosed by the SEC and is publicly available on "EDGAR", unless (x) the Administrative Agent or its Affiliates have a representative on the Board of the Borrower or (y) prior thereto, the Administrative Agent or a Lender, as the case may be, shall have notified the Borrower in writing that it consents to receive such information.

8.02 Notices of Material Events. On or within five (5) Business Days (or such longer or shorter period as may be expressly set forth below) after a Responsible Officer of the Borrower first learns of or acquires knowledge with respect to any of the below events or circumstances, the Borrower shall furnish to the Administrative Agent written notice thereof (prepared in reasonable detail):

(a) The occurrence of any Default.

(b) The occurrence of any event with respect to any property or assets of the Borrower or any of its Subsidiaries resulting in a Loss aggregating $2,500,000 (or the Equivalent Amount in other currencies) or more.

(c) Any written or filed Claim, action, suit, notice of violation, hearing, investigation or other proceedings pending, or to the best of the Borrower's knowledge, threatened against or affecting the Borrower or any of its Subsidiaries or with respect to the ownership, use, maintenance and operation of their respective businesses, operations or properties, whether made by a Governmental Authority or other Person that, if adversely determined could reasonably be expected to result in a Loss of $2,500,000 or more.

(d) (i) On or prior to the date of any filing by Borrower or any of its ERISA Affiliates of any notice of intent to terminate any Title IV Plan that could reasonably be expected to result in a Material Adverse Effect, a copy of such notice and (ii) promptly, and in any event within ten (10) days, after any Responsible Officer of the Borrower knows (A) that an ERISA Event that could reasonably be expected to result in a Material Adverse Effect has occurred or is reasonably expected to occur or (B) that a request for a minimum funding waiver under Section 412 of the Code has been filed with respect to any Title IV Plan or Multiemployer Plan and could reasonably be expected to result in a Material Adverse Effect, a notice (which may be made by telephone if

promptly confirmed in writing) describing such waiver request and any action that any ERISA Affiliate proposes to take with respect to either of the foregoing, together with a copy of any notice filed with the PBGC or the IRS pertaining thereto.

(e) Concurrently with the delivery of the Compliance Certificate pursuant to **Section 8.01(c)**, the receipt by the Borrower or any of its Subsidiaries of any notice of a material breach, subject to any applicable cure period, under or in respect of any Material Agreement.

(f) The reports and notices as required by the Security Documents.

(g) Within thirty (30) days of the date thereof, or, if earlier, on the date of delivery of any financial statements pursuant to **Section 8.01** with respect to the first fiscal period to which such change is applicable, notice of any material change in accounting policies or financial reporting practices by the Obligors; provided that disclosure in the notes to such financial statements, if any, shall be deemed to satisfy the requirements of this Section 8.02(g).

(h) Notice of any labor controversy resulting in or threatening to result in any strike, permanent work stoppage, boycott, shutdown or other material labor disruption against or involving the Borrower or any of its Subsidiaries.

(i) Notice of infringement or alleged infringement of any Material Intellectual Property of another Person by Borrower or any of its Subsidiaries that, if adversely determined could reasonably be expected to result in a Loss of $2,500,000 or more.

(j) Within seven (7) Business Days, any change to Obligors' ownership of Deposit Accounts, Securities Accounts and Commodity Accounts, by delivering to the Administrative Agent, a notice setting forth a complete and correct list of all such accounts as of the date of such change.

Each notice delivered under this **Section 8.02** shall be accompanied by a statement of a Responsible Officer of the Borrower setting forth the details of the event or development requiring such notice and any action taken or proposed to be taken with respect thereto. Information required to be delivered pursuant to this Section 8.02 shall be deemed to have been delivered on the date that such information shall have been made publicly available on "EDGAR" so long as such information has been made publicly available within the five (5) Business Day period set forth above. Nothing in this **Section 8.02** is intended to waive, consent to or otherwise permit any action or omission that is otherwise prohibited by this Agreement or any other Loan Document.

The Borrower hereby acknowledges that the Administrative Agent or the Lenders may not wish to receive material non-public information with respect to the Borrower or its Affiliates, or the respective securities of any of the foregoing, and the Administrative Agent, the Lenders or their respective personnel may be engaged in investment and other market-related activities with respect to such Persons' securities. In order to avoid disclosing material non-public information, the parties hereto covenant and agree that, as except for any notice required pursuant to **clause (a)** above, Borrower will not become obligated to provide the Administrative Agent, any Lender or their respective representatives or agents with any information pursuant to this **Section 8.02** other than information that is required to be publicly disclosed by the SEC and is publicly available on "EDGAR", unless (x) the Administrative Agent or its Affiliates have a representative on the Board

of the Borrower or (y) prior thereto, the Administrative Agent or a Lender, as the case may be, shall have notified the Borrower in writing that it consents to receive such information.

8.03 Existence; Conduct of Business. The Borrower shall, and shall cause each of its Subsidiaries to, do or cause to be done all things necessary to preserve, renew and maintain in full force and effect its legal existence and all Governmental Approvals material to the conduct of its business; provided that the foregoing shall not prohibit any merger, amalgamation, consolidation, liquidation or dissolution permitted under **Section 9.03**.

8.04 Payment of Obligations. The Borrower shall, and shall cause each of its Subsidiaries to, pay and discharge its material obligations, including (i) all material Taxes, fees, assessments and governmental charges or levies imposed upon it or upon its properties or assets prior to the date on which penalties attach thereto, and all lawful Claims for labor, materials and supplies which, if unpaid, might become a Lien upon any properties or assets of the Borrower or any of its Subsidiaries, except to the extent such Taxes, fees, assessments or governmental charges or levies, or such claims are being contested in good faith by appropriate proceedings and are adequately reserved against in accordance with GAAP, and (ii) all other lawful Claims which, if unpaid, would by Law become a Lien upon any properties or assets of the Borrower or any of its Subsidiaries, other than any Permitted Lien.

8.05 Insurance. The Borrower shall, and shall cause each of its Subsidiaries to maintain, with financially sound and reputable insurance companies, insurance in such amounts and against such risks as are customarily maintained by companies engaged in the same or similar businesses operating in the same or similar locations, and with coverage amounts of at least $2,000,000 in general liability insurance with a $5,000,000 umbrella. Upon the request of the Administrative Agent, the Borrower shall furnish to the Administrative Agent from time to time: (i) full information as to the insurance carried by the Borrower and each of its Subsidiaries and, if so requested, copies of all such insurance policies and (ii) a certificate from the Borrower's insurance broker or other insurance specialist stating that all premiums then due on the policies relating to insurance in respect of the Collateral have been paid and that such policies are in full force and effect. The Borrower shall use commercially reasonable efforts to ensure, or cause others to ensure, that all insurance policies in respect of the Collateral shall provide that they shall not be terminated or cancelled without at least thirty (30) days' (ten (10) days for nonpayment of premium) prior written notice to the Borrower and the Administrative Agent. Receipt of notice of cancellation or modification of any such insurance policies or reduction of coverage or amounts thereunder shall entitle any Secured Party to renew any such policies, cause the coverage and amounts thereof to be maintained at levels required pursuant to the first sentence of this **Section 8.05** or otherwise to obtain similar insurance in place of such policies, in each case at the expense of the Borrower (payable on demand).

8.06 Books and Records; Inspection Rights. The Borrower shall, and shall cause each of its Subsidiaries to, keep proper books of record and account in which full, true and correct entries are made of all dealings and transactions in relation to its business and activities. The Borrower shall, and shall cause each of its Subsidiaries to, permit any representatives designated by the Administrative Agent or any Lender, upon reasonable prior written notice and during normal business hours, to visit and reasonably inspect its properties, to reasonably examine and make extracts from its books and records (excluding records subject to attorney-client privilege, subject

to binding confidentiality agreements with third parties that preclude disclosure to any Secured Party (acting in such capacity) not entered into in contemplation of this **Section 8.06** or subject to confidentiality restrictions pursuant to applicable Law (including HIPAA)), and to discuss its affairs, finances and condition (financial or otherwise) with its officers and, if necessary after such discussions with such Obligor's officers, its independent accountants, all at such reasonable times (but not more often than once per year unless an Event of Default has occurred and is continuing) as the Administrative Agent or the Lenders may reasonably request; provided that no notice shall be required if an Event of Default has occurred and is continuing. The Borrower shall pay all reasonable and documented costs and expenses of all such inspections.

8.07 Compliance with Laws and Material Agreements. The Borrower shall, and shall cause each of its Subsidiaries to, (i) comply in all material respects with all applicable Laws and Governmental Approvals (including Environmental Laws and all Healthcare Laws and Healthcare Permits), and (ii) use commercially reasonable efforts to remain in compliance with, and perform all obligations under or in connection with, all Healthcare Permits and Material Agreements in accordance with the terms and conditions set forth in **Section 9.12(b)**.

8.08 Maintenance of Properties, Etc. The Borrower shall, and shall cause each of its Subsidiaries to, maintain and preserve all of its assets and properties, whether tangible or intangible, necessary or useful in the proper conduct of its business in good working order and condition in accordance with the general practice of other Persons of similar character and size or, in accordance with the terms of any lease of a Manufacturing Facility under which the Borrower or its Subsidiaries holds an interest, ordinary wear and tear and damage from casualty or condemnation excepted.

8.09 Governmental Approvals, Etc. The Borrower shall, and shall cause each of its Subsidiaries to, obtain and maintain all Governmental Approvals (including all Healthcare Permits) necessary in connection with (i) the execution, delivery and performance of the Loan Documents, (ii) the consummation of the Transactions and (iii) the operation and conduct of their respective businesses and the ownership of their respective properties, except, in the case of **clause (iii)** above, where the failure to do so could not reasonably be expected to have a Material Adverse Effect on the Borrower's and its Subsidiaries' business.

8.10 Action under Environmental Laws. The Borrower shall, and shall cause each of its Subsidiaries to, upon becoming aware of the release of any Hazardous Materials or the existence of any environmental liability under applicable Environmental Laws with respect to their respective businesses, operations or properties, take all commercially reasonable actions, at their cost and expense, as shall be necessary or advisable to investigate and clean up the condition of their respective businesses, operations or properties, including all required removal, containment and remedial actions, to restore their respective businesses, operations and properties to a condition in each case, in material compliance with applicable Environmental Laws.

8.11 Use of Proceeds. The proceeds of the Loans shall be used only as provided in **Section 2.04**. Without limiting the foregoing, no part of the proceeds of the Loans shall be used, whether directly or indirectly, for any purpose that entails a violation of any of the Regulations of the Board of Governors of the Federal Reserve System, including Regulation T, Regulation U and Regulation X.

8.12 Certain Obligations Respecting Subsidiaries; Further Assurances.

(a) **Subsidiary Guarantors**. The Borrower shall take such action from time to time as shall be necessary to ensure that (x) each of its Subsidiaries that is a party to this Agreement as of the Closing Date will be and will remain an Obligor and Subsidiary Guarantor hereunder (except as otherwise permitted by **Section 9.03**), and (y) each direct or indirect Subsidiary of the Subsidiary Guarantors (other than any Immaterial Subsidiary), whether direct or indirect, now existing or hereafter created, will, within thirty (30) days of becoming a Subsidiary of a Subsidiary Guarantor, become a "Subsidiary Guarantor" pursuant to this **Section 8.12**. Without limiting the generality of the foregoing, in the event that any Subsidiary Guarantor shall form or acquire any new Subsidiary (other than any Immaterial Subsidiary), the Borrower shall, within thirty (30) days (or such longer period as the Administrative Agent, in its reasonable discretion, may consent to) of such formation or acquisition, cause such Subsidiary (other than any Immaterial Subsidiary) to become a "Subsidiary Guarantor" hereunder, a "Grantor" (or the equivalent thereof) under any applicable Security Document, and a "Subsidiary Party" under the Intercompany Subordination Agreement;

(b) except with respect to any Immaterial Subsidiary, take such action or cause such new Subsidiary to take such action (including joining the applicable Security Document and delivering any certificated Equity Interests together with undated transfer powers executed in blank, applicable control agreements and other instruments) as shall be reasonably necessary or reasonably requested by the Administrative Agent to create and perfect, in favor of the Administrative Agent, for the benefit of the Secured Parties, valid and enforceable first priority Liens (other than Permitted Liens) on all Deposit Accounts, Securities Accounts and Commodity Accounts of such new Subsidiary as collateral security for the Obligations hereunder; provided that any such security interest or Lien shall be subject to the applicable Security Documents;

(i) to the extent that the parent of such new Subsidiary (other than any Immaterial Subsidiary) has not pledged Equity Interests in its Subsidiaries in accordance with the terms of the relevant Security Document and this Agreement, cause the parent of such Subsidiary to execute and deliver a pledge agreement in favor of the Administrative Agent, for the benefit of the Secured Parties, in respect of all outstanding issued Equity Interests of such new Subsidiary; and

(ii) deliver such proof of corporate action, incumbency of officers, opinions of counsel and other documents as is consistent with those delivered by the Borrower pursuant to **Section 6.01** or as the Administrative Agent shall have reasonably requested.

(c) **Further Assurances**.

(i) The Borrower shall, and shall cause each of its direct or indirect Subsidiaries (including any newly formed or newly acquired Subsidiaries (other than any Immaterial Subsidiary)) to take such action from time to time as shall reasonably be requested by the Administrative Agent to effectuate the purposes and objectives of this Agreement and the applicable Security Documents.

(ii) Without limiting the generality of the foregoing, within thirty (30) days following written request from the Administrative Agent, the Borrower shall cause each Person that is required to be a Subsidiary Guarantor or an Obligor hereunder to take such action from time to time (including executing and delivering such Security Documents and delivering its certificated Equity Interests together with undated transfer powers executed in blank) as shall be reasonably requested by the Administrative Agent to create, in favor of the Secured Parties, perfected security interests and Liens on the Manufacturing Facilities and all Deposit Accounts, Securities Accounts and Commodity Accounts of such Person and all Equity Interests in each Subsidiary Guarantor as collateral security for the Obligations; provided that any such security interest or Lien shall be subject to Permitted Liens and the relevant requirements of the applicable Security Documents.

8.13 Termination of Non-Permitted Liens. In the event that the Borrower or any of its Subsidiaries shall obtain knowledge of, or be notified by the Administrative Agent or any Lender of the existence of, any outstanding Lien against any assets or property of the Borrower or any of its Subsidiaries, which Lien is not a Permitted Lien, the Borrower shall use commercially reasonable efforts to promptly terminate or cause the termination of such Lien.

8.14 Maintenance of the Governmental Approvals and Intellectual Property. The Borrower shall cause each of its Subsidiaries (to the extent applicable) to, (i) maintain in full force and effect all material Governmental Approvals, Healthcare Permits, Material Intellectual Property and other rights, interest or assets (whether tangible or intangible) reasonably necessary for its ordinary course of business and commercial efforts as currently conducted and as anticipated to be conducted, in each case, except where the failure to do so could not reasonably be expected to result in a Material Adverse Effect, (ii) promptly upon obtaining knowledge thereof, notify the Administrative Agent of any infringement or other violation by any Person of the Borrower's or Subsidiary Guarantors' Material Intellectual Property, and take commercially reasonable efforts to pursue any such infringement or other violation, except in any specific circumstance where the Borrower reasonably determines in good faith that it is not commercially reasonable to do so, (iii) use commercially reasonable efforts to pursue and maintain in full force and effect all new Material Intellectual Property created, developed, or acquired by the Borrower or any of its Subsidiaries, as the case may be, that are necessary for ordinary course commercial or business activities or operations of such Person, and (iv) promptly after obtaining knowledge thereof, notify the Administrative Agent of any written Claim by any Person that the conduct of the business of the Borrower or any of its Subsidiaries has infringed upon any Intellectual Property of such Person that could reasonably be expected to result in a Material Adverse Effect.

8.15 ERISA and Foreign Pension Plan Compliance. Except as could not reasonably be expected to result in a Material Adverse Effect, the Borrower shall comply, and shall cause each of its Subsidiaries to comply, with the provisions of ERISA or applicable Law with respect to any Plans or Foreign Pension Plans to which the Borrower or any such Subsidiary is a party as an employer.

8.16 Cash Management. The Borrower shall, and shall cause Subsidiary Guarantors to:

(a) maintain at all times the Minimum Liquidity Account and all deposit accounts, disbursement accounts, investment accounts (and other similar cash or bank accounts) and lockboxes located in the U.S. or non-U.S. and held by any Subsidiary Guarantor with a bank or

financial institution, except as permitted pursuant to **clause (b)** below, that has executed and delivered to the Administrative Agent an account control agreement (or, in respect of an account in the United Kingdom and Ireland, evidence that each relevant Obligor delivered to the relevant account bank a notice of assignment in respect of the account and has used reasonable endeavors to ensure that each Account Bank acknowledges the notice), in form and substance reasonably acceptable to the Administrative Agent (each of the Minimum Liquidity Account and such deposit account, disbursement account, investment account (or other similar cash or bank account) and lockbox, a "***Controlled Account***"); each such Controlled Account shall secure payment of the Obligations, and each Obligor shall have granted a Lien to the Administrative Agent, for the benefit of the Secured Parties, over such Controlled Accounts. For the avoidance of doubt, no account control agreements shall be required in respect of any bank account held in Ireland or England; and

(b) deposit promptly, and in any event no later than five (5) Business Days after the date of receipt thereof (if and to the extent received), all cash, checks, drafts or other similar items of payment relating to or constituting payments made in respect of any and all accounts receivable, Contracts or any other rights and interests into the applicable Controlled Accounts.

Notwithstanding the foregoing or in any Loan Document to the contrary, neither the Borrower nor any of its Subsidiaries shall be required to obtain an account control agreement (or, in respect of an account in the United Kingdom and Ireland, evidence that each relevant Obligor delivered to the relevant account bank a notice of assignment in respect of the account) for any deposit accounts, disbursement accounts, investment accounts (and other similar cash or bank accounts) and lockboxes that (i) in respect of the Irish Subsidiary Guarantor, are established and maintained in connection with any IDA Grant, in an amount not to exceed €2,200,000 in aggregate at any one time or (ii) in respect of the English Guarantor, are for the sole purpose of holding cash or cash equivalents that serves as collateral security under any letter of credit or other obligation not prohibited by this Agreement.

8.17 Title, Headleases, Power to Remedy. The Borrower shall, and shall cause each of its Subsidiaries to, (i) exercise its rights and comply in all respects with any covenant, stipulation or obligation (restrictive or otherwise) at any time affecting a Manufacturing Facility, (ii) exercise its rights and comply with its obligations under each Headlease in a proper and timely manner, (iii) use its reasonable endeavours to ensure that each landlord complies with its obligations under each Headlease in a proper and timely manner, (iv) if so required by the Administrative Agent, apply for relief against forfeiture of any Headlease in a proper and timely manner, and (v) in the event that an Obligor fails to perform any obligations under the Loan Documents affecting its Manufacturing Facility, that Obligor must allow the Administrative Agent or its agents and contractors (A) to enter any part of its Manufacturing Facility, (B) to comply with or object to any notice served on the Obligor in respect of its Manufacturing Facility and (C) to take any action that the Administrative Agent may reasonably consider necessary or desirable to prevent or remedy any breach of any such term or to comply with or object to any such notice.

8.18 Register of Mortgages and Charges. The Borrower shall, within three (3) Business Days of the Closing Date, update its register of mortgages and charges to reflect the security granted by the Borrower pursuant to the applicable Security Documents, in form and substance reasonably satisfactory to the Administrative Agent.

8.19 Post-Closing Covenants

(a) Within twenty (20) Business Days of the Closing Date (or such later date as an Independent Appraiser may reasonably request or as the Administrative Agent may agree in its reasonable discretion), the Administrative Agent shall have received a valuation and appraisal report, prepared by an Independent Appraiser instructed and appointed by the Administrative Agent (the "***Valuation Report***"), which report shall be in scope and substance reasonably satisfactory to the Administrative Agent and shall confirm the fair market value of:

(i) the London Manufacturing Facility is not less than [***] (or Equivalent Amount); and

(ii) the Shannon Manufacturing Facility is not less than [***] (or Equivalent Amount).

(b) If the fair market value of the London Manufacturing Facility confirmed by the Valuation Report exceeds [***] (or Equivalent Amount) then within 10 Business Days of the receipt of the Valuation Report by the Borrower, the Borrower shall have delivered to the Administrative Agent an endorsement of:

(i) the Dual Asset no-search insurance policy dated 29 July 2022 (with reference 00-87868222N0); and

(ii) the Dual Asset title insurance policy dated 14 December 2018 and varied by an endorsement dated 29 July 2022 (with reference 00-39858418K0),

increasing the indemnity limit of each policy from [***] to the sum equal to the fair market value of the London Manufacturing Facility confirmed by the Valuation Report (or Equivalent Amount) and the Borrower shall pay the premium for each endorsement when it falls due.

(c) Within six (6) weeks of the issue of a certificate of practical completion in relation to the Works, the Borrower shall furnish to the Lenders and their solicitors copies of the following:

(i) an architect's opinion on compliance with planning permission and an architect's opinion on compliance with the building regulations in RIAI format which shall include all confirmations and other documents referred to or relied upon therein;

(ii) a copy of any approvals, consents, permissions and licences of any competent authority that may from time to time be required to enable the Borrower to commence and carry out the Works including without limitation any planning permission, commencement notice, fire safety certificate or disability access certificate required by the Building Control Acts 1990 to 2014 required or obtained in relation to the Works (the "***Requisite Consents***");

(iii) a copy of the receipts for any financial contributions payable by the Borrower pursuant to the Requisite Consents; and

(iv) certificate of compliance on completion within the meaning of the Building Control (Amendment) Regulations 2014.

(d) Within thirty (30) Business Days of the Closing Date, (or such later date as the Administrative Agent may agree in its reasonable discretion), the Borrower shall deliver to the Administrative Agent short form security agreements, in form and substance reasonably satisfactory to the Administrative Agent, evidencing a grant of security over Borrower's rights to insurance proceeds.

SECTION 9
NEGATIVE COVENANTS

The Obligors jointly and severally covenant and agree with the Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations (other than inchoate indemnification and expense reimbursement obligations for which no Claim has been made) have been paid in full in cash:

9.01 Indebtedness. The Borrower shall not, and shall not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Indebtedness, whether directly or indirectly, except:

(a) the Obligations;

(b) Indebtedness existing on the Closing Date and set forth on **Schedule 7.13** and Permitted Refinancings thereof; provided that, in each case, such Indebtedness is subordinated to the Obligations on terms reasonably satisfactory to the Administrative Agent;

(c) accounts payable to trade creditors for goods and services and current operating liabilities (not the result of the borrowing of money) incurred in the ordinary course of the Borrower's or such Subsidiary's business in accordance with customary terms and paid within one hundred twenty (120) days of becoming due, unless contested in good faith by appropriate proceedings and reserved for in accordance with GAAP for any such amounts over $5,000,000;

(d) Indebtedness consisting of guarantees resulting from the endorsement of negotiable instruments for collection in the ordinary course of business;

(e) Indebtedness of any Obligor owing to any of its Subsidiaries or to another Obligor; provided that, in each case, such Indebtedness is subordinated to the Obligations subject to the Intercompany Subordination Agreement;

(f) Guarantees by any Obligor of outstanding Permitted Indebtedness of any other Obligor; provided that to the extent that any such Permitted Indebtedness is subordinated to the Obligations, such Guarantees shall be similarly subordinated;

(g) ordinary course of business equipment financing, leasing and Capital Lease Obligations; provided that (i) if secured, the collateral therefor consists solely of the assets being financed, the products and proceeds thereof and books and records related thereto, and (ii) the aggregate outstanding principal amount of such Indebtedness does not exceed $7,000,000 (or the Equivalent Amount in other currencies) in the aggregate at any time;

(h) Indebtedness under Hedging Agreements permitted by **Section 9.05(e)**;

(i) with respect to any Permitted Acquisition, Indebtedness assumed in connection with such Permitted Acquisition; provided that, (i) no such Indebtedness shall have been created or incurred in connection with, or in contemplation of, such Acquisition or this **Section 9.01(i)**, and (ii) the aggregate amount of Indebtedness permitted pursuant to this **Section 9.01(i)** shall not exceed $5,000,000 (or the Equivalent Amount in other currencies) at any time outstanding, inclusive of all related Contingent Acquisition Obligations;

(j) Indebtedness consisting of the financing of insurance premiums in respect of insurance policies insuring assets or businesses of an Obligor written or arranged in such Obligor's ordinary course of business;

(k) Indebtedness incurred in connection with cash management services, including treasury, depository, overdraft, credit or debit card, purchasing cards, electronic funds transfer, automatic clearing house arrangements, cash pooling arrangements, netting services, over draft protections, merchant services and other cash management and similar arrangements of an Obligor or any of its Subsidiaries, in each case incurred in the ordinary course of business;

(l) Indebtedness incurred under performance, surety, bid, statutory and appeal bonds, completion guarantees and other similar obligations, in each case in the ordinary course of business;

(m) Indebtedness in respect of worker's compensation claims, payment obligations in connection with health, disability or other types of social security benefits, unemployment or other insurance obligations and reclamation and statutory obligations, in each case incurred in the ordinary course of business;

(n) Indebtedness in respect of letters of credit, bank guarantees or similar instruments incurred in the ordinary course of business; provided that the aggregate face amount of all such letters of credit, bank guarantees or other instruments (including letters of credit outstanding on the Closing Date) shall not exceed $5,000,000 at any time outstanding;

(o) Indebtedness consisting of Investments permitted pursuant to **Section 9.05**;

(p) Permitted Convertible Indebtedness; provided that the aggregate amount of all such Indebtedness permitted pursuant to this **Section 9.01(p)** shall not exceed $150,000,000 (or the Equivalent Amount in other currencies) at any time outstanding;

(q) advances or deposits from customers or vendors received in the ordinary course of business;

(r) Indebtedness incurred in connection with IDA Grants not to exceed €2,200,000 in the aggregate at any time outstanding; and

(s) other unsecured Indebtedness in an aggregate amount not to exceed $5,000,000 in the aggregate at any time outstanding.

9.02 Liens. The Borrower shall not, and shall not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Lien on any property now owned by it or such Subsidiary, except:

(a) Liens securing the Obligations;

(b) any Lien on any property or asset of the Borrower or any of its Subsidiaries existing on the Closing Date and set forth on **Schedule 9.02**; provided that (i) no such Lien shall extend to any other property or asset of the Borrower or any of its Subsidiaries and (ii) any such Lien shall secure only those obligations which it secures on the Closing Date and extensions, renewals and replacements thereof that do not increase the outstanding principal amount thereof;

(c) Liens securing Indebtedness permitted under **Section 9.01(g)**; provided that such Liens are restricted solely to the collateral permitted to be secured by **Section 9.01(g)**;

(d) Liens imposed by any applicable Law arising in the ordinary course of business, including (but not limited to) carriers', warehousemen's and mechanics' liens, materialmen and other similar Liens arising in the ordinary course of business and which (x) do not in the aggregate materially detract from the value of the property subject thereto or materially impair the use thereof in the operations of the business of such Person or (y) are being contested in good faith by appropriate proceedings, which proceedings have the effect of preventing the forfeiture or sale of the property subject to such Liens and for which adequate reserves have been made if required in accordance with GAAP;

(e) pledges or deposits made in the ordinary course of business in connection with (i) real property leases entered into in the ordinary course of business, (ii) obligations in respect of workers' compensation, unemployment insurance or other similar social security legislation, to the extent permitted pursuant to **Section 9.01(m)**, or (iii) obligations in respect of surety or appeal bonds, bid or performance bonds, or other obligations of a like nature, to the extent permitted pursuant to **Section 9.01(l)**;

(f) Liens securing Taxes, assessments and other governmental charges, the payment of which is not yet due or is being contested in good faith by appropriate proceedings promptly initiated and diligently conducted and for which such reserve or other appropriate provisions, if any, as shall be required by GAAP shall have been made;

(g) servitudes, easements, rights of way, restrictions and other similar encumbrances on real property imposed by any applicable Law or by any lease pursuant to which an Obligor holds its interest in a Manufacturing Facility and Liens consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor imperfections in title thereto which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere in any material respects with the ordinary conduct of the business of any of the Obligors or any of their Subsidiaries;

(h) with respect to any real property, (i) such defects or encroachments as might be revealed by an up-to-date survey of such real property; (ii) the reservations, limitations, provisos and conditions expressed in the original grant, deed or patent of such property by the original owner of such real property pursuant to applicable Law or expressed in any lease pursuant to which an Obligor holds its interest in a Manufacturing Facility; (iii) rights of expropriation, access or user or any similar right conferred or reserved by or in any applicable Law, which, in the aggregate for **clauses (i)**, **(ii)** and **(iii)**, are not material, and which do not in any case materially detract from the

value of the property subject thereto or interfere in any material respects with the ordinary conduct of the business of any of the Obligors or its Subsidiaries and (iv) leases or subleases of real property in the ordinary course of business;

(i) bankers' liens, rights of setoff and similar Liens incurred on deposits made to a bank on deposit accounts to the extent permitted to be made hereunder in the ordinary course of business;

(j) any judgment Lien not constituting an Event of Default;

(k) interests of lessors and sublessors under operating leases, interests of licensors or sublicensors under license agreements, and with respect to any realty occupied by any Obligor or any of its Subsidiaries, all easements, rights of way, reservations, licenses, covenants encroachments, variations and similar restrictions, charges and encumbrances on title that, in any such case or event, do not secure monetary obligations (other than any Permitted Lien set out in **Schedule 9.02**) and do not materially impair the use of such property for its intended purposes;

(l) Liens on cash held on deposit to secure letters of credit, bank guarantees or similar instruments permitted under **Section 9.01(n)** in an amount not to exceed the face amount of such letters of credit, bank guarantees or similar instruments, so long as such cash is held in segregated accounts maintained with the issuers of such letters of credit, bank guarantees or similar instruments;

(m) Liens securing Indebtedness permitted under **Section 9.01(i)**; provided that (i) such Lien is not created in contemplation of or in connection with such Permitted Acquisition or this Agreement, (ii) such Lien shall not apply to any other property or assets of the Borrower or any of its Subsidiaries other than the property or assets being acquired pursuant to such Permitted Acquisition, (iii) such Lien shall secure only those obligations that it secured immediately prior to the consummation of such Permitted Acquisition and extensions, renewals and replacements thereof that do not increase the outstanding principal amount thereof and (iv) such Lien does not secure any Contingent Acquisition Obligation;

(n) (i) Liens arising from rights of licensees or licensors, as the case may be, arising under licenses permitted pursuant to **Section 9.19**, and (ii) any ordinary course interest or title of a licensor, sublicensor, lessor or sublessor with respect to any assets under any inbound license or lease agreement permitted pursuant to **Section 9.19**;

(o) Liens securing Indebtedness permitted by **Section 9.01(j)**; provided that such Lien shall be solely limited to the applicable insurance policies, supporting documentation relating thereto and the Obligor's right to receive proceeds under such insurance policy with respect to which such Indebtedness has been incurred;

(p) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods;

(q) Liens referred to in any Certificate of Title;

(r) Liens securing Indebtedness permitted under **Section 9.01(r)**; or

(s) Liens on the Specified Assets so long as the Specified Assets Conditions are satisfied both immediately before and after giving effect to the creation of any such Lien.

9.03 Fundamental Changes, Acquisitions, Etc. The Borrower shall not, and shall not permit any of its Subsidiaries to, (i) enter into any transaction of merger, amalgamation or consolidation, (ii) liquidate, wind up or dissolve itself (or suffer any liquidation or dissolution), (iii) sell or issue any Disqualified Equity Interests, or (iv) other than Permitted Acquisitions, make any Acquisition or otherwise acquire any business or substantially all the property from, or Equity Interests of, or be a party to any Acquisition of, any Person, except, so long as no Event of Default has occurred and is continuing or could reasonably be expected to occur as a result therefrom, for the following:

(a) Investments permitted under **Section 9.05**;

(b) any Permitted Acquisitions;

(c) the merger, amalgamation or consolidation of (i) any Subsidiary with or into any Obligor; provided that with respect to any such transaction involving the Borrower or any other Obligor, the Borrower or such Obligor, as the case may be, must be the surviving or successor entity of such transaction and (ii) any Immaterial Subsidiary with or into any other Immaterial Subsidiary;

(d) the sale, lease, transfer or other disposition by any Subsidiary of any or all of its property (upon voluntary liquidation or otherwise) to any other Obligor;

(e) (i) the sale, lease, transfer or other disposition by any Immaterial Subsidiary of any or all of its property (upon voluntary liquidation or otherwise) to any other Immaterial Subsidiary or to any Obligor, or (ii) the sale, transfer or other disposition of the Equity Interests of any Immaterial Subsidiary to any other Immaterial Subsidiary or to any Obligor; and

(f) the issuance, sale, transfer or other disposition of the Equity Interests of any Subsidiary Guarantor to any other Obligor.

9.04 Lines of Business. The Borrower shall not, and shall not permit any of its Subsidiaries to, engage in any business other than the business engaged in on the Closing Date by such Persons or a business reasonably related or ancillary thereto or a reasonable extension thereof.

9.05 Investments. The Borrower shall not, and shall not permit any of its Subsidiaries to, make, directly or indirectly, or permit to remain outstanding any Investments except:

(a) Investments outstanding on the Closing Date and identified on **Schedule 9.05** and any modification, replacement, renewal or extension thereof to the extent not involving new or additional Investments;

(b) extensions of credit in the nature of accounts receivable or notes receivable arising from (i) the sales of goods or services in the ordinary course of business and prepaid royalties, (ii) the satisfaction or partial satisfaction thereof to the extent reasonably necessary in order to prevent or limit loss and any prepayment and other credits to suppliers made in good faith and in the ordinary course of business or (iii) the satisfaction, partial satisfaction or enforcement of

Indebtedness or Claims due or owing to an Obligor or its Subsidiaries (in bankruptcy of customers or suppliers or otherwise outside the ordinary course of business) or as security for any such Indebtedness or Claims in good faith and in the ordinary course of business;

(c) Permitted Cash Equivalent Investments;

(d) Investments by Borrower or any other Subsidiary of the Borrower in (i) the Borrower, (ii) any Subsidiary Guarantor, or (iii) any other Subsidiary of the Borrower for (A) operating expenses incurred in the ordinary course of business and consistent with past practices or (B) other Investments to any other Subsidiary of the Borrower; provided that the fair value of all such Investments made pursuant to this clause (iii)(B) shall not exceed $2,000,000 in the aggregate per fiscal year;

(e) Hedging Agreements entered into in the Borrower's or any of its Subsidiaries' ordinary course of business for the purpose of hedging currency risks or interest rate risks (but not for speculative purposes) and in an aggregate notional amount for all such Hedging Agreements not in excess of $5,000,000 (or the Equivalent Amount in other currencies);

(f) Investments consisting of prepaid expenses, negotiable instruments held for collection or deposit, security deposits with utilities and landlords to secure office space and other like Persons and deposits in connection with workers' compensation and similar deposits, in each case, made in the ordinary course of business;

(g) employee loans, travel advances and guarantees in accordance with the Borrower's usual and customary practices with respect thereto (if permitted by applicable Law) which in the aggregate shall not exceed $1,000,000 outstanding at any time (or the Equivalent Amount in other currencies);

(h) Investments received in connection with any Insolvency Proceedings in respect of any customers, suppliers or clients and in settlement of delinquent obligations of, and other disputes with, customers, suppliers or clients;

(i) Investments permitted under **Section 9.03**;

(j) advances and extensions of credit (including to trade creditors) in the nature of trade payables made in connection with the purchases of goods or services in the ordinary course of business;

(k) Investments made or acquired as a result of consideration received in connection with any Asset Sale permitted under **Section 9.09** or Permitted Acquisition; provided that all such Investments made pursuant to this **clause (k)** shall not exceed €2,200,000 in the aggregate since the Closing Date;

(l) Investments in the form of non-cash loans and advances in an aggregate amount not to exceed $2,500,000 outstanding at any one time to employees, officers, and directors of any Obligor or any of its Subsidiaries for the purpose of purchasing Qualified Equity Interests in the Borrower so long as the proceeds of such loans are used in their entirety to purchase such Qualified Equity Interests in the Borrower;

(m) the entry into and payment of any premium in connection with any Permitted Bond Hedge Transaction;

(n) Investments involving the Specified Assets so long as the Specified Assets Conditions are met and satisfied;

(o) Investments in connection with IDA Grants in an aggregate amount not to exceed €2,200,000 at any time outstanding;

(p) Investments by the Obligors in Subsidiaries pursuant to Tax sharing arrangements, transfer pricing arrangements or cost plus arrangements, in each case, solely as between or among the Obligors and one or more of their Subsidiaries; and

(q) other Investments in an aggregate amount not to exceed $2,500,000 in the aggregate since the Closing Date.

9.06 Restricted Payments. The Borrower shall not, and shall not permit any of its Subsidiaries to, declare or make, or agree to pay or make, directly or indirectly, any Restricted Payment; provided that the following Restricted Payments shall be permitted so long as no Event of Default has occurred and is continuing or could reasonably be expected to occur or result from such Restricted Payment:

(a) dividends with respect to the Borrower's Equity Interests payable solely in shares of its Qualified Equity Interests (or the equivalent thereof);

(b) the Borrower's purchase, redemption, retirement or other acquisition of its Equity Interests that (i) with respect to any such Person, the aggregate purchase, redemption, retirement or other acquisition cost or price does not exceed $1,000,000 in the aggregate since the Closing Date and (ii) with respect to all such purchases, redemptions, retirements or other acquisitions made pursuant to this **Section 9.06(b)** since the Closing Date, the aggregate cost or price does not exceed $4,000,000;

(c) dividends paid by any Subsidiary Guarantor to any other Obligor;

(d) upon the death, incapacity or termination of any natural person that is a holder of Qualified Equity Interests of the Borrower or the exercise of a right of first refusal or similar right in respect of any such holder, the Borrower may repurchase the stock of such Qualified Equity Interests of such holder or such holder's family, trusts, estates and heirs pursuant to stock repurchase agreements in an amount not to exceed $1,000,000 per fiscal year;

(e) cash in lieu of the issuance of fractional shares not to exceed $1,000,000 per fiscal year;

(f) dividends paid by any Immaterial Subsidiary to any other Immaterial Subsidiary or to any Obligor;

(g) repurchases of Qualified Equity Interests deemed to occur upon the exercise of stock options or warrants if such repurchased Qualified Equity Interests represents a portion of the exercise price of such options or warrants pursuant to a "cashless exercise" or similar feature;

(h) repurchases of Qualified Equity Interests deemed to occur upon withholding of a portion of the Qualified Equity Interests granted or awarded to a current or former director, officer, employee or consultant to pay for the taxes payable by such Person upon such grant or award (or upon vesting thereof); provided that, in each case, no such repurchases shall exceed $1,000,000 per year (calculated since the Closing Date), in the aggregate for all employees; and

(i) (i) the payment of the purchase price of any Permitted Bond Hedge Transaction or (ii) the settlement, unwinding or termination of all or any portion of any Permitted Warrant Transaction by (I) set-off against the concurrent settlement, unwind or other termination of all or any portion of any related Permitted Bond Hedge Transaction or (II) delivery of ordinary shares.

Notwithstanding anything to the contrary in the foregoing, the issuance of, performance of obligations under (including any payments of interest), and conversion, exercise, repurchase, redemption (including, for the avoidance of doubt, a required repurchase in connection with the redemption of Permitted Convertible Indebtedness upon satisfaction of a condition related to the stock price of the ordinary shares), settlement or early termination or cancellation of (whether in whole or in part and including by netting or set-off) (in each case, whether in cash, ordinary shares, following a merger event or other change of the ordinary shares, other securities or property), or the satisfaction of any condition that would permit or require any of the foregoing, any Permitted Convertible Indebtedness shall not constitute a Restricted Payment by the Borrower for the purposes of this **Section 9.06**; provided that, to the extent both (a) the aggregate amount of cash payable upon conversion or payment of any Permitted Convertible Indebtedness (excluding any required payment of interest with respect to such Permitted Convertible Indebtedness and excluding any payment of cash in lieu of a fractional share due upon conversion thereof) exceeds the aggregate principal amount thereof and (b) such conversion or payment does not trigger or correspond to an exercise or early unwind or settlement of a corresponding portion of the Permitted Bond Hedge Transactions relating to such Permitted Convertible Indebtedness (including, for the avoidance of doubt, the case where there is no Bond Hedge Transaction relating to such Permitted Convertible Indebtedness), the payment of such excess cash shall not be permitted by this paragraph.

Notwithstanding the foregoing, the Borrower may repurchase, exchange or induce the conversion of Permitted Convertible Indebtedness by delivery of shares of ordinary shares and/or a different series of Permitted Convertible Indebtedness and/or by payment of cash (in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of ordinary shares and/or Permitted Convertible Indebtedness plus the net cash proceeds, if any, received by Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the Permitted Convertible Indebtedness that is so repurchased, exchanged or converted, Borrower shall exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted

Bond Hedge Transactions and Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Indebtedness that are so repurchased, exchanged or converted.

9.07 Payments of Indebtedness. The Borrower shall not, and shall not permit any of its Subsidiaries to, make any payments in respect of any Indebtedness other than (i) payments of the Obligations and (ii) scheduled or other mandatory payments of other Permitted Indebtedness (other than any Permitted Convertible Indebtedness) that are not otherwise prohibited or limited pursuant to any subordination or similar contract that is binding upon the Borrower, any such Subsidiary or any holder of such Permitted Indebtedness.

Notwithstanding anything to the contrary in the foregoing, the issuance of, performance of obligations under (including any payments of interest), and conversion, exercise, repurchase, redemption (including, for the avoidance of doubt, a required repurchase in connection with the redemption of Permitted Convertible Indebtedness upon satisfaction of a condition related to the stock price of the ordinary shares), settlement or early termination or cancellation of (whether in whole or in part and including by netting or set-off) (in each case, whether in cash, ordinary shares, following a merger event or other change of the ordinary shares, other securities or property), or the satisfaction of any condition that would permit or require any of the foregoing, any Permitted Convertible Indebtedness shall not violate this **Section 9.07**; provided that, to the extent both (a) the aggregate amount of cash payable upon conversion or payment of any Permitted Convertible Indebtedness (excluding any required payment of interest with respect to such Permitted Convertible Indebtedness and excluding any payment of cash in lieu of a fractional share due upon conversion thereof) exceeds the aggregate principal amount thereof and (b) such conversion or payment does not trigger or correspond to an exercise or early unwind or settlement of a corresponding portion of the Permitted Bond Hedge Transactions relating to such Permitted Convertible Indebtedness (including, for the avoidance of doubt, the case where there is no Bond Hedge Transaction relating to such Permitted Convertible Indebtedness), the payment of such excess cash shall not be permitted by the preceding sentence.

Notwithstanding the foregoing, Borrower may repurchase, exchange or induce the conversion of Permitted Convertible Indebtedness by delivery of shares of ordinary shares and/or a different series of Permitted Convertible Indebtedness and/or by payment of cash (in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of ordinary shares and/or Permitted Convertible Indebtedness plus the net cash proceeds, if any, received by Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the Permitted Convertible Indebtedness that is so repurchased, exchanged or converted, Borrower shall exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Indebtedness that are so repurchased, exchanged or converted.

9.08 Change in Fiscal Year. The Borrower shall not, and shall not permit any of its Subsidiaries to, change the last day of its fiscal year from that in effect on the Closing Date, except to change the fiscal year of a Subsidiary acquired in connection with a Permitted Acquisition to conform its fiscal year to that of the Borrower.

9.09 Sales of Assets, Etc. Except as set forth below, the Borrower shall not, and shall not permit any of its Subsidiaries to sell, lease, transfer, or otherwise dispose of any of its assets or property (including accounts receivable, Material Intellectual Property or Equity Interests of Subsidiaries), grant or enter into any Exclusive License (other than any Exclusive License that is not prohibited by this Agreement), forgive, release or compromise any amount owed to the Borrower or such Subsidiary, in each case, in one transaction or series of transactions (any thereof, an "***Asset Sale***"); provided that Asset Sales of the type described in **clauses (c)**, **(d)**, **(e)**, **(f)**, **(i)**, **(l)** and **(m)** shall only be permitted so long as no Event of Default has occurred or could reasonably be expected to result from such Asset Sale:

(a) sales of inventory in the ordinary course of its business on ordinary business terms;

(b) the forgiveness, release or compromise of any amount owed to any Obligor or Subsidiary in the ordinary course of business;

(c) transfers of assets or property by any Subsidiary to an Obligor;

(d) transfers of assets or property by an Immaterial Subsidiary to any other Immaterial Subsidiary;

(e) dispositions of any assets or property that is obsolete or worn out or no longer used or useful in the Business;

(f) in connection with any transaction permitted under **Sections 9.02**, **9.03**, **9.05** or **9.06** or **9.10**;

(g) the sale, assignment, transfer, disposition or discount, in each case, without recourse, of accounts receivable arising in the ordinary course of business that have been written down by the Borrower acting in good faith and consistent with its historical collection practices;

(h) any dispositions as a result of any involuntary loss, damage or destruction of property as a result of a Casualty Event or transfers of property to insurance companies in exchange for casualty insurance proceeds;

(i) the sale or issuance of Qualified Equity Interests of the Borrower and the issuance by any of the Borrower's Subsidiaries of Qualified Equity Interests to the Borrower or any Obligor;

(j) the abandonment of issued Patents, issued Trademarks and issued Copyrights of the Borrower and its Subsidiaries to the extent such issued Patents, issued Trademarks and issued Copyrights do not qualify as Material Intellectual Property and are not in the good faith judgment of the Borrower useful to, or required in, the conduct of the business of the Obligors or any of their Subsidiaries;

(k) the abandonment or other disposition of a lease or sublease of real property that is, in the commercially reasonable judgment of the Borrower, not used or useful in the conduct of the business of the Obligors or any of their Subsidiaries;

(l) licenses, development and other collaborative agreements where such arrangement provide for the license of Patents, Trademarks, Copyrights and other Intellectual Property Rights to the extent permitted pursuant to **Section 9.19** hereof;

(m) dispositions of property to the extent that such property is exchanged for credit against the purchase price of similar replacement property;

(n) dispositions or licenses of the Specified Assets so long as the Specified Assets Conditions are met and satisfied; and

(o) dispositions of assets (other than accounts receivable or Intellectual Property) not otherwise permitted pursuant to **clauses (a)** through **(n)** above; provided that such dispositions are made at fair market value for cash and the aggregate fair market value of all assets disposed of in all such dispositions (including the proposed disposition) would not exceed $2,500,000 in the aggregate since the Closing Date.

9.10 Transactions with Affiliates. The Borrower shall not, and shall not permit any of its Subsidiaries to, sell, lease, license or otherwise transfer any assets to, or purchase, lease, license or otherwise acquire any assets from, or otherwise engage in any other transactions or arrangements with, any of its Affiliates, except:

(a) transactions between or among Obligors and their Subsidiaries to the extent permitted hereunder (including, for the avoidance of doubt, any such transactions that are permitted by **Section 9.05**);

(b) customary compensation and indemnification of, and other employment arrangements with, directors, officers and employees of the Borrower or any of its Subsidiaries in the ordinary course of business;

(c) payments by the Obligors and their Subsidiaries pursuant to Tax sharing arrangements, transfer pricing arrangements or cost plus arrangements, in each case, solely as between or among the Obligors and one or more of their Subsidiaries;

(d) issuance of Qualified Equity Interests not resulting in a Change of Control and otherwise permitted hereunder;

(e) transactions between or involving Perceptive Credit Holdings III, LP and its Affiliates;

(f) transactions in connection with the Janssen Collaboration Agreement; and

(g) any other transaction of any Obligor or any of its Subsidiaries that is (i) on fair and reasonable terms that are no less favorable (including with respect to the amount of cash or other consideration receivable or payable in connection therewith) to such Obligor or such Subsidiary, as applicable, than it could obtain in an arm's-length transaction with a Person that is not an Affiliate of such Obligor or such Subsidiary and (ii) of the kind which would be entered into by a prudent Person in the position of such Obligor or such Subsidiary, as applicable, with another Person that is not an Affiliate of such Obligor or such Subsidiary, as applicable.

9.11 Restrictive Agreements. The Borrower shall not, and shall not permit any of its Subsidiaries to, directly or indirectly, enter into, incur or permit to exist any Restrictive Agreement other than (i) restrictions and conditions imposed by applicable Laws or by the Loan Documents, (ii) customary restrictions and conditions contained in agreements relating to an Asset Sale permitted pursuant to **Section 9.09**; provided that such restrictions and conditions apply only to the Subsidiary or property or asset that is to be sold and were not created or imposed in contemplation of this Agreement, (iii) restrictions and conditions imposed by any agreement relating to Permitted Indebtedness that is secured by a Permitted Lien so long as such restrictions or conditions apply only to the property or assets securing such Permitted Indebtedness and were not created or imposed in contemplation of this Agreement, (iv) any agreement or restriction or condition in effect at the time any Person becomes a Subsidiary pursuant to a Permitted Acquisition, so long as such agreement or restriction or condition was not entered into in contemplation of such Person becoming a Subsidiary and does not extend to any assets, properties or businesses other than those acquired pursuant to such Permitted Acquisition, (v) customary provisions in leases and subleases entered into in compliance with **Section 9.13** or licenses entered into in compliance with **Section 9.19**, in either case restricting the assignment thereof or restricting the grant of Liens in such lease, sublease or license, as the case may be, (vi) restrictions on pledges or deposits made in the ordinary course of business in connection with leases or obligations permitted pursuant to **Section 9.02(e)**, and (vii) Restrictive Agreements set forth on **Schedule 7.15**; provided further that, any term or provision of the foregoing notwithstanding, no such Restrictive Agreement otherwise permitted under this Section shall be permitted in the event it in any way restricts, prohibits or otherwise prevents (x) the execution, delivery and performance of the Obligations or any Secured Party's rights or remedies in respect thereof, (y) the exercise of remedies by the Administrative Agent against the Borrower or any Subsidiary following an Event of Default as contemplated by the Loan Documents or (z) the performance of the obligations of the Borrower pursuant to **Section 8.12** hereof.

9.12 Modifications of Organic Documents; **Termination of Material Agreements**. The Borrower shall not, and shall not permit any of its Subsidiaries to:

(a) waive, amend, terminate, replace or otherwise modify any term or provision of any Organic Document that could reasonably be expected to have a negative adverse effect on (x) any Obligations or any interests, rights or remedies of any Secured Party in respect of the Loan Documents or (y) any rights or remedies of any Lender in respect of any Warrant Certificate (or, to the extent the Lender has exercised its rights under any Warrant Certificate, such Lender's rights as a holder of the Borrower's Equity Interests) except, for purposes of this **clause (y)** only, to the extent such modification would not negatively adversely and disproportionately affect such Lender when compared with the effect of such modification on all other holders of the same series or class of Equity Interests; or

(b) Except with respect to the Material Agreements set forth on Schedule 9.12(b), take or omit to take any action that results in the termination of, or permits any other Person to terminate, any Material Agreement or; or take any action that permits any Material Agreement to be terminated by any counterparty thereto prior to its stated date of expiration, in each case, only to the extent such termination would negatively adversely and disproportionately affect the Administrative Agent or the Lenders.

9.13 Sales and Leasebacks. Except as disclosed on **Schedule 9.13**, the Borrower shall not, and shall not permit any of its Subsidiaries to, become liable, directly or indirectly, with respect to any lease, whether an operating lease or a Capital Lease Obligation, of any property (whether real, personal, or mixed), whether now owned or hereafter acquired, (i) which such Person has sold or transferred or is to sell or transfer to any other Person and (ii) which such Person intends to use for substantially the same purposes as property which has been or is to be sold or transferred.

9.14 Hazardous Material. The Borrower shall not, and shall not permit any of its Subsidiaries to, use, generate, manufacture, install, treat, release, store or dispose of any Hazardous Material, except in compliance with all applicable Environmental Laws or where the failure to comply, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect.

9.15 Accounting Changes. The Borrower shall not, and shall not permit any of its Subsidiaries to, make any significant change in accounting treatment or reporting practices, except as required or permitted by GAAP.

9.16 Compliance with ERISA. Neither Borrower nor any of its ERISA Affiliates shall cause or suffer to exist (i) any event that could result in the imposition of a Lien with respect to any Title IV Plan or Multiemployer Plan or (ii) any other ERISA Event that, in the aggregate, could reasonably be expected to result in a Material Adverse Effect. Neither the Borrower nor any of its Subsidiaries shall cause or suffer to exist any event that could result in the imposition of a Lien with respect to any Benefit Plan that could reasonably be expected to result in a Material Adverse Effect.

9.17 [Reserved].

9.18 Sanctions; Anti-Corruption Use of Proceeds. The Borrower shall not, directly or knowingly indirectly, use the proceeds of the Loans, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, (i) in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any Person in violation of any applicable anti-corruption Law, or (ii) (A) to fund any activities or business of or with any Person, that, at the time of such funding, is, or whose government is, the subject of Sanctions or in any Designated Jurisdiction, or (B) in any other manner that would result in a violation of Sanctions by any Person (including any Person participating in the Loans, whether as Administrative Agent, Lender, underwriter, advisor, investor, or otherwise).

9.19 Inbound and Outbound Licenses.

(a) **Inbound Licenses.** Except for the UCL Licenses and Janssen Collaboration Agreement, the Borrower shall not, and shall not permit any of its Subsidiaries to, enter into or become bound by any inbound license agreement that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect, which agreement, and that requires the Borrower or any of its Subsidiaries, as the case may be, during any twelve (12) month period during the term of such license agreement, to make aggregate payments in excess of [***] unless (i) the licensor under such license is a non-Affiliated third party and (ii) such license has been

entered into by the Borrower or one of its Subsidiaries as the case may be, in the ordinary course of business and the commercial terms of such license otherwise comply with **Section 9.10**; provided that inbound license agreements in the nature of ordinary course customer contracts, application programming interfaces (APIs), over the counter software that are commercially available to the public shall not be prohibited by this **clause (a)**.

(b) **Outbound Licenses.** The Borrower shall not, and shall not permit any of its Subsidiaries to, enter into or become bound by any outbound license of Material Intellectual Property that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect unless such outbound license (i) does not impair the Administrative Agent or any Secured Party from fully exercising their respective rights in respect of Collateral under any of the Loan Documents in the event of the exercise of remedies, including a disposition or liquidation in connection with a foreclosure of any such Collateral, or any rights, assets or property related thereto, and (ii) is not an Exclusive License; provided that, any term or provision of this **Section 9.19(b)** or otherwise in this Agreement to the contrary notwithstanding, so long as the Specified Assets Conditions are met and satisfied as of the effective time of any outbound license (or similar arrangement) of Specified Assets, this **Section 9.19(b)** shall not apply to any outbound license of Specified Assets.

9.20 Title, Headleases, Development. The Borrower shall not, and shall not permit any of its Subsidiaries to, (i) agree to any amendment, supplement, waiver, surrender or release of any covenant, stipulation or obligation (restrictive or otherwise) at any time affecting a Manufacturing Facility, (ii) agree to any amendment, supplement, waiver, surrender or release of any Headlease, (iii) exercise any right to break, determine or extend any Headlease, (iv) agree to any rent review in respect of any Headlease, (v) do or allow to be done any act as a result of which any Headlease may become liable to forfeiture or otherwise be terminated, (vi) do or allow to be done any act as a result of which the Overage Deed may be amended or triggered or (vii) make or allow to be made any application for planning permission in respect of any part of any Manufacturing Facility or carry out, or allow to be carried out, any demolition, construction, structural alterations or additions, development or other similar operations in respect of any part of any Manufacturing Facility, other than (A) the maintenance of the buildings, plant, machinery, fixtures and fittings in accordance with the Loan Documents, (B) any alterations or improvements which a tenant is entitled to undertake in accordance with the terms of the relevant Lease Document and in respect of which an Obligor in its capacity as landlord is required to give its consent pursuant to the terms of that Lease Document, (C) the carrying out of non-structural improvements or alterations which affect only the interior of any building on any Manufacturing Facility or (D) as disclosed in the Certificate of Title for the Shannon Manufacturing Facility and the continued planned buildout of the Shannon Manufacturing Facility up to an aggregate principal amount of [***] pursuant to Borrower's Board approved projected budget; provided that, to the extent (A) through (D) do not apply, any such actions can be undertaken by the Borrower or its Subsidiaries with the consent of the Administrative Agent (not to be unreasonably withheld or delayed).

SECTION 10
FINANCIAL COVENANTS

10.01 Minimum Liquidity. The Borrower shall at all times maintain a minimum aggregate balance of three million dollars ($3,000,000) in cash and Permitted Cash Equivalent Investments

in a Controlled Account maintained with a commercial bank or similar deposit-taking institution in the U.S. (such Controlled Account, the "***Minimum Liquidity Account***") that is free and clear of all Liens, other than Permitted Liens.

10.02 Phase III Trial. The Borrower shall have enrolled in a Phase III trial for AAV–RPGR with Johnson & Johnson on or before June 30, 2023.

10.03 Shannon Manufacturing Facility. The Shannon Manufacturing Facility meets or satisfies all applicable "good manufacturing practice" requirements on or before December 31, 2023 and any additional quality standards the facility markets or represents it satisfies, including without limitation cGMP.

SECTION 11
EVENTS OF DEFAULT

11.01 Events of Default. Each of the following events shall constitute an "***Event of Default***":

(a) **Principal or Interest Payment Default**. The Borrower shall fail to pay any principal of the Loans, when and as the same shall become due and payable, whether at the due date thereof, at a date fixed for prepayment thereof or otherwise.

(b) **Other Payment Defaults**. Any Obligor shall fail to pay any Obligation (other than an amount referred to in **Section 11.01(a)**) when and as the same shall become due and payable, and such failure shall continue unremedied for a period of three (3) Business Days of the due date thereof.

(c) **Representations and Warranties**. Any representation or warranty made or deemed made by or on behalf of the Borrower or any of its Subsidiaries in or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof, or in any report, certificate, financial statement or other document furnished pursuant to or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof, shall, when taken as a whole: (i) prove to have been incorrect when made or deemed made to the extent that such representation or warranty contains any materiality or Material Adverse Effect qualifier; or (ii) prove to have been incorrect in any material respect when made or deemed made to the extent that such representation or warranty does not otherwise contain any materiality or Material Adverse Effect qualifier.

(d) **Certain Covenants**. Any Obligor shall fail to observe or perform any covenant, condition or agreement contained in **Sections 8.02, 8.03** (with respect to the Borrower's existence) **8.11**, **8.12**, **8.19**, **Section 9** or **Sections 10.01** or **10.02**.

(e) **Other Covenants**. Any Obligor shall fail to observe or perform any covenant, condition or agreement contained in this Agreement (other than those specified in **Section 11.01(a)**, **11.01(b)** or **11.01(d)**) or any other Loan Document, and in the case of any failure that is capable of cure, such failure shall continue unremedied for a period of thirty (30) or more days.

(f) **Payment Default on Other Indebtedness**. Any Obligor or any of its Subsidiaries shall fail to make any payment (whether of principal or interest and regardless of amount) in respect of any Material Indebtedness, when and as the same shall become due and payable after giving effect to any applicable grace or cure period as originally provided by the terms of such Indebtedness.

(g) **Other Defaults on Other Indebtedness**. Any material breach of, or "event of default" or similar event under, any Contract governing any Material Indebtedness shall occur, or and shall continue after the applicable grace period, if any, (x) that results in any Material Indebtedness becoming due prior to its scheduled maturity or (y) that enables or permits (with or without the giving of notice, the lapse of time or both) the holder or holders of such Material Indebtedness or any trustee or agent on its or their behalf to cause such Material Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity; provided that this **Section 11.01(g)** shall not apply to (x) secured Indebtedness that becomes due as a result of the voluntary sale or transfer of the property or assets securing such Material Indebtedness, or (y) any redemption, exchange, repurchase, conversion or settlement with respect to any Permitted Convertible Indebtedness, or satisfaction of any condition giving rise to or permitting the foregoing, pursuant to their terms unless such redemption, repurchase, conversion or settlement results from a default thereunder or an event of the type that constitutes an Event of Default.

(h) **Insolvency, Bankruptcy, Etc**.

(i) Any Obligor does not or becomes unable to pay its debts or meet its liabilities as the same become due, or admits in writing its inability to pay its debts generally, or declares any general moratorium on its indebtedness, or enters into a compromise or arrangement or deed of company arrangement between it and any class of its creditors.

(ii) Any Obligor commits an act of bankruptcy or makes an assignment of its property for the general benefit of its creditors or makes a proposal (or files a notice of its intention to do so).

(iii) Any Obligor institutes any proceeding seeking to adjudicate it an insolvent, or seeking liquidation, dissolution, winding-up, reorganization, compromise, arrangement, adjustment, protection, moratorium, relief, stay of proceedings of creditors generally (or any class of creditors), or composition of it or its debts or any other relief, under any applicable Law, whether U.S. or non-U.S., now or hereafter in effect relating to bankruptcy, winding-up, insolvency, reorganization, receivership, examinership, plans of arrangement or relief or protection of debtors or at common law or in equity, or files an answer admitting the material allegations of a petition filed against it in any such proceeding (in each case, other than any liquidation, dissolution or winding-up permitted pursuant to Section 9.03).

(iv) Any Obligor applies for the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, trustee, liquidator, provisional liquidator, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property.

(v) Any Obligor takes any action, corporate or otherwise, to approve, effect, consent to or authorize any of the actions described in this **Section 11.01(h)**, or otherwise acts in furtherance thereof or fails to act in a timely and appropriate manner in defense thereof.

(vi) Any petition is filed, application made or other proceeding instituted in a court of competent jurisdiction against or in respect of any Obligor:

(A) seeking to adjudicate it as insolvent;

(B) seeking a receiving order against it;

(C) seeking liquidation, dissolution, winding-up, reorganization, compromise, arrangement, adjustment, protection, moratorium, relief, stay of proceedings of creditors generally (or any class of creditors), deed of company arrangement or composition of it or its debts or any other relief under any applicable Law, whether U.S. or non-U.S., now or hereafter in effect relating to bankruptcy, winding-up, insolvency, reorganization, receivership, examinership, plans of arrangement or relief or protection of debtors or at common law or in equity; or

(D) seeking the entry of an order for relief or the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, trustee, liquidator, provisional liquidator, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property, and such petition, application or proceeding (i.e. clauses (A) through (D) of this provision) continues undismissed, or unstayed and in effect, for a period of sixty (60) days after the institution thereof; provided that if an order, decree or judgment is granted or entered (whether or not entered or subject to appeal) against any Obligor thereunder in the interim, such grace period will cease to apply; provided, further, that if such Obligor files an answer admitting the material allegations of a petition filed against it in any such proceeding, such grace period will cease to apply.

(vii) Any other event occurs which, under the applicable Law of any applicable jurisdiction, has an effect equivalent to any of the events referred to in **Section 11.01(h)**.

(i) **Judgments**. One or more final judgments for the payment of money in an aggregate amount in excess of $2,000,000 (or the Equivalent Amount in other currencies) (exclusive of any amounts fully covered by insurance (less any applicable deductible) and as to which the insurer has not rejected responsibility to cover such judgment) shall be rendered against the Borrower or any Obligor or any combination thereof and the same shall remain undismissed, unsatisfied or undischarged for a period of sixty (60) calendar days during which execution shall not be effectively stayed, or any action shall be legally taken by a judgment creditor to attach or levy upon any assets of any Obligor to enforce any such judgment.

(j) **ERISA and Pension Plans**. An ERISA Event shall have occurred that, when taken together with all other ERISA Events that have occurred, could reasonably be expected to result in a Material Adverse Effect.

(k) **Change of Control**. A Change of Control shall have occurred.

(l) **Material Adverse Change, Etc.** A Material Adverse Change or Material Adverse Effect shall have occurred.

(m) **Impairment of Security, Etc.** If any of the following events occurs, and with respect to the following **clause (i)**, other than as a result of the acts or omissions of the Administrative Agent or any Lender: (i) any Lien created by any of the Security Documents shall at any time not constitute a valid and perfected Lien on the applicable Collateral in favor of the Secured Parties, free and clear of all other Liens (other than Permitted Liens) to the extent perfection is required herein or therein, other than solely as the result of any action(s) taken by the Administrative Agent or the failure of the Administrative Agent to take any action(s) within its control, or any combination thereof, which does not arise from a breach of any Loan Document by an Obligor, (ii) except for expiration in accordance with its terms, any of the Security Documents or any Guarantee of any of the Obligations (including that contained in **Section 13**) shall for whatever reason cease to be in full force and effect, or (iii) any Obligor shall, directly or indirectly, contest in any manner such effectiveness, validity, binding nature or enforceability of any such Lien or any Loan Document.

11.02 Remedies. Upon the occurrence and during the continuance of any Event of Default, then, and in every such event (other than an Event of Default described in **Section 11.01(h)**), the Administrative Agent may, by notice to the Borrower, declare the Loans then outstanding to be due and payable in whole (or in part, in which case any principal not so declared to be due and payable may thereafter be declared to be due and payable), and thereupon the principal of the Loans so declared to be due and payable, together with accrued interest thereon and all fees and other Obligations, shall become due and payable immediately (in the case of the Loans, at the Prepayment Price therefor), without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor; and in case of an Event of Default described in **Section 11.01(h)**, the principal of the Loans then outstanding, together with accrued interest thereon and all fees and other Obligations, shall automatically become due and payable immediately (in the case of the Loans, at the Prepayment Price therefor), without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor.

11.03 Additional Remedies. In the event any Event of Default has occurred and is continuing, if the Borrower or any of its Subsidiaries shall be in uncured default under a Material Agreement, the Administrative Agent or the Lenders shall have the right (but not the obligation) to cause the default or defaults under such Material Agreement to be remedied (including without limitation by paying any unpaid amount thereunder) and otherwise exercise any and all rights of the Borrower or such Subsidiary, as the case may be, thereunder, as may be necessary to prevent or cure any default. Without limiting the foregoing, upon any such default, the Borrower and each of its Subsidiaries shall promptly execute, acknowledge and deliver to the Administrative Agent such instruments as may reasonably be required of the Borrower or such Subsidiary to permit the Administrative Agent and the Lenders to cure any default under the applicable Material Agreement or permit the Administrative Agent and the Lenders to take such other action required to enable the Administrative Agent and the Lenders to cure or remedy the matter in default and preserve the interests of the Administrative Agent or Lenders. Any amounts paid by the Administrative Agent or Lenders pursuant to this **Section 11.03** shall be payable on demand by Obligors, shall accrue interest at the Default Rate if not paid on demand, and shall constitute "***Obligations***."

SECTION 12
THE ADMINISTRATIVE AGENT

12.01 Appointment and Duties. Subject in all cases to **clause (c)** below:

(a) **Appointment of the Administrative Agent**. Each of the Lenders hereby irrevocably appoints Perceptive Credit Holdings III, LP (together with any successor the Administrative Agent pursuant to **Section 12.09**) as the Administrative Agent hereunder and authorizes the Administrative Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from the Borrower or any of its Subsidiaries, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to the Administrative Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto.

(b) **Duties as Collateral and Disbursing Agent**. Without limiting the generality of **Section 12.01(a)**, the Administrative Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any proceeding described in **Section 11.01(h)** or any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Secured Party is hereby authorized to make such payment to the Administrative Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of the Secured Parties with respect to any Obligation in any proceeding described in **Section 11.01(h)** or any other bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Secured Party), (iii) act as collateral agent for each Secured Party for purposes of the perfection of all Liens created by such agreements and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, exercise all remedies given to the Administrative Agent and the other Secured Parties with respect to the Collateral, whether under the Loan Documents, applicable Laws or otherwise and (vii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; provided that the Administrative Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for the Administrative Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any deposit account maintained by any Obligor with, and cash and Permitted Cash Equivalent Investments held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to the Administrative Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed.

(c) **Limited Duties**. The Lenders and the Obligors hereby each acknowledge and agree that the Administrative Agent (i) has undertaken its role hereunder purely as an accommodation to the parties hereto and the Transactions, (ii) is receiving no compensation for undertaking such role and (iii) subject only to the notice provisions set forth in **Section 12.09**, may resign from such role at any time for any reason or no reason whatsoever. Without limiting the foregoing, the parties

hereto further acknowledge and agree that under the Loan Documents, the Administrative Agent (i) is acting solely on behalf of the Lenders (except to the limited extent provided in **Section 12.11**), with duties that are entirely administrative in nature and do not (and are not intended to) create any fiduciary obligations, notwithstanding the use of the defined term "the Administrative Agent", the terms "agent", "administrative agent" and "collateral agent" and similar terms in any Loan Document to refer to the Administrative Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Secured Party and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document (fiduciary or otherwise), and each Lender hereby waives and agrees not to assert any claim against the Administrative Agent based on the roles, duties and legal relationships expressly disclaimed in this **clause (c)**.

12.02 Binding Effect. Each Lender agrees that (i) any action taken by the Administrative Agent or the Majority Lenders (or, if expressly required hereby, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by the Administrative Agent in reliance upon the instructions of the Majority Lenders (or, where so required, such greater proportion) and (iii) the exercise by the Administrative Agent or the Majority Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Secured Parties.

12.03 Use of Discretion.

(a) **No Action without Instructions**. The Administrative Agent shall not be required to exercise any discretion or take, or to omit to take, any action, including with respect to enforcement or collection, except (subject to **clause (b)** below) any action it is required to take or omit to take (i) under any Loan Document or (ii) pursuant to instructions from the Majority Lenders (or, where expressly required by the terms of this Agreement, a greater proportion of the Lenders).

(b) **Right Not to Follow Certain Instructions**. Notwithstanding **Section 12.03(a)** or any other term or provision of this **Section 12**, the Administrative Agent shall not be required to take, or to omit to take, any action (i) unless, upon demand, the Administrative Agent receives an indemnification satisfactory to it from the Lenders (or, to the extent applicable and acceptable to the Administrative Agent, any other Secured Party) against all liabilities that, by reason of such action or omission, may be imposed on, incurred by or asserted against the Administrative Agent or any Related Parties thereof or (ii) that is, in the opinion of the Administrative Agent, in its sole and absolute discretion, contrary to any Loan Document, applicable Law or the best interests of the Administrative Agent or any of its Affiliates or Related Parties.

12.04 Delegation of Rights and Duties. The Administrative Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Secured Party). Any such Person shall benefit from this **Section 12** to the extent provided by the Administrative Agent.

12.05 Reliance and Liability.

(a) The Administrative Agent may, without incurring any liability hereunder, (i) consult with any of its Related Parties and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, any Obligor) and (ii) rely and act upon any document and information and any telephone message or conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties.

(b) Neither the Administrative Agent nor any of its Related Parties shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and the Borrower hereby waives and shall not assert (and the Borrower shall cause each other Obligor to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting primarily from the fraudulent conduct or behavior of the Administrative Agent or, as the case may be, such Related Party (each as determined in a final, non-appealable judgment or order by a court of competent jurisdiction) in connection with the duties expressly set forth herein. Without limiting the foregoing, the Administrative Agent:

(i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Majority Lenders or for the actions or omissions of any of their Related Parties selected with reasonable care (other than employees, officers and directors of the Administrative Agent, when acting on behalf of the Administrative Agent);

(ii) shall not be responsible to any Secured Party for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document;

(iii) makes no warranty or representation, and shall not be responsible, to any Secured Party for any statement, document, information, representation or warranty made or furnished by or on behalf of any Related Party, in or in connection with any Loan Document or any transaction contemplated therein, whether or not transmitted by the Administrative Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by the Administrative Agent in connection with the Loan Documents; and

(iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of any Obligor or as to the existence or continuation or possible occurrence or continuation of any Default or Event of Default and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from the Borrower, any Lender describing such Default or Event of Default clearly labeled “notice of default” (in which case the Administrative Agent shall promptly give notice of such receipt to all Lenders);

and, for each of the items set forth in clauses (i) through (iv) above, each Lender and the Borrower hereby waives and agrees not to assert (and the Borrower shall cause each other Obligor to waive and agree not to assert) any right, claim or cause of action it might have against the Administrative Agent based thereon.

12.06 Administrative Agent Individually. The Administrative Agent and its Affiliates may make loans and other extensions of credit to, acquire Equity Interests of, engage in any kind of business with, any Obligor or Affiliate thereof as though it were not acting as the Administrative Agent and may receive separate fees and other payments therefor. To the extent the Administrative Agent or any of its Affiliates makes any Loan or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Majority Lender", and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, the Administrative Agent or such Affiliate, as the case may be, in its individual capacity as Lender or as one of the Majority Lenders, respectively.

12.07 Lender Credit Decision. Each Lender acknowledges that it has, independently and without reliance upon the Administrative Agent, any Lender or any of their Related Parties or upon any document solely or in part because such document was transmitted by the Administrative Agent or any of its Related Parties, conducted its own independent investigation of the financial condition and affairs of each Obligor and has made and continues to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate.

12.08 Expenses; Indemnities.

(a) Each Lender agrees to reimburse the Administrative Agent and each of its Related Parties (to the extent not reimbursed by any Obligor) promptly upon demand for such Lender's Proportionate Share of any costs and expenses (including fees, charges and disbursements of financial, legal and other advisors and Other Taxes paid in the name of, or on behalf of, any Obligor) that may be incurred by the Administrative Agent or any of its Related Parties in connection with the preparation, syndication, execution, delivery, administration, modification, consent, waiver or enforcement (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding or otherwise) of, or legal advice in respect of its rights or responsibilities under, any Loan Document.

(b) Each Lender further agrees to indemnify the Administrative Agent and each of its Related Parties (to the extent not reimbursed by any Obligor), from and against such Lender's aggregate Proportionate Share of the liabilities (including taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to on or for the account of any Lender) that may be imposed on, incurred by or asserted against the Administrative Agent or any of its Related Parties in any matter relating to or arising out of, in connection with or as a result of any Loan Document or any other act, event or transaction related, contemplated in or attendant to any such Loan Document, or, in each case, any action taken or omitted to be taken by the Administrative Agent or any of its Related Parties under or with respect to any of the foregoing; provided that no Lender shall be liable to the Administrative Agent or any of its Related Parties to

the extent such liability has resulted primarily from the gross negligence or willful misconduct of the Administrative Agent or, as the case may be, such Related Party, as determined by a court of competent jurisdiction in a final non-appealable judgment or order.

12.09 Resignation of the Administrative Agent.

(a) At any time upon not less than five (5) Business Days prior written notice, the Administrative Agent may resign as the "the Administrative Agent" hereunder, in whole or in part (in the sole and absolute discretion of the Administrative Agent), effective on the date set forth in such notice, which effective date shall not be less than five (5) (or more than thirty (30)) days following delivery of such notice. If the Administrative Agent delivers any such notice, the Majority Lenders shall have the right to appoint a successor (which successor shall not be a Disqualified Institution) to the Administrative Agent; provided that if a successor to the Administrative Agent has not been appointed on or before the effectiveness of the resignation of the resigning Administrative Agent, then the resigning Administrative Agent may, on behalf of the Lenders, appoint any Person reasonably chosen by it (other than a Disqualified Institution) as the successor to the Administrative Agent.

(b) Effective immediately upon its resignation, (i) the resigning Administrative Agent shall be discharged from its duties and obligations under the Loan Documents to the extent set forth in the applicable resignation notice, (ii) the Lenders shall assume and perform all of the duties of the Administrative Agent until a successor the Administrative Agent shall have accepted a valid appointment hereunder, (iii) the resigning Administrative Agent and its Related Parties shall no longer have the benefit of any provision of any Loan Document other than with respect to (x) any actions taken or omitted to be taken while such resigning Administrative Agent was, or because the Administrative Agent had been, validly acting as the Administrative Agent under the Loan Documents or (y) any continuing duties such resigning Administrative Agent continues to perform, and (iv) subject to its rights under **Section 12.04**, the resigning Administrative Agent shall take such action as may be reasonably necessary to assign to the successor the Administrative Agent its rights as the Administrative Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as the Administrative Agent, a successor the Administrative Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the resigning Administrative Agent under the Loan Documents.

12.10 Release of Collateral or Guarantors. Each Lender hereby consents to the release and hereby directs the Administrative Agent to release (or, in the case of **Section 12.10(b)(ii)**, release or subordinate) the following:

(a) any Subsidiary of the Borrower from its guaranty of any Obligation of any Obligor if all of the Equity Interests in such Subsidiary owned by any Obligor or any of its Subsidiaries are disposed of in an Asset Sale permitted under the Loan Documents (including pursuant to a waiver or consent), to the extent that, after giving effect to such Asset Sale, such Subsidiary would not be required to guaranty any Obligations pursuant to **Section 8.12(a)**; and

(b) any Lien held by the Administrative Agent for the benefit of the Secured Parties against (i) any Collateral that is disposed of by an Obligor or any of its Subsidiaries in an Asset Sale permitted by the Loan Documents (including pursuant to a valid waiver or consent), (ii) any

property subject to a Lien described in **Section 9.02(c)** and (iii) all of the Collateral and all Obligors, upon (w) termination of the Commitments, (x) payment and satisfaction in full of all Loans and all other Obligations (other than (i) for the Warrant Obligations and (y) contingent obligations as to which no Claims have been asserted) that the Administrative Agent has been notified in writing are then due and payable, (y) deposit of cash collateral with respect to all contingent Obligations, in amounts and on terms and conditions and with parties satisfactory to the Administrative Agent and each Indemnified Party that is owed such Obligations and (z) to the extent requested by the Administrative Agent, receipt by the Secured Parties of liability releases from the Obligors each in form and substance acceptable to the Administrative Agent.

Each Lender hereby directs the Administrative Agent, and the Administrative Agent hereby agrees, upon receipt of reasonable advance notice from the Borrower, to execute and deliver or file such documents and to perform other actions reasonably necessary to release the guarantees and Liens when and as directed in this **Section 12.10**.

12.11 Additional Secured Parties. The benefit of the provisions of the Loan Documents directly relating to the Collateral or any Lien granted thereunder shall extend to and be available to any Secured Party that is not a Lender so long as, by accepting such benefits, such Secured Party agrees, as among the Administrative Agent and all other Secured Parties, that such Secured Party is bound by (and, if requested by the Administrative Agent, shall confirm such agreement in a writing in form and substance acceptable to the Administrative Agent) this **Section 12** and the decisions and actions of the Administrative Agent and the Majority Lenders (or, where expressly required by the terms of this Agreement, a greater proportion of the Lenders) to the same extent a Lender is bound; provided that, notwithstanding the foregoing, (i) such Secured Party shall be bound by **Section 12.08** only to the extent of liabilities, costs and expenses with respect to or otherwise relating to the Collateral held for the benefit of such Secured Party, in which case the obligations of such Secured Party thereunder shall not be limited by any concept of Proportionate Share or similar concept, (ii) each of the Administrative Agent and each Lender shall be entitled to act at its sole discretion, without regard to the interest of such Secured Party, regardless of whether any Obligation to such Secured Party thereafter remains outstanding, is deprived of the benefit of the Collateral, becomes unsecured or is otherwise affected or put in jeopardy thereby, and without any duty or liability to such Secured Party or any such Obligation and (iii) such Secured Party shall not have any right to be notified of, consent to, direct, require or be heard with respect to, any action taken or omitted in respect of the Collateral or under any Loan Document.

SECTION 13
GUARANTEE

13.01 The Guarantee. The Subsidiary Guarantors hereby jointly and severally guarantee to the Administrative Agent and the Lenders, and their successors and assigns, the prompt payment in full when due (whether at stated maturity, by acceleration or otherwise) of the principal of and interest on the Loans, all fees and other amounts and Obligations from time to time owing to the Administrative Agent and the Lenders by the Borrower and each other Obligor under this Agreement or under any other Loan Document (other than in the case of the Irish Subsidiary Guarantor, the Warrant Certificate), in each case strictly in accordance with the terms hereof and thereof (such obligations being herein collectively called the "***Guaranteed Obligations***"). The Subsidiary Guarantors hereby further jointly and severally agree that if the Borrower or any other

Obligor shall fail to pay in full when due (whether at stated maturity, by acceleration or otherwise) any of the Guaranteed Obligations, the Subsidiary Guarantors shall promptly pay the same, without any demand or notice whatsoever, and that in the case of any extension of time of payment or renewal of any of the Guaranteed Obligations, the same shall be promptly paid in full when due (whether at extended maturity, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

13.02 Obligations Unconditional. The obligations of the Subsidiary Guarantors under **Section 13.01** are absolute and unconditional, joint and several, irrespective of the value, genuineness, validity, regularity or enforceability of the obligations of the Borrower or any other Subsidiary Guarantor under this Agreement or any other agreement or instrument referred to herein, or any substitution, release or exchange of any other guarantee of or security for any of the Guaranteed Obligations, and, to the fullest extent permitted by all applicable Laws, irrespective of any other circumstance whatsoever that might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor, it being the intent of this **Section 13.02** that the obligations of the Subsidiary Guarantors hereunder shall be absolute and unconditional, joint and several, under any and all circumstances. Without limiting the generality of the foregoing, it is agreed that the occurrence of any one or more of the following shall not alter or impair the liability of the Subsidiary Guarantors hereunder, which shall remain absolute and unconditional as described above:

(a) at any time or from time to time, without notice to the Subsidiary Guarantors, the time for any performance of or compliance with any of the Guaranteed Obligations shall be extended, or such performance or compliance shall be waived;

(b) any of the acts mentioned in any of the provisions of this Agreement or any other agreement or instrument referred to herein shall be done or omitted;

(c) the maturity of any of the Guaranteed Obligations shall be accelerated, or any of the Guaranteed Obligations shall be modified, supplemented or amended in any respect, or any right under this Agreement or any other agreement or instrument referred to herein shall be waived or any other guarantee of any of the Guaranteed Obligations or any security therefor shall be released or exchanged in whole or in part or otherwise dealt with; or

(d) any lien or security interest granted to, or in favor of, the Secured Parties as security for any of the Guaranteed Obligations shall fail to be perfected.

The Subsidiary Guarantors hereby expressly waive diligence, presentment, demand of payment, protest and all notices whatsoever, and any requirement that the Administrative Agent or any Lender exhaust any right, power or remedy or proceed against the Borrower or any other Subsidiary Guarantor under this Agreement or any other agreement or instrument referred to herein, or against any other Person under any other guarantee of, or security for, any of the Guaranteed Obligations.

13.03 Reinstatement. The obligations of the Subsidiary Guarantors under this **Section 13** shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of the Borrower in respect of the Guaranteed Obligations is rescinded or must be otherwise restored

by any holder of any of the Guaranteed Obligations, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, and the Subsidiary Guarantors jointly and severally agree that they shall indemnify the Secured Parties on demand for all reasonable costs and expenses (including reasonable and documented fees of counsel) properly incurred by such Persons in connection with such rescission or restoration, including any such costs and expenses properly incurred in defending against any claim alleging that such payment constituted a preference, fraudulent transfer or similar payment under any bankruptcy, insolvency or similar law.

13.04 Subrogation. The Subsidiary Guarantors hereby jointly and severally agree that, until the payment and satisfaction in full in cash of all Guaranteed Obligations (other than contingent obligations for which no Claim has been asserted) and the expiration and termination of the Commitments, they shall not exercise any right or remedy arising by reason of any performance by them of their guarantee in **Section 13.01**, whether by subrogation or otherwise, against the Borrower or any other guarantor of any of the Guaranteed Obligations or any security for any of the Guaranteed Obligations.

13.05 Remedies. The Subsidiary Guarantors jointly and severally agree that, as between the Subsidiary Guarantors, on one hand, and the Administrative Agent and the Lenders, on the other hand, the obligations of the Borrower under this Agreement and under the other Loan Documents may be declared to be forthwith due and payable as provided in **Section 11** (and shall be deemed to have become automatically due and payable in the circumstances provided in **Section 11**) for purposes of **Section 13.01** notwithstanding any stay, injunction or other prohibition preventing such declaration (or such obligations from becoming automatically due and payable) as against the Borrower and that, in the event of such declaration (or such obligations being deemed to have become automatically due and payable), such obligations (whether or not due and payable by the Borrower) shall forthwith become due and payable by the Subsidiary Guarantors for purposes of **Section 13.01**.

13.06 Instrument for the Payment of Money. Each Subsidiary Guarantor hereby acknowledges that the guarantee in this **Section 13** constitutes an instrument for the payment of money, and consents and agrees that the Administrative Agent and the Lenders, at their sole option, in the event of a dispute by such Subsidiary Guarantor in the payment of any moneys due hereunder, shall have the right to proceed by motion for summary judgment in lieu of complaint pursuant to N.Y. Civ. Prac. L&R § 3213.

13.07 Continuing Guarantee. The guarantee in this **Section 13** is a continuing guarantee, and shall apply to all Guaranteed Obligations whenever arising.

13.08 General Limitation on Guarantee Obligations. (a) In any action or proceeding involving any provincial, territorial or state corporate Law, or any state or federal bankruptcy, insolvency, reorganization or other Law affecting the rights of creditors generally, if the obligations of any Subsidiary Guarantor under **Section 13.01** would otherwise be held or determined to be void, invalid or unenforceable, or subordinated to the claims of any other creditors, on account of the amount of its liability under **Section 13.01**, then, notwithstanding any other provision hereof to the contrary, the amount of such liability shall, without any further action by such Subsidiary

Guarantor, the Administrative Agent, any Lender or any other Person, be automatically limited and reduced to the highest amount that is valid and enforceable and not subordinated to the claims of other creditors as determined in such action or proceeding; and (b) notwithstanding anything to the contrary in this Agreement, the obligations, liabilities and undertakings under this Agreement (including in the guarantee in this section 13) shall not be deemed to be undertaken or incurred by an Irish Subsidiary Guarantor to the extent that the same would constitute unlawful financial assistance prohibited by Section 82 of the Irish Companies Act (or any analogous provision of any other applicable Law).

SECTION 14
MISCELLANEOUS

14.01 No Waiver. No failure on the part of the Administrative Agent or the Lenders to exercise and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under any Loan Document shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under any Loan Document preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The remedies provided herein are cumulative and not exclusive of any remedies provided by Law.

14.02 Notices. All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Agreement) or in the other Loan Documents shall be given or made in writing (including by telecopy or email) delivered, if to the Borrower, another Obligor, the Administrative Agent or any Lender, to its address specified on the signature pages hereto or its Guarantee Assumption Agreement, as the case may be, or at such other address as shall be designated by such party in a written notice to the other parties. Except as otherwise provided in this Agreement or therein, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof, in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication). Notwithstanding anything to the contrary in this Agreement or any other Loan Document, notices, documents, certificates and other deliverables to the Lenders by any Obligor may be made solely to the Administrative Agent and the Administrative Agent shall promptly deliver such notices, documents, certificates and other deliverables to the Lenders.

14.03 Expenses, Indemnification, Etc.

(a) **Expenses**. Borrower agrees to pay or reimburse (i) the Administrative Agent and the Lenders for all of their reasonable and documented out of pocket costs and expenses (including the reasonable and documented fees and expenses of Morrison & Foerster LLP, counsel to the Administrative Agent, and printing, reproduction, document delivery, communication and travel costs) in connection with (x) the negotiation, preparation, execution and delivery of this Agreement and the other Loan Documents and the making of the Loans (exclusive of post-closing costs), (y) post-closing costs and expenses (including in connection with any amendments, consents, waivers or other modifications, if any) and (z) the negotiation or preparation of any modification, supplement or waiver of any of the terms of this Agreement or any of the other Loan Documents (whether or not consummated) and (ii) the Administrative Agent and the Lenders for

all of their reasonable and documented out of pocket costs and expenses (including the reasonable and documented out of pocket fees and expenses of legal counsel) in connection with any enforcement or collection proceedings resulting from the occurrence of an Event of Default.

(b) **Exculpation, Indemnification, etc.**

(i) In no event shall any party hereto, any successor, transferee or assignee of any party hereto, or any of their respective Affiliates, directors, officers, employees, attorneys, agents, advisors or controlling parties (each, an "***Exculpated Party***") have any obligation or responsibility for (and the Obligors and the Secured Parties, as applicable, jointly and severally waive any claims they may have in respect of) any Loss, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or any of the Transactions or the actual or proposed use of the proceeds of the Loans; provided that, nothing in this **clause (i)** shall relieve any Obligor of any obligation such Obligor may have to indemnify an Indemnified Party, as provided in **clause (ii)** below, against any special, indirect, consequential or punitive damages asserted against such Indemnified Party by a third party. Each party hereto agrees, to the fullest extent permitted by applicable Law, that it will not assert, directly or indirectly, any Claim against any Exculpated Party with respect to any of the foregoing.

(c) Each Obligor, jointly and severally, hereby indemnifies the Administrative Agent, each Lender, each of their respective permitted successors, transferees and assigns and each of their respective Affiliates, directors, officers, employees, attorneys, agents, advisors and controlling parties (each, an "***Indemnified Party***") from and against, and agrees to hold them harmless against, any and all Claims and Losses of any kind (including reasonable fees and disbursements of counsel), joint or several, that may be incurred by or asserted or awarded against any Indemnified Party, in each case arising out of or in connection with or relating to any investigation, litigation or proceeding (each, a "***Proceeding***") or the preparation of any defense with respect thereto arising out of or in connection with or relating to this Agreement or any of the other Loan Documents or the Transactions or any use made or proposed to be made with the proceeds of the Loans, whether or not such Proceeding is brought by any Obligor, any of its Subsidiaries, any of its shareholders or creditors, an Indemnified Party or any other Person, or an Indemnified Party is otherwise a party thereto, and whether or not any of the conditions precedent set forth in **Section 6** are satisfied or the other transactions contemplated by this Agreement are consummated, except to the extent such Claim or Loss is found in a final, non-appealable judgment by a court of competent jurisdiction to have resulted from such Indemnified Party's gross negligence or willful misconduct. No Obligor shall assert any Claim against any Indemnified Party, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or any of the Transactions or the actual or proposed use of the proceeds of the Loans. This **Section 14.03(b)** shall not apply with respect to Taxes other than any Taxes that represent Losses arising from any non-Tax Claim.

14.04 Amendments, Etc. Except as otherwise expressly provided in this Agreement, any provision of this Agreement and any other Loan Document may be modified or supplemented only by an instrument in writing signed by the Borrower, the Administrative Agent and the Majority Lenders; provided that:

(a) any such modification or supplement that is disproportionately adverse to any Lender as compared to other Lenders or subjects any Lender to any additional obligation shall not be effective without the consent of such affected Lender;

(b) the consent of all of the Lenders shall be required to:

(i) amend, modify, discharge, terminate or waive any of the terms of this Agreement or any other Loan Document if such amendment, modification, discharge, termination or waiver would increase the amount of the Loans or any Commitment;

(ii) postpone or delay any date fixed for, or reduce or waive, any scheduled installment of principal or any payment of interest, fees or other amounts (other than principal) due to the Lenders;

(iii) reduce the principal of, or the rate of interest specified herein (it being agreed that waiver of the default interest shall only require the consent of Majority Lenders) or the amount of interest payable in cash specified herein on any Loan, or of any fees or other amounts payable hereunder or under any other Loan Document;

(iv) amend or waive compliance with the conditions precedent to the obligations of Lenders to make Loans in **Section 6**;

(v) amend, modify, discharge, terminate or waive any Security Document if the effect is to discharge the Borrower or any Subsidiary from their respective Obligations, or release a material part of the Collateral, in each case other than pursuant to the terms of hereof and thereof; or

(vi) amend this **Section 14.04** or the definition of "**Majority Lenders**".

(c) if the Administrative Agent and the Borrower shall have jointly identified an obvious error or any error or omission of a technical nature, in each case, in any provision of the Loan Documents, then the Administrative Agent and the Borrower shall be permitted to amend such provision, and, in each case, such amendment shall become effective without any further action or consent of any other party to any Loan Document if the same is not objected to in writing by the Majority Lenders to the Administrative Agent within ten (10) Business Days following receipt of notice thereof.

14.05 Successors and Assigns.

(a) **General**. The provisions of this Agreement and the other Loan Documents shall be binding upon and shall inure to the benefit of the parties hereto or thereto and their respective successors and assigns permitted hereby or thereby, except that no Obligor may assign or otherwise transfer any of its rights or obligations hereunder without the prior written consent of the Administrative Agent. Any Lender may assign or otherwise transfer any of its rights or obligations hereunder or under any of the other Loan Documents (i) to an assignee in accordance with the provisions of **Section 14.05(b)**, (ii) by way of participation in accordance with the provisions of **Section 14.05(e)**, or (iii) by way of pledge or assignment of a security interest subject to the restrictions of **Section 14.05(h)**. Nothing in this Agreement, expressed or implied, shall be

construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby, Participants to the extent provided in **Section 14.05(f)** and, to the extent expressly contemplated hereby, the Related Parties of each of the Administrative Agent and the Lenders) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) **Assignments by Lender**. Any Lender may at any time assign to one or more Eligible Transferees that is a UK Qualifying Lender (or, if an Event of Default has occurred and is continuing, to any Person) all or a portion of its rights and obligations under this Agreement (including all or a portion of the Loans at the time owing to it) and the other Loan Documents; provided that (i) no such assignment shall be made to any Obligor, any Affiliate of any Obligor, or any employees or directors of any Obligor at any time, (ii) no such assignment shall be made without the prior written consent of the Administrative Agent, and (iii) so long as no Event of Default shall have occurred and is continuing, no such assignment shall be made without the prior written consent of the Borrower (such consents not to be unreasonably withheld, delayed or conditioned) to a Disqualified Institution; provided that the Borrower shall be deemed to have consented to any such assignment unless it shall object thereto by written notice to the Administrative Agent within five (5) Business Days after having received notice thereof. Subject to the recording thereof by the Lender pursuant to **Section 14.05(d)**, from and after the effective date specified in each Assignment and Assumption, the assignee thereunder shall be a party to this Agreement and, to the extent of the interest assigned by such Assignment and Assumption, have the rights and obligations of the Lender under this Agreement and the other Loan Documents, and correspondingly the assigning Lender shall, to the extent of the interest assigned by such Assignment and Assumption, be released from its obligations under this Agreement (and, in the case of an Assignment and Assumption covering all of the Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) and the other Loan Documents but shall continue to be entitled to the benefits of **Section 5** and **Section 14.03**. Any assignment or transfer by the Lender of rights or obligations under this Agreement that does not comply with this **Section 14.05(b)** shall be treated for purposes of this Agreement as a sale by such Lender of a participation in such rights and obligations in accordance with **Section 14.05(e)**.

(c) **Amendments to Loan Documents**. Each of the Administrative Agent, the Lenders, the Borrower and its Subsidiaries agrees to enter into such amendments to the Loan Documents, and such additional Security Documents and other instruments and agreements, in each case in form and substance reasonably acceptable to the Administrative Agent, the Lenders the Borrower and its Subsidiaries, as shall reasonably be necessary to implement and give effect to any assignment made under this **Section 14.05**.

(d) **Register**. The Administrative Agent, acting solely for this purpose as a non-fiduciary agent of the Borrower, shall maintain at one of its offices in the United States a copy of each Assignment and Assumption delivered to it and a register for the recordation of the names and addresses of the Lenders, and the Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "**Register**"). The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Administrative Agent and the Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.

(e) **Participations**. Any Lender may at any time, without the consent of, or notice to, the Borrower, sell participations to any Person (other than a Disqualified Institution (so long as no Event of Default shall have occurred and is continuing), natural person or any Obligor or any of its Subsidiaries or Affiliates) (each, a "***Participant***") in all or a portion of the Lender's rights and/or obligations under this Agreement (including all or a portion of the Commitment and/or the Loans owing to it); provided that (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of such obligations and (iii) the Borrower shall continue to deal solely and directly with such Lender in connection therewith. Any agreement or instrument pursuant to which any Lender sells such a participation shall provide that such Lender shall retain the sole right to enforce the Loan Documents and to approve any amendment, modification or waiver of any provision of the Loan Documents; provided that such agreement or instrument may provide that such Lender shall not, without the consent of the Participant, agree to any amendment, modification or waiver that would (i) increase or extend the term of such Lender's Commitment, (ii) extend the date fixed for the payment of principal of or interest on the Loans or any portion of any fee hereunder payable to the Participant, (iii) reduce the amount of any such payment of principal, or (iv) reduce the rate at which interest is payable thereon to a level below the rate at which the Participant is entitled to receive such interest. Subject to **Section 14.05(f)**, the Borrower agrees that each Participant shall be entitled to the benefits of **Section 5** (subject to the requirements and limitations therein including the requirements under **Section 5.03(f)** (it being understood that the documentation required under **Section 5.03(f)** shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to **Section 14.05(b)**; provided that such Participant agrees to be subject to the provisions of **Section 5.03(h)** as if it were an assignee under **Section 14.05(b)** above. To the extent permitted by applicable Law, each Participant also shall be entitled to the benefits of **Section 4.03(a)** as though it were a Lender.

(f) **Limitations on Rights of Participants**. A Participant shall not be entitled to receive any greater payment under **Sections 5.01** or **5.03** than such Lender would have been entitled to receive with respect to the participation sold to such Participant, except to the extent such entitlement to receive a greater payment results from a Change in Law that occurs after the Participant acquired the applicable participation.

(g) **Participant Register**. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of the Borrower, maintain a register on which it enters the name and address of each Participant and the principal amounts (and stated interest) of each Participant's interest in the Loans or other Obligations under the Loan Documents (the "***Participant Register***"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any Participant or any information relating to a Participant's interest in any Commitments, Loans, or its other Obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such Commitment, Loan, or other Obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, the Administrative Agent (in its capacity as Administrative Agent) shall have no responsibility for maintaining a Participant Register.

(h) **Certain Pledges**. Any Lender may at any time pledge or assign a security interest in all or any portion of its rights under the Loan Documents to secure obligations of such Lender, including any pledge or assignment to secure obligations to a Federal Reserve Bank; provided that no such pledge or assignment shall release such Lender from any of its obligations hereunder or substitute any such pledgee or assignee for such Lender as a party hereto.

14.06 Survival. The obligations of the Borrower under **Sections 5.01**, **5.02**, **5.03**, **14.03**, **14.05**, **14.06**, **14.09**, **14.10**, **14.11**, **14.12**, **14.13**, **14.14** and the obligations of the Subsidiary Guarantors under **Section 13** (solely to the extent guaranteeing any of the obligations under the foregoing Sections) shall survive the repayment of the Obligations and the termination of the Commitment and, in the case of the Lenders' assignment of any interest in the Commitment or the Loans hereunder, shall survive, in the case of any event or circumstance that occurred prior to the effective date of such assignment, the making of such assignment, notwithstanding that the Lenders may cease to be "Lenders" hereunder. In addition, each representation and warranty made, or deemed to be made by a Borrowing Notice, herein or pursuant hereto shall survive the making of such representation and warranty.

14.07 Captions. The table of contents and captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Agreement.

14.08 Counterparts; Electronic Signatures. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Agreement by signing any such counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or electronic transmission (in PDF format) shall be effective as delivery of a manually executed counterpart hereof. Any signature (including, without limitation, (x) any electronic symbol or process attached to, or associated with, a contract or other record and adopted by a Person with the intent to sign, authenticate or accept such contract or record and (y) any facsimile or .pdf signature) hereto or to any other certificate, agreement or document related to this Agreement, and any contract formation or record-keeping, in each case, through electronic means, shall have the same legal validity and enforceability as a manually executed signature or use of a paper-based record-keeping system to the fullest extent permitted by applicable Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any similar state law based on the Uniform Electronic Transactions Act, and the parties hereto hereby waive any objection to the contrary. Each party hereby consents to the execution of this Agreement by way of electronic signature.

14.09 Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; provided that Section 5-1401 of the New York General Obligations Law shall apply.

14.10 Jurisdiction, Service of Process and Venue.

(a) **Submission to Jurisdiction**. Each Obligor agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or

any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in New York, New York and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 14.10(a)** is for the benefit of the Administrative Agent and the Lenders only and, as a result, no Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by any applicable Law, the Lenders may take concurrent proceedings in any number of jurisdictions.

(b) **Alternative Process**. Nothing herein shall in any way be deemed to limit the ability of the Administrative Agent and the Lenders to serve any process or summons in any manner permitted by any applicable Law.

(c) **Waiver of Venue, Etc**. Each Obligor irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Agreement or any other Loan Document and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which such Obligor is or may be subject, by suit upon judgment.

14.11 Waiver of Jury Trial. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE OTHER LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

14.12 Waiver of Immunity. To the extent that any Obligor may be or become entitled to claim for itself or its property or revenues any immunity on the ground of sovereignty or the like from suit, court jurisdiction, attachment prior to judgment, attachment in aid of execution of a judgment or execution of a judgment, and to the extent that in any such jurisdiction there may be attributed such an immunity (whether or not claimed), such Obligor hereby irrevocably agrees not to claim and hereby irrevocably waives such immunity with respect to its obligations under this Agreement and the other Loan Documents.

14.13 Entire Agreement. This Agreement and the other Loan Documents constitute the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof, including (a) any confidentiality (or similar) agreements and (b) the Proposal Letter. EACH OBLIGOR ACKNOWLEDGES, REPRESENTS AND WARRANTS THAT IN DECIDING TO ENTER INTO THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS OR IN TAKING OR NOT TAKING ANY ACTION HEREUNDER OR THEREUNDER, IT HAS NOT RELIED, AND SHALL NOT RELY, ON ANY STATEMENT, REPRESENTATION, WARRANTY, COVENANT, AGREEMENT OR UNDERSTANDING, WHETHER WRITTEN OR ORAL, OF OR WITH ADMINISTRATIVE AGENT OR THE LENDERS OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS.

14.14 Severability. If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by any applicable Law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof.

14.15 No Fiduciary Relationship. The Borrower acknowledges that the Administrative Agent and the Lenders have no fiduciary relationship with, or fiduciary duty to, the Borrower arising out of or in connection with this Agreement or the other Loan Documents, and the relationship between the Lenders and the Borrower is solely that of creditor and debtor. This Agreement and the other Loan Documents do not create a joint venture among the parties.

14.16 Confidentiality. The Administrative Agent and each Lender agree to keep confidential all non-public and other confidential information provided to them in writing by any Obligor pursuant to this Agreement that is designated by such Obligor as confidential in accordance with its customary procedures for handling its own confidential information; provided that nothing herein shall prevent the Administrative Agent or any Lender from disclosing any such information (i) subject to an agreement to comply with the provisions of this Section, to the Administrative Agent, any other Lender, any Affiliate of a Lender or any Eligible Transferee or other assignee permitted under **Section 14.05(b)**, (ii) subject to an agreement to comply with the provisions of this Section, to any actual or prospective direct or indirect counterparty to any Hedging Agreement (or any professional advisor to such counterparty), (iii) to its employees, officers, directors, agents, attorneys, accountants, trustees and other professional advisors or those of any of its affiliates (collectively, its "***Related Parties***"); provided that such Related Parties are subject to obligations of confidentiality at least as restrictive as set forth in this **Section 14.16**, and the applicable Lender shall remain liable hereunder for any breach of this Section 14.16 by any of its Related Parties, (iv) upon the request or demand of any Governmental Authority or any Governmental Authority having jurisdiction over such Person or its Related Parties (including any self-regulatory authority, such as the National Association of Insurance Commissioners), (v) in response to any order of any court or other Governmental Authority or as may otherwise be required pursuant to any applicable Law, (vi) if requested or required to do so in connection with any litigation or similar proceeding; provided that, unless otherwise prohibited by applicable Law, court order or decree, the Administrative Agent and each Lender, as applicable, shall provide prior notice to the Obligor to allow such Obligor an opportunity to obtain a protective order, (vii) that has been publicly disclosed (other than as a result of a disclosure in violation of this **Section 14.16**), (viii) to the National Association of Insurance Commissioners or any similar organization or any nationally recognized rating agency that requires access to information about a Lender's investment portfolio in connection with ratings issued with respect to such Lender, (ix) in connection with the exercise of any remedy permitted hereunder or under any other Loan Document, (x) on a confidential basis to (A) any rating agency in connection with rating the Borrower or any of its Subsidiaries or the Loans or (B) the CUSIP Service Bureau or any similar agency in connection with the issuance and monitoring of CUSIP numbers of other market identifiers with respect to the Loans or (xi) to any other party hereto.

14.17 Interest Rate Limitation. Notwithstanding anything herein to the contrary, if at any time the interest rate applicable to any Loan, together with all fees, charges and other amounts that are treated as interest on such Loan under applicable Law (collectively, "***charges***"), shall exceed the maximum lawful rate (the "***Maximum Rate***") that may be contracted for, charged, taken, received or reserved by the Administrative Agent and the Lender holding such Loan in accordance with

applicable Law, the rate of interest payable in respect of such Loan hereunder, together with all charges payable in respect thereof, shall be limited to the Maximum Rate. To the extent lawful, the interest and charges that would have been paid in respect of such Loan but were not paid as a result of the operation of this Section shall be cumulated and the interest and charges payable to such Lender in respect of other Loans or periods shall be increased (but not above the amount collectible at the Maximum Rate therefor) until such cumulated amount, together with interest thereon at the Federal Funds Effective Rate for each day to the date of repayment, shall have been received by such Lender. Any amount collected by such Lender that exceeds the maximum amount collectible at the Maximum Rate shall be applied to the reduction of the principal balance of such Loan so that at no time shall the interest and charges paid or payable in respect of such Loan exceed the maximum amount collectible at the Maximum Rate.

14.18 Early Prepayment Fee. The parties hereto acknowledge and agree that, to the extent the Early Prepayment Fee is applicable to any repayment or prepayment of principal of any Loan at any time, such Early Prepayment Fee is not intended to be a penalty assessed as a result of any such repayment or prepayment of the Loans, but rather is the product of a good faith, arm's length commercial negotiation between the Borrower and the Lenders relating to the mutually satisfactory compensation payable to the Lenders by the Borrower in respect of the Loans made hereunder. In furtherance of the foregoing, to the fullest extent permitted by applicable Law, the Obligors hereby jointly and severally waive any rights or Claims any of them may have under any such applicable Law (whether or not in effect on the Closing Date) that would prohibit or restrict the payment of the Early Prepayment Fee under any of the circumstances provided herein or in any other Loan Document, including payment after acceleration of the Loans.

14.19 Judgment Currency.

(a) If, for the purposes of obtaining judgment in any court, it is necessary to convert a sum due hereunder in Dollars into another currency, the parties hereto agree, to the fullest extent permitted by Law, that the rate of exchange used shall be that at which, in accordance with normal banking procedures, the Administrative Agent could purchase Dollars with such other currency at the buying spot rate of exchange in the New York foreign exchange market on the Business Day immediately preceding that on which any such judgment, or any relevant part thereof, is given.

(b) The obligations of the Obligors in respect of any sum due to the Administrative Agent hereunder and under the other Loan Documents shall, notwithstanding any judgment in a currency other than Dollars, be discharged only to the extent that on the Business Day following receipt by the Administrative Agent of any sum adjudged to be so due in such other currency the Administrative Agent may, in accordance with normal banking procedures, purchase Dollars with such other currency. If the amount of Dollars so purchased is less than the sum originally due to the Administrative Agent in Dollars, the Borrower agrees, to the fullest extent that it may effectively do so, as a separate obligation and notwithstanding any such judgment, to indemnify the Administrative Agent against such loss. If the amount of Dollars so purchased exceeds the sum originally due to the Administrative Agent in Dollars, the Administrative Agent shall remit such excess to the Borrower.

14.20 USA PATRIOT Act. The Administrative Agent and the Lenders hereby notify the Obligors that pursuant to the requirements of the USA PATRIOT Act (Title III of Pub. L. 107-56

(signed into law October 26, 2001)) (the "***Patriot Act***"), they are required to obtain, verify and record information that identifies the Obligors, which information includes the name and address of each Obligor and other information that will allow such Person to identify such Obligor in accordance with the Patriot Act.

14.21 Acknowledgement and Consent to Bail-In of Affected Financial Institutions. Notwithstanding anything to the contrary in any Loan Document or in any other agreement, arrangement or understanding among any such parties, each party hereto acknowledges that any liability of any Affected Financial Institution arising under any Loan Document, to the extent such liability is unsecured, may be subject to the Write-Down and Conversion Powers of the applicable Resolution Authority and agrees and consents to, and acknowledges and agrees to be bound by:

(a) the application of any Write-Down and Conversion Powers by the applicable Resolution Authority to any such liabilities arising hereunder which may be payable to it by any party hereto that is an EEA Financial Institution; and

(b) the effects of any Bail-In Action on any such liability, including, if applicable:

(i) a reduction in full or in part or cancellation of any such liability;

(ii) a conversion of all, or a portion of, such liability into shares or other instruments of ownership in such Affected Financial Institution, its parent undertaking, or a bridge institution that may be issued to it or otherwise conferred on it, and that such shares or other instruments of ownership will be accepted by it in lieu of any rights with respect to any such liability under this Agreement or any other Loan Document; or

(iii) the variation of the terms of such liability in connection with the exercise of the Write-Down and Conversion Powers of the applicable Resolution Authority.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered as of the day and year first above written.

BORROWER:

MEIRAGTX HOLDINGS PLC

By /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

Address for Notices:

[***]

SUBSIDIARY GUARANTORS:

MEIRAGTX UK II LIMITED

By /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

Address for Notices:

[***]

MEIRAGTX IRELAND DAC

By /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

Address for Notices:

[***]

ADMINISTRATIVE AGENT:

PERCEPTIVE CREDIT HOLDINGS III, LP

By: PERCEPTIVE CREDIT OPPORTUNITIES GP, LLC, its general partner

By /s/ Sandeep Dixit
Name: Sandeep Dixit
Title: Chief Credit Officer

By /s/ Sam Chawla
Name: Sam Chawla
Title: Portfolio Manager

Address for Notices:

[***]

LENDERS:

PERCEPTIVE CREDIT HOLDINGS III, LP

By: PERCEPTIVE CREDIT OPPORTUNITIES GP, LLC, its general partner

By /s/ Sandeep Dixit
Name: Sandeep Dixit
Title: Chief Credit Officer

By /s/ Sam Chawla
Name: Sam Chawla
Title: Portfolio Manager

Address for Notices:

[***]

Exhibit 31.1

CERTIFICATION

I, Alexandria Forbes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 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: November 10, 2022

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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 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: November 10, 2022

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 Quarterly Report of MeiraGTx Holdings plc (the "Company") on Form 10-Q for the quarterly period ended September 30, 2022 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: November 10, 2022

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 Quarterly Report of MeiraGTx Holdings plc (the "Company") on Form 10-Q for the quarterly period ended September 30, 2022 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: November 10, 2022

By: /s/ Richard Giroux

Richard Giroux
Chief Financial Officer and Chief Operating Officer
(principal financial officer)