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

FORM 8-K

**Current Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **March 14, 2024**

MeiraGTx Holdings plc

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction of incorporation or
organization)

001-38520
(Commission File Number)

98-1448305
(I.R.S. Employer Identification No.)

**450 East 29th Street, 14th Floor
New York, NY 10016**
(Address of principal executive offices) (Zip code)

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

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, \$0.0003881 par value per share	MGTX	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On March 14, 2024, MeiraGTx Holdings plc (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2023. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of MeiraGTx Holdings plc, dated March 14, 2024.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document).

SIGNATURE

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 hereunto duly authorized.

Date: March 14, 2024

MEIRAGTX HOLDINGS PLC

By: /s/ Richard Giroux
Name: Richard Giroux
Title: Chief Financial Officer and Chief Operating Officer

MeiraGTx Reports Fourth Quarter and Full Year 2023 Financial and Operational Results and Recent Business Updates

- *Company aligned with FDA on requirements for ongoing Phase 2 AQUAx2 clinical trial for Grade 2/3 radiation-induced xerostomia to be considered pivotal supporting potential BLA filing*
- *Company to present data from the Phase 1 AQUAx study in an oral presentation at the American Academy of Oral Medicine 2024 annual meeting (AAOM) April 17-20, 2024*
- *Completed dosing the three-arm randomized, sham-controlled Phase 1 clinical bridging study for AAV-GAD for the treatment of Parkinson's disease*
- *Company to present positive data on AAV-AIPL1 treatment of 8 LCA4 patients each with meaningful responses in second quarter 2024*
- *Entered into an asset purchase agreement with Janssen Pharmaceuticals, Inc. (Janssen) related to botaretigene sparoparvovec (bota-vec, formerly AAV-RPGR) for the treatment of X-linked retinitis pigmentosa (XLRP) for up to \$415 million, as well as a commercial supply agreement pursuant to which the Company will manufacture and supply bota-vec to Janssen*
- *Received \$30 million strategic investment from Sanofi and entered into a right of first negotiation (ROFN) agreement for the use of MeiraGTx's riboswitch gene regulation technology for certain Central Nervous System (CNS) and Immunology and Inflammation (I&I) targets, as well as for GLP-1 and other gut peptides for metabolic disease, and for MeiraGTx's Phase 2 xerostomia program*

LONDON and NEW YORK, March 14, 2024 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial and operational results for the fourth quarter and full-year ended December 31, 2023, and provided a corporate update.

“We are very pleased with the progress made at MeiraGTx in the past year across every area of the company, as well as the two transactions that we executed in the fourth quarter of 2023, bolstering our balance sheet. We advanced each of our three lead clinical programs, and we now have three studies in late-stage clinical development. For our program for radiation-induced xerostomia, we presented unprecedented positive data from our Phase 1 AQUAx study in June 2023; we opened the Phase 2 AQUAx2 study mid-year 2023, a randomized, double-blind placebo-controlled study of AAV-hAQP1, and last month we aligned with the FDA on the requirements for this Phase 2 study to be pivotal supporting a potential BLA. This is a



completely transformative treatment for this large addressable patient population, and we are excited to have the opportunity to expedite the development of this therapy for these patients who currently have no options for treatment. In addition, the data from our Phase 1 AQUAx study will be presented at an oral session at AAOM next month,” said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx.

Dr. Forbes continued, “In the area of ophthalmology, in the third quarter of 2023, we completed enrollment in the large multi-center Phase 3 study of bota-vec for XLRP-RPGR in collaboration with Janssen. Data from this global pivotal study is expected after the third quarter of 2024. Additionally, in the retinal disease space, we recently received data from our ongoing compassionate use program under a Specials License for children with LCA4 due to mutations in the *AIP1* gene. MeiraGTx developed and optimized the AAV-AIP1 vector and manufactured it in-house at our London facility, which we believe is the only viral vector manufacturing facility with a Specials License under the UK Medicines and Healthcare products Regulatory Agency (MHRA) regulations. Manufacturing at our site under the Specials License allows this material to be supplied and delivered to patients at UK hospitals, with 8 LCA4 children ages 1 to 3 years old having been treated to date. The responses seen in each of these children have been remarkable, and we are now moving forward with regulators to expedite access to this transformative treatment to patients globally.”

Professor Michel Michaelides, Consultant Ophthalmologist at Moorfields Eye Hospital (MEH) in the Departments of Inherited Eye Disease, Medical Retina, and Paediatric Ophthalmology involved in the treatment of these LCA4 children said, “The improvements in vision have been incredible. Children with *AIP1*-LCA are legally blind from birth, generally with light perception only. Of the 8 children who have received treatment to date, all 8 have developed vision-guided behaviour with recordable visual acuities - something that never happens during the natural history of this inexorably progressive disease. Improvements of this magnitude, in one of the severest congenital onset retinal dystrophies, are life changing.”

Dr. Forbes continued, “In addition, we have completed the bridging safety study of our AAV-GAD product candidate for Parkinson’s disease, allowing us to move forward towards a pivotal study in patients who no longer respond adequately to dopamine. All of our clinical programs are supported by our leading end-to-end manufacturing capabilities and infrastructure. We have internalized plasmid production, we have two flexible, scalable viral vector production facilities fit for commercial supply, and a QC testing facility which has now received both commercial and clinical licenses from the Irish Health Products Regulatory Authority (HPRA). We have manufactured multiple capsids and vector genomes using our proprietary platform process with both yield and full ratios at the top end of published industry standards. We have had iterative feedback from the FDA and 15 other global regulators on our manufacturing capabilities for commercial supply and as a result, we are in a position to now initiate INDs using material that is fit for commercial supply, therefore avoiding many years of potential development timeline delays. This reduces our development timelines and significantly reduces costs, decreasing risk and increasing the value of each of our programs. We also entered into a commercial manufacturing supply agreement for bota-vec with Janssen in the fourth quarter of 2023 and we continue to attract interest across the board in our CMC capabilities from potential strategic partners and collaborators.”

“Finally, we are most excited by the incredible progress we have made in moving our riboswitch gene regulation technology platform towards the clinic. We are focusing on two areas initially, cell therapy and metabolic disease, where our pre-clinical data *in vivo* has been quite remarkable. We look forward to presenting this data in an R&D day later this year. In the area of metabolic disease, we have successfully delivered multiple combinations of gut peptides *in vivo*, including GLP-1, GIP, PYY, Glucagon and Amylin, as well as novel peptides that drive muscle metabolism, via the riboswitch platform that allows daily dosing with a small molecule to activate physiologically relevant levels and combinations of peptides within the body. This provides a platform for addressing not just weight loss via reduced appetite but also muscle strength, fat metabolism and cardiovascular health in metabolic disease, with daily oral small molecules. This is one of the broad areas of interest in our Sanofi relationship which we entered into during the fourth quarter of 2023.”

Recent Development Highlights and Anticipated 2024 Milestones

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

Grade 2/3 radiation-induced xerostomia (RIX) is a severely debilitating consequence of radiation treatment for head and neck cancer that affects approximately 30-40% of all patients treated with radiation for head and neck cancer. This is a completely unmet need with no treatment options, and a large addressable market with over 170,000 patients currently in the U.S., and an additional 15,000 new patients in the U.S. each year. Treatment with AAV-hAQP1 involves a small dose locally delivered to the salivary gland via a non-invasive procedure, that can be delivered in a dental office or oncology center where these patients are seen at least annually following radiation treatment. The small local dose of AAV-hAQP1 manufactured in-house at MeiraGTx allows for a low cost of goods, and the potential long term durability and ease of delivery make this large addressable market a compelling commercial opportunity.

- The Company continues to enroll and dose participants at multiple sites in the U.S. and Canada in the AQUAx2 Phase 2 randomized, double-blind, placebo-controlled study.
- The Company aligned with FDA on requirements for the ongoing Phase 2 AQUAx2 clinical trial for Grade 2/3 radiation-induced xerostomia to be considered pivotal to support potential BLA filing.
- Received Clinical Trial Authorization approval from MHRA for AQUAx2 study in the UK.
- The Company will deliver an oral presentation of the Phase 1 AQUAx study at the American Academy of Oral Medicine 2024 annual meeting (AAOM) taking place from April 17-20, 2024.

Title: Results of a Phase 1, Open-label, Dose-escalation Study of Gene Therapy with AAV2-hAQP1 as Treatment for Grade 2 and 3 Radiation-induced Late Xerostomia and Parotid Gland Hypofunction

ID: 196

AAV-AIPL1 Specials License in UK:

LCA4 is an ultra rare and severe inherited retinal disease (IRD) resulting from mutations in the



aryl hydrocarbon receptor interacting protein-like 1 gene (*AIPPL1*). Children with LCA4 are blind from birth due to the absence of *AIPPL1*, a retinal photoreceptor-specific protein expressed in cones and rods. By the age of 4 years old, retinal degeneration is complete. MeiraGTx has developed AAV-AIPPL1 to deliver the *AIPPL1* gene to the retina of children with LCA4. This product candidate, manufactured at MeiraGTx's London facility, is available for treatment of children with LCA4 under a Specials License from the MHRA.

- MeiraGTx's AAV-AIPPL1 gene therapy has been made available at 3 different hospitals in the UK with 8 patients aged 1 to 3 years old treated to date via a Specials License under MHRA regulations.
- Meaningful responses have been observed in all 8 of the children treated to date.
- Given the positive results, the Company intends to use data produced under the Specials License to engage with regulatory agencies to enable MeiraGTx to make this intervention more widely available to the LCA4 patient population globally.
- MeiraGTx intends to host a webinar in the second quarter of 2024 to present the data from the LCA4 children treated with AAV-AIPPL1 to date.
- The Company's AAV-AIPPL1 for treatment of inherited retinal dystrophy due to defects in the *AIPPL1* gene has been granted orphan drug designation by the FDA and orphan designation by the European Commission.

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

Parkinson's is the second most common neurodegenerative disease after Alzheimer's with approximately 90,000 patients diagnosed annually in the U.S. Most Parkinson's patients respond to dopamine replacement therapy, however, after about 5 years even higher doses of dopamine no longer manage the motor symptoms of the disease, leaving little effective treatment for this large population of patients. One treatment that has efficacy in this patient population is deep brain stimulation (DBS), which requires multiple surgeries and in-dwelling hardware with onerous safety and tolerability issues. In contrast, MeiraGTx's gene therapy treatment for Parkinson's involves the delivery of a very small dose of AAV-GAD encoding the enzyme that converts the activating neurotransmitter glutamate to the calming neurotransmitter GABA, to the specific nucleus of the brain targeted by DBS. We have demonstrated that localized treatment with AAV-GAD leads to a change in circuitry to the motor cortex which results in alleviation of motor symptoms. This is a one-time treatment, involving no in-dwelling hardware or subsequent tuning, no off target side effects, and with a small dose of viral vector that has a low cost of goods.

- The Company has completed dosing patients in the AAV-GAD clinical trial under a new IND using material manufactured in its GMP facility in London, UK using MeiraGTx's proprietary production process.
 - The AAV-GAD trial is a three-arm, randomized, double-blind, sham-controlled Phase 1 clinical bridging study with subjects randomized to one of two doses of AAV-GAD or sham control.
 - 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.
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Riboswitch Gene Regulation Technology Platform:

MeiraGTx's riboswitch technology allows for repeatable, long-term delivery of any messenger RNA (mRNA) from the DNA template encoding any peptide or protein on stimulation by bespoke orally delivered small molecules.

- The Company continues to make significant progress in moving the first regulated mRNA and protein targets towards the clinic, initially focusing on two areas, cell therapy and metabolic disease.
- For obesity and metabolic disease, the Company has successfully delivered multiple combinations of gut peptides *in vivo* including GLP-1, GIP, PYY, Glucagon and Amylin, as well as novel peptides that drive muscle metabolism, via the riboswitch platform that allows daily dosing with a small molecule to activate physiologically relevant peptide combinations within the body. This provides a platform for addressing not just weight loss via reduced appetite, but also muscle strength, fat metabolism and cardiovascular health in metabolic disease, with daily oral small molecules.
- In CAR-T for both oncology and autoimmune disease, precise control of the CAR via the Company's riboswitch platform has demonstrated significant impact on CAR-T efficacy, with a 3-4 fold improvement in *in vivo* potency of cells with regulated CAR compared to the currently approved CAR-T with unregulated constitutively active CAR. In addition, MeiraGTx's regulated CAR-T display a normal naïve T-cell profile, lacking exhaustion markers and retaining proliferation and killing ability *in vitro* in contrast to CAR-T with unregulated constitutive CAR expression.
- The Company intends to present data from its riboswitch gene regulation technology platform at an R&D day in the second half of 2024.

Asset Purchase Agreement with Janssen:

- On December 20, 2023, MeiraGTx entered into an asset purchase agreement with Janssen related to bota-vec for the treatment of XLRP for a total of up to \$415 million; the agreement enabled the Company to receive \$130 million in near-term milestone payments, which included a \$65 million upfront payment that was received upon signing of the agreement.
- On February 13, 2024, MeiraGTx announced the achievement of the first near-term milestone payments under the asset purchase agreement with Janssen which triggered a \$50 million payment; MeiraGTx anticipates receiving the remaining \$15 million in near-term milestone payments later in 2024.
- The Company will receive up to a further \$285 million upon first commercial sales of bota-vec in the U.S. and EU, for manufacturing technology transfer and upon regulatory approval of a Janssen-selected manufacturing facility in each of the United States and European Union for commercial manufacture of bota-vec.
- MeiraGTx also entered into a commercial supply agreement with J&J for bota-vec manufacturing, which the Company anticipates will generate additional revenue upon product launch.

Strategic Investment from Sanofi:

- On October 30, 2023, Sanofi purchased \$30 million of ordinary shares of the Company at a price of \$7.50 per share.
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- Sanofi received a right of first negotiation (ROFN) for the use of MeiraGTx's riboswitch gene regulation technology for certain Central Nervous System (CNS) and Immunology and Inflammation (I&I) targets, including IL-4 and IL-13, as well as for GLP-1 and other gut peptides for obesity, and for MeiraGTx's Phase 2 xerostomia program.

End-to-End Manufacturing Infrastructure:

MeiraGTx has comprehensive end-to end-manufacturing capabilities with a commercial ready platform process and GMP-licensed manufacturing and QC facilities in both the UK and Ireland, comprising the following:

- Two flexible and scalable viral vector manufacturing facilities both fit for commercial production of viral vectors, one approximately 30,000 sq. ft. in London, UK, with the second approximately 150,000 sq. ft. in Shannon, Ireland.
- In-house plasmid production facility (Shannon) under the same quality systems as the GMP approved production and QC facilities. Plasmid produced in-house is therefore GMP grade as a starting material for GMP vector production.
- In-house QC facility (Shannon) for full stability and release of manufactured viral vectors, which received both a Commercial and Clinical license from the Irish HPRA in 2023.
- MSAT facility (London) for the development of our proprietary platform process for viral vector production, as well as development and validation of the QC assays required for viral vector release and stability. Over the past 8 years, our MSAT team have built immense data lakes of information supporting our platform process developed using multiple different capsids and vector genomes with both yield and full ratio at the top of the range published in the industry.
- As part of the Janssen transaction in the fourth quarter of 2023, MeiraGTx entered into a commercial supply agreement with Janssen for the manufacture of bota-vec.
- Our infrastructure, manufacturing and assay development capabilities and proprietary production process continues to attract the attention of potential strategic and manufacturing partners.

As of December 31, 2023, MeiraGTx had cash and cash equivalents of approximately \$129.6 million. In addition, the Company received a milestone payment of \$50.0 million in the first quarter of 2024 from Janssen in connection with the asset purchase agreement and expects to receive \$10.1 million from receivables which is expected to be collected in the first quarter of 2024 from Janssen in connection with the collaboration agreement. The Company believes that with such funds, as well as anticipated near-term milestones from Janssen under the asset purchase agreement, it will have sufficient capital to fund operating expenses and capital expenditure requirements into the first quarter of 2026. This estimate does not include the \$285.0 million in milestones the Company is eligible to receive under the asset purchase agreement upon first commercial sale of bota-vec in the United States and in at least one of the United Kingdom, France, Germany, Spain and Italy, for completion of the transfer of certain manufacturing technology to Janssen and upon regulatory approval of a Janssen-selected manufacturing facility in each of the United States and European Union for commercial manufacture of bota-vec.



For more information related to our clinical trials, please visit www.clinicaltrials.gov

Financial Results

Cash, cash equivalents and restricted cash were \$130.6 million as of December 31, 2023, compared to \$115.5 million as of December 31, 2022.

License revenue was \$14.0 million for the year ended December 31, 2023, compared to \$15.9 million for the year ended December 31, 2022. This decrease is a result of MeiraGTx recognizing the deferred revenue progress of the \$100.0 million upfront payment and the \$30.0 million milestone payment received in connection with the Janssen collaboration agreement through the termination date of the Janssen collaboration agreement on December 20, 2023.

General and administrative expenses were \$47.3 million for the year ended December 31, 2023, compared to \$46.6 million for the year ended December 31, 2022. The increase of \$0.7 million was primarily due to an increase in legal and accounting fees, payroll and payroll-related costs, share-based compensation and rent and facilities costs, which was partially offset by decreases in other general and administrative costs, insurance, consulting fees and depreciation.

Research and development expenses were \$103.8 million for the year ended December 31, 2023, compared to \$85.7 million for the year ended December 31, 2022. The increase of \$18.0 million was primarily due to an increase in clinical trial expenses primarily related to our bota-vec and AAV-hAQP1 programs, manufacturing costs, other research and development expenses and a decrease in research funding provided under the Janssen collaboration agreement. These increases were partially offset by decreases in expenses related to our preclinical programs primarily related to preclinical ocular diseases.

Foreign currency gain was \$9.3 million for the year ended December 31, 2023, compared to a loss of \$9.5 million for the year ended December 31, 2022. The change of \$18.8 million was primarily due to the strengthening of the U.S. dollar against the pound sterling and euro during the year ended December 31, 2023 as it relates to the valuation of our intercompany payables and receivables.

Interest income was \$2.3 million for the year ended December 31, 2023, compared to \$0.8 million for the year ended December 31, 2022. The increase was due to higher interest rates and cash balances during 2023.

Interest expense was \$13.2 million for the year ended December 31, 2023, compared to \$4.9 million for the year ended December 31, 2022. The increase was primarily due to the interest expense and amortization of the debt discount in connection with the Company's outstanding debt. Twelve months of interest was recorded during the year ended December 31, 2023 compared to five months of interest recorded during the year ended December 31, 2022.

Gain on sale of nonfinancial assets was \$54.2 million for the year ended December 31, 2023 compared to \$0 for the year ended December 31, 2022. This increase was a result of the recognition of the value allocated to the nonfinancial assets sold and assigned to Janssen including a License Agreement between the Company and UCL Business Plc (now UCL)



Business Ltd.) relating to the research, development, manufacture and exploitation of bota-vec, and other related assets pursuant to the asset purchase agreement, net of carrying value.

Net loss attributable to ordinary shareholders for the year ended December 31, 2023, was \$84.0 million, or \$1.49 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of \$129.6 million, or \$2.87 basic and diluted net loss per ordinary share for the year ended December 31, 2022.

About MeiraGTx

MeiraGTx (Nasdaq: MGTX) is a vertically integrated, clinical-stage gene therapy company with a broad pipeline of late-stage clinical programs supported by end-to-end manufacturing capabilities. MeiraGTx has an internally developed manufacturing platform process, internal plasmid production for GMP, two GMP viral vector production facilities as well as an in-house Quality Control hub for stability and release, all fit for IND through commercial supply. MeiraGTx has core capabilities in viral vector design and optimization and a potentially transformative riboswitch gene regulation platform technology that allows for the precise, dose-responsive control of gene expression by oral small molecules. MeiraGTx is focusing the riboswitch platform on delivery of metabolic peptides including GLP-1, GIP, Glucagon and PYY using oral small molecules, as well as cell therapy for oncology and autoimmune diseases. Although initially focusing on the eye, central nervous system, and salivary gland, MeiraGTx has developed the technology to apply genetic medicine to more common diseases, increasing efficacy, addressing novel targets, and expanding access in some of the largest disease areas where the unmet need remains great.

For more information, please visit www.meiragtx.com

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding our product candidate development, our ability to manufacture product candidates, potential milestone payments and the achievement of such milestones, including the receipt of such milestone payments and the impact on our cash runway, and our pre-clinical and clinical data, reporting of such data and the timing of results of data and regulatory matters, 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, our incurrence of significant losses; any inability to achieve or maintain profitability, raise additional capital, repay our debt obligations, identify additional and develop existing product candidates, successfully execute strategic transactions or priorities, bring product candidates to market, expansion of our manufacturing facilities and processes, successfully enroll patients in and complete clinical trials, accurately predict growth assumptions, recognize benefits of any orphan



drug designations, retain key personnel or attract qualified employees, or incur expected levels of operating expenses; the impact of pandemics, epidemics or outbreaks of infectious diseases on the status, enrollment, timing and results of our clinical trials and on our business, results of operations and financial condition; failure of early data to predict eventual outcomes; failure to obtain FDA or other regulatory approval for product candidates within expected time frames or at all; the novel nature and impact of negative public opinion of gene therapy; failure to comply with ongoing regulatory obligations; contamination or shortage of raw materials or other manufacturing issues; changes in healthcare laws; risks associated with our international operations; significant competition in the pharmaceutical and biotechnology industries; dependence on third parties; risks related to intellectual property; changes in tax policy or treatment; our ability to utilize our loss and tax credit carryforwards; litigation risks; and the other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC’s website at www.sec.gov. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. 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 press release.

Contacts

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or

Media:

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

	For the Years Ended December 31,	
	2023	2022
License revenue - related party	\$ 14,017	\$ 15,920
Operating expenses:		
General and administrative	47,293	46,550
Research and development	103,785	85,725
Total operating expenses	151,078	132,275
Loss from operations	(137,061)	(116,355)
Other non-operating income (expense):		
Foreign currency gain (loss)	9,300	(9,452)
Interest income	2,272	777
Interest expense	(13,245)	(4,946)
Gain on sale of nonfinancial assets	54,208	—
Fair value adjustment	499	361
Net loss	(84,027)	(129,615)
Other comprehensive (loss) income:		
Foreign currency translation (loss) gain	(7,482)	8,718
Comprehensive loss	\$ (91,509)	\$ (120,897)
Net loss	\$ (84,027)	\$ (129,615)
Basic and diluted net loss per ordinary share	\$ (1.49)	\$ (2.87)
Weighted-average number of ordinary shares outstanding	56,486,525	45,177,857



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

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 129,566	\$ 115,516
Accounts receivable - related party	10,138	21,334
Prepaid expenses	5,625	8,133
Tax incentive receivable	13,277	7,689
Other current assets	1,016	1,667
Total Current Assets	159,622	154,339
Property, plant and equipment, net	115,896	109,266
Intangible assets, net	1,118	1,335
In-process research and development	—	742
Restricted cash	1,083	—
Other assets	1,917	1,402
Equity method and other investments	6,766	6,326
Right-of-use assets - operating leases, net	15,910	20,109
Right-of-use assets - finance leases, net	24,432	24,718
TOTAL ASSETS	\$ 326,744	\$ 318,237
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 16,042	\$ 16,616
Accrued expenses	42,639	39,818
Lease obligations, current	4,193	3,884
Deferred revenue - related party, current	2,926	15,123
Other current liabilities	1,278	6,631
Total Current Liabilities	67,078	82,072
Deferred revenue - related party	34,017	27,436
Lease obligations	12,952	17,331
Asset retirement obligations	2,401	2,179
Deferred income tax liability	—	186
Note payable, net	72,119	71,033
Other long-term liabilities	—	262
TOTAL LIABILITIES	188,567	200,499
COMMITMENTS AND CONTINGENCIES (Note 14)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, \$0.00003881 par value, 1,288,327,750 authorized, 63,601,015 and 48,477,209 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	2	2
Capital in excess of par value	693,841	581,893
Accumulated other comprehensive (loss) income	(1,435)	6,047
Accumulated deficit	(554,231)	(470,204)
Total Shareholders' Equity	138,177	117,738
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 326,744	\$ 318,237