MeiraGTx Reports Full Year 2018 Financial Results

March 26, 2019

LONDON and NEW YORK, March 26, 2019 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (NASDAQ:MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the fourth quarter and full year ended December 31, 2018.

“2018 was a transformative year for MeiraGTx with us successfully moving multiple programs through clinical development, and meeting our strategic and financial goals,” said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. “In 2018, we treated patients across four ongoing clinical trials, our cGMP manufacturing facility was certified, and we initiated manufacturing of material for use in our clinical programs. We are well positioned to achieve multiple milestones in 2019, including the presentation of topline data from our ongoing inherited retinal disease studies. As a result of our collaboration with Janssen and our private placement financing in the first quarter of 2019, we have sufficient funding to accelerate the clinical development of our neurodegenerative, salivary gland and ocular disease programs.”

As of December 31, 2018, MeiraGTx had cash and cash equivalents of approximately $68.1 million. In the first quarter of 2019, the company received approximately $80 million of gross proceeds from a private placement of ordinary shares to institutional investors and is to receive an additional $100 million in the first quarter of 2019 from a collaboration, option and license agreement with Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson. MeiraGTx believes this capital will be sufficient to fund its operating expenses and capital expenditure requirements into 2022.

Recent Corporate Development Highlights

Entered into strategic collaboration: In January 2019, MeiraGTx entered into a strategic collaboration with Janssen to develop and commercialize gene therapies for the treatment of inherited retinal diseases (IRDs). Under the terms of the agreement, MeiraGTx is to receive a $100 million upfront cash payment. Janssen and MeiraGTx will collaborate to develop MeiraGTx’s current clinical programs to treat retinitis pigmentosa and two genetic forms of achromatopsia, and Janssen has the exclusive right to globally commercialize the product candidates for the gene therapy treatments. MeiraGTx will manufacture these products for commercial supply. Janssen has agreed to pay 100% of the clinical and commercialization costs of the products, and MeiraGTx is eligible to receive untiered 20% royalties on net sales of products and additional development and commercialization milestones of up to $340 million. In addition, MeiraGTx and Janssen entered into a research collaboration to develop a pipeline of IRD gene therapy candidates, with Janssen paying for a significant portion of the research costs. Janssen has the right to exclusively license and commercialize any product coming out of the collaboration at the time of clearance of the Investigational New Drug application by the FDA. Janssen will pay 100% of the clinical and commercialization costs for these products, and MeiraGTx will receive a high teens untiered royalty on net sales, as well as development milestones. The companies have also entered into a manufacturing research collaboration to further develop processes for manufacturing AAV viral vectors in which the costs of the research will be shared.

Strengthened balance sheet: In March 2019, MeiraGTx raised approximately $80 million of gross proceeds in a private placement of approximately 5.8 million of its ordinary shares. Johnson & Johnson Innovation —JJDC, Inc., the investment arm of Johnson & Johnson, and additional institutional investors participated in the offering.

Recent Clinical Development Highlights and Anticipated 2019 Milestones

MeiraGTx is currently treating patients in three ongoing Phase 1/2 trials evaluating the Company’s gene therapy product candidates. In 2018, dosing was completed in MeiraGTx’s first IRD Phase 1/2 study.

Phase 1/2 trial of AAV-RPE65 for RPE65-Deficiency: MeiraGTx has completed the Phase 1/2 study. Fifteen patients were treated: nine adults in dose escalation cohorts and six pediatric patients in an expansion cohort.

The Company expects to report topline six-month follow up safety and efficacy data in the first half of the year with full data expected to be presented in a scientific forum in the second half of the year.

Phase 1/2 trial of AAV-RPGR for X-Linked Retinitis Pigmentosa (XLRP): In the dose finding portion of the study, MeiraGTx has treated 11 patients. Ten young adults (age 18 to 30) were treated in dose escalation cohorts. One patient has been treated in a pediatric expansion cohort which is expected to complete enrollment in the first half of 2019. MeiraGTx expects to treat up to 40 additional patients in the extension cohorts of this study this year.

The Company expects to report preliminary safety and efficacy data from the dose escalation cohorts in the second half of the year.

Phase 1/2 trial of AAV-CNGB3 for Achromatopsia: MeiraGTx has treated 20 patients, including 11 adults in dose escalation cohorts and nine pediatric patients in an expansion cohort. The Company may treat up to four additional pediatric patients in the U.S. in the first half of 2019.

MeiraGTx expects to report topline six-month follow up safety and efficacy data in the second half of the year.

Phase 1/2 trial of AAV-CNGA3 for Achromatopsia: AAV-CNGA3 clinical material is currently being manufactured at MeiraGTx’s cGMP facility. MeiraGTx expects to release material for this trial in the first half of 2019 and initiate a Phase 1/2 dose escalation trial in pediatric patients shortly thereafter.

MeiraGTx is planning to present preclinical data describing the Company’s AAV-CNGA3 vector optimization work in a scientific forum in the first half of 2019.

AAV-GAD for Parkinson's Disease: MeiraGTx is preparing to meet with the FDA in mid-2019 in order to define the clinical pathway to support regulatory approval of AAV-GAD in advanced Parkinson's disease. The Company anticipates providing a regulatory and clinical development update in the second half of 2019 following interactions with regulators.

AAV-hAQP1 for Grade 2/3 Radiation-Induced Xerostomia: Six patients have been treated in the first two cohorts of a Phase 1/2 trial at the National Institutes of Health (NIH). MeiraGTx anticipates initiating a multi-center Phase 1/2 trial in 2019.

Financial Results

Cash and cash equivalents were $68.1 million as of December 31, 2018, compared to $8.5 million as of December 31, 2017.

Research and development expenses were $33.6 million for the year ended December 31, 2018, compared to $22.4 million for the year ended December 31, 2017. The increase of $11.2 million was primarily due to increased clinical trial costs related to ocular programs, costs for acquired neurology research and development, increased costs of payroll and consultants and costs associated with the Company's manufacturing facility.

General and administrative expenses were $44.5 million for the year ended December 31, 2018, compared to $9.3 million for the year ended December 31, 2017. The increase of $35.2 million was primarily due to increases in payroll, share-based compensation, legal and accounting fees and insurance costs.

Foreign currency loss was $3.8 million for the year ended December 31, 2018 compared to a gain of $1.7 million for the year ended December 31, 2017. The change of $5.5 million was primarily due to a strengthening U.S. dollar against the pound sterling in 2018.

Net loss for the year ended December 31, 2018 was $82.9 million, or ($4.47) basic and diluted net loss per ordinary share, compared to a net loss of $31.1 million, or ($3.72) basic and diluted net loss per ordinary share for the year ended December 31, 2017.

About MeiraGTx
MeiraGTx (NASDAQ:MGTX) is a vertically integrated, clinical stage gene therapy company with five programs in clinical development and a broad pipeline of preclinical and research programs. MeiraGTx 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, MeiraGTx has taken a portfolio approach by licensing, acquiring and developing technologies that give depth across both product candidates and indications. MeiraGTx's initial focus is on three distinct areas of unmet medical need: inherited retinal diseases, neurodegenerative diseases and severe forms of xerostomia and xerophthalmia. Though initially focusing on the eye, central nervous system and salivary gland, MeiraGTx intends to expand its focus in the future to develop additional gene therapy treatments for patients suffering from a range of serious diseases.

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 and anticipated 2019 milestones regarding its pre-clinical and clinical data, as well as statements that include the words "expect," "intend," "plan," "believe," "project," "forecast," "estimate," "may," "should," "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, acquire additional capital, identify additional and develop existing product candidates, continue operating as a going concern, successfully execute strategic priorities, bring product candidates to market, build-out the manufacturing facility 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; 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; 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; litigation risks; and the other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018 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.

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MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Year Ended December 31,	
	2018	2017
Operating expenses:		
General and administrative	$ 44,483,938	$ 9,325,017
Research and development	33,620,223	22,359,712
Total operating expenses	78,104,161	31,684,729
Loss from operations	(78,104,161)	(31,684,729)
Other non-operating income (expense):		
Other income	83,075	—
Foreign currency (loss) gain	(3,824,383)	1,676,117
Convertible note inducement expense	-	(553,500)
Change in fair value of warrant liability	(1,514,775)	(465,633)
Interest income	53,408	26,073
Interest expense	(33,429)	(42,863)
Loss before income taxes	(83,340,265)	(31,044,535)
Benefit for income taxes	474,391	—
Net loss	(82,865,874)	(31,044,535)
Other comprehensive income (loss):		
Foreign currency translation, net of tax of $474,391 and $0 in 2018 and 2017, respectively	2,316,143	(1,361,365)
Total comprehensive loss	(80,549,731)	(32,405,900)
Net loss	$ (82,865,874)	$ (31,044,535)
Accretion on convertible preferred C shares and warrants	(1,806,512)	(806,963)
Adjusted net loss	$ (84,672,386)	$ (31,851,498)
Basic and diluted net loss per ordinary share	$ (4.47)	$ (3.72)
Weighted-average number of ordinary shares outstanding	18,948,520	8,572,315

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	**December 31, 2017**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 68,080,175	$ 8,548,638
Prepaid expenses	1,937,785	1,961,243
Other current assets	4,634,105	965,233
Total Current Assets	74,652,065	11,475,114
Property, plant and equipment, net	22,014,237	14,255,729
Security deposits	105,085	-
Restricted cash	123,376	123,376
TOTAL ASSETS	$ 96,894,763	$ 25,854,219

LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 3,042,861	$ 7,055,380
Accrued expenses	11,991,697	9,332,944
Note payable	—	1,442,009
Warrant liability	—	2,679,633
Capitalized lease obligation - current portion	27,199	30,850
Due to Kadmon	—	861,030
Other current liabilities	437,053	—
Total Current Liabilities	15,498,810	21,401,846
Capitalized lease obligation	7,097	34,298
Deferred rent	201,264	266,290
Asset retirement obligation	128,119	178,419
TOTAL LIABILITIES	15,835,290	21,880,853
COMMITMENTS		
CONVERTIBLE PREFERRED C SHARES		
Convertible Preferred C Shares 0 and 5,005,935 outstanding at December 31, 2018 and December 31, 2017, respectively (liquidation preference of $52,455,700 at December 31, 2017)	—	51,338,631
SHAREHOLDERS' EQUITY (DEFICIT):		
Ordinary Shares, $0.00003881 nominal value, 1,288,327,750 authorized 27,386,632 issued and outstanding at December 31, 2018 8,826,190 issued and 8,714,563 issued and outstanding at December 31, 2017	1,064	342
Capital in excess of nominal value	229,054,460	20,080,713
Accumulated other comprehensive income (loss)	293,666	(2,022,477)
Accumulated deficit	(148,289,717)	(65,423,843)
Total Shareholders' Equity (Deficit)	81,059,473	(47,365,265)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)	$ 96,894,763	$ 25,854,219

Source: MeiraGTx