MeiraGTx Reports Second Quarter 2019 Financial Results and Provides Corporate Update

August 7, 2019

LONDON and NEW YORK, Aug. 07, 2019 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the quarter ended June 30, 2019 and provided an update on recent clinical progress.

MeiraGTx today announced the initiation of a Phase 1/2 clinical trial of AAV-CNGA3, the Company's fourth ocular gene therapy program to enter the clinic. MeiraGTx and Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, are jointly developing AAV-CNGA3 as part of a broader collaboration to develop and commercialize gene therapies for the treatment of inherited retinal diseases. AAV-CNGA3 is an investigational gene therapy being developed as a potential treatment for patients with achromatopsia associated with disease-causing variants in the *CNGA3* gene.

Additionally, MeiraGTx today announced the initiation of a Phase 1/2 multi-site clinical trial of AAV-AQP1 for the treatment of patients with Grade 2/3 radiation-induced xerostomia. Xerostomia is a chronic and debilitating disorder of the salivary glands in which saliva production is impaired. AAV-AQP1 is an investigational gene therapy that is designed to increase water conduction in salivary glands that have been damaged by radiation therapy. The gene therapy introduces a water conducting channel into the damaged glands.

"With the initiation of our AAV-CNGA3 and AAV-AQP1 clinical trials, we are continuing to rapidly progress our broad pipeline of investigational therapies," said Alexandria Forbes, Ph.D., president and CEO, MeiraGTx. "We now have six gene therapy programs in clinical development across our ocular, neurodegenerative and salivary gland therapeutic areas of focus. We are expanding our clinical footprint globally to reach patients in need of new therapeutic options."

Recent Clinical Development Highlights

Phase 1/2 trial of AAV-CNGA3 for Achromatopsia: MeiraGTx has initiated the open-label, multi-center, dose-finding Phase 1/2 trial and is currently recruiting children aged 3-15 years.

The primary objective of this trial is to evaluate the safety of AAV-CNGA3. Secondary objectives include determining the effect on visual function, retinal function and quality of life.

Phase 1/2 AQUAx trial of AAV-AQP1 for Grade 2/3 Radiation-Induced Xerostomia: MeiraGTx has initiated the multi-site, dose-finding, Phase 1/2 trial and is recruiting patients with radiation-induced Grade 2/3 xerostomia following treatment for head and neck cancer.

The Company's single center Phase 1 dose finding study of AAV-AQP1 also continues to enroll patients at the National Institutes of Health.

Phase 1/2 trial of AAV-RPE65 for RPE65-Deficiency: In May 2019, MeiraGTx reported positive 6-month data, showing the trial achieved the primary endpoint of safety and tolerability of AAV-RPE65. Additionally, AAV-RPE65 demonstrated statistically significant improvement across several secondary endpoints designed to assess clinical activity.

MeiraGTx expects to meet with global regulatory authorities in 2019 to define the development pathway for regulatory approval. The Company anticipates data from this trial will be presented in a scientific forum later this year.

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

Manufacturing

Manufacturing to support MeiraGTx's clinical programs is ongoing in our wholly owned cGMP manufacturing facility in London.

Recent Corporate Highlights

Expansion of Process Development, Manufacturing and Clinical Operations Teams: MeiraGTx has substantially increased key personnel in our organization to advance our broad pipeline of optimized investigational gene therapies. The MeiraGTx team now includes more than 100 full-time employees.

Second Quarter 2019 Financial Results

As of June 30, 2019, MeiraGTx had cash and cash equivalents of approximately $204.3 million. This capital will be sufficient to fund its operating expenses and capital expenditure requirements into 2022.

Comparison of Three Months Ended June 30, 2019 and 2018

General and administrative expenses were $13.4 million for the three months ended June 30, 2019, compared to $17.4 million for the three months ended June 30, 2018.

The decrease of $3.9 million was primarily due to decreases in payroll and share-based compensation, which was partially offset by increases in legal and accounting fees, insurance and travel expenses, consulting fees and other general and administrative expenses.

Research and development expenses for the three months ended June 30, 2019 were $9.8 million, compared to $7.8 million for the three months

ended June 30, 2018. The increase of $2.0 million was primarily due to an increase in costs related to our clinical trials, consulting fees and facility costs, which was partially offset by $2.5 million in research funding provided by our license and collaboration agreements with Janssen, and other research and development expenses.

Foreign currency gain was $0.3 million for the three months ended June 30, 2019 compared to a loss of $2.7 million for the three months ended June 30, 2018. The increase of $3.0 million was primarily due to a strengthening of the U.S. dollar against the pound sterling during the three months ended June 30, 2019.

Net loss for the three months ended June 30, 2019 was $20.8 million, or $(0.63) basic and diluted net loss per ordinary share, compared to a net loss of $30.0 million, or $(2.29) basic and diluted net loss per ordinary share for the three months ended June 30, 2018.

MeiraGTx ended the second quarter of 2019 with $204.3 million in cash and cash equivalents, compared to $102.1 million as of June 30, 2018.

About MeiraGTx
MeiraGTx (Nasdaq: MGTX) is a vertically integrated, clinical stage gene therapy company with six 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 our pre-clinical and clinical data and reporting of such data, meetings with regulatory authorities regarding pathways for regulatory approval of our product candidates, timing of results of data in connection with AAV-AQP1 for the treatment of patients with radiation-induced Grade 2/3 xerostomia, 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, 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 June 30, 2019, 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

Investors:
MeiraGTx
Elizabeth Broder
(646) 860-7983
Investors@meiragtx.com

or

Media:
W2O pure
Christiana Pascale
(212) 257-6722
cpascale@purecommunications.com

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2019	December 31, 2018

	(unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 204,273,017	$ 68,080,175
Prepaid expenses	3,265,612	1,937,785
Other current assets	5,336,569	4,634,105
Total Current Assets	212,875,198	74,652,065
Right-of-use assets	23,820,541	-
Property and equipment, net	15,907,334	22,014,237
Security deposits	349,592	105,085
Restricted cash	123,376	123,376
TOTAL ASSETS	$ 253,076,041	$ 96,894,763
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,233,478	$ 3,042,861
Accrued expenses	9,576,307	11,991,697
Lease obligations, current	1,660,319	27,199
Deferred revenue - related party, current	26,320,060	—
Other current liabilities	—	437,053
Total Current Liabilities	40,790,164	15,498,810
Deferred revenue - related party	67,197,377	—
Lease obligations	15,392,543	7,097
Deferred rent	-	201,264
Asset retirement obligations	132,846	128,119
TOTAL LIABILITIES	123,512,930	15,835,290
COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, $0.00003881 nominal value, 1,288,327,750 authorized 33,342,791 issued and outstanding at June 30, 2019 27,386,632 issued and outstanding at December 31, 2018	1,295	1,064
Capital in excess of nominal value	315,915,997	229,054,460
Accumulated other comprehensive income	739,865	293,666
Accumulated deficit	(187,094,046)	(148,289,717)
Total Shareholders' Equity	129,563,111	81,059,473
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 253,076,041	$ 96,894,763

MEIRAGTX HOLDINGS PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	For the Three-Month Period Ended June 30,		**For the Six-Month Period Ended June 30,**	
	2019	**2018**	**2019**	**2018**
License revenue - related party	$ 1,981,676	$ -	$ 2,766,636	$ -
Operating expenses:				
General and administrative	$ 13,437,171	$ 17,378,052	$ 21,936,646	$ 28,500,068
Research and development	9,771,754	7,790,694	22,747,983	14,718,016
Total operating expenses	23,208,925	25,168,746	44,684,629	43,218,084
Loss from operations	(21,227,249)	(25,168,746)	(41,917,993)	(43,218,084)
Other non-operating income (expense):				

Foreign currency gain (loss)	283,175	(2,726,624)	3,001,575	(1,748,000)
Change in fair value of warrant liability	-	(2,184,183)	-	(1,514,775)
Other income	-	83,075	-	83,075
Interest income	39,726	25,354	39,726	50,662
Interest expense	(9,454)	(9,708)	(19,028)	(37,063)
Loss before income taxes	(20,913,802)	(29,980,832)	(38,895,720)	(46,384,185)
Benefit for income taxes	91,390	-	91,390	-
Net loss	(20,822,412)	(29,980,832)	(38,804,330)	(46,384,185)
Other comprehensive income:				
Foreign currency translation, net of tax of $91,390 and $0 for the three and six-month periods ended June 30, 2019 and 2018, respectively	1,579,882	1,979,007	446,199	1,221,242
Total comprehensive loss	$ (19,242,530)	$ (28,001,825)	$ (38,358,131)	$ (45,162,943)
Net loss	$ (20,822,412)	$ (29,980,832)	$ (38,804,330)	$ (46,384,185)
Accretion on convertible preferred C shares and warrants	-	(1,141,794)	-	(1,806,512)
Adjusted net loss	$ (20,822,412)	$ (31,122,626)	$ (38,804,330)	$ (48,190,697)
Basic and diluted adjusted net loss per ordinary share	$ (0.63)	$ (2.29)	$ (1.26)	$ (4.27)
Weighted-average number of ordinary shares outstanding	32,827,029	13,611,452	30,814,639	11,280,804

Source: MeiraGTx