MeiraGTx Reports Third Quarter 2018 Financial Results and Provides Corporate Update

November 8, 2018

LONDON and NEW YORK, Nov. 08, 2018 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (NASDAQ:MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the third quarter of 2018 and provided a corporate update.

"The third quarter was very productive for MeiraGTx, marked by clinical progress across our pipeline, several corporate announcements and important regulatory designations," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "In the past month, we entered into an exclusive licensing agreement with the NIH for a gene therapy treatment for Sjögren's syndrome, announced a collaboration agreement with Janssen Pharmaceuticals focused on our proprietary riboswitch technology and acquired a novel Phase 2 Parkinson's gene therapy product candidate. The hard work of our employees and partners continues to have meaningful impact, both for MeiraGTx and for patients suffering from the devastating, debilitating diseases that we are seeking to address."

Corporate Highlights

NIH exclusive license: On September 7, 2018, MeiraGTx entered into an exclusive licensing agreement with the National Institute of Dental and Craniofacial Research, a division of the National Institutes of Health (NIH), for gene therapy treatment for Sjögren's syndrome and associated xerostomia (dry mouth) or xerophthalmia (dry eye). Under the agreement, MeiraGTx will receive worldwide rights to adeno-associated virus vector mediated gene delivery of aquaporin-1, designated AAV-AQP1, for Sjögren's syndrome patients with associated xerostomia (dry mouth) or xerophthalmia (dry eye).

Phase 2 Parkinson's Disease program: On October 5, 2018, MeiraGTx acquired Vector Neurosciences Inc. in an all-stock transaction. As a result of the acquisition, MeiraGTx expanded its portfolio of clinical stage product candidates to include adeno-associated virus encoding glutamic acid decarboxylase (AAV-GAD). A prior Phase 2 clinical trial of AAV-GAD was completed and was the first successful randomized, double-blind, sham-controlled trial of its kind for a gene therapy product candidate targeting a brain disorder.

Janssen Pharmaceuticals collaboration agreement: On October 9, 2018, MeiraGTx entered into a research collaboration and evaluation agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson. As part of the agreement, MeiraGTx will use its proprietary riboswitch technology to engineer regulatable gene therapy constructs encoding proprietary gene sequences from Janssen. Evaluation of the performance of these constructs will determine the utility of this approach in future product development.

Clinical Development Highlights

AAV-CNGB3: Treated two additional pediatric patients in the extension phase of the Phase 1/2 study, bringing the total number of patients treated to 16 (11 adults and five pediatrics). The Company anticipates completing dosing the pediatric extension phase in 2018.

AAV-RPGR: Completed dose escalation phase of the Phase 1/2 study, bringing the total number treated to 10 patients. The Company expects to initiate dosing in the pediatric extension phase of the study in 2018.

AAV-RPE65: Dosing in the Phase 1/2 clinical study was completed in the second quarter of 2018. A total of nine adults were treated in three escalating dose cohorts. Six pediatric patients were treated in the pediatric extension arm of the study.

AAV-CNGA3: cGMP manufacturing of clinical material is ongoing in our manufacturing facility. We anticipate release in the next few months with the initiation of the treatment study in early 2019.

Regulatory Highlights

FDA Rare Pediatric Disease Designation for Achromatopsia Treatment (AAV-CNGA3): On August 21, 2018, the Offices of Orphan Products Development and Pediatric Therapeutics of the U.S. Food and Drug Administration ("FDA") granted rare pediatric disease designation for the Company's gene therapy product candidate AAV-CNGA3 for the treatment of patients with achromatopsia (ACHM) caused by mutations in the *CNGA3* gene.

FDA Fast Track Designation for Achromatopsia Treatment (AAV-CNGB3): On August 16, 2018, the FDA granted Fast Track designation for the Company's AAV-CNGB3 gene therapy product candidate for the treatment of achromatopsia (ACHM) caused by mutations in the *CNGB3* gene.

FDA Orphan Drug Designation for Achromatopsia Treatment (AAV-CNGA3): On August 7, 2018, the FDA granted orphan drug designation (ODD) for the Company's AAV-CNGA3 gene therapy product candidate for the treatment of achromatopsia (ACHM) caused by mutations in the *CNGA3* gene.

Third Quarter 2018 Financial Results

Comparison of Three Months Ended September 30, 2018 and 2017

General and administrative expenses were $6.6 million for the three months ended September 30, 2018, compared to $2.4 million for the three months ended September 30, 2017. The increase of $4.2 million was primarily due to increases of $1.7 million in payroll, $1.8 million in share-based compensation, $0.7 million in legal and accounting fees, $0.2 million in investor relations costs and $0.3 million in insurance costs, which was partially offset by decreases of $0.4 million in rent and $0.1 million in depreciation expenses.

Research and development expenses for the three months ended September 30, 2018 were $8.1 million, compared to $6.4 million for the three months ended September 30, 2017. The increase of $1.7 million was primarily due to an increase in costs of $2.1 million related to preparation of our manufacturing facility for production, $0.6 million in share-based compensation expense and $0.2 million in legal fees, which was partially offset by a decrease of $1.2 million in clinical trial material costs.

Foreign currency loss was $0.7 million for the three months ended September 30, 2018 compared to a gain of $0.4 million for the three months ended September 30, 2017. The increase of $1.1 million was primarily due to a strengthening U.S. dollar against the pound sterling during the three-months ended September 30, 2018.

Net loss for the three months ended September 30, 2018 was $15.4 million, or $(0.59) basic and diluted net loss per ordinary share, compared to a net loss of $8.4 million, or $(1.00) basic and diluted net loss per ordinary share for the three months ended September 30, 2017.

MeiraGTx ended the third quarter of 2018 with $88.6 million in cash and cash equivalents, compared to $8.5 million as of December 31, 2017.

About MeiraGTx
MeiraGTx (NASDAQ:MGTX) is a vertically integrated, clinical stage gene therapy company with four ongoing clinical programs 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, severe forms of xerostomia and neurodegenerative diseases. Though initially focusing on the eye, salivary gland and central nervous system, 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 Statements
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 product pipeline, anticipated product benefits, goals and strategic priorities, product candidate development, growth expectations or targets and 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 final prospectus under Rule 424(b) filed with the U.S. Securities and Exchange Commission ("SEC") in connection with our initial public offering 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
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
CURRENT ASSETS:		

Cash	$ 88,560,634	$ 8,548,638
Prepaid expenses	2,029,327	1,961,243
Other current assets	716,737	965,233
Total Current Assets	91,306,698	11,475,114
Property and equipment, net	13,624,968	14,255,729
Security deposits	180,870	-
Restricted cash	123,376	123,376
TOTAL ASSETS	$ 105,235,912	$ 25,854,219
LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 2,415,667	$ 7,055,380
Accrued expenses	6,042,290	9,332,944
Note payable	—	1,442,009
Warrant liability	—	2,679,633
Capitalized lease obligation - current portion	29,284	30,850
Due to Kadmon	—	861,030
Total Current Liabilities	8,487,241	21,401,846
Capitalized lease obligation	12,092	34,298
Deferred rent	210,993	266,290
Asset retirement obligation	181,515	178,419
TOTAL LIABILITIES	8,891,841	21,880,853
COMMITMENTS		
CONVERTIBLE PREFERRED C SHARES		
Convertible Preferred C Shares 0 and 5,005,935 outstanding at September 30, 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 27,184,132 issued and outstanding at September 30, 2018 8,826,190 issued and 8,714,563 issued and outstanding at December 31, 2017	1,055	342
Capital in excess of nominal value	223,868,465	20,080,713
Accumulated other comprehensive loss	(292,477)	(2,022,477)
Accumulated deficit	(127,232,972)	(65,423,843)
Total Shareholders' Equity (Deficit)	96,344,071	(47,365,265)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED C SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)	$ 105,235,912	$ 25,854,219

See Notes to Condensed Consolidated Financial Statements

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

	For the Three-Month Period Ended September 30,		For the Nine-Month Period Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
General and administrative	$ 6,629,052	$ 2,374,527	$ 35,129,120	$ 6,744,963
Research and development	8,109,160	6,388,227	22,827,176	16,575,129
Total operating expenses	14,738,212	8,762,754	57,956,296	23,320,092
Loss from operations	(14,738,212)	(8,762,754)	(57,956,296)	(23,320,092)
Other non-operating income (expense):				

Other income	-	—	83,075	—
Foreign currency (loss) gain	(677,488)	391,521	(2,425,488)	990,395
Change in fair value of warrant liability	-	—	(1,514,775)	—
Interest income	264	2,915	50,926	21,295
Interest expense	(9,508)	(72,736)	(46,571)	(131,756)
Net loss	(15,424,944)	(8,441,054)	(61,809,129)	(22,440,158)
Comprehensive income (loss):				
Foreign currency translation	508,758	(348,338)	1,730,000	(824,252)
Total comprehensive loss	$ (14,916,186)	$ (8,789,392)	$ (60,079,129)	$ (23,264,410)
Net loss	$ (15,424,944)	$ (8,441,054)	$ (61,809,129)	$ (22,440,158)
Accretion on convertible preferred C shares and warrants	-	(191,758)	(1,806,512)	(244,920)
Adjusted net loss	$ (15,424,944)	$ (8,632,812)	$ (63,615,641)	$ (22,685,078)
Basic and diluted net loss per ordinary share	$ (0.59)	$ (1.00)	$ (3.89)	$ (2.66)
Weighted-average number of ordinary shares outstanding	26,340,450	8,607,832	16,355,849	8,536,447

See Notes to Condensed Consolidated Financial Statements

Source: MeiraGTx