MeiraGTx Reports Second Quarter 2021 Financial and Operational Results

August 11, 2021

LONDON and NEW YORK, Aug. 11, 2021 (GLOBE NEWSWIRE) -- MeiraGTx Holdings plc (Nasdaq: MGTX), a vertically integrated, clinical stage gene therapy company, today announced financial results for the second quarter ended June 30, 2021 and provided an update on recent progress.

"As we move into the second half of 2021, we are enthusiastic about the progress of our clinical programs and our gene regulation technology," said Alexandria Forbes, Ph.D., president and chief executive officer of MeiraGTx. "Our leading position in XLRP has been strengthened as we head into our Phase 3 pivotal trial for this large unmet need. We also remain on track to complete enrollment in our Phase 1 AQUAx study in grade 2/3 radiation-induced xerostomia this year and file our IND for AAV-GAD for Parkinson's Disease."

Dr. Forbes continued, "In a testament to the quality and expertise of our manufacturing team at MeiraGTx, we anticipate having at least six different clinical programs using material made and released from our cGMP facilities in the next 12 months. Our proprietary process and end-to-end capabilities have allowed us to successfully manufacture products using multiple capsids and genes across ocular, neurodegenerative, and salivary gland programs."

As of June 30, 2021, MeiraGTx had cash and cash equivalents of approximately $172.6 million, as well as approximately $18.0 million due in receivables from development partner Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, as part of a broader collaboration to develop and commercialize gene therapies for the treatment of inherited retinal diseases.

The Company believes it will have sufficient capital to fund operating expenses and capital expenditure requirements into the second quarter of 2023.

Anticipated Upcoming Milestones and Corporate Activities

- Initiate, with Janssen, the Phase 3 Lumeos clinical trial evaluating AAV-RGPR as a treatment for patients with X-Linked retinitis pigmentosa (XLRP) in the second half of 2021.
- Initiate a Phase 3 pivotal trial of AAV-RPE65 for patients with *RPE65*-associated retinal dystrophy in the second half of 2021.
- Complete enrollment of the Phase 1 AQUAx trial of AAV-AQP1 for the treatment for Grade 2/3 radiation-induced xerostomia in the second half of 2021.
- File Investigational New Drug (IND) application for AAV-GAD for the treatment of Parkinson's Disease in the third quarter of 2021.
- Present *in-vivo* data from the Company's riboswitch gene regulation platform at R&D day demonstrating regulation of multiple therapeutic targets in multiple tissues in the fourth quarter of 2021. Data from the Company's proprietary promoter engineering platforms will also be presented.
- Advance, with Janssen, development of AAV-CNGB3 and AAV-CNGA3 for the treatment of achromatopsia (ACHM) associated with mutations in the *CNGB3* and *CNGA3* genes to late-stage clinical trials.
- Continue to progress several pre-clinical programs towards INDs in 2022.

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

Financial Results

License revenue was $5.1 million for the quarter ended June 30, 2021, compared to $2.5 million for the quarter ended June 30, 2020. The increase represents increased amortization of the $100.0 million upfront payment that the Company received in March 2019 from its collaboration agreement with Janssen.

General and administrative expenses were $10.4 million for the quarter ended June 30, 2021, compared to $11.5 million for the quarter ended June 30, 2020. The decrease of $1.1 million was primarily due to a decrease in payroll and payroll related costs and share-based compensation due to certain restricted ordinary shares issued to certain members of senior management in June 2018 becoming fully vested in June 2020, legal and accounting fees and other office related costs. These decreases were partially offset by increases in rent and facilities costs and insurance costs.

Research and development expenses were $15.2 million for the quarter ended June 30, 2021, compared to $16.2 million for the quarter ended June 30, 2020. The decrease of $1.0 million was primarily due to a decrease for the non-cash acquisition costs in connection with the acquisition of Emrys Bio Inc. during the second quarter of 2020, and an increase in research funding provided under our collaboration agreement with Janssen. The decrease was partially offset by increases in costs related to our pre-clinical research and clinical trials, costs related to the manufacture of material for our clinical trials, payroll and payroll related costs due to the expansion of our clinical trials and manufacturing capabilities, share-based compensation, depreciation and other research and development costs.

Foreign currency gain was $0.4 million for the quarter ended June 30, 2021, compared to a loss of $0.4 million for the quarter ended June 30, 2020. The change in the amount of $0.8 million was primarily due to a weakening of the U.S. dollar against the pound sterling and euro during the three months ended June 30, 2021.

Net loss attributable to ordinary shareholders for the quarter ended June 30, 2021 was $20.1 million, or $0.46 basic and diluted net loss per ordinary share, compared to a net loss attributable to ordinary shareholders of $25.4 million, or $0.69 basic and diluted net loss per ordinary share for the quarter ended June 30, 2020.

Cash and cash equivalents were $172.6 million as of June 30, 2021, compared to $194.8 million as of June 30, 2020.

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: ocular, including inherited retinal diseases and large degenerative diseases, neurodegenerative diseases and severe forms of xerostomia. 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 2021 milestones regarding our pre-clinical and clinical data and reporting of such data and the timing of results of data, including 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, our incurrence of significant losses; any inability to achieve or maintain profitability, raise additional capital, identify additional and develop existing product candidates, successfully execute strategic 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 the COVID-19 pandemic 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, 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 STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share amounts)

	For the Three-Month Periods Ended June 30,		For the Six-Month Periods Ended June 30,	
	2021	2020	2021	2020
License revenue - related party	$ 5,116	$ 2,474	$ 9,711	$ 6,683
Operating expenses:				
General and administrative	10,409	11,497	20,327	23,303

Research and development	15,190	16,202	31,900	24,285
Total operating expenses	25,599	27,699	52,227	47,588
Loss from operations	(20,483)	(25,225)	(42,516)	(40,905)
Other non-operating income (expense):				
Foreign currency gain (loss)	381	(352)	(1,234)	(1,109)
Interest income	67	193	156	983
Interest expense	(51)	(34)	(110)	(68)
Net loss	(20,086)	(25,418)	(43,704)	(41,099)
Other comprehensive (loss) income:				
Foreign currency translation (loss) gain	(407)	518	(678)	4,464
Total comprehensive loss	$ (20,493)	$ (24,900)	$ (44,382)	$ (36,635)
Net loss	$ (20,086)	$ (25,418)	$ (43,704)	$ (41,099)
Basic and diluted net loss per ordinary share	$ (0.46)	$ (0.69)	$ (0.99)	$ (1.12)
Weighted-average number of ordinary shares outstanding	44,137,773	36,969,682	44,056,535	36,797,316

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

	June 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 172,556	$ 209,520
Accounts receivable - related party	17,966	38,479
Prepaid expenses	6,506	7,082
Tax incentive receivable	7,428	12,930
Other current assets	2,588	4,565
Total Current Assets	207,044	272,576
Property and equipment, net	54,679	44,042
Intangible assets, net	1,994	2,119
In-process research and development	823	852
Security deposits	1,201	812
Other assets	206	214
Equity method and other investments	6,665	—
Right-of-use assets	54,156	43,082
TOTAL ASSETS	$ 326,768	$ 363,697
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 11,644	$ 7,134
Accrued expenses	17,559	20,861
Lease obligations, current	3,173	2,583
Deferred revenue - related party, current	24,877	23,545
Other current liabilities	—	24
Total Current Liabilities	57,253	54,147
Deferred revenue - related party	39,333	49,297
Lease obligations	22,357	19,666
Asset retirement obligations	1,897	1,814
Deferred income tax liability	206	214
TOTAL LIABILITIES	121,046	125,138
COMMITMENTS (Note 10)		
SHAREHOLDERS' EQUITY:		

Ordinary Shares, $0.00003881 par value, 1,288,327,750 authorized, 44,309,453 and 44,189,150 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	2	2
Capital in excess of par value	516,027	504,482
Accumulated other comprehensive loss	(5,575)	(4,897)
Accumulated deficit	(304,732)	(261,028)
Total Shareholders' Equity	205,722	238,559
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 326,768	$ 363,697