Omega Therapeutics Reports First Quarter 2024 Financial Results and Highlights Recent Company Progress

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- *Advanced MYCHELANGELO™ I trial dose escalation to Cohort 5; Presentation of additional monotherapy data and planned expansion into Phase 2 settings expected in mid-2024*
- *Presented new preclinical data demonstrating potential of a MYC-targeting epigenomic controller in NSCLC at AACR 2024*
- *Company to present new preclinical data demonstrating durable epigenomic upregulation and other OMEGA platform capabilities at ASGCT 2024*

CAMBRIDGE, Mass., May 06, 2024 (GLOBE NEWSWIRE) -- Omega Therapeutics, Inc. (Nasdaq: OMGA) ("Omega"), a clinical-stage biotechnology company pioneering the development of a new class of programmable epigenomic mRNA medicines, today announced financial results for the first quarter ended March 31, 2024, and highlighted recent Company progress.

"Our consistent focus on execution in the past quarter led to meaningful progress in both our clinical and preclinical programs as we work to maximize the value and potential of our unique OMEGA platform," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "We continue to evaluate OTX-2002 in the ongoing MYCHELANGELO™ I trial, including the advancement to a higher dose of 0.3 mg/kg in Cohort 5. We expect to present safety and preliminary efficacy data from dose escalation as well as expand into Phase 2 settings in mid-2024. We continue to enhance our platform capabilities with the evaluation of new targets, advancement of upregulation and multiplexed epigenomic control and further progress our internal delivery efforts to the lung and other high-value tissues. We look forward to executing on these important milestones as we advance on our mission to bring programmable epigenomic mRNA medicines to patients in need."

Recent Highlights and Key Anticipated Milestones

Development Pipeline and Platform

- **Advanced to Cohort 5 in dose escalation of the Phase 1/2 MYCHELANGELO I clinical trial evaluating OTX-2002 in patients with hepatocellular carcinoma (HCC):** The trial is currently enrolling patients in Cohort 5 at the 0.3 mg/kg dose level at clinical sites across the U.S. and Asia. The Company expects to report additional clinical data from monotherapy dose escalation and expand into monotherapy and combination settings in mid-2024.
- **Presented new preclinical data supporting the development of a MYC-targeting epigenomic controller for EGFR inhibitor-resistant non-small cell lung cancer at the American Association for Cancer Research (AACR) Annual Meeting 2024:** Data demonstrated the anti-tumor effect of a MYC-targeting epigenomic controller (MYC-EC) in preclinical models of EGFR inhibitor (EGFRi)-resistant non-small cell lung cancer (NSCLC), regardless of the underlying resistance mechanism. These data support the potential development of a NSCLC MYC-EC in EGFR-mutant NSCLC as a combination therapy with osimertinib, and as a monotherapy in osimertinib-resistant NSCLC. The Company also presented preclinical data validating a novel pharmacodynamic biomarker assay for monitoring on-target engagement and activity of OTX-2002**.**
- **New preclinical data demonstrating durable upregulation of gene expression, further supporting Omega's diverse platform capabilities, to be presented at the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting:** Poster titled "Tuned Upregulation of Diverse Gene Targets Using Programmable Epigenomic Controllers" to be presented during the Epigenetic Editing and RNA Editing poster session on May 8, 2024, from 12:00 p.m. to 7:00 p.m. ET.

First Quarter 2024 Financial Results

As of March 31, 2024, the Company had cash and cash equivalents totaling $60.0 million. This cash balance, along with a cost reduction and strategic prioritization initiative that occurred during the first quarter, is expected to fund operations into Q1 2025.

Research and development (R&D) expenses for the first quarter of 2024 were $15.4 million, compared to $20.1 million for the first quarter of 2023. The $4.7 million decrease in R&D expenses was primarily driven by a decrease in external research and manufacturing costs, personnel-related expenses, and clinical development costs, partially offset by an increase in facilities expenses.

General and administrative (G&A) expenses for the first quarter of 2024 were $7.4 million, compared to $6.2 million for the first quarter of 2023. The $1.2 million increase in G&A expenses was primarily driven by an increase in facilities expenses.

Net loss for the first quarter of 2024 was $20.1 million, compared to $25.3 million for the first quarter of 2023. The decrease in net loss was driven predominantly by the decrease in R&D expenses.

About Omega Therapeutics

Omega Therapeutics is a clinical-stage biotechnology company pioneering the development of a new class of programmable epigenomic mRNA medicines to treat or cure a broad range of diseases. By pre-transcriptionally modulating gene expression, Omega's approach enables precision epigenomic control of nearly all human genes, including historically undruggable and difficult-to-treat targets, without altering native nucleic acid sequences. Founded in 2017 by Flagship Pioneering following breakthrough research by world-renowned experts in the field of epigenetics, Omega is led by a seasoned and accomplished leadership team with a track record of innovation and operational excellence. The Company is committed to revolutionizing genomic medicine and has a pipeline of therapeutic candidates derived from its OMEGA platform spanning oncology, regenerative medicine, and multigenic diseases including inflammatory and cardiometabolic conditions.

For more information, visit omegatherapeutics.com, or follow us on X and LinkedIn.

About the OMEGA Platform

The OMEGA platform leverages the Company's deep understanding of gene regulation, genomic architecture and epigenetic mechanisms to design programmable epigenomic mRNA medicines that precisely target and modulate gene expression at the pre-transcriptional level. Combining world-class data science capabilities with rational drug design and customized delivery, the OMEGA platform enables control of fundamental epigenetic processes and reprogramming of cellular physiology to address the root cause of disease. Omega's modular and programmable mRNA medicines, called epigenomic controllers, target specific genomic loci within insulated genomic domains with high specificity to durably tune single or multiple genes to treat and cure diseases through unprecedented precision epigenomic control.

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 the timing, progress and design of our ongoing Phase 1/2 MYCHELANGELO™ I clinical trial and our preclinical studies, as well as the timing of announcements of data related thereto; the potential of the OMEGA platform to engineer programmable epigenomic mRNA therapeutics that successfully regulate gene expression by targeting insulated genomic domains; expectations surrounding the potential of our product candidates, including OTX-2002; expectations regarding our pipeline, including trial design, initiation of preclinical studies and advancement of multiple preclinical development programs in oncology, immunology, regenerative medicine, and select monogenic diseases; potential franchise opportunities; our anticipated cash runway into the first quarter of 2025; our prioritization of certain preclinical programs and platform efforts; our plans to ensure that we have sufficient resources to advance our lead program, support long term growth, and accomplish our mission; and upcoming events and presentations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our 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, the following: the novel technology on which our product candidates are based makes it difficult to predict the time and cost of preclinical and clinical development and subsequently obtaining regulatory approval, if at all; the substantial development and regulatory risks associated with epigenomic controllers due to the novel and unprecedented nature of this new category of medicines; our limited operating history; the incurrence of significant losses and the fact that we expect to continue to incur significant additional losses for the foreseeable future; our need for substantial additional financing; volatility in capital markets and general economic conditions; our investments in research and development efforts that further enhance the OMEGA platform, and their impact on our results; uncertainty regarding preclinical development, especially for a new class of medicines such as epigenomic controllers; potential delays in and unforeseen costs arising from our clinical trials; the fact that our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their regulatory development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences; difficulties manufacturing the novel technology on which our epigenomic controller candidates are based; our ability to adapt to rapid and significant technological change; our reliance on third parties for the manufacture of materials; our ability to successfully acquire and establish our own manufacturing facilities and infrastructure; our reliance on a limited number of suppliers for lipid excipients used in our product candidates; our ability to advance our product candidates to clinical development; and our ability to obtain, maintain, enforce and adequately protect our intellectual property rights. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, and our other filings with the SEC, 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, we disclaim any obligation to do so, even if subsequent events cause our views to change.

Omega Therapeutics, Inc.
Consolidated statements of operations and comprehensive loss
(Unaudited, In thousands except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Collaboration revenue	$ 2,360	$ 516
Operating expenses:		
Research and development	15,415	20,091

General and administrative	7,396	6,243
Total operating expenses	22,811	26,334
Loss from operations	(20,451)	(25,818)
Other income (expense), net:		
Interest income, net	331	682
Other expense, net	(9)	(143)
Total other income, net	322	539
Net loss	$ (20,129)	$ (25,279)
Net loss per common stock attributable to common stockholders, basic and diluted	$ (0.36)	$ (0.50)
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	55,150,507	50,627,287
Comprehensive loss:		
Net loss	$ (20,129)	$ (25,279)
Other comprehensive income (loss):		
Unrealized gain on marketable securities	14	251
Comprehensive loss	$ (20,115)	$ (25,028)

Omega Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited, In thousands)

	March 31, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 60,033	$ 68,443
Marketable securities	—	4,986
Other assets	123,647	130,937
Total assets	**$ 183,680**	**$ 204,366**
Liabilities and stockholders' equity		
Liabilities	$ 142,326	$ 146,350
Stockholders' equity	41,354	58,016
Total liabilities and stockholders' equity	**$ 183,680**	**$ 204,366**

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