Omega Therapeutics Reports Third Quarter 2023 Financial Results and Highlights Recent Company Progress

November 9, 2023 12:01 PM EST

- *Announced promising preliminary clinical data for OTX-2002 from ongoing MYCHELANGELO™ I trial; clinical proof-of-platform established with potential applicability across a broad range of diseases*
- *Advanced OMEGA platform capabilities and presented new preclinical data on multiple epigenomic controller programs at medical meetings*
- *Further strengthened Board of Directors with appointment of Chris Schade as Chairman and addition of Michelle C. Werner*

CAMBRIDGE, Mass., Nov. 09, 2023 (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 third quarter ended September 30, 2023, and highlighted recent Company progress.

"The promising initial data from our ongoing MYCHELANGELO™ I trial establish clinical proof for our pioneering OMEGA platform and support the potential of epigenomic controllers, our programmable mRNA candidates, as a new class of therapeutics," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "We are thrilled to have clearly demonstrated the ability to site-specifically target and controllably modulate the expression of MYC in all eight patients evaluated in the initial two dose cohorts of the trial. MYC, considered a "holy grail" oncogene, is just the first of many broadly-implicated targets in oncology where an epigenomic controller may provide therapeutic value. Moreover, these data highlight the promise of precision epigenomic control to address a broad range of diseases."

Mr. Karande added, "In parallel, we have made tremendous progress advancing our pipeline, with recent and upcoming presentations of new preclinical data demonstrating the breadth and versatility of our platform capabilities at scientific and medical meetings this fall. We look forward to building on this growing body of data and delivering a new class of medicines to patients."

Recent Highlights and Key Anticipated Milestones

Development Pipeline and Platform

- **Reported promising preliminary safety, tolerability, pharmacokinetic and translational data from the ongoing MYCHELANGELO I clinical trial evaluating OTX-2002 (data cut-off date of September 18, 2023):**
  - Data from the initial two dose level cohorts (n=8) from the monotherapy dose escalation portion of the Phase 1/2 study evaluating OTX-2002 in patients with hepatocellular carcinoma (HCC) and other solid tumors associated with the c-MYC (MYC) gene showed that all eight patients treated with OTX-2002 achieved highly specific on-target genomic engagement, intended epigenetic state change and rapid, robust and durable downregulation of MYC expression.
  - OTX-2002 was generally well tolerated at both dose levels, with no dose-limiting toxicities. Consistent dose-dependent pharmacokinetics were observed, and no drug accumulation was observed following repeat doses.
  - These data represent the first-known clinical observation of pre-transcriptional gene modulation using a programmable epigenomic mRNA candidate and establish clinical proof-of-platform.
  - Based on these encouraging data, OTX-2002 continues to advance in monotherapy dose escalation and the Company is actively evaluating patients with HCC in Cohort 3. Omega expects to report updated clinical data from monotherapy dose escalation in the first half of 2024.

- The Company is planning to initiate expansion cohorts in monotherapy and in combination settings with standard of care agents mid-2024.

- **Presented new preclinical data supporting the potential of OTX-2101 for the treatment of non-small cell lung cancer (NSCLC) at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics:**
  - The combination of a MYC-targeting epigenomic controller with immune checkpoint or EGFR inhibitors significantly enhanced anti-tumor activity in multiple preclinical models of NSCLC.
  - Omega continues to advance OTX-2101 in Investigational New Drug (IND)-enabling studies.

- **Presented preclinical proof-of-concept data for CXCL 1-8 program at the International mRNA Health Conference:**
  - New preclinical data demonstrate the ability of the Company's CXCL 1-8-targeting epigenomic controller to multiplex and specifically modulate gene expression of the multigenic locus in multiple models of inflammatory disease.
  - Omega has completed lead optimization activities for this program, including demonstration of *in vivo* proof-of-concept efficacy. The CXCL 1-8-targeting epigenomic controller has potential in multiple inflammatory indications including neutrophilic asthma, acute respiratory distress syndrome (including COVID-19-related), dermatological and rheumatological indications, and oncology, representing a potential franchise opportunity.

- **Announced upcoming presentation of preclinical proof-of-concept data on liver inflammation and fibrosis epigenomic controller programs at the American Association for the Study of Liver Diseases (AASLD) annual meeting:** Omega will present new preclinical data from its hepatology programs in two posters at AASLD's "The Liver Meeting ®" annual meeting, being held November 10-14, 2023, in Boston, Massachusetts.
  - One poster will highlight a CXCL 9-11-targeting epigenomic controller candidate for the treatment autoimmune hepatitis (AIH).
  - A second poster will highlight new *in vitro* and *in vivo* data demonstrating the ability of an investigational epigenomic controller to durably upregulate HNF4α expression to drive liver regeneration in preclinical models of fibrosis.

- **Continued to advance and expand OMEGA platform capabilities:**
  - The Company continues to advance multiple epigenomic controller programs through discovery and lead optimization, and to further progress and characterize its internal formulation and lipid nanoparticle (LNP) delivery technologies for the delivery of programmable mRNA therapeutics to the lung and other tissues.

Corporate

- **Further strengthened Board of Directors:** In August, Omega announced the appointment of Chris Schade as Chairman of the Board. In addition, Michelle C. Werner, CEO of Alltrna and CEO-Partner at Flagship Pioneering, joined the Board, bringing with her over 20 years of biopharma experience spanning commercial and R&D responsibilities.
- **Named to BioSpace's Best Places to Work 2024 report in small employer category:** The annual report lists 60 U.S. operating employers that are recognized as the most sought-after in the industry by the life sciences community. Recognition by BioSpace is determined by input

from company employees as well as voting from more than 3,000 life sciences professionals.

Third Quarter 2023 Financial Results

As of September 30, 2023, the Company had cash, cash equivalents and marketable securities totaling $89.3 million.

Research and development (R&D) expenses for the third quarter of 2023 were $16.5 million, compared to $20.7 million for the third quarter of 2022. The $4.2 million decrease in R&D expenses was primarily driven by decreases in external manufacturing costs and study costs, partially offset by an increase in facilities expense and, to a lesser extent, increases in personnel-related expenses and clinical development costs.

General and administrative (G&A) expenses for the third quarter of 2023 were $7.9 million, compared to $5.2 million for the third quarter of 2022. The $2.7 million increase in G&A expenses was primarily driven by an increase in facilities expense and, to a lesser extent, increases in professional and consulting fees, partially offset by a decrease in personnel-related expenses.

Net loss for the third quarter of 2023 was $22.2 million, compared to $25.8 million for the third quarter of 2022, driven predominantly by a 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 diverse pipeline of therapeutic candidates derived from its OMEGA platform spanning oncology, regenerative medicine, multigenic diseases including immunology, and select monogenic diseases.

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 a biology-first approach and world-class data science capabilities with rational drug design and customized delivery, the OMEGA platform enables control of fundamental epigenetic processes to correct the root cause of disease by returning aberrant gene expression to a normal range. 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 Phase 1/2 MYCHELANGELO™ I clinical trial and our preclinical studies, as well as the timing of announcements of data related thereto; the impact of Board composition changes on our long-term growth; 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 and OTX-2101; 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; 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; 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; the impact of increased demand for the manufacture of mRNA and LNP based vaccines to treat COVID-19 on our development plans; 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 September 30, 2023, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue from related party	$ 831	$ 595	$ 2,105	$ 1,338

Operating expenses:				
Research and development	16,475	20,670	61,454	54,329
General and administrative	7,869	5,198	20,030	16,466
Related party expense, net	(610)	712	183	2,342
Total operating expenses	23,734	26,580	81,667	73,137
Loss from operations	(22,903)	(25,985)	(79,562)	(71,799)
Other income (expense), net:				
Interest income (expense), net	684	184	2,323	(26)
Other income (expense), net	(29)	2	25	(50)
Total other income (expense), net	655	186	2,348	(76)
Net loss	$ (22,248)	$ (25,799)	$ (77,214)	$ (71,875)
Net loss per common stock attributable to common stockholders, basic and diluted	$ (0.40)	$ (0.54)	$ (1.44)	$ (1.50)
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	55,140,058	47,854,965	53,629,468	47,837,490
Comprehensive loss:				
Net loss	$ (22,248)	$ (25,799)	$ (77,214)	$ (71,875)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	85	89	393	(855)
Comprehensive loss	$ (22,163)	$ (25,710)	$ (76,821)	$ (72,730)

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

	September 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 81,768	$ 70,615
Marketable securities	7,532	54,063
Other assets	128,508	21,320
Total assets	**$ 217,808**	**$ 145,998**
Liabilities and stockholders' equity		
Liabilities	$ 141,765	$ 40,027
Stockholders' equity	76,043	105,971
Total liabilities and stockholders' equity	**$ 217,808**	**$ 145,998**

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