

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 4, 2023

Omega Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40657
(Commission File Number)

81-3247585
(IRS Employer
Identification No.)

20 Acorn Park Drive
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02140
(Zip Code)

Registrant's Telephone Number, Including Area Code: 617 949-4360

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	OMGA	The NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 4, 2023, Omega Therapeutics, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 31, 2023. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K (including Exhibit 99.1 hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit No.	Description
99.1	Press Release, dated May 4, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Omega Therapeutics, Inc.

Date: May 4, 2023

By: /s/ Mahesh Karande

Mahesh Karande

President and Chief Executive Officer

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

- *Continued to Advance Monotherapy Dose Escalation Stage of Ongoing Phase 1/2 MYCHELANGELOTM I Study; Preliminary Data Anticipated in 2023*
- *Announced Clinical Supply Agreement with Roche to Evaluate OTX-2002 in Combination with Atezolizumab in MYCHELANGELO I Study*
- *Advanced Other Pipeline Programs and OMEGA Platform Development*
- *Cash, Cash Equivalents and Marketable Securities of \$136.8 Million as of March 31, 2023*

CAMBRIDGE, Mass., May 4, 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 first quarter ended March 31, 2023, and highlighted recent Company progress.

"During the first quarter we made progress across our clinical and preclinical programs in line with our broader strategic vision," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "We continue to enroll patients in the monotherapy arm of our Phase 1/2 MYCHELANGELOTM I study and remain on track to announce preliminary data this year. Additionally, we executed a key clinical supply agreement with Roche to evaluate the potential of our lead epigenomic controller, OTX-2002, in combination with atezolizumab, a leading anti-PD-L1 therapy, to explore the broader clinical potential of our new class of therapeutics. We expect that 2023 will be a pivotal year for Omega and we remain focused on advancing our novel approach to developing programmable epigenomic mRNA medicines in the service of patients."

Recent Corporate Highlights

- **Announced a Clinical Supply Agreement with Roche:** In March 2023, the Company announced a clinical supply agreement with Roche to evaluate OTX-2002 in combination with atezolizumab, an anti-PD-L1 therapy, for the treatment of c-Myc (MYC)-driven hepatocellular carcinoma (HCC) as part of Omega's Phase 1/2 MYCHELANGELO I clinical trial. Under the terms of this agreement, Roche will supply atezolizumab and Omega will evaluate the combination as part of the overall conduct of the trial.
- **Continued Enrollment into the MYCHELANGELO I Clinical Trial Evaluating OTX-2002:** The Phase 1/2 study is evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of OTX-2002, the Company's

lead Omega Epigenomic Controller™ (OEC) designed to downregulate MYC expression pre-transcriptionally, as a monotherapy (Part 1) and in combination with standard of care therapies (Part 2) in patients with relapsed or refractory HCC and other solid tumor types known for the association with the MYC oncogene. Trial enrollment continues to progress as planned at clinical sites across the U.S. and Asia. Preliminary data from the Phase 1 monotherapy dose escalation portion of the study, including initial safety, tolerability, pharmacologic and translational data, is expected in 2023.

- **Abstract Accepted for Poster Presentation at the Upcoming American Society of Clinical Oncology (ASCO) 2023 Annual Meeting:** New preclinical data further validating Omega's OEC platform will be shared in a poster presentation titled "Effect of MYC-targeting programmable epigenetic mRNA therapeutics on TME and immunotherapy responses" during the Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary session on June 5, 2023, from 8:00 a.m. to 11:00 a.m. CDT.
- **Advanced Preclinical Evaluation of OTX-2101 for NSCLC and Other OEC Development Candidates:** Investigational New Drug (IND)-enabling studies for OTX-2101, the Company's development candidate for the treatment of MYC-driven non-small cell lung cancer (NSCLC), continue to progress. Additional preclinical work is ongoing for other OEC development programs, including a CXCL 1-8-targeting OEC with potential in multiple indications including neutrophilic asthma, acute respiratory distress syndrome (including COVID-related), oncology, and dermatological and rheumatological indications, representing a potential franchise opportunity.

First Quarter 2023 Financial Results

As of March 31, 2023, the Company had cash, cash equivalents and marketable securities totaling \$136.8 million, which includes the previously disclosed approximately \$39.7 million in net proceeds received from a registered direct offering of common stock in February 2023. The Company anticipates that this balance will be sufficient to fund its operations into the second half of 2024.

Research and development (R&D) expenses for the first quarter of 2023 were \$20.0 million, compared to \$14.2 million for the first quarter of 2022. The \$5.8 million increase in R&D expenses was primarily due to increases in personnel-related expenses, clinical development costs, and external manufacturing costs and study costs to support the advancement of our programs.

General and administrative expenses (G&A) for the first quarter of 2023 were \$6.0 million, compared with \$5.4 million for the first quarter of 2022. The \$0.6 million increase in G&A expenses was primarily due to higher personnel-related expenses to support business growth.

Net loss for the first quarter of 2023 was \$25.3 million, compared with \$20.2 million for the first quarter of 2022. The increase in net loss was primarily due to increases in R&D expenses to support the Company's programs and growth.

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 [Twitter](#) 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, Omega 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 sufficiency of our cash, cash equivalents and marketable securities to fund our operations; expectations regarding the agreement with Roche; 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; 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 OEC 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, 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.

CONTACT

Investor contact:

Eva Stroynowski
617.949.4370
estroynowski@omegatx.com

Media contact:

Jason Braco, LifeSci Communications
646.751.4361
jbraco@lifescicomms.com

Omega Therapeutics, Inc.
Condensed consolidated statements of operations and comprehensive loss
(Unaudited, In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue from related party	\$ 516	\$ 268
Operating expenses:		
Research and development	19,968	14,191
General and administrative	5,954	5,406
Related party expense, net	412	630
Total operating expenses	<u>26,334</u>	<u>20,227</u>
Loss from operations	(25,818)	(19,959)
Other income (expense), net:		
Interest income (expense), net	682	(155)
Other expense, net	(143)	(50)
Total other income (expense), net	<u>539</u>	<u>(205)</u>
Net loss	<u>\$ (25,279)</u>	<u>\$ (20,164)</u>
Net loss per common stock attributable to common stockholders, basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.42)</u>
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	<u>50,627,287</u>	<u>47,807,209</u>
Comprehensive loss:		
Net loss	\$ (25,279)	\$ (20,164)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	251	(797)
Comprehensive loss	<u>\$ (25,028)</u>	<u>\$ (20,961)</u>

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

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Cash and cash equivalents	\$ 104,541	\$ 70,615
Marketable securities	32,246	54,063
Other assets	19,528	21,320
Total assets	\$ 156,315	\$ 145,998
Liabilities and stockholders' equity		
Liabilities	\$ 33,315	\$ 40,027
Stockholders' equity	123,000	105,971
Total liabilities and stockholders' equity	\$ 156,315	\$ 145,998

