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): August 6, 2024

Omega Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40657**	**81-3247585**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
140 First Street Suite 501 Cambridge, Massachusetts		**02141**
(Address of Principal Executive Offices)		**(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 August 6, 2024, Omega Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the quarter ended June 30, 2024. 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 August 6, 2024
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: August 6, 2024

By: /s/ Mahesh Karande
Mahesh Karande
President and Chief Executive Officer

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

- *Advanced MYCHELANGELO™ I trial; Company expects to select recommended dose for expansion and initiate monotherapy and combination expansion cohorts in fourth quarter of 2024*
- *Reinforced diverse capabilities of the OMEGA platform at scientific meetings, including demonstration of precise and durable upregulation of gene expression*
- *Strengthened leadership team with appointment of Kaan Certel, Ph.D., as Chief Business Officer and election of Richard N. Kender to Board of Directors*

CAMBRIDGE, Mass., August 6, 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 second quarter ended June 30, 2024, and highlighted recent Company progress.

"We are excited by the meaningful progress achieved to date with our MYCHELANGELO™ I trial, having generated clinical proof-of-platform data that validates the potential of epigenomic controllers as a new class of programmable mRNA therapeutics. As we approach identification of the recommended dose for expansion for OTX-2002, we look forward to sharing updated dose escalation data and initiating expansion cohorts in monotherapy and combination settings in the fourth quarter of this year," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "We are equally energized by the advances we have made with the OMEGA platform, including new preclinical data presented at this year's ASGCT Annual Meeting showing durable and robust upregulation of gene expression with epigenomic controllers across a broad range of targets. We believe these achievements underscore the potential of our platform to create tremendous value through its ability to prospectively engineer epigenomic controllers with diverse and meaningful therapeutic applications across nearly any human disease."

Recent Highlights and Key Anticipated Milestones

Development Pipeline and Platform

- **Progressed dose escalation portion of Phase 1/2 MYCHELANGELO™ I clinical trial evaluating OTX-2002 in patients with hepatocellular carcinoma (HCC):** Made steady progress towards identifying the recommended dose for expansion (RDE) of OTX-2002, with patient enrollment ongoing in Cohort 6 at the 0.2 mg/kg dose level across sites in the U.S. and Asia. The Company expects to report updated clinical data and is planning for expansion into monotherapy and combination settings in the fourth quarter of 2024.

- **Presented new preclinical data demonstrating durable upregulation of gene expression at the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting:** Data demonstrated durable and robust upregulation of gene expression across a diverse set of gene types and regulatory mechanisms, including turning on inactive genes, augmenting expression of genes with existing but low baseline expression levels, and increasing expression of poised genes that are typically only responsive to certain external stimuli. Additional data showed reversible downregulation and multiplexed upregulation of gene expression. These findings further demonstrate the OMEGA platform's potential to engineer an entirely novel therapeutic modality to directly target key drivers of disease across therapeutic areas.
- **Continued to advance and enhance the OMEGA platform:** The Company is evaluating multiple epigenomic controller programs in preclinical studies, including OTX-2101 for non-small cell lung cancer (NSCLC), an HNF4A program in liver regeneration, and development of an epigenomic controller for the management of obesity in collaboration with Novo Nordisk. Core work on platform biology, epigenomic controller design, and characterization of LNP delivery to the lung and other high-value tissues continues to progress.

Corporate

- **Strengthened leadership team with appointment of Kaan Certel, Ph.D., as Chief Business Officer and election of Richard N. Kender to Board of Directors:**
  Dr. Certel is a seasoned biopharmaceutical leader and is responsible for Omega's global business development activities, including strategic partnerships. Mr. Kender brings extensive expertise across corporate finance, business development and corporate licensing, among other roles he held during his career in the pharmaceutical industry, including 35 years spent at Merck & Co., Inc.

Second Quarter 2024 Financial Results

As of June 30, 2024, the Company had cash and cash equivalents totaling $45.9 million, which is expected to fund operations into Q1 2025.

Research and development (R&D) expenses for the second quarter of 2024 were $12.9 million, compared to $25.0 million for the second quarter of 2023. The $12.1 million decrease in R&D expenses was primarily driven by a decrease in external research costs, contract manufacturing costs, and personnel-related expenses.

General and administrative (G&A) expenses for the second quarter of 2024 were $5.8 million, compared to $6.6 million for the second quarter of 2023. The $0.8 million decrease in G&A expenses was primarily driven by a decrease in personnel-related expenses and consulting and professional fees.

Net loss for the second quarter of 2024 was $16.3 million, compared to $29.7 million for the second 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, regenerative medicine, and multigenic diseases including inflammatory and cardiometabolic conditions; potential franchise opportunities; our anticipated cash runway into the first quarter of 2025; 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 June 30, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 2,134	$ 759	$ 4,494	$ 1,274
Operating expenses:				
Research and development	12,940	25,042	28,355	45,132
General and administrative	5,774	6,557	13,170	12,800
Total operating expenses	18,714	31,599	41,525	57,932
Loss from operations	(16,580)	(30,840)	(37,031)	(56,658)
Other income (expense), net:				
Interest income, net	299	957	630	1,639
Other income (expense), net	(24)	196	(33)	53
Total other income, net	275	1,153	597	1,692
Net loss	$ (16,305)	$ (29,687)	$ (36,434)	$ (54,966)
Net loss per common stock attributable to common stockholders, basic and diluted	$ (0.30)	$ (0.54)	$ (0.66)	$ (1.04)
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	55,150,507	55,071,469	55,152,746	52,861,655
Comprehensive loss:				
Net loss	$ (16,305)	$ (29,687)	$ (36,434)	$ (54,966)
Other comprehensive income (loss):				
Unrealized gain on marketable securities	—	57	14	308
Comprehensive loss	$ (16,305)	$ (29,630)	$ (36,420)	$ (54,658)

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

	June 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 45,852	$ 68,443
Marketable securities	—	4,986
Other assets	122,373	130,937
Total assets	**$ 168,225**	**$ 204,366**
Liabilities and stockholders' equity		
Liabilities	$ 141,963	$ 146,350
Stockholders' equity	26,262	58,016
Total liabilities and stockholders' equity	**$ 168,225**	**$ 204,366**