

**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): September 10, 2021

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 (I.R.S. Employer Identification No.)
--	---	--

20 Acorn Park Drive, Cambridge, MA 02140
(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 Symbols	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 September 10, 2021, Omega Therapeutics, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended June 30, 2021. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 10, 2021
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 hereunto duly authorized.

Omega Therapeutics, Inc.

By: /s/ Mahesh Karande

Mahesh Karande

President and Chief Executive Officer

Date: September 10, 2021



Omega Therapeutics Reports Second Quarter 2021 Financial Results and Outlines Key Corporate Objectives

- *Strong Balance Sheet to Fund Pipeline of Omega Epigenomic Controllers™ with \$122.4 Million in Cash and Cash Equivalents as of June 30, 2021 and additional \$141.1 Million in Gross Proceeds from the Initial Public Offering (IPO) in the Third Quarter 2021*
- *IND Submission for Lead Program, OTX-2002, for the Treatment of Hepatocellular Carcinoma, Remains on Track for First Half of 2022*

CAMBRIDGE, Mass, September 10, 2021 -- Omega Therapeutics, Inc. (Nasdaq: OMGA) (“Omega”), a development-stage biotechnology company pioneering the first systematic approach to use mRNA therapeutics as programmable epigenetic medicines by leveraging its OMEGA Epigenomic Programming™ platform, today announced financial results for the second quarter ended June 30, 2021.

“Our recent successful IPO reinforces our commitment to bring potentially transformative programmable mRNA therapeutics that target the epigenetic basis of disease to precisely control gene expression to patients across a wide range of diseases. We are thrilled to bring in new investors through our IPO and to have the continued support of our existing stockholders,” said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. “The funding provides the necessary financial resources to advance our lead Omega Epigenomic Controller (OEC) candidate, OTX-2002, for the treatment of Hepatocellular Carcinoma through an Investigational New Drug (IND) filing and initial clinical readouts, as well as to continue pre-clinical and IND-enabling studies for several additional OEC development candidates.”

Recent Business Highlights and Corporate Update

Financial and Corporate

- In August 2021, Omega completed a successful IPO, including shares sold pursuant to the partial exercise of the underwriters' option to purchase additional shares, raising \$141.1 million in aggregate gross proceeds, before deducting underwriting discounts and commissions and estimated offering expenses, and listed on The Nasdaq Global Select Market. The IPO followed the closing of a Series C crossover financing of \$126 million in gross proceeds in March 2021.
- In May 2021, Luke Beshar was appointed to the Omega Board of Directors and currently serves as the Chair of the Audit Committee. Mr. Beshar is an industry and corporate finance veteran who currently serves on the Board of Directors of Trillium Therapeutics and Protara Therapeutics, and most recently served as Executive Vice President and Chief Financial Officer at NPS Pharmaceuticals, Inc., through its acquisition by Shire PLC.

- In March 2021, Elliott M. Levy, M.D., was appointed to the Omega Board of Directors and currently serves on the Nominating and Corporate Governance Committee. Dr. Levy is an industry veteran with over 20 years of senior leadership roles in research and development at global pharmaceutical companies, including Amgen and Bristol-Myers Squibb.

Development Pipeline and Platform

- **OTX-2002:** IND-enabling studies are ongoing for Omega's lead OEC candidate OTX-2002, a novel, engineered, and programmable mRNA therapeutic being developed for the downregulation of c-Myc oncogene expression in patients with hepatocellular carcinoma. In preclinical studies, OTX-2002 demonstrated its ability to potently down-regulate c-Myc oncogene expression. The Company continues to be on track to file an IND for OTX-2002 in the first half of 2022.
- **OMEGA Epigenomic Programming Platform:** Omega is creating a new generation of programmable mRNA therapeutics, one that is designed to enable control of fundamental epigenetic processes to correct the root cause of disease by returning aberrant gene expression to a normal range without altering native nucleic acid sequences. Omega has developed a highly rational and deterministic approach to drug design that enables the Company to rapidly develop and optimize novel OECs engineered for highly specific targeting and controlled tunability and durability of gene expression. Omega is advancing multiple pre-clinical development programs in regenerative medicine, multigenic diseases including immunology, oncology and select monogenic diseases.

Milestones and Key Priorities

- Complete IND-enabling studies for OTX-2002 and successfully file IND application to FDA during the first half of 2022.
- Nominate additional OEC development candidates in the first half of 2022.
- File a second IND application targeted for second half of 2022.
- Continue to develop the OMEGA Epigenomic Programming™ platform and investigate additional development programs to expand pipeline.
- Publish relevant pre-clinical and early clinical data supporting our programs and platform development.

Second Quarter 2021 Financial Results

As of June 30, 2021, the Company had cash and cash equivalents totaling \$122.4 million, which does not include the gross proceeds of \$141.1 million from the Company's IPO.

Research and development (R&D) expenses for the second quarter of 2021 were \$11.2 million, compared with \$4.9 million for the second quarter of 2020. The \$6.3 million increase in R&D expenses was primarily due to an increase in discovery and preclinical development costs, related laboratory materials and supplies, and personnel and related expenses as the Company continues to advance its development pipeline.

General and administrative expenses (G&A) for the second quarter of 2021 were \$3.6 million, compared with \$1.0 million for the second quarter of 2020. The \$2.6 million increase in G&A expense was primarily due to higher personnel and related expenses and an increase in professional fees to support business growth.

Net loss for the second quarter of 2021 was \$15.4 million, compared with \$6.3 million for the second quarter of 2020. The increase in net loss for the second quarter was primarily due to increased research and development and G&A expenses to support the Company's growth.

About Omega Therapeutics

Omega Therapeutics is a development-stage biotechnology company pioneering the first systematic approach to use mRNA therapeutics as programmable epigenetic medicines by leveraging its OMEGA Epigenomic Programming™ platform. The OMEGA™ platform harnesses the power of epigenetics, the mechanism that controls gene expression and every aspect of an organism's life from cell genesis, growth and differentiation to cell death. 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 without altering native nucleic acid sequences. Omega's engineered, modular, and programmable mRNA-encoded epigenetic medicines, Omega Epigenomic Controllers™, target specific intervention points amongst the thousands of mapped and validated novel DNA-sequence-based epigenomic loci to durably tune single or multiple genes to treat and cure disease through Precision Genomic Control™. Omega is currently advancing a broad pipeline of development candidates spanning a range of disease areas, including oncology, regenerative medicine, multigenic diseases including immunology, and select monogenic diseases.

For more information, visit omegatherapeutics.com, or follow us on [Twitter](#) and [LinkedIn](#).

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 our expectations surrounding the potential of our product candidates, including our lead OEC candidate OTX-2002; development timelines; anticipated timing of regulatory submissions and filings; and expectations regarding our pipeline, including trial design, initiation of preclinical studies and our goal of declaring additional OEC development candidates. 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 controller machines 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; 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 period ended June 30, 2021 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.

Investor contact:

Kevin Murphy/Brendan Burns
Argot Partners
212.600.1902
ArgotOmega@argotpartners.com

Media contact:

David Rosen
Argot Partners
212.600.1902
david.rosen@argotpartners.com

Omega Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 11,184	\$ 4,895	\$ 20,933	\$ 8,416
General and administrative	3,637	1,010	6,452	2,375
Related party expense, net	384	225	763	567
Total operating expenses	<u>15,205</u>	<u>6,130</u>	<u>28,148</u>	<u>11,358</u>
Loss from operations	(15,205)	(6,130)	(28,148)	(11,358)
Other expense, net:				
Interest expense, net	(190)	(194)	(402)	(387)
Change in fair value of warrant liability	(11)	1	(340)	4
Other expense, net	(4)	—	(8)	—
Total other expense, net	<u>(205)</u>	<u>(193)</u>	<u>(750)</u>	<u>(383)</u>
Net loss and comprehensive loss	<u>\$ (15,410)</u>	<u>\$ (6,323)</u>	<u>\$ (28,898)</u>	<u>\$ (11,741)</u>
Net loss per common stock attributable to common stockholders, basic and diluted	<u>\$ (3.36)</u>	<u>\$ (1.58)</u>	<u>\$ (6.36)</u>	<u>\$ (2.99)</u>
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	<u>4,588,500</u>	<u>4,007,606</u>	<u>4,542,832</u>	<u>3,929,900</u>

Omega Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Cash and cash equivalents	\$ 122,411	\$ 22,951
Other assets	7,635	5,132
Total assets	\$ 130,046	\$ 28,083
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Liabilities	\$ 21,937	\$ 17,486
Redeemable convertible preferred stock	200,593	75,225
Stockholders' deficit	(92,484)	(64,628)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	\$ 130,046	\$ 28,083