

**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): November 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
(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 November 10, 2021, Omega Therapeutics, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended September 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.**

Exhibit No.	Description
99.1	Press Release, dated November 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.

Date: November 10, 2021

By: /s/ Mahesh Karande

Mahesh Karande

President and Chief Executive Officer



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

- *OTX-2002, the Company's Lead Program Targeting c-MYC for the Treatment of Hepatocellular Carcinoma, is Currently Advancing Through IND-Enabling Studies; Good Progress Across Broad Pipeline*
- *Established Strategic Collaboration with Stanford University School of Medicine for Potential Future Omega Epigenomic Controller™ Development Candidates to Further Diversify Pipeline*
- *Strong Balance Sheet to Fund Pipeline of Omega Epigenomic Controllers with \$234.3 Million in Cash and Cash Equivalents as of September 30, 2021*

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

"We continue to progress our pioneering OMEGA platform and our pipeline of Omega Epigenomic Controllers (OECs) with our first candidate, OTX-2002 for the treatment of hepatocellular carcinoma, which we believe is one of many potential therapeutic applications of our platform, currently advancing through Investigational New Drug (IND)-enabling studies. The third quarter was marked by our successful initial public offering (IPO), which left us well capitalized to continue advancing our other high priority pipeline programs, including OECs targeting CXCL 1-3/IL8 for acute respiratory distress syndrome (ARDS), SFRP1 for alopecia, c-MYC for non-small cell lung cancer (NSCLC) and HNF4a for liver disease," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "We are also excited to have announced our research collaboration with the Ophthalmology Department of Stanford University School of Medicine, which allows us to expand and further diversify our pipeline."

Recent Business Highlights and Corporate Update

Financial and Corporate

- Omega has made progress advancing its preclinical programs and developing the OMEGA platform. The Company continues to evaluate new DNA-sequence-based epigenomic zip codes, EpiZips™, and Insulated Genomic Domains (IGDs) for biologically validated gene targets through its OMEGA platform with the goal of further broadening its pipeline and bringing its new class of mRNA therapeutics as

programmable epigenetic medicines, OECs, to patients across a broad range of diseases.

- In October 2021, Omega announced a strategic research collaboration with the Stanford University School of Medicine. The collaboration will explore the therapeutic potential of OECs to control ocular disease genes associated with inflammation or regeneration of ocular tissues. Using the OMEGA platform, the Ophthalmology Department of Stanford University School of Medicine will discover and research novel ocular targets for potential future OEC development candidates.
- In August 2021, Omega completed a successful IPO, 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.

Development Pipeline and Platform

- **OTX-2002:** IND-enabling studies are ongoing for Omega's lead OEC candidate OTX-2002, the first in a new class of programmable epigenetic medicines targeting proprietary EpiZips in the MYC IGD and 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 target filing an IND for OTX-2002 in the first half of 2022.
- **Additional OEC Development:** The Company is working on multiple programs in pre-clinical studies, including ARDS with CXCL1-3/IL8, alopecia with SFRP1, NSCLC with c-MYC and liver disease with HNF4a, and is targeting the identification of additional development candidates for the first half of 2022 and an additional IND for the second half of 2022 or early 2023.
- **OMEGA Epigenomic Programming Platform:** Omega continues to evolve and develop its OMEGA platform, most notably, continual integration and updating of its suite of technologies that enable the development of potentially breakthrough medicines. These include state of the art artificial intelligence (AI) tools, proprietary and public data sets for target identification, machine learning (ML) based predictive models and a high throughput automated lab for genetic engineering. This digital infrastructure, paired with the Company's process of systematic, rational and integrative drug design, enables Omega to efficiently develop breakthrough therapeutics with a higher predicted success rate and a lower cost. Against the backdrop of the advancements to the platform, Omega continues to identify additional gene targets and evaluate them in preclinical studies.

Third Quarter 2021 Financial Results

As of September 30, 2021, the Company had cash and cash equivalents totaling \$234.3 million, which include the net proceeds of \$128.1 million from the Company's IPO.

Research and development (R&D) expenses increased to \$12.3 million for the third quarter of 2021 from \$5.5 million for the third quarter of 2020 primarily due to an increase in discovery and preclinical development costs and personnel and related expenses as the Company continues to advance its pipeline and discovery portfolio.

General and administrative expenses (G&A) increased to \$4.4 million from \$2.0 million for the third quarter of 2020 primarily due to higher personnel and related expenses and increased costs to operate as a public company, in addition to higher professional fees to support business growth.

Net loss for the third quarter of 2021 was \$18.5 million, compared with \$8.2 million for the third quarter of 2020. The increase in net loss for the third quarter was primarily due to increased R&D and G&A expenses to support the Company's growth and to operate as a public company.

About Omega Therapeutics

Omega Therapeutics is a development-stage biotechnology company pioneering the first systematic approach to use mRNA therapeutics as a new class of 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. Using a suite of technologies, paired with Omega's process of systematic, rational and integrative drug design, 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 proprietary and novel DNA-sequence-based epigenomic loci, EpiZips™ 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; the success of our collaboration with Stanford; 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 September 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 12,289	\$ 5,505	\$ 33,222	\$ 13,921
General and administrative	4,459	2,047	10,911	4,422
Related party expense, net	473	493	1,235	1,060
Total operating expenses	<u>17,221</u>	<u>8,045</u>	<u>45,368</u>	<u>19,403</u>
Loss from operations	(17,221)	(8,045)	(45,368)	(19,403)
Other expense, net:				
Interest expense, net	(339)	(196)	(741)	(584)
Change in fair value of warrant liability	(970)	1	(1,310)	5
Other income (expense), net	2	(1)	(7)	—
Total other expense, net	<u>(1,307)</u>	<u>(196)</u>	<u>(2,058)</u>	<u>(579)</u>
Net loss and comprehensive loss	<u>\$ (18,528)</u>	<u>\$ (8,241)</u>	<u>\$ (47,426)</u>	<u>\$ (19,982)</u>
Net loss per common stock attributable to common stockholders, basic and diluted	<u>\$ (0.57)</u>	<u>\$ (1.97)</u>	<u>\$ (3.41)</u>	<u>\$ (4.98)</u>
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	<u>32,303,540</u>	<u>4,180,696</u>	<u>13,898,089</u>	<u>4,014,800</u>

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

	<u>September 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Cash and cash equivalents	\$ 234,275	\$ 22,951
Other assets	8,996	5,132
Total assets	\$ 243,271	\$ 28,083
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Liabilities	\$ 22,932	\$ 17,486
Redeemable convertible preferred stock	—	75,225
Stockholders' equity (deficit)	220,339	(64,628)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$ 243,271	\$ 28,083

