

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): March 1, 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 March 1, 2023, Omega Therapeutics, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 31, 2022. 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 March 1, 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: March 1, 2023

By: /s/ Mahesh Karande

Mahesh Karande

President and Chief Executive Officer



Omega Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

- *Advanced Company's Lead Program, OTX-2002, in the Clinic; Preliminary Data from Phase 1/2 MYCHELANGELO™ I Trial Anticipated in 2023*
- *Progressed IND-enabling Studies for OTX-2101; Company's Development Candidate for MYC-driven Non-Small Cell Lung Cancer to Utilize a Novel Lung-Targeting Lipid Nanoparticle*
- *Ended the Year with Cash, Cash Equivalents and Marketable Securities of \$124.7 Million as of December 31, 2022*
- *Further Strengthened Balance Sheet with \$40 Million Registered Direct Offering*

CAMBRIDGE, Mass., March 1, 2023 -- Omega Therapeutics, Inc. (Nasdaq: OMGA) ("Omega"), a clinical-stage biotechnology company pioneering the development of a new class of programmable epigenetic mRNA medicines, today announced financial results for the fourth quarter and full year ended December 31, 2022 and provided a corporate update.

"2022 was a pivotal year for Omega, marked by tremendous progress and consistent execution. Our first programmable epigenetic mRNA medicine, OTX-2002, received IND clearance and orphan drug designation from the FDA and we launched our landmark MYCHELANGELO™ I clinical trial for the treatment of hepatocellular carcinoma and other solid tumor types known for association with the MYC oncogene. We also made significant advancements across our pipeline, including the selection of our second development candidate, OTX-2101 for MYC-driven non-small cell lung cancer with a novel lung-targeting lipid nanoparticle, and characterized our CXCL1-8 preclinical program in multiple potential indications," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics.

"This year, we aim to generate clinical proof-of-platform through MYCHELANGELO I and replicate our preclinical findings for OTX-2002. In addition to characterizing safety and tolerability, we are collecting translational data, assessing epigenetic state changes, correlating mRNA and protein changes, and evaluating anti-tumor activity," Karande continued. "We are excited at the prospect to deliver on the promise of epigenetics and make a meaningful impact on transforming medicine in service of patients. With additional capital from our recently completed registered direct offering further strengthening our balance sheet, we believe we are well positioned to build on our momentum through the potential value inflection milestones this year."

Recent Corporate Highlights and Upcoming Anticipated Milestones

Development Pipeline and Platform

- **Advanced MYCHELANGELO I Clinical Trial for OTX-2002, the Company's Lead Omega Epigenomic Controller™ (OEC):** Enrollment continues in the Phase 1/2 trial evaluating OTX-2002 as a monotherapy (Part 1) and in combination with standard of care therapies (Part 2) in patients with relapsed or refractory hepatocellular carcinoma (HCC) and other solid tumor types known for association with the c-Myc (MYC) oncogene. Trial enrollment is progressing as planned with multiple clinical sites initiated across the U.S. and Asia; additional sites are expected to activate in these regions. Preliminary data from the Phase 1 monotherapy dose escalation portion of the study are anticipated in 2023.
- **Presented a Trial-in-Progress Poster at ASCO Gastrointestinal Cancers Symposium:** In January 2023, a trial-in-progress poster titled "A phase 1/2 open-label study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity of OTX-2002 as a single agent and in combination with standard of care in patients with hepatocellular carcinoma and other solid tumor types known for association with the MYC oncogene (MYCHELANGELO I)" was presented at the American Society for Clinical Oncology 2023 Gastrointestinal Cancers Symposium (ASCO-GI).
- **Advanced Preclinical Development of Multiple OEC Programs:** The Company continues to advance multiple OECs from the OMEGA platform through preclinical studies. OTX-2101, declared as Omega's second development candidate, is being evaluated in Investigational New Drug (IND)-enabling studies for the treatment of MYC-driven non-small cell lung cancer (NSCLC), an area of significant unmet patient need. The CXCL 1-8-targeting OEC has been characterized in preclinical studies and has potential in several indications including neutrophilic asthma, acute respiratory distress syndrome (including COVID-related), oncology, and dermatological and rheumatological indications, representing a potential franchise opportunity.

Corporate

- **Strengthened Balance Sheet with Registered Direct Offering:** In February 2023, the Company closed a registered direct offering of its common stock resulting in net proceeds of approximately \$39.7 million. The offering included participation from new and existing investors.
 - **Recognized for Culture and Innovation in Industry Awards:** In November 2022, BioSpace named Omega among its Best Places to Work 2023 report in the small employers category. The Company was also named as a finalist for the Reuters Events Pharma Awards USA 2022 in the Health Entrepreneur category.
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Fourth Quarter and Full Year 2022 Financial Results

As of December 31, 2022, the Company had cash, cash equivalents and marketable securities totaling \$124.7 million. Subsequent to the close of 2022, the Company received approximately \$39.7 million in net proceeds from a registered direct offering of common stock.

Research and development (R&D) expenses for the fourth quarter of 2022 were \$25.7 million, compared to \$14.7 million for the fourth quarter 2021. R&D expenses for 2022 were \$80.0 million compared to \$47.9 million in 2021. The \$32.1 million increase in R&D expenses in 2022 compared to 2021 was primarily due to increases in discovery and preclinical development costs, clinical development costs, and personnel and related expenses as the Company continues to advance its pipeline and discovery portfolio.

General and administrative (G&A) expenses for the fourth quarter of 2022 were \$5.4 million, compared with \$5.7 million for the fourth quarter of 2021. G&A expenses for 2022 were \$21.8 million, compared to \$16.6 million in 2021. The \$5.2 million increase in G&A expenses in 2022 compared to 2021 was 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 fourth quarter of 2022 was \$30.8 million, compared with \$20.9 million for the fourth quarter of 2021. Net loss for the year ended December 31, 2022 was \$102.7 million, compared to a net loss of \$68.3 million for the year ended December 31, 2021. The increase in net loss for 2022 compared to 2021 was primarily due to increases in R&D and G&A expenses to support the Company's growth and operations as a public company.

About Omega Therapeutics

Omega Therapeutics, founded by Flagship Pioneering, is a clinical-stage biotechnology company pioneering the development of a new class of programmable epigenetic mRNA medicines. The Company's 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 modular and programmable mRNA medicines, Omega Epigenomic Controllers™, target specific epigenomic loci within insulated genomic domains, EpiZips, from amongst thousands of unique, mapped, and validated genome-wide DNA-sequences, with high specificity to durably tune single or multiple genes to treat and cure diseases through unprecedented precision epigenomic control. Omega's pipeline of product candidates spans 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 the timing, progress and design of our Phase 1/2 MYCHELANGELO™ I clinical trial and our preclinical trials, as well as the timing of announcements of data related thereto; the sufficiency of our cash, cash equivalents and marketable securities, including the proceeds from our registered direct offering in February 2023, to fund our operations; the potential of the OMEGA platform to engineer programmable epigenetic 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; and 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. 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 Annual Report on Form 10-K for the year ended December 31, 2022, 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.
Consolidated statements of operations and comprehensive loss
(Unaudited, In thousands except share data and per share data)

| | <u>Three Months Ended December 31,</u> | | <u>Year Ended December 31,</u> | |
|---|--|--------------------|--------------------------------|--------------------|
| | <u>2022</u> | <u>2021</u> | <u>2022</u> | <u>2021</u> |
| Collaboration revenue from related party | \$ 735 | \$ 144 | \$ 2,073 | \$ 144 |
| Operating expenses: | | | | |
| Research and development | 25,667 | 14,676 | 79,996 | 47,865 |
| General and administrative | 5,355 | 5,659 | 21,821 | 16,603 |
| Related party expense, net | 680 | 473 | 3,022 | 1,708 |
| Total operating expenses | <u>31,702</u> | <u>20,808</u> | <u>104,839</u> | <u>66,176</u> |
| Loss from operations | (30,967) | (20,664) | (102,766) | (66,032) |
| Other income (expense), net: | | | | |
| Interest income (expense), net | 248 | (170) | 222 | (910) |
| Change in fair value of warrant liability | — | — | — | (1,310) |
| Other income (expense), net | (107) | (20) | (157) | (28) |
| Total other income (expense), net | <u>141</u> | <u>(190)</u> | <u>65</u> | <u>(2,248)</u> |
| Net loss | <u>\$ (30,826)</u> | <u>\$ (20,854)</u> | <u>\$ (102,701)</u> | <u>\$ (68,280)</u> |
| Net loss per common stock attributable to common stockholders, basic and diluted | <u>\$ (0.64)</u> | <u>\$ (0.44)</u> | <u>\$ (2.14)</u> | <u>\$ (3.05)</u> |
| Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted | <u>47,895,083</u> | <u>47,781,701</u> | <u>47,880,819</u> | <u>22,404,058</u> |
| Comprehensive loss: | | | | |
| Net loss | \$ (30,826) | \$ (20,854) | \$ (102,701) | \$ (68,280) |
| Other comprehensive loss: | | | | |
| Unrealized gain (loss) on marketable securities | 438 | (62) | (417) | (62) |
| Comprehensive loss | <u>\$ (30,388)</u> | <u>\$ (20,916)</u> | <u>\$ (103,118)</u> | <u>\$ (68,342)</u> |

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

| | December 31, | December 31, |
|---|-------------------|-------------------|
| | 2022 | 2021 |
| Assets | | |
| Cash and cash equivalents | \$ 70,615 | \$ 186,482 |
| Marketable securities | 54,063 | 38,845 |
| Other assets | 21,320 | 8,006 |
| Total assets | \$ 145,998 | \$ 233,333 |
| Liabilities and stockholders' equity | | |
| Liabilities | \$ 40,027 | \$ 32,705 |
| Stockholders' equity | 105,971 | 200,628 |
| Total liabilities and stockholders' equity | \$ 145,998 | \$ 233,333 |

