Omega Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Outlines Key Corporate Objectives for 2022

March 10, 2022

- Investigational New Drug Application for OTX-2002 for c-Myc Driven Hepatocellular Carcinoma On Track to be Submitted in the First Half of 2022

- Additional Omega Epigenomic Controller™ Development Candidates Targeted to be Announced in the First Half of 2022

- Strong Balance Sheet to Fund Pipeline of Omega Epigenomic Controllers with $225.3 Million in Cash, Cash Equivalents and Marketable Securities as of December 31, 2021

CAMBRIDGE, Mass., March 10, 2022 /PRNewswire/ -- 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 fourth quarter and full year ended December 31, 2021.

"In 2021, we made significant strides across all aspects of our business highlighted by the successful completion of our initial public offering, the nomination of OTX-2002 as the industry's first programmable epigenetic medicine to be developed for the treatment of c-Myc (MYC)-driven hepatocellular carcinoma (HCC), and the continued development of our groundbreaking platform and pipeline," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "With our funding in 2021 and recent key additions to our team, we are well positioned to steadily advance a broad portfolio of Omega Epigenomic Controllers™ (OECs). Looking ahead, we are targeting to submit an Investigational New Drug application (IND) for OTX-2002 and nominate two OEC candidates in the first half of 2022. We are also planning for an additional IND in the second half of 2022 or early 2023 and several scientific presentations and publications throughout the year."

Recent Business Highlights and Corporate Update

Development Pipeline and Platform

- **American Association for Cancer Research (AACR) Annual Meeting 2022:** An abstract titled, "Epigenetic Modulation of the MYC oncogene as a potential novel therapy for HCC" was selected for a poster presentation at the upcoming AACR 2022 Annual Meeting. The presentation will highlight the mechanism of action of OTX-2002 and its potential as a differentiated and viable approach to the treatment of HCC.
- **OTX-2002:** IND-enabling studies are ongoing for Omega's lead OEC candidate OTX-2002, a novel, engineered, and programmable mRNA therapeutic targeting the MYC oncogene in patients with HCC. In preclinical studies, OTX-2002 demonstrated its ability to potently downregulate MYC oncogene expression. The Company continues to be on track to file 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 acute respiratory distress syndrome (ARDS) with CXCL1-3/IL8, non-small cell lung cancer (NSCLC) with MYC, alopecia with SFRP1, and liver disease with HNF4a.
- **OMEGA Epigenomic Programming Platform:** Omega is creating a new generation of programmable epigenetic mRNA medicines that are designed to control the fundamental epigenetic processes to correct the root cause of disease by restoring 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 with high target specificity to durably tune the expression of single or multiple genes. Omega is advancing multiple pre-clinical development programs in oncology, multigenic diseases including immunology, regenerative medicine, and select monogenic diseases.

Corporate

- In January 2022, Yan Moore, M.D., was appointed Chief Medical Officer of Omega. Dr. Moore has extensive management, research, translational drug development and medical affairs experience across various pharmaceutical and biotechnology companies.

Anticipated Milestones and Key Priorities for 2022

- Complete IND-enabling studies for OTX-2002 and file the Company's first IND to the U.S. Food and Drug Administration (FDA) during the first half of 2022.

- Declare two OEC development candidates in the first half of 2022.
- Target submission of an additional IND application in the second half of 2022 or early 2023.
- Continue to develop the OMEGA Epigenomic Programming platform and investigate additional development programs to expand pipeline.
- Publish and present relevant preclinical and early clinical data supporting programs and platform development.

Fourth Quarter and Full Year 2021 Financial Results

As of December 31, 2021, the Company had cash, cash equivalents and marketable securities totaling $225.3 million.

Research and development (R&D) expenses for the fourth quarter of 2021 were $14.7 million, compared with $7.1 million for the fourth quarter of 2020. R&D expenses for 2021 were $47.9 million, compared to $21.1 million in 2020. The $26.8 million increase in R&D expenses in 2021 compared to 2020 was 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) for the fourth quarter of 2021 were $5.7 million, compared with $1.9 million for the fourth quarter of 2020. G&A expenses for 2021 were $16.6 million, compared to $6.2 million in 2020. The $10.4 million increase in G&A expenses in 2021 compared to 2020 was primarily due to higher personnel and related expense and increased costs to operate as a public company, in addition to the higher professional fees to support business growth.

Net loss for the fourth quarter of 2021 was $20.9 million, compared with $9.5 million for the fourth quarter of 2020. Net loss for the year ended December 31, 2021 was $68.3 million, compared to a net loss of $29.4 million for the year ended December 31, 2020. The increase in net loss for 2021 compared to 2020 was primarily due to increased 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 development-stage biotechnology company pioneering a systematic approach to use mRNA therapeutics as a new class of programmable epigenetic medicines. The company's OMEGA Epigenomic Programming™ 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 deterministic OMEGA platform enables control of fundamental epigenetic processes to correct the root cause of disease by restoring aberrant gene expression to a normal range without altering native nucleic acid sequences. Omega's programmable and modular mRNA epigenetic 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 Precision Genomic Control™. Omega is currently advancing a broad pipeline of development candidates spanning a range of disease areas, including oncology, multigenic diseases including immunology, regenerative medicine, 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 Annual Report on Form 10-K for the year ended December 31, 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.
Consolidated statements of operations and comprehensive loss
(in thousands, except share and per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2021	**2020**	**2021**	**2020**
Collaboration revenue from related party	$ 144	$ —	$ 144	$ —
Operating expenses:				
Research and development	14,676	7,099	47,865	21,063
General and administrative	5,659	1,858	16,603	6,236
Related party expense, net	473	286	1,708	1,346
Total operating expenses	20,808	9,243	66,176	28,645
Loss from operations	(20,664)	(9,243)	(66,032)	(28,645)
Other expense, net:				
Interest expense, net	(170)	(193)	(910)	(777)
Change in fair value of warrant liability	—	(1)	(1,310)	3
Other expense, net	(20)	(28)	(28)	(28)
Total other expense, net	(190)	(222)	(2,248)	(802)
Net loss	$ (20,854)	$ (9,465)	$ (68,280)	$ (29,447)
Net loss per common stock attributable to common stockholders, basic and diluted	$ (0.44)	$ (2.18)	$ (3.05)	$ (7.54)
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	47,781,701	4,337,263	22,404,058	3,906,168
Comprehensive loss:				
Net loss	$ (20,854)	$ (9,465)	$ (68,280)	$ (29,447)
Other comprehensive loss:				
Unrealized loss on marketable securities	(62)	—	(62)	—
Comprehensive loss	$ (20,916)	$ (9,465)	$ (68,342)	$ (29,447)

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

	December 31,	
	2021	**2020**
Assets		
Cash and cash equivalents	$186,482	$ 22,951
Marketable securities	38,845	—
Other assets	8,006	5,132
Total assets	**$233,333**	**$ 28,083**
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Liabilities	$ 32,705	$ 17,486
Redeemable convertible preferred stock	—	75,225
Stockholders' equity (deficit)	200,628	(64,628)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	**$233,333**	**$ 28,083**

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