Omega Therapeutics Reports Third Quarter 2022 Financial Results and Recent Corporate Highlights

November 8, 2022

- *First Patient Dosed in Phase 1/2 MYCHELANGELO™ I Trial of OTX-2002*
- *OTX-2002 Granted Orphan Drug Designation by U.S. FDA for the Treatment of Hepatocellular Carcinoma*
- *OTX-2101 for MYC-Driven Non-Small Cell Lung Cancer Selected as Second Omega Epigenomic Controller™ Development Candidate*
- *$148.3 Million in Cash, Cash Equivalents and Marketable Securities as of September 30, 2022*

CAMBRIDGE, Mass., Nov. 8, 2022 /PRNewswire/ -- Omega Therapeutics, Inc. (Nasdaq: OMGA) ("Omega"), a clinical-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, 2022 and highlighted recent Company progress.

"The significant progress we are making on all fronts across our development pipeline is exciting, including the initiation of the MYCHELANGELO™ clinical program for OTX-2002, which represents the first-ever dosing of an epigenomic controller in a patient and marks a significant milestone in our journey to bring novel and programmable mRNA therapeutics to patients," said Mahesh Karande, President and Chief Executive Officer of Omega Therapeutics. "We were also delighted to announce our next development candidate, OTX-2101 for the treatment of patients with MYC-driven non-small cell lung cancer. Our focus is on advancing our lead programs, OTX-2002 and OTX-2101, as well as driving additional discovery and preclinical assets forward to further expand our pipeline."

Recent Corporate Highlights

Development Pipeline and Platform

- **First Patient Dosed in Landmark MYCHELANGELO I Clinical Trial for OTX-2002, the First-Ever Omega Epigenomic Controller™ (OEC):** The Phase 1/2 study is the first-ever study to evaluate this new class of programmable mRNA therapeutics designed to treat or cure serious diseases through precision genomic control. The study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity of 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. The study is expected to enroll approximately 190 patients at clinical trial sites in the United States, Asia, and Europe.
- **OTX-2002 Granted Orphan Drug Designation by U.S. Food and Drug Administration (FDA) for Hepatocellular Carcinoma (HCC):** OTX-2002 is a rationally engineered, novel and programmable mRNA therapeutic designed to downregulate MYC expression pre-transcriptionally through epigenetic modulation while potentially overcoming MYC autoregulation. The FDA's Orphan Drug Designation Program provides orphan status to drugs intended for the treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States.
- **OTX-2101 for MYC-Driven Non-Small Cell Lung Cancer (NSCLC) Selected as Second Omega Epigenomic Controller Development Candidate:** OTX-2101 is the second candidate in this new class of programmable mRNA therapeutics designed to downregulate MYC expression pre-transcriptionally through epigenetic modulation while potentially overcoming MYC autoregulation. Preclinical data presented at the 2022 American Society of Gene & Cell Therapy (ASGCT) Annual Meeting demonstrated OTX-2101 potently downregulates MYC in multiple NSCLC cell lines. OTX-2101 effectively reduced tumor growth *in vivo* and was well tolerated in murine xenograft models, further supporting its clinical potential. Investigational New Drug (IND)-enabling studies for OTX-2101 are underway.
- **Completed Development Candidate-enabling Activities for Several OECs:** Beyond HCC and NSCLC, the Company continues to advance multiple OECs from the OMEGA Epigenomic Programming platform through preclinical studies. 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. The Company continues additional preclinical work for its OEC development programs spanning oncology, multigenic diseases including immunology, regenerative medicine, and select monogenic diseases.

Corporate

- **Rainer Boehm Appointed to Board of Directors**: Mr. Boehm joined the Board on August 30, 2022. He serves on the Company's audit and compensation committees. He brings over 30 years of successful and diverse clinical, managerial,

drug development, and commercialization experience to Omega.

Third Quarter 2022 Financial Results

As of September 30, 2022, the Company had cash, cash equivalents and marketable securities totaling $148.3 million.

Research and development (R&D) expenses for the third quarter of 2022 were $20.7 million, compared to $12.3 million for the third quarter of 2021. The $8.4 million increase in R&D expense was primarily driven by an increase in personnel-related expenses, external manufacturing costs, and study costs in support of the advancement of our programs.

General and administrative (G&A) expenses for the third quarter of 2022 were $5.2 million, compared to $4.5 million for the third quarter of 2021. The $0.7 million increase in G&A expense was primarily driven by an increase in personnel-related expenses to support business growth.

Net loss for the third quarter of 2022 was $25.8 million, compared to $18.5 million for the third quarter of 2021, driven predominantly by 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 clinical-stage biotechnology company pioneering the first 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 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™, are designed to 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, regenerative medicine, multigenic diseases including immunology, and select monogenic diseases, including alopecia.

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 and design of our Phase 1/2 MYCHELANGELO™ I clinical trial; 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 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; 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 most recent Quarterly Report on Form 10-Q and 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.

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Omega Therapeutics, Inc.
Condensed consolidated statements of operations and comprehensive loss
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue from related party	$ 595	$ —	$ 1,338	$ —
Operating expenses:				
Research and development	20,670	12,289	54,329	33,222
General and administrative	5,198	4,459	16,466	10,911
Related party expense, net	712	473	2,342	1,235
Total operating expenses	26,580	17,221	73,137	45,368
Loss from operations	(25,985)	(17,221)	(71,799)	(45,368)
Other expense, net:				
Interest income (expense), net	184	(339)	(26)	(741)
Change in fair value of warrant liability	—	(970)	—	(1,310)
Other income (expense), net	2	2	(50)	(7)
Total other income (expense), net	186	(1,307)	(76)	(2,058)
Net loss	$ (25,799)	$ (18,528)	$ (71,875)	$ (47,426)
Net loss per common stock attributable to common stockholders, basic and diluted	$ (0.54)	$ (0.57)	$ (1.50)	$ (3.41)
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	47,854,965	32,303,540	47,837,490	13,898,089
Comprehensive loss:				
Net loss	$ (25,799)	$ (18,528)	$ (71,875)	$ (47,426)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	89	—	(855)	—
Comprehensive loss	$ (25,710)	$ (18,528)	$ (72,730)	$ (47,426)

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

	September 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 76,614	$ 186,482
Marketable securities	71,732	38,845
Other assets	21,719	8,006
Total assets	**$ 170,065**	**$ 233,333**
Liabilities and stockholders' equity		
Liabilities	$ 36,414	$ 32,705
Stockholders' equity	133,651	200,628
Total liabilities and stockholders' equity	**$ 170,065**	**$ 233,333**

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