

Moderna Provides Business Updates and Reports Third Quarter 2019 Financial Results

Positive interim results announced from Phase 1 CMV vaccine (mRNA-1647) study

Positive interim results announced from Phase 1 mRNA encoding chikungunya antibody (mRNA-1944) study

First participant dosed in Phase 1b age de-escalation study of hMPV+PIV3 vaccine (mRNA-1653)

Cash, cash equivalents and investments at the end of the quarter were \$1.34 billion, and are expected to be approximately \$1.20 billion at the end of 2019

Net cash used in operating activities and purchases of property and equipment is expected to total approximately \$500 million in 2019, and between \$490 million and \$510 million in 2020

CAMBRIDGE, Mass., November 6, 2019 — Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today provided business updates and reported financial results for the third quarter of 2019.

New updates and recent progress include:

Infectious Diseases

- Positive interim results announced from Phase 1 CMV vaccine (mRNA-1647) study; Moderna is advancing mRNA-1647 to a dose-confirmation Phase 2 study in the near term while planning for a pivotal Phase 3 study
- First participant dosed in Phase 1b age de-escalation study of hMPV+PIV3 vaccine (mRNA-1653)
- FDA granted Fast Track designation for Zika vaccine (mRNA-1893)

Immuno-Oncology

- First patient dosed in Phase 2 PCV (mRNA-4157) study in patients with resected melanoma
- OX40L (mRNA-2416) Phase 2 expansion cohort in ovarian cancer to focus only on the combination with durvalumab (IMFINZI®)

Rare Diseases

- Positive interim results announced from Phase 1 chikungunya antibody (mRNA-1944) study; dosing of two additional cohorts planned to begin in the near term
- Phase 1/2 MMA (mRNA-3704) study is actively recruiting patients at U.S. sites following a protocol amendment expanding the eligibility criteria to patients 8 years and older
- FDA granted Fast Track designation for PA program (mRNA-3927); study start-up is ongoing for the open-label, multi-center Phase 1/2 study of multiple ascending doses of mRNA-3927 in pediatric patients with PA in the U.S.

Research

- Moderna announced a multi-year [mRNA immunotherapy research collaboration](#) with Harvard University to explore fundamental immunological processes and identify potential therapeutic opportunities

“The positive Phase 1 cytomegalovirus vaccine results announced this quarter represent an important step toward the prevention of congenital CMV infections. These data resulted from investment in our mRNA technology platform, which has now generated six positive infectious disease vaccine clinical readouts. Additionally, the recent positive Phase 1 chikungunya antibody results help de-risk a delivery technology shared by our rare disease programs, further validating our approach into new areas where mRNA medicines have the potential to treat a wide range of diseases,” said Stéphane Bancel, Moderna’s chief executive officer. “We ended the quarter with a strong cash balance of \$1.34 billion and up to \$187 million in additional untapped grant funding, giving us up to \$1.5 billion to invest in the Company moving forward. We expect investment levels in 2020 to be approximately \$500 million, similar to 2019. We intend to expand our group of biopharmaceutical partners and bring in additional non-dilutive grant and government funding as we advance our development pipeline and create new modalities.”

Moderna currently has 21 mRNA development candidates in its portfolio with 13 in clinical studies. Across Moderna’s pipeline, more than 1,400 participants have been enrolled in clinical studies. The Company’s updated pipeline can be found at www.modernatx.com/pipeline. Moderna and collaborators have published more than 40 peer-reviewed papers, including 23 over the last 12 months.

The Company has established a wide range of strategic alliances with leading biopharmaceutical companies, as well as government-sponsored and private organizations focused on global health initiatives. Strategic collaborators contribute their therapeutic expertise, help to validate Moderna’s mRNA platform and have provided a quarter of the Company’s total capital to date. As of September 30, 2019, Moderna had up to \$187 million in additional funding available from grants (including amounts not yet committed)¹.

Summary of Program Highlights by Modality

***Prophylactic vaccines:** Moderna is developing vaccines against viral diseases where there is unmet medical need - including complex vaccines with multiple antigens for common diseases, as well as vaccines against epidemic and pandemic threats to global public health.*

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** At the Company’s annual R&D Day, Moderna [announced](#) positive data from the three-month interim analysis of safety and immunogenicity of the Phase 1 study of mRNA-1647. Vaccination immunized seronegative participants to levels consistent with or above seropositive titers and boosted baseline titers in seropositive participants. The vaccine was generally well-tolerated; the most common solicited local adverse event was injection site pain, and the most common systemic adverse events were headaches and chills. The next readout from the study will be from a seven-month interim analysis. Moderna also recently announced that it is advancing mRNA-1647 to a dose-confirmation Phase 2 study in the near term. Preparation has also begun for a pivotal Phase 3 study designed to evaluate the efficacy of mRNA-1647 against primary CMV infection. The Phase 2 study will test the intended Phase 3 formulation, which contains the same proprietary lipid

¹ Biomedical Advanced Research and Development Authority (BARDA), Defense Advanced Research Projects Agency (DARPA) and The Bill and Melinda Gates Foundation (BMGF). Additional funding is subject to agreement on scope of additional projects.

nanoparticle (LNP) used in this Phase 1 study. mRNA-1647 is wholly owned by Moderna.

- **Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653):** The first participant in the Phase 1b age de-escalation study of hMPV+PIV3 vaccine (mRNA-1653) has been dosed. Moderna previously [announced](#) positive data from the second pre-planned interim analysis of the Phase 1 study of mRNA-1653. mRNA-1653 is wholly owned by Moderna.
- **Respiratory syncytial virus (RSV) vaccine (mRNA-1172 or V172):** The Phase 1 study of mRNA-1172 led by Merck is ongoing.
- **Zika virus vaccine (mRNA-1893):** In August, Moderna [announced](#) that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for mRNA-1893. The Phase 1 study of mRNA-1893 is ongoing.
- **Presentations of note:** Moderna presented data from its prophylactic vaccines at [IDWeek](#), World Vaccine Congress Europe and the International Society of Vaccines Annual Congress, including interim Phase 1 hMPV and PIV3 vaccine (mRNA-1653) data, preclinical Zika vaccine (mRNA-1893) data and interim Phase 1 CMV vaccine (mRNA-1647) data.

***Cancer Vaccines:** These programs focus on stimulating a patient's immune system with antigens derived from tumor-specific mutations to enable the immune system to elicit a more effective anti-tumor response.*

- **Personalized cancer vaccine (PCV) (mRNA-4157):** The first patients have been dosed in the randomized Phase 2 study investigating a 1 mg dose of mRNA-4157 in combination with Merck's pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma. The Phase 1 study is ongoing.
- **PCV (NCI-4650):** The National Cancer Institute (NCI) Phase 1 study of NCI-4650 as a monotherapy for patients with advanced metastatic cancers has completed enrollment with five participants. No responses to monotherapy in this heavily pretreated group were observed. NCI-4650 uses Moderna's mRNA technology but uses a different neoantigen selection process and study design than Moderna's Phase 1 mRNA-4157 study. [Interim results](#) from NCI-4650 were reported at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in June and have been submitted for publication.
- **KRAS vaccine (mRNA-5671 or V941):** The Phase 1 open-label, multi-center study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with pembrolizumab, led by Merck, is ongoing.

***Intratumoral Immuno-Oncology:** These programs aim to drive anti-cancer T cell responses by injecting mRNA therapies directly into tumors.*

- **OX40L (mRNA-2416):** Based on available data, the Company has decided to focus its development of mRNA-2416 for the treatment of patients with ovarian cancer in combination with durvalumab (IMFINZI®), a PD-L1 inhibitor. The safety cohort of the combination arm (mRNA-2416 and durvalumab) of this Phase 1/2 study is ongoing and will be followed by a Phase 2 expansion cohort in

patients with advanced ovarian carcinoma. The Company will not move forward with the mRNA-2416 monotherapy ovarian cancer arm of this study.

- **OX40L + IL23 + IL36 γ (Triplet) (mRNA-2752):** The Phase 1 trial evaluating mRNA-2752 as a single agent and in combination with durvalumab in patients with accessible solid tumors and lymphomas is ongoing. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators.
- **IL12 (MEDI1191):** The Phase 1 open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with durvalumab in patients with advanced solid tumors, led by AstraZeneca, is ongoing. MEDI1191 is an mRNA encoding for IL12, a potent immunomodulatory cytokine.

***Systemic Secreted Therapeutics:** In this modality, mRNA is delivered systemically to create proteins that are secreted outside the cell with the aim of producing pharmaceutically active proteins with therapeutic effects across the human body.*

- **Antibody against the chikungunya virus (mRNA-1944):** Moderna recently [announced](#) positive interim data from the first analysis of safety and activity in the Phase 1 study evaluating escalating doses of mRNA-1944 administered via intravenous infusion in healthy adults. mRNA-1944 successfully encoded for functional antibody (CHKV-24) in humans at all dose levels tested (0.1, 0.3 and 0.6 mg/kg). Antibody level predicted to protect against chikungunya infection was achieved within hours and was projected to be maintained for at least 16 weeks at the middle and high doses. No significant adverse events were observed at the low and middle doses; infusion-related adverse events were observed at the high dose, which resolved spontaneously without treatment. These results mark the first systemic mRNA therapeutic to show production of therapeutic levels of a secreted protein in humans, demonstrating predictable translation from preclinical species. mRNA-1944 uses the same proprietary LNP delivery technology as the systemic intracellular therapeutics targeting MMA and PA. The safety and pharmacology of mRNA-1944 will continue to be explored in two additional cohorts: one cohort with steroid premedication at the 0.6 mg/kg dose and a second cohort with two doses of 0.3 mg/kg (without steroid premedication) given one week apart.
- **Presentation of note:** In October, Moderna presented data from the [Phase 1 study of its chikungunya antibody \(mRNA-1944\)](#) at the Annual Meeting of the Oligonucleotide Therapeutics Society.

***Systemic Intracellular Therapeutics:** These programs aim to deliver mRNA into cells within target organs as a therapeutic approach for diseases caused by a missing or defective protein.*

- **Methylmalonic acidemia (MMA) (mRNA-3704):** The Phase 1/2 open-label, dose escalation study is actively recruiting patients for the first cohort at U.S. sites following a protocol amendment expanding the eligibility criteria to patients 8 years and older. This study is evaluating mRNA-3704 for the treatment of MMA due to methylmalonyl-CoA mutase (MUT) deficiency. The Company is planning to initiate several sites outside the U.S. and recently received Medicines and Healthcare products Regulatory Agency (MHRA) approval in the U.K. The objectives of this study are to evaluate safety and tolerability, assess the pharmacodynamic response and characterize the pharmacokinetic profile of mRNA-3704. This is Moderna's first rare disease program to advance into clinical testing. The mRNA-3704 program uses the same LNP formulation as mRNA-1944.

- **Propionic acidemia (PA) (mRNA-3927):** This quarter, Moderna announced an [open Investigational New Drug](#) (IND) and [FDA Fast Track designation](#) for mRNA-3927. Study start-up is ongoing for the open-label, multi-center Phase 1/2 study of multiple ascending doses of mRNA-3927 in pediatric patients with PA in the U.S. The objectives of this study are to evaluate the safety and tolerability of mRNA-3927 administered via IV infusion, assess the pharmacodynamic response as assessed by changes in plasma biomarkers and characterize the pharmacokinetic profile of mRNA-3927. The mRNA-3927 program uses the same LNP formulation as mRNA-1944.
- **MMA and PA Natural History Study (MaP):** As of October 2019, a total of 87 patients have been enrolled in the study (37 MMA, 50 PA). This is a global, multi-center, non-interventional study for patients with confirmed diagnosis of MMA due to MUT deficiency or PA and is designed to identify and correlate clinical and biomarker endpoints for these disorders.

Information about each development candidate in Moderna's pipeline, including those discussed in this press release, can be found on the investor relations page of its website: <https://investors.modernatx.com>.

Research Update

- In September, Moderna [announced](#) a multi-year research collaboration with Harvard University with the goal of identifying and developing novel therapeutic approaches that could improve the lives of patients with immunological diseases. Additional funding from Moderna to Harvard Medical School (HMS) has established an initiative at HMS called the Alliance for RNA Therapies for the Modulation of the Immune System (ARTiMIS), which will enable basic science research in the field of immunology using Moderna's mRNA and nanoparticle delivery technology.

Corporate Updates

- Moderna appointed [Tracey Franklin](#) as Chief Human Resources Officer.
- Moderna was named a [top biopharmaceutical employer by Science](#) for the fifth consecutive year.
- The Company will host its Manufacturing and Digital Day on March 4, 2020 at its Norwood, MA facility.

Financial Guidance

- The Company expects to end 2019 with approximately \$1.20 billion in cash, cash equivalents and investments.
- For 2019, the Company expects net cash used in operating activities and purchases of property and equipment to total approximately \$500 million.
- In 2020, the Company expects net cash used in operating activities and purchases of property and equipment to be similar to 2019, between \$490 million and \$510 million.

Third Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and investments as of September 30, 2019 and December 31, 2018 were \$1.34 billion and \$1.69 billion, respectively.

- **Net Cash Used in Operating Activities:** Net cash used in operating activities was \$363.2 million for the nine months ended September 30, 2019 compared to \$239.8 million for the same period in 2018. Net cash used in operating activities includes \$22.0 million and \$25.0 million for the nine months ended September 30, 2019 and 2018, respectively, of in-licensing payments to Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc., to sublicense certain patent rights. After the first quarter of 2019, we have no further in-licensing payment obligations to Cellscript and its affiliate.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was \$24.9 million for the nine months ended September 30, 2019 compared to \$92.1 million for the same period in 2018.
- **Revenue:** Total revenue was \$17.0 million for the three months ended September 30, 2019 compared to \$41.8 million for the same period in 2018. Total revenue was \$46.2 million for the nine months ended September 30, 2019 compared to \$99.6 million for the same period in 2018. On January 1, 2019, we adopted Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers (ASC 606), using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. The total revenue decreases in 2019 were due to decreases in collaboration revenue across all our strategic alliances, particularly AstraZeneca and Merck, largely driven by our adoption of ASC 606. Total revenue under the previous revenue recognition standard would have been \$24.7 million and \$80.2 million for the three months and nine months ended September 30, 2019, respectively.
- **Research and Development Expenses:** Research and development expenses were \$119.7 million for the three months ended September 30, 2019 compared to \$109.1 million for the same period in 2018. Research and development expenses were \$378.8 million for the nine months ended September 30, 2019 compared to \$303.7 million for the same period in 2018. The increases were primarily attributable to an increase in personnel related costs, including stock-based compensation, with additional increases for the nine months ended September 30, 2019 being driven by higher clinical trial and manufacturing costs, an increase in lab supplies and materials, and an increase in consulting and outside services.
- **General and Administrative Expenses:** General and administrative expenses were \$28.2 million for the three months ended September 30, 2019 compared to \$18.5 million for the same period in 2018. General and administrative expenses were \$84.0 million for the nine months ended September 30, 2019 compared to \$56.2 million for the same period in 2018. These increases were mainly due to the additional costs of operating as a publicly traded company, including an increase in personnel related costs and stock-based compensation, consulting and outside services, legal and insurance related costs.
- **Net Loss:** Net loss was \$123.2 million for the three months ended September 30, 2019 compared to \$80.3 million for the same period in 2018. Net loss was \$390.9 million for the nine months ended September 30, 2019 compared to \$243.3 million for the same period in 2018.

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Wednesday, November 6, 2019. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 6287715. A webcast of the call will also be available under “Events and Presentations” in the Investors section of the Moderna website at <https://investors.modernatx.com>. The archived webcast will be

available on Moderna's website approximately two hours after the conference call and will be available for 30 days following the call.

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Moderna's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing the Company the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and cardiovascular diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca, Plc. and Merck, Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense and the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Moderna has been named a top biopharmaceutical employer by *Science* for the past five years. To learn more, visit www.modernatx.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning: initiating clinical trial sites outside of the U.S. for mRNA-3704; study start-up for mRNA-3927; anticipated commencement of a dose-confirmation Phase 2 study and planning for a pivotal Phase 3 study for mRNA-1647; the Company's intent to expand its group of biopharmaceutical partners and bring in additional non-dilutive grant and government funding; the availability of additional funding from grants (including amounts not yet committed); the dosing of two additional cohorts in the near term for mRNA-1944; projected protection against chikungunya infection for at least sixteen weeks at the 0.3 and 0.6 mg/kg doses of mRNA-1944; the Company's expected cash, cash equivalents, and investments at December 31, 2019; and the Company's expected net cash used in operating activities and purchases of property and equipment in 2019 and 2020. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: whether the interim Phase 1 results for mRNA-1944 will be predictive of any future clinical studies for mRNA-1944 or other development candidates with the same LNP formulation, including mRNA-3704 and mRNA-3927; preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no mRNA drug has been approved in this new potential class of medicines, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory

agencies may not agree with our regulatory approval strategies, components of our or filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; and those risks and uncertainties described under the heading “Risk Factors” in Moderna’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC’s website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna’s current expectations and speak only as of the date hereof.

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MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	\$ 13,338	\$ 36,662	\$ 37,483	\$ 89,696
Grant revenue	3,708	5,095	8,671	9,951
Total revenue	17,046	41,757	46,154	99,647
Operating expenses:				
Research and development	119,715	109,050	378,786	303,653
General and administrative	28,188	18,525	83,994	56,229
Total operating expenses	147,903	127,575	462,780	359,882
Loss from operations	(130,857)	(85,818)	(416,626)	(260,235)
Interest income	9,252	6,519	30,546	18,129
Other expense, net	(1,767)	(1,032)	(5,351)	(1,044)
Loss before income taxes	(123,372)	(80,331)	(391,431)	(243,150)
(Benefit from) provision for income taxes	(178)	—	(526)	158
Net loss	<u>\$ (123,194)</u>	<u>\$ (80,331)</u>	<u>\$ (390,905)</u>	<u>\$ (243,308)</u>

MODERNA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS AND STATEMENTS OF CASH
FLOWS DATA
(Unaudited, in thousands)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Cash, cash equivalents and investments	\$ 1,338,400	\$ 1,694,417
Total assets	1,590,899	1,962,149
Total liabilities	339,092	431,908
Total stockholders' equity	1,251,807	1,530,241
Total liabilities and stockholders' equity	1,590,899	1,962,149

	<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>
Net cash used in operating activities	\$ 363,195	\$ 239,845
Purchases of property and equipment	24,892	92,129