Moderna Reports 2018 Fourth Quarter and Full Year Financial Results and Highlights Recent Pipeline Progress

March 6, 2019

Shows Continued Execution Across its Pipeline of Infectious Disease, Immuno-Oncology and Rare Disease Programs

Ends Year With $1.7 Billion in Cash, Cash Equivalents and Investments

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 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 reported financial results for the fourth quarter and full year of 2018 and highlighted pipeline progress since the Company's last corporate update in January.

New updates announced today include:

Infectious Diseases

- Moderna is preparing an IND for submission to the US Food and Drug Administration (FDA) for a follow-on Zika vaccine program (mRNA-1893); no further development planned for its first Zika vaccine candidate (mRNA-1325)

Immuno-Oncology

- Randomized Phase 2 protocol submitted to the FDA for personalized cancer vaccine (PCV) (mRNA-4157) study in patients with resected melanoma
- IND opened for Phase 1 study of mRNA encoding IL12 (MEDI1191) injected intratumorally in solid tumors

Rare Diseases

- FDA grants Fast Track designation for methylmalonic acidemia (MMA) program (mRNA-3704); IND opened for Phase 1/2 study of pediatric patients

"Execution by our team has enabled us to make important pipeline progress so far this year. We now have two additional programs ready for Phase 2 clinical development, newly opened INDs for our first rare disease program and a fifth immuno-oncology program, dosed the first cohort in a study of our systemically delivered mRNA that encodes for a secreted monoclonal antibody, and recently reported positive interim Phase 1 data for a novel combination vaccine designed to protect against viruses that can cause severe respiratory diseases in children," said Stéphane Bancel, Moderna's chief executive officer. "We look forward to generating new clinical data for programs across our portfolio over the next 12-24 months. Our strong cash position enables us to focus on advancing investigational medicines in our pipeline, pursue new candidates within our existing modalities and continue to invest in our mRNA platform to discover new modalities and treatments for patients across a broader range of disease areas."

Moderna currently has 20 mRNA development candidates in its portfolio, with 11 in clinical studies. Across Moderna's pipeline more than 1,000 subjects have been enrolled in clinical studies. The Company's updated pipeline can be found at www.modernatx.com/pipeline.

Summary of Recent 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.

- **hMPV+PIV3 (mRNA-1653):** In February, Moderna announced positive data from a planned interim analysis of safety and immunogenicity from its Phase 1 study of mRNA-1653 in healthy adults. mRNA-1653 is designed to protect against human Metapneumovirus (hMPV) and Parainfluenza Virus Type 3 (PIV3), two viruses that cause respiratory illnesses.It is a combination vaccine that consists of two distinct mRNA sequences encoding the fusion (F) proteins of hMPV and PIV3 formulated in Moderna's proprietary lipid nanoparticle (LNP) technology. Moderna plans to advance mRNA-1653 into a Phase 1b study of pediatric subjects.
- **Zika Vaccine (mRNA-1893):** Moderna's follow-on Zika vaccine candidate, mRNA-1893, continues to progress toward an IND filing. There will be no further development of Moderna's first Zika candidate, mRNA-1325. The Biomedical Advanced Research and Development Authority (BARDA) remains committed to its grant of up to approximately $125 million for development of a Zika vaccine.*
- **Publication of Note:** In February, Moderna researchers published new data in the scientific journal *Molecular Therapy: Nucleic Acids* that demonstrate how mRNA vaccines delivered with a proprietary Moderna lipid nanoparticle (LNP) show enhanced tolerability and comparable immunogenicity relative to legacy LNPs.

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 antitumor response.*

- **Personalized Cancer Vaccine (PCV) (mRNA-4157):** In February,Moderna and Merck submitted a new protocol to the FDA to commence a randomized Phase 2 study to assess whether post-operative adjuvant therapy with mRNA-4157, in combination with Merck's PD-1 inhibitor KEYTRUDA ®, improves recurrence-free survival compared to KEYTRUDA alone. The study has a primary endpoint of recurrence-free survival with a primary analysis at 12 months and will be conducted with patients that have had complete resection of cutaneous melanoma but remain at high risk of recurrence.

  Moderna's PCV is designed and manufactured individually based on the DNA sequence of a patient's tumor, encoding for peptides containing mutations found in their cancer in order to deliver multiple unique and personalized neoantigens in a single vaccine. Moderna's PCV now includes up to 34 neoantigens, up from 20. Moderna has also fully operationalized its personalized vaccine unit at its manufacturing site in Norwood, Mass., which is expected to further enhance supply chain management and enable the Company to accelerate manufacturing of individualized cancer treatments for patients.

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

- **OX40L + IL23 + IL36γ (Triplet) (mRNA-2752):** mRNA-2752 has cleared dosing of the first cohort of patients in the Phase 1 study and the dosing of a second cohort has commenced. mRNA-2752, also known as the Triplet, is an intratumoral injection comprising three mRNAs encoding for OX40L + IL23 + IL36γ for the treatment of advanced or metastatic solid tumor malignancies or lymphoma. The open-label, multi-center study is evaluating the safety and tolerability of mRNA-2752 as a single agent and in combination either with AstraZeneca's durvalumab or tremelimumab, and will assess anti-tumor activity, protein expression in tumors and pharmacokinetics.
- **IL12 (MEDI1191):** An IND has been opened for a Phase 1 study of mRNA encoding IL12 injected intratumorally inadvanced or metastatic solid tumors. Moderna's strategic collaborator AstraZeneca will lead this open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with a checkpoint inhibitor. Moderna provided the preclinical data package to support the IND submission and will provide clinical supply for this trial. MEDI1191 is an mRNA encoding for IL12, a potent immunomodulatory cytokine, which aims to enhance immune response in immunologically "cold" tumors.
- **Publication of Note:** In January,Moderna announced the publication of pre-clinical data in the scientific journal *Science Translational Medicine* that showed local delivery of the Triplet (mRNA-2752) induced a broad immune response and caused tumor regression in both injected lesions and distant un-injected tumors in mice. When combined with checkpoint inhibitors, mRNA-2752 was able to induce responses in tumor models that are otherwise unresponsive to checkpoint inhibitors.

Localized Regenerative Therapeutics: *These programs focus on the potential for the localized production of proteins to be used as a regenerative medicine for damaged tissues.*

- **Publication of Note**: In February, Moderna announced the publication of data from a Phase 1a/b study in *Nature Communications* showing the potential of mRNA encoding for vascular endothelial growth factor A (VEGF-A) as a regenerative therapeutic. When injected directly into the skin of patients with diabetes mellitus, the mRNA encoding VEGF-A was well tolerated, showed protein expression as demonstrated by dose-dependent protein translation and demonstrated protein pharmacology with evidence of increased blood flow. The data supported advancement of AZD8601, which now is in an ongoing Phase 2a study led by AstraZeneca.

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):** Dosing of the first cohort has been completedin Moderna's Phase 1 study evaluating the safety and tolerability of escalating doses of mRNA-1944 via intravenous infusion in healthy adults. This is the first monoclonal antibody encoded by mRNA to be dosed in a human and the first development candidate from the Company's systemic therapeutics modalities to start clinical testing. Modernaannounced the dosing of the first patient in the study in February. mRNA-1944 encodes a fully human IgG antibody originally isolated from B cells of a patient with a prior history of potent immunity against chikungunya infection and is composed of two mRNAs that encode the heavy and light chains of this anti-chikungunya antibody within Moderna's proprietary lipid nanoparticle (LNP) technology. This formulation was developed by Moderna and is utilized for IV delivery of each of its systemic therapeutics, including its rare disease programs.

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 FDA has granted Fast Track designation for mRNA-3704, the first for a Moderna investigational medicine. Moderna now has an open IND and is preparing to begin a Phase 1/2 open-label, multi-center, multiple ascending dose study of mRNA-3704 in pediatric patients with isolated MMA due to MUT enzyme deficiency. The objectives of the study are to evaluate safety and tolerability, assess the pharmacodynamic response and characterize the pharmacokinetic profile of mRNA-3704. The program previously received Rare Pediatric Disease

Designation by the FDA and Orphan Drug Designation by both the FDA and the European Medicines Agency (EMA). This is Moderna's first rare disease program to advance into clinical trials.

Information about each program 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/.

Fourth Quarter and Full Year 2018 Financial Results

- **Cash Position:** Cash, cash equivalents and investments as of December 31, 2018 and December 31, 2017 were $1.7 billion and $0.9 billion, respectively.
- **Net Cash Used in Operating Activities:** Net cash used in operating activities was $330.9 million for the year ended December 31, 2018 compared to $331.5 million for the year ended December 31, 2017.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was $105.8 million for the year ended December 31, 2018 compared to $58.4 million for the year ended December 31, 2017. Of these amounts, cash disbursements specifically related to the Norwood manufacturing facility were $94.5 million and $41.2 million for the years ended December 31, 2018 and 2017, respectively. The Norwood plant opened in July 2018.
- **Revenue:** Total revenue was $35.4 million for the fourth quarter of 2018 compared to $91.9 million for the fourth quarter of 2017. Total revenue was $135.1 million for the year ended December 31, 2018 compared to $205.8 million for the year ended December 31, 2017. The decreases in both periods were mainly attributable to the termination of the Alexion strategic alliance arrangement in October 2017, and a decrease in grant revenue from the BARDA contract, primarily due to revisions to the Zika program and a focus on preclinical studies of mRNA-1893, the follow on to mRNA-1325. The decreases were partially offset by increases in collaboration revenue from AstraZeneca and Merck.
- **Research and Development Expenses:** Research and development expenses were $150.4 million for the fourth quarter of 2018 compared to $117.8 million for the fourth quarter of 2017. Research and development expenses were $454.1 million for the year ended December 31, 2018 compared to $410.5 million for the year ended December 31, 2017. The increases in both periods were primarily due to an increase in personnel related cost, including stock-based compensation, mainly driven by an increase in the number of employees supporting research and development programs, an increase in consulting and outside services, and an increase in facility and equipment related costs.
- **General and Administrative Expenses:** General and administrative expenses were $38.0 million for the fourth quarter of 2018 compared to $15.9 million for the fourth quarter of 2017. General and administrative expenses were $94.3 million for the year ended December 31, 2018 compared to $64.7 million for the year ended December 31, 2017. The increases in both periods were mainly attributable to increases in personnel related costs, including stock-based compensation, primarily driven by an increase in the number of employees, and consulting and outside services costs, both of which were in support of public company readiness.
- **Net Loss:** Net loss was $141.4 million for the fourth quarter of 2018 compared to $37.9 million for the fourth quarter of 2017. Net loss was $384.7 million for the year ended December 31, 2018 compared to $255.9 million for the year ended December 31, 2017.

2019 Expected Cash Position

Cash, cash equivalents and investments at December 31, 2019 are expected to be in the range of $1.15 billion to $1.20 billion.

Other Corporate Updates

- **Moderna Added to Russell Indexes:**In February 2019, Moderna was selected for addition to the Russell 1000® and Russell 3000® indexes as part of the Russell Investments' quarterly reconstitution, effective March 18, 2019. FTSE Russell determines membership for its Russell U.S. Indexes primarily by objective, market-capitalization rankings and style attributes. Approximately $9 trillion in assets are benchmarked against Russell U.S. Indexes.
- **Company Management:** Moderna today announced the appointment of Lavina Talukdar, who will join the Company in April as head of investor relations. Ms. Talukdar joins Moderna from the Abu Dhabi Investment Authority (ADIA) where she serves as senior portfolio manager. She was previously a partner and research analyst at Lord Abbett and a senior research analyst at MFS Investment Management.

Annual Company Events

Moderna today announced that its annual Science Day will take place on May 7, 2019 in Cambridge, Mass. and its annual R&D Day will take place on September 12, 2019 in New York City.

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Wednesday, March 6, 2019. To access the call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 8294495. A webcast of the call will also be available under "Events & 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 can have a therapeutic or preventive benefit and have 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 Moderna 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 ranked in the top ten of *Science's* list of top biopharma industry employers for the past four years. To learn more, visit www.modernatx.com.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

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Forward Looking Statement

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: the planned next steps in the Company's pipeline programs and specifically including, but not limited to, statements regarding the Company's plans regarding a Phase 1/2 study of mRNA-3704 for methylmalonic acidemia (MMA); plans to initiate a Phase 1 study of mRNA-1893, a Zika vaccine; plans by AstraZeneca to initiate a Phase 1 clinical trial for MEDI1191 an mRNA for IL12, following the opening of the filed IND; plans to initiate a Phase 1b study of mRNA-1653, a combination vaccine against hMPV and PIV3; and the Company's cash, cash equivalents, and investments at December 31, 2019. 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 the Company'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: preclinical and clinical development is lengthy and uncertain, especially for a new category 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 category 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 category of medicines; and those risks and uncertainties described under the heading "Risk Factors" and those described in Moderna's Prospectus filed with the U.S. Securities and Exchange Commission (SEC) on December 7, 2018 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.

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in thousands)

	Three Months Ended December 31,		**Years Ended December 31,**	
	2018	**2017**	**2018**	**2017**
Revenue:				
Collaboration revenue	$ 32,816	$ 88,416	$ 122,512	$ 176,974
Grant revenue	2,605	3,488	12,556	28,851
Total revenue	35,421	91,904	135,068	205,825
Operating expenses:				
Research and development	150,429	117,827	454,082	410,459
General and administrative	38,023	15,905	94,252	64,722
Total operating expenses	188,452	133,732	548,334	475,181
Loss from operations	(153,031)	(41,828)	(413,266)	(269,356)
Interest income	8,894	3,783	27,023	15,235
Other income (expense), net	2,879	(70)	1,835	(1,875)
Loss before provision for (benefit from) income taxes	(141,258)	(38,115)	(384,408)	(255,996)
Provision for (benefit from) income taxes	168	(171)	326	(80)
Net loss	$ (141,426)	$ (37,944)	$ (384,734)	$ (255,916)

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS AND STATEMENTS OF CASH FLOWS DATA

(Unaudited, in thousands)

	December 31,	
	2018	**2017**
Cash, cash equivalents and investments	$ 1,694,417	$ 901,880
Total assets	1,962,149	1,084,489
Total liabilities	431,908	459,193
Total stockholders' equity (deficit)	1,530,241	(551,365)

	Years Ended December 31,	
	2018	**2017**
Net cash used in operating activities	$ (330,865)	$ (331,484)
Cash used for purchases of property and equipment [(1)]	(105,766)	(58,401)

[(1)] Includes $94.5 million and $41.2 million for the years ended December 31, 2018 and 2017, respectively, related to our Norwood manufacturing facility.

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