

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 6, 2019

MODERNA, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-38753 (Commission File Number)	81-3467528 (IRS Employer Identification No.)
200 Technology Square Cambridge, MA (Address of principal executive offices)		02139 (Zip code)

Registrant's telephone number, including area code: (617) 714-6500

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 203.425)
- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or (§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 6, 2019, Moderna, Inc. (the “Company”) issued a press release announcing its results of operations and financial condition for the fourth quarter and year ended December 31, 2018. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On March 6, 2019, the Company issued its 2018 Shareholder Letter. A copy of this letter is furnished as Exhibit 99.2 and is incorporated herein by reference.

The information contained in Items 2.02 and 7.01 (including Exhibit 99.1 and Exhibit 99.2) to this Current Report on Form 8-K shall not be deemed to be “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 such information 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 issued by Moderna, Inc. dated March 6, 2019
99.2	Moderna, Inc. 2018 Shareholder Letter

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 hereunto duly authorized.

MODERNA, INC.

Date: March 6, 2019

By: /s/ Lorence Kim, M.D.

Lorence Kim, M.D.
Chief Financial Officer

**MODERNA REPORTS 2018 FOURTH QUARTER AND FULL YEAR FINANCIAL RESULTS
AND HIGHLIGHTS RECENT PIPELINE PROGRESS**

*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., March 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 + IL36 γ (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 + IL36 γ 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 in advanced 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.
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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 completed in 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. Moderna announced 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
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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.

* This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201600029C.

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.

Contacts

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Moderna, Inc. 2018 Shareholder Letter

March 6, 2019

Dear Fellow Shareholders:

By nearly all measures, 2018 was a year of tremendous progress and technical achievement for Moderna, a year where we made important strides in validating and advancing our mRNA science and pipeline, generated clinical data in multiple therapeutic areas and bolstered our company's foundation for future growth. Today, I believe we are better positioned than we have ever been to deliver on the promise of our science and bring forward a new class of mRNA medicines to improve the lives of patients.

Our objectives for the year focused on continuing to advance our expanding pipeline of development candidates; increasing emphasis on our oncology and rare disease portfolio, specifically in the area of intracellular therapeutics; and investing in our mRNA platform and science, exploring new modalities and the delivery of mRNA to identify new potential approaches to treating a broad array of diseases. Further, we aimed to bring online the proprietary manufacturing capabilities required to enable us to meet the demands of our pre-clinical and clinical-stage programs.

I believe that the team at Moderna executed in all areas of the business and I am pleased with the many milestones reached by our colleagues this past year. We achieved key objectives, from our clinical pipeline execution, to opening our manufacturing plant in Norwood, to raising the capital required to support our enterprise for the long-term and becoming a public company. Moving forward, we intend to fully leverage the breadth of our resources to build on this progress as we further advance our pipeline programs in human studies.

At Moderna, we ask three questions as we consider the potential of our investigational medicines entering clinical studies:

1. Is our mRNA well tolerated?
2. Does it translate the encoded protein?
3. Is the encoded protein functional?

By the end of 2018 we generated data from human trials in four of our six current modalities, showing our mRNA is well tolerated, that it expresses the protein encoded and demonstrates evidence of pharmacologic effect in programs spanning vaccines, cancer therapies and regenerative medicine. Across modalities, we have repeatedly shown that tolerability, expression and pharmacology translates from pre-clinical animal studies to humans in clinical studies. By year end, more than 760 subjects had been dosed with a therapeutic or vaccine candidate developed with Moderna's mRNA technology and in the months ahead, we anticipate sharing data from programs that will help further the understanding of how our investigational mRNA medicines are answering these questions.

We ended 2018 with 21 programs in our pipeline, 11 of which were in clinical studies. These included new development candidates for three rare diseases, propionic acidemia (PA), Fabry disease and

phenylketonuria (PKU). We also unveiled a new development candidate, mRNA-1944, a program that directs liver expression of an antibody that can potentially neutralize the chikungunya virus. These new programs – and the speed at which they were introduced – were an important demonstration of our ability to leverage our mRNA platform to quickly validate and advance new programs once we have demonstrated that our mRNA can effectively be delivered to a specific tissue, into cells or systemically throughout the body.

Advances within Our Modalities

The cornerstone of our efforts to advance a new category of medicines at Moderna is our concept of “modalities,” an approach and focus at the core to how we have rapidly built our pipeline for patients, while also enabling us to create long-term value for investors by reducing technology risks often associated with drug development.

Hundreds of Moderna scientists support our platform, working to identify technologies that can be used to create groupings of potential medicines which leverage similar mRNA technologies, delivery technologies and manufacturing processes. While the programs within a modality may target diverse diseases, they all rely on these shared features – and we have built our pipeline based on the belief that once we achieve technical success pursuing a disease in one modality, we should be able to pursue many others using the same technical approach.

Today we have *six* modalities that we view as six potentially distinct multiproduct pipelines. We believe our approach to developing modalities provides unique advantages and mitigates risk in several ways: first, while programs within a modality often have correlated technology risk, because they pursue diverse diseases they often have uncorrelated biology risk. Second, we believe the risk correlation within a modality allows us to rapidly accelerate the expansion of the pipeline in that modality based on learnings from the initial programs. And third, we believe the lower risk correlation between modalities allows us to mitigate the risks of expanding into new areas.

Moving forward, we will continue to make significant investments in our mRNA platform technology as we pursue new modalities and further diversify our pipeline with therapies for diseases with few or no treatment options.

In 2018 we demonstrated important progress in all six of our modalities, whether through proof of concept studies or moving clinical programs into Phase 2 trials. This progress included:

Prophylactic Vaccines: At year end we had nine programs in this modality, seven of which are in the clinic with four of those having demonstrated desired pharmacology, in the form of immunogenicity, in Phase 1 clinical trials. We are now developing increasingly complex vaccines with multiple antigens for common diseases and this past year we made significant progress in these programs. We commenced two new Phase 1 studies: mRNA-1647, our cytomegalovirus (CMV) vaccine candidate; and mRNA-1653, a combination of human metapneumovirus and parainfluenza virus type 3 (hMPV+PIV3) to protect against two respiratory viruses. And with Merck we also disclosed the targeted virus for mRNA-1278, a VZV (Varicella zoster virus) vaccine development candidate for shingles. We anticipate a number of key milestones in this modality over the next 12-24 months, some of which have already been announced as of the date of this letter, including:

- Safety and immunogenicity data from our hMPV+PIV3 vaccine (mRNA-1653);

- Safety and immunogenicity data for our cytomegalovirus vaccine (mRNA-1647); as well as
- The start of a Phase 2a trial by our strategic collaborator Merck for our respiratory syncytial virus (RSV) vaccine.

We are also continuing our work to develop vaccines of global health importance aimed at helping prevent future epidemics and pandemics. We are taking additional steps toward developing our Zika program (mRNA-1893), which continues to be supported by the Biomedical Advanced Research and Development Authority (BARDA). At present, we do not plan to continue development of our avian flu or Chikungunya vaccine programs without funding from and partnership with governments or non-governmental organizations, though we remain fully committed to vaccine development to address many diseases that can have significant impact on populations around the world.

Cancer vaccines: These programs focus on stimulating a patient's immune system to tumor-related antigens to enable the immune system to elicit a more effective antitumor response. During 2018 we were pleased to report important interim data from our personalized cancer vaccine program (mRNA-4157), sharing initial findings from a small group of patients where we saw no dose limiting toxicities up to the third of four dose levels as a monotherapy in subjects with resected solid tumors – and in combination with the Merck's anti-PD-1 therapy KEYTRUDA® in subjects with unresectable solid tumors.

Interim Phase 1 immunogenicity data for mRNA-4157 as a monotherapy also has shown potential antigen-specific T cell responses. The Phase 1 study continues in the dose-escalation phase of the protocol and we are planning a randomized Phase 2 study comparing PCV and KEYTRUDA against KEYTRUDA alone.

Our second program within this modality, mRNA-5671, is for a frequently mutated oncogene in epithelial cancers, primarily in non-small cell lung, colorectal and pancreatic cancers, known as KRAS. In 2018, we announced the expansion of our relationship with Merck, broadening our collaboration to develop and commercialize novel personalized messenger RNA cancer vaccines. As part of this agreement, we transferred the open IND for KRAS to Merck, which will now lead a Phase 1 study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with KEYTRUDA.

Intratumoral immuno-oncology: We also made exciting progress in this modality, which aims to drive anti-cancer T cell responses by injecting mRNA therapies directly into tumors. At the end of 2018, 28 patients had been dosed in the ongoing Phase 1 trial for mRNA-2416 in patients with advanced relapsed/refractory solid tumor malignancies and lymphomas. Based on clinical observations in two out of two patients with advanced ovarian carcinoma in the Phase 1 study, as well as the urgent need for new treatments for women with this devastating cancer, we submitted a new protocol to the FDA to commence a Phase 2 cohort of mRNA-2416 as a monotherapy in advanced ovarian carcinoma within our ongoing Phase 1 study.

We also dosed the first patient in the Phase 1 study of mRNA-2752, an intratumoral injection comprising three mRNAs encoding for the immunomodulators OX40L + IL23 + IL36γ (also known as the Triplet) for the treatment of advanced or metastatic solid tumor malignancies or lymphoma. Our third program in this modality, IL12 (MEDI1191), is being developed in collaboration with AstraZeneca.

Localized regenerative therapeutics: We believe that localized production of proteins has the potential to be used as a regenerative medicine for damaged tissues and to stimulate angiogenesis, or the re-growing of blood vessels. With AstraZeneca we have a program (AZD8601) for an mRNA encoding for vascular

endothelial growth factor A (VEGF-A) that began Phase 2 studies this past year. In this study, patients receive epicardial injections of AZD8601 while undergoing coronary artery bypass grafting surgery.

The Phase 2a program is built on data we shared this past year from a Phase 1a/b study which showed the therapeutic potential of a VEGF mRNA for re-growing blood vessels. We believe the clinical data from this study was an important milestone in the field of mRNA therapeutics, as it began to address many key questions regarding the direct injection of mRNA in human tissue. The study showed that AZD8601 was well-tolerated when injected in the skin, that VEGF-A protein was produced in a dose-dependent manner, and that the VEGF was functional, causing increased blood flow at injection sites observed up to seven-days post-dose.

Systemic secreted therapeutics: In pre-clinical studies, we have shown that mRNA can be delivered systemically to create proteins that are secreted outside the cell with the aim of producing pharmaceutically active therapeutic proteins with effects across the human body. We have three systemic secreted therapeutics development candidates in our pipeline which includes our first monoclonal antibody candidate, mRNA-1944, which is aimed at chikungunya virus. We submitted an IND for mRNA-1944 in late 2018. Two additional programs, Relaxin (AZD7970) which we are developing with AstraZeneca for the treatment of heart failure, and mRNA-3630 for Fabry disease, both continue to progress in IND-enabling GLP toxicology studies.

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. In 2018, we submitted an IND application to the FDA for mRNA-3704, an investigational medicine for MMA. This is Moderna's first rare disease program to advance into clinical trials. We were also pleased to announce that a second program for a related organic acidemia known as propionic acidemia, or PA (mRNA-3927), was granted Orphan Drug Designation by the FDA in December 2018. We will continue to enroll patients in a global natural history study of MMA and PA (MaP Study) designed to identify and correlate clinical and biomarker endpoints for these disorders. PA and our third intracellular therapeutic program, mRNA-3283 for phenylketonuria, or PKU, are both progressing in IND-enabling GLP toxicology studies.

Key Milestones

To support these modalities and our expanding pipeline, we took a major step forward this past year with the opening of our state-of-the-art cGMP manufacturing site in Norwood, Massachusetts. Commencing operations in Norwood was a major infrastructure goal and we believe it provides a key strategic advantage by enabling us to supply our pre-clinical and Phase 1 and Phase 2 clinical development programs, the capacity to develop materials for preclinical toxicology studies and to manufacture, test and run fill/finish operations for our portfolio of mRNA development candidates.

For Moderna, Norwood is more than just a manufacturing facility: we view it as the intersection of our science and R&D; our investment in technology and having a fully digital, cloud-based and highly automated site to help speed development; a facility where we can show the flexibility in our platform with interchangeable suites to run development programs at various stages; and the manifestation of our commitment to sustainability in the form of building designed for LEED certification.

Finally, we ended the year with a major milestone as we become a public company, raising more than \$560 million in net proceeds in an initial public offering that we will now use to invest in our platform and manage numerous research programs and clinical studies. This was our second financing in 2018,

having raised over \$660 million in preferred equity financings as a private company earlier in the year. Combined, these funds will support our commitment to driving our pipeline forward, running multiple clinical trials in tandem and furthering our investment in research and basic science. In total, we ended 2018 with approximately \$1.7 billion in cash, cash equivalents and investments, providing us a multi-year runway.

I want to thank the investors who supported our company and vision over the past eight years, many of whom provided necessary capital in the early days of our company and continued to invest over time. To all of our investors, know that we deeply appreciate your belief in our vision. We recognize our responsibility to optimize the capital you have provided and to maximize the opportunity we have to create a new class of medicines based on messenger RNA.

Looking Ahead and 2019 - 2020 Corporate Objectives:

Over the next two years our primary focus will be on making significant advances to our pipeline as we work to bring multiple programs into Phase 2 clinical trials and generate human proofs-of-concept for our investigational programs; execute against our current development pipeline; and leverage our mRNA platform to create both new development candidates and potential new modalities where we believe there may be an opportunity to develop therapies for a broad range of diseases.

While we were proud of all we achieved in 2018, we know there is a long way to go. We are excited to learn from the clinical data expected in the months ahead and the opportunity our pipeline presents for our science, our business and for patients.

As we work to build a company that can have a real impact for patients, we also care deeply about building a company that is socially responsible. For us this means a deep commitment to developing medicines for public health and ultra-rare diseases; to creating a company that attracts and retains an exceptional, motivated and diverse workforce; to the sustainability of our environment; to the communities where we work and live; and to ensuring hold ourselves to the highest ethical standards across all areas of our business, and with stakeholders—both internally and externally—while ensuring we have the governance and practices in place to meet these standards.

Our remarkable employees are the engine behind everything we have been able to accomplish. In 2018, Moderna was named one of the top ten global biopharmaceutical industry employers in *Science Careers'* 2018 Top Employers Survey, the 4th year in a row that we were on the list, and great recognition for the organization that has been built here. Our team is bold, collaborative, curious and relentless, and I am forever thankful for their drive and commitment to advancing our technology and to creating potential new medicines for patients.

It has been a remarkable eight years, but I believe we are just at the beginning.

Thank you for joining us on this journey.

Warmest regards,



Stéphane Bancel
Chief Executive Officer

Forward Looking Statement

This Shareholder Letter 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: Moderna's 2019 - 2020 Corporate Objectives, including bringing multiple programs into Phase 2 clinical trials and generating human proofs-of-concept for our investigational programs, executing against our current development pipeline, and creating new development candidates and potential new modalities; achieving key milestones in the prophylactic vaccines modality, including reporting safety and immunogenicity data for mRNA-1647 and starting the Phase 2a trial for mRNA- mRNA-1777; taking additional steps toward developing our Zika program (mRNA-1893); and continuing the clinical trials for mRNA-4157. 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 Shareholder Letter 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 Shareholder Letter 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.