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): January 4, 2021

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

Delaware	001-38753	81-3467528
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Technology Square Cambridge, MA	02139
(Address of principal executive offices)	(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 230.425)

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**MRNA**	**The NASDAQ Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 January 4, 2021, Moderna, Inc. (the "Company") issued a letter to its shareholders, which included the Company's current expectations with respect to its cash, cash equivalents, and investments in marketable securities as of December 31, 2020. A copy of the letter is attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

On January 4, 2021, the Company issued a letter to its shareholders. A copy of the letter is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Items 2.02 and 7.01 (including Exhibit 99.1) 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	Letter dated January 4, 2021, from Moderna, Inc. to its shareholders
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: January 4, 2021

MODERNA, INC.

By: /s/ Lori Henderson
Lori Henderson
General Counsel and Secretary

Exhibit 99.1

January 4, 2021
Cambridge, Mass., USA

Dear fellow shareholders,

By nearly all measures, 2020 was a historic year in our lives. It was also a historic year for Moderna.

We started the year not knowing there was going to be a new virus, which would be declared a global pandemic—the first of its kind in 100 years since the Spanish flu. We ended the year with an Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) and an Interim Order from Health Canada for use of our COVID-19 vaccine.

Today, our team is working as hard as they can to manufacture with high quality as many doses of the vaccine as they can. We know that each additional dose we can make will be used to protect one more life.

It took our team less than 12 months to go from the sequence made available online by the Chinese authorities to having completed a Phase 1, a Phase 2 and a 30,000 participant, placebo-controlled Phase 3 trial, and to get the vaccine authorized for use in the U.S. and Canada, with several other regulatory rolling reviews in process around the world. That is an extraordinary accomplishment for a biotech company of 1,300 people.

Moderna is now a commercial company.

Our mid-stage pipeline doubled in size, growing from two to four Phase 2 candidates, building on significant clinical data from 2019 that validated our mRNA platform. In support of our strategy to accelerate new development candidates in our core modalities, we introduced five development candidates in the first two months alone, adding to a rich, diversified pipeline of programs across infectious diseases, immuno-oncology, cardiovascular diseases, rare diseases, and autoimmune and inflammatory diseases.

We saw a transformation in the number of patients and healthy volunteers enrolled in our studies from just above 2,000 a year ago to more than 32,000 today. Thanks to the hard work of many in support of our commitment to inclusion, our trial participants are representative of the communities at highest risk and of our diverse society.

The early investment we made in our manufacturing and digital capabilities prepared us to rapidly scale our production to accommodate at least 500 million doses and potentially up to 1 billion doses of our COVID-19 vaccine in 2021. With this scale-up, our talented team grew significantly to support manufacturing, late-stage clinical development, regulatory and commercial readiness. As we expanded our geographic footprint, we built and deepened our relationships with partners across the globe including the National Institutes of Health (NIH), Lonza, Catalent, ROVI, Vertex and others.

As we close our books for 2020, we expect that cash, cash equivalents and investments as of December 31, 2020 were approximately $5.25 billion. This means that our cash position has been approximately multiplied by four compared to 12 months ago, and we generated positive cash flows from operations in the third quarter for the first time in the company's history.

Looking back to our 2019-2020 objectives, we set out to generate human proof-of-concept data for multiple medicines, execute on our current development pipeline, create new development candidates in existing modalities and invent new modalities. We made tremendous progress against these objectives over the past two years and, at a time of unparalleled global disruption, **we are emerging stronger** than I could have imagined.

I would like to thank and congratulate our relentless team of employees, many quite new to Moderna. They did all this and much more to advance our Mission for patients during a very complicated pandemic.

Indeed, the SARS-CoV-2 virus changed everything. The positive Phase 3 analysis of our vaccine against COVID-19 has meaningful implications for all of our vaccines in development, all the vaccines in our research pipeline and all the vaccines that we are not yet working on in the labs. This is where the power of mRNA as an information molecule comes into play.

We always said that it made no sense for Moderna to be a one-product company. We would be a zero-product company if we failed to get a product approved before running out of cash or **we would have many dozens of products over time, changing medicine forever and impacting the lives of millions**.

Moderna is entering 2021 as a **commercial company**, with a **strong cash position, clear strategic priorities and a team poised to continue advancing mRNA vaccines and therapeutics** into new areas of high unmet need. I believe we have a very exciting journey ahead and we are pleased to have you with us.

When I reflect on what the team has accomplished in the last 10 years since Moderna's inception, going from a revolutionary but unproven concept to a commercial organization with more than 20 programs in development and the ability to generate cash to invest to rapidly scale our platform company, I wonder what Moderna will look like 10 years from now, in 2030.

Creating an mRNA Vaccine Candidate Against COVID-19

COVID-19 will forever be a part of Moderna's history.

The entire world has been focused on the pandemic and the race against the virus, both with therapeutics and vaccines. The Moderna team itself was incredibly focused in 2020 on getting **mRNA-1273**, our vaccine candidate against COVID-19, to the market safely and in record time.

In January, just two days after the Chinese authorities shared the genetic sequence of the novel coronavirus, NIH and Moderna's infectious disease research team finalized the sequence for mRNA-1273. We recognized important similarities to the MERS virus and, based on good preclinical data and analysis from the previous two years of collaboration with NIH, decided to encode for the full-length Spike (S) protein. At that time, the National Institute of Allergy and Infectious Diseases (NIAID), a part of the NIH, also disclosed its intent to run a Phase 1 study using our mRNA-1273 vaccine in response to the coronavirus threat. We quickly mobilized toward clinical manufacture.

In just 42 days from sequence identification, we released our first batch of mRNA-1273 for human use. Vials of mRNA-1273 were shipped to NIAID to be used in the planned Phase 1 study in the U.S.

On March 11, the World Health Organization (WHO) declared the novel coronavirus a pandemic and just days later, on March 16, NIH announced that the first participant in its Phase 1 study of mRNA-1273 was dosed—only 63 days from sequence selection to first human dosing. Moderna was the first company to launch a SARS-CoV-2 vaccine trial in humans. It was a historic moment.

Exactly one month later, on April 16, we announced an award from the Biomedical Advanced Research and Development Authority (BARDA) for up to $483 million to accelerate development of mRNA-1273. Time was of the essence to provide a vaccine against this pandemic virus. We had already begun to prepare supply for a Phase 2 trial at our own expense. By investing in our manufacturing process to enable large-scale production for pandemic response, we believed that we could supply millions of doses per month in 2020 and, with further investments, tens of millions per month in 2021.

To enable larger scale manufacture of mRNA-1273 globally, we announced a 10-year strategic collaboration agreement with Lonza on May 1. Lonza shared our commitment to rapidly addressing the pandemic and enabled us to accelerate our manufacturing capacity for mRNA-1273—and our ability to help protect as many people as possible.

On May 18, we announced positive interim Phase 1 clinical trial data. By the end of the month, the first participant had been dosed in the Phase 2 study and the Moderna team continued to focus on moving as fast and as safely as possible to start our pivotal Phase 3 study.

July brought the publication of positive interim Phase 1 data in the *New England Journal of Medicine* and the initiation of our Phase 3 COVE study, which completed enrollment of more than 30,000 total participants in October. It was another historic moment for our company. The subsequent months also brought the presentation and publication of Phase 1 data from older adult age cohorts, which gave us optimism in demonstrating mRNA-1273's protection in this high-risk population.

We are extremely grateful to the thousands of participants in our studies, as well as the staff at clinical trial sites who have been on the front lines of the fight against the virus. We thank them for putting their trust in us.

It is very important to the Moderna team that we ensure quality and transparency so that the public has trust in COVID-19 vaccines. To that end, we reported weekly enrollment progress in our COVE study, including enrollment numbers from diverse communities. And when we recognized a shortcoming with minority representation in our Phase 3 study, we decided to slow down the overall study enrollment to ensure the participants were representative of the communities at highest risk for COVID-19 and of our diverse society.

In September, we signed the biopharma pledge to only submit for regulatory approval for mRNA-1273 when we had adequate safety and efficacy data. We were also the first company to file the full, un-redacted version of our Phase 3 protocol online to ensure clinicians around the world could see, in full transparency, the design of our COVE study. We were pleased to set the standard and have others in the industry follow our lead.

On November 30, the primary analysis of our Phase 3 COVE study demonstrated a vaccine efficacy of 94.1 percent and, importantly, mRNA-1273's ability to prevent severe COVID-19 disease. This positive data analysis confirmed the high efficacy observed in the first Phase 3 interim analysis of mRNA-1273, and the vaccine was generally well-tolerated, with no serious safety concerns identified by an independent Data Safety Monitoring Board. It also confirmed our ability to potentially change the course of this pandemic and help prevent severe disease, hospitalizations and death.

In December, we received an Emergency Use Authorization from the FDA and an Interim Order from Health Canada authorizing the vaccine in the U.S. and Canada. We continue forging ahead with the rolling reviews that have already been initiated with several regulatory agencies across the globe: Europe, the United Kingdom, Israel, Switzerland, Singapore and the WHO, which is important for middle- and low-income countries. At the end of December, we also published our Phase 3 data in the *New England Journal of Medicine.*

Looking ahead, we could receive a Biologics License Application (BLA) approval for the Moderna COVID-19 Vaccine in 2021. With a manufacturing base plan of 500 million to potentially 1 billion doses per year, we should have a multi-billion-dollar revenue line in 2021. If we execute and achieve this, it will allow us to invest in R&D, scale our development pipeline and maximize what we can do for patients, without the need for additional near-term capital raises.

Advancing mRNA Medicines

Moderna is not solely a COVID-19 vaccine company. It is a very large technology platform company which has one of the best COVID-19 vaccines.

While we have been advancing our Moderna COVID-19 Vaccine toward a BLA in just over a year, we have also continued to honor our existing commitments to patients and communities by progressing the other 20 development candidates in our pipeline.

I am especially proud of the Moderna team for their deep sense of responsibility and bold determination to execute on both of these commitments. Under normal circumstances, delivering on either one would be an unprecedented achievement in our industry.

As you may know, our pipeline is organized into six modalities based on similar mRNA technologies, delivery technologies and manufacturing processes. Our approach is to leverage early programs within a modality to generate clinical data and insights that reduce the technology risk of subsequent programs and accelerate the expansion of the pipeline in that modality.

In early 2020, due to the positive clinical data generated by our infectious disease vaccine portfolio and chikungunya antibody program, we decided to nominate two of our modalities as core modalities: 1) prophylactic vaccines; and 2) systemic secreted & cell surface therapeutics. We decided to double down in these modalities because we believe that they have been de-risked from a technology standpoint.

I will highlight some of our team's accomplishments across our core and exploratory modalities to give you a better idea of our progress throughout 2020.

Building Core Modalities

Prophylactic Vaccines

Vaccines continue to be the best hope to control infectious diseases. We are focused on developing more innovative commercial vaccines—including complex vaccines with multiple antigens for common diseases, as well as public health vaccines by collaborating with foundations and government agencies.

At our annual R&D Day in September, we announced the positive Phase 2 readout for **mRNA-1647**, our Cytomegalovirus (CMV) vaccine candidate. We are on track to start the pivotal Phase 3 study for CMV in 2021. There is no approved vaccine against CMV and it is the number one cause of birth defects in the U.S. and the developed world. Moderna owns global rights to mRNA-1647 and we believe our CMV vaccine has the potential for annual peak sales between 2 and 5 billion dollars.

We also announced our intention to enter the seasonal flu vaccine business. The WHO reports there are 3 million to 5 million severe cases of flu each year around the world, leading to between 290,000 and 650,000 deaths annually. We believe we have a chance to change that and develop a more effective flu vaccine in light of the elderly data we have generated across our platform with COVID-19 and RSV.

RSV, or respiratory syncytial virus, is also a common cause of acute respiratory disease in children and is associated with a substantial burden of hospitalizations and outpatient visits throughout the first five years of life. Despite the need, there is currently no approved vaccine for RSV. In October, we started Phase 1 dosing for our vaccine against RSV, **mRNA-1345**, which marked our eleventh infectious disease vaccine to enter human trials and another exciting milestone for our vaccines portfolio as we look to advance mRNA-1345 in the pediatric population.

Systemic Secreted & Cell Surface Therapeutics

In these therapeutics, mRNA is delivered systemically to create proteins that are either secreted or expressed on the cell surface. The goal is to provide secreted proteins, such as antibodies or enzyme replacement therapies across a wide range of diseases, including heart failure, infectious diseases, and rare genetic diseases.

Our antibody against chikungunya virus, **mRNA-1944**, for which we have enrolled additional cohorts in the Phase 1 study, read out important new data as well. Our 2-dose regimen of chikungunya antibody demonstrated our platform's ability to safely *repeat dosing* of a therapeutic in humans, another milestone in the development of our mRNA platform.

We introduced two additional development candidates in our new autoimmune therapeutic area in 2020. We are planning to conduct Phase 1 studies for our IL-2 candidate, **mRNA-6231**, and our PD-L1 candidate, **mRNA-6981**, as an initial step to addressing a range of autoimmune indications. Both potential medicines are wholly owned by Moderna and share the same delivery technology as mRNA-1944, reducing technology risk.

Technology risk encompasses the challenges of developing the product features of mRNA medicines, including delivery, controlling interactions with the immune system, pharmaceutical properties and manufacturing. We stage program development within a modality like this one, leveraging the first program to generate insights that reduce the risk and accelerate the development of subsequent programs within the modality.

Investigating Exploratory Modalities

Cancer Vaccines & Intratumoral Immuno-Oncology

Moderna's personalized cancer vaccine (PCV) 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. Our intratumoral immuno-oncology programs aim to drive anti-cancer T cell responses by injecting mRNA therapies directly into tumors.

We were encouraged by the interim data from our PCV program, which involves designing and manufacturing a unique vaccine for each patient based on their specific tumor. The Phase 1 study demonstrated the ability of our PCV, **mRNA-4157**, to elicit clinical activity when given in combination with Merck's Keytruda®[1]. We were also encouraged to see the preliminary data in HPV(-) head and neck cancer that we presented at The Society for Immunotherapy of Cancer's Annual Meeting (SITC 2020). We are expanding the cohort to see if that early signal is confirmed. Additionally, the mutant KRAS vaccine, **mRNA-5671 or V941**, Phase 1 study to evaluate safety and tolerability, led by Merck, is ongoing.

Our intratumoral OX40L program, **mRNA-2416**, is now dosing patients in the Phase 2 expansion study. The Phase 1 trial evaluating OX40L/IL-23/IL-36g (Triplet), **mRNA-2752**, in patients with advanced solid tumor malignancies and lymphoma is ongoing. Our collaborators at AstraZeneca are progressing an mRNA encoding for IL-12 with durvalumab also in Phase 1.

Localized Regenerative Therapeutics

The Phase 2a study of **AZD8601** VEGF-A, which is being developed for patients with ischemic heart disease undergoing coronary artery bypass grafting surgery with moderately impaired systolic function, led by AstraZeneca, is ongoing. The Phase 1 data showed the potential of mRNA encoding for vascular endothelial growth factor A (VEGF-A) as a regenerative therapeutic. Based on these early data, this approach may provide benefit to patients where proper blood flow is compromised in areas such as heart disease and diabetes, as well as for other vascular complications.

[1] Keytruda® is a registered trademark of Merck & Co., Inc.

Systemic Intracellular Therapeutics

In rare diseases, our programs aim to deliver mRNA into cells within target organs as a therapeutic approach for diseases caused by a missing or defective protein.

Study startup activities under an amended protocol for our Phase 1 Propionic Acidemia (PA) candidate, **mRNA-3927**, are underway following a COVID-19 related pause. Additionally, we received rare pediatric designation for our next generation Methylmalonic Acidemia (MMA) candidate, **mRNA-3705**.

We are implementing changes that we believe will help to accelerate the clinical development of MMA, including the introduction of a new drug product with better pharmacology as well as a protocol revision to enhance operational performance and patient outreach. I am particularly proud of our team's efforts to develop our next generation MMA candidate, for which we plan to file an investigational new drug (IND) application and a clinical trial application (CTA).

Building Our Capabilities

Moderna entered 2020 with a strong cash position of approximately $1.3 billion. We have built a diverse clinical portfolio of vaccines and therapeutics across six modalities. Our portfolio approach has helped us reduce risk as our pipeline has grown to 21 development candidates.

Over the 10 years since our inception, we have sustained large investments in platform science, including both mRNA and Lipid Nanoparticle (LNP) formulation. And we have established a large intellectual property (IP) portfolio that will protect and enhance our ability to continue to invest in innovative medicines.

We have also made large investments in process development. Further, we own a fully integrated plant that has allowed us to go from raw materials to filled vials for all our clinical needs at scale and with unprecedented speed. Our integrated plant also has the capacity to flex into full-scale commercial production and has been an important facility in manufacturing our U.S. supply of the Moderna COVID-19 Vaccine.

During 2020, we built on this strong foundation to help secure our place as the most advanced mRNA platform in the industry.

We continued to make substantial investments in our basic science to advance our platform's capabilities and our further understanding of how to use mRNA as a medicine. At our third annual Science Day in June, we highlighted novel approaches to our LNP technology and provided an update on our collaboration with International AIDS Vaccine Initiative (IAVI), NIAID and the Bill & Melinda Gates Foundation toward the development of an HIV vaccine using our mRNA platform.

We entered into new collaborations with partners across the globe. Our second collaboration with Vertex aims to use our mRNA technology and Vertex's expertise and investment in **gene editing** technology, to try to bring together an innovative treatment for cystic fibrosis patients. A new partnership with Italian pharmaceutical company Chiesi is aimed at the discovery and development of mRNA therapeutics for the treatment of pulmonary arterial hypertension, a rare disease with an incidence of 2-5 per million adults.

New manufacturing and fill-finish partners like Lonza, Catalent and ROVI helped us scale-up our manufacturing capabilities on the global stage. As I mentioned earlier, this worldwide strategic collaboration will enable larger scale manufacture of the Moderna COVID-19 Vaccine and additional Moderna products in the future.

While our IP portfolio and expertise uniquely positioned us to respond to the COVID-19 pandemic quickly, we felt a special obligation under the circumstances to use our resources to pledge, while the pandemic continues, that we will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our IP for COVID-19 vaccines to others for the post-pandemic period.

We grew our workforce significantly in the U.S. and across new geographies, welcoming colleagues in Canada, Spain and Switzerland, as well as the UK, and announcing our first commercial organization outside North America in Switzerland. As we welcomed new employees at all levels, we remained focused on the health and safety of our people by implementing on-site COVID-19 testing, track and trace technology, thermal temperature screening and a digital health screening app.

Additionally, Moderna adopted more flexible work structures while fostering collaboration and continuing to prioritize our employees' well-being. We also introduced a new employee assistance program, additional child and backup care, a new virtual onboarding program and seminars on wellness and inclusion. I am proud that Moderna was named a *Science* top employer for the sixth year in a row and recognized for our commitment to continuous innovation, corporate social responsibility, and fostering a culture of respect for the individual.

I am also pleased to share that we strengthened our commitment to diversity and inclusion in our communities, specifically through our work with our clinical research sites to reach communities that are representative of our diverse society. In a year that has put a spotlight on inequality, increasing equity for all is more important than ever.

Emerging Stronger

As I look to the end of 2021, I believe that if we successfully launch the Moderna COVID-19 Vaccine as a commercial product, we will emerge from the pandemic crisis as the strongest mRNA company in the world.

The U.S. government has taken a very thoughtful approach with Operation Warp Speed (OWS). They decided to support three vaccine technologies, including mRNA, and to back only two companies per technology type. Moderna was one of the two mRNA companies from which the U.S. government ordered an initial 100 million doses. In December, the U.S. government exercised its option to purchase an additional 100 million doses of the Moderna COVID-19 Vaccine, bringing the total to 200 million doses. That is unique market access. We are grateful for the trust the U.S. government and OWS has placed in our vaccine, our development process and our technology.

We intend to re-invest the potential returns from the sales of the vaccine into our pipeline development and hope to bring many more mRNA medicines to the market. I believe the long-term strategic implications for this are enormous. We expect to have a strong cash balance at the end of 2021, building upon the expected $5.25 billion of cash, cash equivalents and investments on hand as of year-end 2020, plus the cash flow that we expect to generate in fiscal year 2021.

Moderna has been built to successfully scale because mRNA is an information molecule. We have invested relentlessly in science at a pace that no other mRNA company could match—in robotics, in digital and AI, in process development and in a large manufacturing plant in Massachusetts.

What limited our ability to do more and scale faster in the last five years was cash. We always kept several years of runway on our balance sheet to manage financing risk. To the extent we can eliminate this financing risk because we are commercial and are generating cash from our first year of commercial operations, I believe that this will change—in a very material way—how we operate during fiscal 2021 and beyond, and the speed at which we scale moving forward.

Additionally, the approval of the Moderna COVID-19 Vaccine for authorized use, and ultimately for commercialization, would provide a unique de-risking of the entire Moderna vaccine platform. We use the same chemistry to make each mRNA vaccine; the same manufacturing process to make the mRNA; the same chemistry for our lipid; the same manufacturing process to formulate the mRNA in our lipid.

Think about what our team can accomplish over the next 10 years starting from a growing cash balance in excess of $5 billion, the knowledge that our mRNA vaccine can have high efficacy and be approved by regulators, and the experience of having developed our technology into an approved product.

Looking Ahead

I believe 2021 will be the most important inflection point in Moderna's history.

Our strategic priorities for 2021 are clear. First priority: maximize the impact of Moderna COVID-19 Vaccine access and the value creation of this product between now and the end of 2021. This will allow us to pursue our second priority: accelerate vaccine development to advance our pipeline and bring new vaccines to market.

In turn, this will make way for our third priority: generate human proof-of-concept data in autoimmune diseases, cardiovascular diseases, oncology and rare diseases. And this will allow for our fourth priority: continue to expand the use of mRNA technology to maximize the potential impact we can have on patients. We continue to believe that Moderna will have, over time, many modalities with commercial products.

By executing on these priorities, we will continue to advance our Mission for patients and deliver value to our shareholders, our employees, our communities and our partners.

I am extremely grateful for what the team has done to get us to this point.

Thank you to our long-term investors who have provided capital over the years, so that we could build the best version of Moderna possible. The scale of investment in science and the manufacturing process development that we have made in the last decade is unique, based on the trust our shareholders have put in us. It took several billion dollars of capital to get to this point. We could not have built this version of Moderna on a billion dollars or less.

I also want to thank the thousands of participants in our clinical studies, as well as the staff at clinical trial sites who have been on the frontlines of the fight against COVID-19. I would again like to thank our partners at NIH, NIAID, BARDA and OWS who have helped us advance the clinical development of the Moderna COVID-19 Vaccine. We are very appreciative of our suppliers and partners for their work on the research, development and manufacturing that helped position Moderna to respond to the COVID-19 pandemic quickly.

My deepest gratitude goes to the incredible team at Moderna. Their commitment to our Mission was exemplary in 2020. People sacrificed vacations, weekends, evenings and much more—and we all did it because it was our duty, our Mission.

I would also like to thank the members of our board of directors, who have worked relentlessly to guide us, to support us and to help us navigate the many complex decisions we made in real time with incomplete information over the years, but especially in 2020 during the development of our COVID-19 Vaccine.

I am saddened by the tragic loss of life the world has experienced due to this pandemic, by the increase in mental health challenges due to joblessness and lockdowns, and by the lost educational opportunities for many children in 2020. It is our responsibility as an industry, as a company and as global citizens to help ensure a pandemic of this magnitude never happens again. More on that in 2021.

As a company, we are closer than ever before to launching several first-in-class medicines for patients where there are no treatments today. The next period of Moderna's history is just beginning. I cannot wait to see what Moderna looks like 10 years from now.

Thank you for your trust and support over the years.

Warmest regards,

Stéphane Bancel
Chief Executive Officer

Forward-Looking Statements

This letter contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: Moderna's development of a vaccine against the novel coronavirus; the potential for the Moderna COVID-19 Vaccine to prevent COVID-19 disease and slow the spread of SARS-CoV-2; the safety profile for the Moderna COVID-19 Vaccine; the scale and timing of manufacturing of the Moderna COVID-19 Vaccine; the process for obtaining regulatory review and approval for the use and distribution of the Moderna COVID-19 Vaccine in the U.S. and other jurisdictions; potential licensing of the technology related to the Moderna COVID-19 Vaccine; anticipated clinical next steps and catalysts for each of Moderna's development programs; Moderna's financial operations; expectations regarding future cash balances, cash flow generation and capital efficiency; and future growth of Moderna's pipeline and development programs, investments therein, as well as the company's intellectual property portfolio and future prospects. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "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 statement 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, 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: the fact that there has never been a commercial product utilizing mRNA technology approved for use; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the safety, tolerability and efficacy profile of the Moderna COVID-19 Vaccine observed to date may change adversely in ongoing analyses of trial data or subsequent to commercialization; despite having ongoing interactions with the U.S. Food and Drug Administration (FDA) or other regulatory agencies, the FDA or such other regulatory agencies may not agree with the Company's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; Moderna may encounter delays in meeting manufacturing or supply timelines or disruptions in its distribution plans for the Moderna COVID-19 Vaccine; whether and when any biologics license applications and/or additional emergency use authorization applications may be filed in various jurisdictions and ultimately approved by regulatory authorities; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and clinical trials, supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q 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.

Authorized Use

The Moderna COVID-19 Vaccine has been authorized for emergency use by the FDA for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older and has been authorized by Health Canada for the immunization of Canadians 18 years of age and older under an Interim Order. Moderna has submitted the final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.