

**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): May 6, 2021

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

Not Applicable
(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 (17CFR 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 (§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 May 6, 2021, Moderna, Inc. (the “Company”) issued a press release announcing its results of operations and financial condition for the first quarter ended March 31, 2021. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “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 it 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 filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Moderna, Inc. dated May 6, 2021
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.

MODERNA, INC.

Date: May 6, 2021

By: /s/ David W. Meline
David W. Meline
Chief Financial Officer

Moderna Reports First Quarter Fiscal Year 2021 Financial Results and Provides Business Updates

SARS-CoV-2 Variant Booster Program Update: Single booster dose of 50 µg of mRNA-1273 or mRNA-1273.351 increased neutralizing titers against SARS-CoV-2 and two Variants of Concern (B.1.351, P.1) in previously vaccinated clinical trial participants

TeenCOVE Study Update: Initial analysis of the Phase 2/3 TeenCOVE study of mRNA-1273 showed vaccine efficacy against COVID-19 of 96%; mRNA-1273 was generally well tolerated with no serious safety concerns identified to date

2021 and 2022 Vaccine Manufacturing: Company increased its 2021 supply forecast to between 800 million and 1 billion doses; Company making investments to increase global supply for COVID-19 Vaccine to up to 3 billion doses in 2022

Company plans to initiate rolling submission for BLA in the U.S. this month

First patient dosed in Phase 1/2 study of propionic acidemia (PA) candidate (mRNA-3927); Company now has infectious disease, cardiovascular, oncology and rare disease programs in the clinic

Company increases R&D investments in infectious diseases and other therapeutic areas to increase new development candidates from the lab to the clinic

First GAAP profitable quarter in company history

CAMBRIDGE, Mass., May 6, 2021 — Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today reported financial results and provided business updates for the first quarter 2021 and highlighted pipeline progress.

“In the first quarter, the Moderna team delivered on its supply commitments to many governments and helped protect more than 100 million people. This accomplishment translated into our first profitable quarter in the company’s history, after 10 years of scientific innovation and several billion dollars invested to make our mRNA platform a reality,” said Stéphane Bancel, Chief Executive Officer of Moderna. “Based on these first quarter accomplishments and our current manufacturing scale-up trajectory, we were pleased to again increase our base plan for 2021 to 800 million doses. The Moderna team and our manufacturing partners are working hard to get as close to 1 billion doses in 2021 as we can. The feedback from governments around the world requesting high-efficacy mRNA vaccines and variant boosters is overwhelming. We are now actively engaged in discussions and agreements for 2022 with all of the governments we are currently supplying for 2021. On top of that, new partnerships, like COVAX, for up to 466 million doses in 2022 and discussions with new governments in Asia, Middle East, Africa and Latin America, make us believe that our total advance purchase agreements for 2022 should be higher than those in 2021.”

New updates and recent progress include:

COVID-19 Vaccine Development

- Increased 2021 supply forecast to between 800 million and 1 billion doses; making additional investments to increase global supply for COVID-19 Vaccine to up to 3 billion doses in 2022 (depending on the mix)
- Company recently announced data supporting 3-month refrigerated (2-8°C) stable formulation

- New data shows a single booster dose of 50 µg of mRNA-1273 or mRNA-1273.351 increased neutralizing titers against SARS-CoV-2 and two variants of concern (B.1.351, P.1) in previously vaccinated clinical trial participants
- Initial analysis of the Phase 2/3 TeenCOVE study of mRNA-1273 in adolescents ages 12 to 17 years showed vaccine efficacy against COVID-19 of 96%; mRNA-1273 was generally well tolerated with no serious safety concerns identified to date
- Phase 3 study of mRNA-1273 in adults with a kidney or liver transplant is ongoing
- Company plans to initiate rolling submission for BLA in the U.S. this month

Infectious Diseases

- Positive interim data from Phase 1 study of RSV vaccine candidate (mRNA-1345) in younger adults (ages 18-49 years)
- Positive seven-month interim data from Phase 2 study of cytomegalovirus (CMV) vaccine candidate (mRNA-1647) announced during Vaccines Day on April 14; Moderna preparing for pivotal Phase 3 study expected to begin in 2021

Rare Diseases

- First patient dosed in Propionic Acidemia (mRNA-3927) Phase 1/2 Paramount study

Moderna currently has 24 mRNA development programs in its portfolio with 14 having entered clinical studies. The Company's updated pipeline can be found at www.modernatx.com/pipeline. Moderna and collaborators have published more than 65 peer-reviewed papers.

Summary of Program Highlights by Modality

Core Modalities

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 threats to global public health. The Company's global public health portfolio is focused on epidemic and pandemic diseases for which funding has been sought from governments and non-profit organizations.

COVID-19 Vaccine Development

- **Moderna COVID-19 Vaccine:** The Company shared an update on the Phase 3 COVE study of the Moderna COVID-19 Vaccine (mRNA-1273) at its annual Vaccines Day on April 14, 2021. An updated review of adjudicated cases identified over 900 cases of COVID-19 in the COVE study as of April 9th, including over 100 cases of severe COVID-19, as defined in the protocol, with a median follow-up of approximately 6 months post dose 2. Vaccine efficacy starting two weeks following the second dose and based on the updated adjudicated cases remains consistent with prior updates, including greater than 90% efficacy against all cases of COVID-19, and greater than 95% efficacy against severe cases of COVID-19. The COVE study is ongoing and reported results remain preliminary. Throughout the year, Moderna will be sharing updated data from the Phase 3 COVE study including efficacy against asymptomatic infection, genotyping data, additional antibody persistence data and information regarding potential correlates of protection. Moderna has also received emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, the World Health Organization (WHO), and the Philippines. The Company plans to initiate rolling submission for a Biologics License Application (BLA) for the vaccine in the U.S. this month. Moderna is working with additional health agencies on the authorization of its vaccine in additional jurisdictions. BARDA, part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), partially supported the research and development of the Moderna COVID-19 Vaccine with federal funding under Contract no. 75A50120C00034. Moderna retains worldwide rights to develop and commercialize the Moderna COVID-19 Vaccine.

- **Temperature Stability Update:** Moderna recently announced that ongoing development data related to the current formulation of the Moderna COVID-19 Vaccine (mRNA-1273) could support a 3-month refrigerated (2-8°C) shelf life for the vaccine in alternative formats to facilitate easier distribution to doctor's offices and other smaller settings, if authorized. Currently, the Moderna COVID-19 Vaccine is approved for storage up to 1 month at refrigerated temperatures (2-8°C) and up to 7 months in a standard freezer (-20°C). The Moderna COVID-19 Vaccine is also the only authorized mRNA vaccine that does not require on-site dilution. The Company also announced that it is working on formulations of mRNA-1273 and a next generation vaccine (mRNA-1283) that it believes will extend refrigerated shelf life even further.
- **Publication of Note:** Antibody persistence data out to 6 months following the second dose of the Moderna COVID-19 Vaccine were recently published in *The New England Journal of Medicine*. This study analyzed 33 healthy adult participants in the NIH-led Phase 1 study of Moderna's COVID-19 Vaccine at 6 months following the second 100 µg dose (day 209). As detected by three distinct serologic assays, antibodies elicited by the Moderna COVID-19 Vaccine persisted through 6 months after the second dose. Antibody decay was estimated using two approaches and was consistent with published observations of convalescent patients with COVID-19 through 8 months after symptom onset.
- **Addressing Variants of Concern:** On February 24, Moderna announced that it completed manufacturing of clinical trial material for its variant-specific vaccine candidate, mRNA-1273.351, against the SARS-CoV-2 variant known as B.1.351 first identified in the Republic of South Africa and has shipped doses to the NIH for a Phase 1 clinical trial that will be led and funded by the NIH's NIAID. The Company also provided an update on its strategy for addressing SARS-CoV-2 variants of concern.
 - **Publication of Note:** Initial data from Moderna's Phase 2 study showed that a single 50 µg dose of mRNA-1273 or mRNA-1273.351 given as a booster to previously vaccinated individuals increased neutralizing antibody titer responses against SARS-CoV-2 and two variants of concern, B.1.351 (first identified in South Africa) and P.1 (first identified in Brazil). A booster dose of mRNA-1273.351, the Company's strain-matched booster, achieved higher neutralizing antibody titers against the B.1.351 variant of concern than a booster dose of mRNA-1273. Safety and tolerability profiles following third dose booster injections of 50 µg of mRNA-1273 or mRNA-1273.351 were generally comparable to those observed after the second dose of mRNA-1273 in the previously reported Phase 2 and Phase 3 studies.
 - **Publication of Note:** Preclinical data on the Company's variant booster vaccine candidates have been submitted as a preprint to *bioRxiv* showed that both mRNA-1273.351 and mRNA-1273.211 increase neutralizing titers against SARS-CoV-2 variants of concern in mice. Specifically, this preclinical data confirms improved neutralizing titers with the mRNA-1273.351 vaccine primary series. The multi-valent vaccine provided the broadest level of immunity. A boost at 6 months with mRNA-1273.351 closed the neutralizing titer gap for the variants of concern. Following the mRNA-1273.351 boost, neutralizing titers were comparable between the ancestral strain (Wuhan) and the new B.1.351 variant.

- **Further Clinical Studies of mRNA-1273**

- **Phase 2/3 “TeenCOVE” study of mRNA-1273 in adolescents:** The Phase 2/3 study of mRNA-1273 in adolescents ages 12-17 years has completed enrollment in the U.S. An initial analysis of 3,235 participants randomized 2:1 in TeenCOVE Study showed a vaccine efficacy rate of 96% in seronegative participants who received at least one injection. The analysis included 12 cases starting 14 days after first dose and based on the CDC definition of COVID-19, which requires one COVID-19 symptom and paired with a nasopharyngeal (NP) swab or saliva sample positive for SARS-CoV-2 by RT-PCR. Because the incidence rate of COVID-19 is lower in adolescents, the case definition is less stringent than for COVE, resulting in vaccine efficacy against milder disease. The median duration for follow-up in this initial analysis was 35 days following the second dose. mRNA-1273 was generally well tolerated. The majority of adverse events were mild or moderate in severity. No serious safety concerns have been identified to date. The most common solicited local adverse event was injection site pain. The most common solicited systemic adverse events after the second dose of mRNA-1273 were headache, fatigue, myalgia and chills. The Company is continuing to collect data in TeenCOVE and is in discussions with regulators about a potential amendment to its regulatory filings.
- **Phase 2 “KidCOVE” study of mRNA-1273 in young children:** The Phase 2 study of mRNA-1273 in pediatric population ages 6 months to 11 years is ongoing.
- **Phase 1/2 study of mRNA-1273 in Japan:** The Phase 1/2 study of Moderna’s vaccine candidate against COVID-19 (mRNA-1273 or TAK-919) in Japan, led by Takeda Pharmaceutical Co., Ltd is ongoing.
- **Phase 3 “COVE Transplant” study of mRNA-1273:** The Phase 3 study of mRNA-1273 in adults with a kidney or liver transplant is ongoing.
- **Next-generation vaccine against COVID-19 (mRNA-1283):** The Phase 1 study of mRNA-1283 is ongoing. mRNA-1283 is a next-generation vaccine candidate against COVID-19 that encodes for the portions of the SARS-CoV-2 spike protein critical for neutralization, specifically the Receptor Binding Domain (RBD) and N-terminal Domain (NTD). The encoded mRNA-1283 antigen is shorter than mRNA-1273 and is being developed as a potential refrigerator stable mRNA vaccine that will facilitate easier distribution and administration by healthcare providers. mRNA-1283 is intended to be evaluated for use as a booster dose for previously vaccinated or infected individuals as well as in a primary series for seronegative individuals.

Vaccines requiring complex antigens and against highly prevalent infections

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** Positive seven-month data from the Phase 2 study assessing the safety, reactogenicity, and immunogenicity of different dose levels (50 µg, 100 µg and 150 µg) of mRNA-1647 were presented at Moderna’s annual Vaccines Day on April 14, 2021. mRNA-1647 was generally well tolerated. The most common solicited local adverse reaction (AR) was injection site pain and the most common solicited systemic ARs were headache, fatigue, myalgia, arthralgia and chills. Rates of Grade 3 solicited ARs after the third vaccination were similar to, or lower than the rates of Grade 3 solicited ARs after the second vaccination. In CMV-seronegative participants in mRNA-1647 treatment groups after the third vaccination, neutralizing antibody geometric mean titers (GMTs) against epithelial cell infection were at least 20-fold higher than the baseline GMT of the CMV-seropositive group and neutralizing antibody GMTs against fibroblast infection approximated the baseline GMT of the CMV-seropositive group. In CMV positive participants in mRNA-1647 treatment groups after the third vaccination: neutralizing antibody GMTs against epithelial cell infection increased to at least 6.8-fold over baseline and neutralizing antibody GMTs against fibroblast infection increased to approximately 2-fold over baseline. Based on the interim analysis of the Phase 2 study, the 100 µg dose has been chosen for the Phase 3 pivotal study, which is expected to begin in 2021. Moderna owns worldwide commercial rights for mRNA-1647.
- **Epstein-Barr virus (EBV) vaccine (mRNA-1189):** mRNA-1189 is a vaccine against EBV containing five mRNAs that encode viral proteins (gp350, gB, gp42, gH and gL) in EBV. Similar to Moderna’s CMV vaccine (mRNA-1647), the viral proteins in mRNA-1189 are expressed in their native membrane-bound form for recognition by the immune system. Moderna is planning to begin a Phase 1 study of mRNA-1189 in 2021. There is no approved vaccine for EBV. Moderna owns worldwide commercial rights to mRNA-1189.

Vaccines against respiratory infections

- **Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653):** Moderna is enrolling seropositive pediatric participants (12-36 months of age) in the Phase 1 study of hMPV/PIV3 study (mRNA-1653). The first cohort in this study has been fully enrolled. Moderna owns worldwide commercial rights to mRNA-1653.
- **Respiratory syncytial virus (RSV) vaccine (mRNA-1345):** mRNA-1345 is a vaccine against RSV encoding for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state. RSV is the leading cause of respiratory illness in young children. Older adults (65+) are at high risk for severe RSV infections. mRNA-1345 uses the same lipid nanoparticle (LNP) as Moderna's authorized COVID-19 vaccine and contains optimized protein and codon sequences. The Phase 1 study of mRNA-1345 to evaluate the tolerability and reactogenicity of mRNA-1345 in younger adults, older adults and children is ongoing. All four cohorts of younger adults (ages 18-49 years) are fully enrolled. Dosing in the older adult cohort (ages 65-79 years) is ongoing. The age range of toddlers in this de-escalation Phase 1 study is 12-59 months. The Company shared the first interim analysis of the Phase 1 study of mRNA-1345, through 1-month post-vaccination, of the younger adult cohorts at its annual Vaccines Day on April 14, 2021. The Company also intends to evaluate the potential of combinations of mRNA-1345 with its vaccines against other respiratory pathogens in children and separately in older adults. There is no approved vaccine for RSV. Moderna owns worldwide commercial rights to mRNA-1345.
- **Seasonal influenza vaccine (mRNA-1010, mRNA-1020, mRNA-1030):** Seasonal flu (type A and type B) epidemics occur seasonally and vary in severity each year, causing respiratory illnesses and placing substantial burden on healthcare systems. The World Health Organization (WHO) estimates approximately 3-5 million severe cases of flu each year globally, and 290,000-650,000 flu-related respiratory deaths. Approximately 8% of the U.S. population experiences symptoms from flu each year. In the U.S., the estimated average economic burden of flu is approximately \$11 billion per year. Current flu vaccines are only approximately 40-60% effective and their formulation is decided 9 months before the vaccines are intended to be used. Egg-based vaccine production also has the potential to cause unintended antigenic change to the vaccine virus. The Company plans to explore potential combination vaccines against flu, SARS-CoV-2, RSV and human metapneumovirus (hMPV). The Company's first-generation flu program will evaluate multiple candidates comprising multiple antigen combinations against the four seasonal viruses recommended by the WHO. The Company expects to begin a Phase 1 clinical trial for the program in 2021.

Public health vaccines

- **Zika virus vaccine (mRNA-1893):** Moderna is preparing for a Phase 2 study of mRNA-1893, which is expected to begin in 2021. mRNA-1893 is being developed in collaboration with BARDA. Moderna owns worldwide commercial rights to mRNA-1893.
- **HIV vaccine (mRNA-1644 & mRNA-1574):** HIV is the virus responsible for acquired immunodeficiency syndrome (AIDS), a lifelong, progressive illness with no effective cure. Approximately 38 million people worldwide are currently living with HIV with 1.2 million in the U.S. Approximately 2 million new infections of HIV are acquired worldwide every year and approximately 690,000 people die annually due to complications from HIV/AIDS. The primary routes of transmission are sexual intercourse and IV drug use, putting young adults at the highest risk of infection. From 2000 to 2015, a total of \$562.6 billion globally was spent on care, treatment and prevention of HIV, representing a significant economic burden. mRNA-1644, a collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill and

Melinda Gates Foundation, is a novel approach to HIV vaccine strategy in humans designed to elicit broadly Neutralizing HIV-1 Antibodies (bNAbs). A Phase 1 study for mRNA-1644 will use iterative human testing to validate the approach and antigens and multiple novel antigens will be used for germline-targeting and immuno-focusing. A second approach, mRNA-1574, is being evaluated in collaboration with the NIH and includes multiple native-like trimer antigens. The Company expects to begin Phase 1 studies for both mRNA-1644 and mRNA-1574 in 2021.

- **Nipah virus (NiV) Vaccine (mRNA-1215):** NiV is a zoonotic virus transmitted to humans from animals, contaminated food, or through direct human-to-human transmission and causes a range of illnesses including fatal encephalitis. Severe respiratory and neurologic complications of NiV have no treatment other than intensive supportive care. The case fatality rate among those infected is estimated at 40-75%. NiV outbreaks cause significant economic burden to impacted regions due to loss of human life and interventions to prevent further spread, such as the slaughter of infected animals. NiV has been identified as the cause of isolated outbreaks in India, Bangladesh, Malaysia, and Singapore since 2000 and is included on the WHO R&D Blueprint list of epidemic threats needing urgent R&D action. mRNA-1215 was co-developed by Moderna and the NIH's Vaccine Research Center (VRC).
- **Pandemic influenza/H7N9 vaccine (mRNA-1851):** Discussions regarding funding the Company's pandemic influenza/H7N9 vaccine program through approval are ongoing.

Systemic Secreted & Cell Surface Therapeutics: In this modality, mRNA is delivered systemically to create proteins that are either secreted or expressed on the cell surface.

- **Antibody against the chikungunya virus (mRNA-1944):** Positive interim data from the Phase 1 study evaluating escalating doses of mRNA-1944 in the 0.6 mg/kg dose with steroid premedication cohort and two doses of 0.3 mg/kg (without steroid premedication) given one week apart cohort were presented at Moderna's annual R&D Day in September and demonstrated dose-dependent increases in levels of antibody against chikungunya. Safety and increased CHKV-IgG production in the two-dose regimen shows the platform's ability for repeat dosing.
- **IL-2 (mRNA-6231):** mRNA-6231 is an mRNA encoding for a long-acting tolerizing IL-2. This autoimmune development candidate is designed to preferentially activate and expand the regulatory T cell population. The Company plans to conduct a Phase 1 study of mRNA-6231 in healthy adult volunteers. mRNA-6231 uses the same LNP formulation as mRNA-1944. The Phase 1 study of mRNA-6231 will be the first clinical demonstration of subcutaneous administration of this delivery technology. Moderna owns worldwide commercial rights to mRNA-6231.
- **PD-L1 (mRNA-6981):** mRNA-6981 is an mRNA encoding for PD-L1. This autoimmune development candidate is designed to augment cell surface expression of PD-L1 on myeloid cells to provide co-inhibitory signals to self-reactive lymphocytes. As an initial step to addressing a range of autoimmune indications, the Company intends to pursue proof-of-concept in a Phase 1 study of mRNA-6981 in type 1 autoimmune hepatitis (AIH), a condition that involves liver inflammation and can lead to cirrhosis and liver failure. mRNA-6981 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-6981.
- **Relaxin (AZD7970):** Moderna has regained all rights to the Relaxin development candidate from AstraZeneca. Moderna now owns worldwide commercial rights to this development candidate.

Exploratory Modalities

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

- **Personalized cancer vaccine (PCV) (mRNA-4157):** The randomized Phase 2 study investigating a 1 mg dose of mRNA-4157 in combination with Merck's pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma is ongoing. Phase 1 in multiple cohorts is ongoing. The upsized head & neck cohort is recruiting additional patients. Moderna shares worldwide commercial rights to mRNA-4157 with Merck.
- **Mutant KRAS vaccine (mRNA-5671 or V941):** The Phase 1 open-label, multi-center study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with pembrolizumab, led by Merck, is ongoing. Moderna shares worldwide commercial rights to mRNA-5671 with Merck.

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

- **OX40L (mRNA-2416):** The Phase 1/2 study of mRNA-2416 alone and in combination with durvalumab (IMFINZI®) is ongoing. The Phase 2 dose expansion study of mRNA-2416 in combination with durvalumab in ovarian cancer patients is enrolling and the first patients have been dosed. Moderna owns worldwide commercial rights to mRNA-2416.
- **OX40L/IL-23/IL-36g (Triplet) (mRNA-2752):** The Phase 1 trial evaluating mRNA-2752 as a single agent and in combination with durvalumab in patients with advanced solid tumor malignancies and lymphoma is ongoing. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators. Moderna owns worldwide commercial rights to mRNA-2752.
- **IL-12 (MEDI1191):** The Phase 1 open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with durvalumab in patients with advanced solid tumors, led by AstraZeneca, is ongoing. MEDI1191 is an mRNA encoding for IL-12, a potent immunomodulatory cytokine. Moderna shares worldwide commercial rights to MEDI1191 with AstraZeneca.

Localized Regenerative Therapeutics: *Localized production of proteins has the potential to be used as a regenerative medicine for damaged tissues.*

- **VEGF-A (AZD8601):** The Phase 2a study of AZD8601 VEGF-A, which is being developed for patients with ischemic heart disease undergoing coronary artery bypass grafting (CABG) surgery with moderately impaired systolic function, led by AstraZeneca, is ongoing. Moderna has licensed worldwide commercial rights to AZD8601 to AstraZeneca.

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.*

- **Propionic acidemia (PA) (mRNA-3927):** The first patient in the Phase 1/2 Paramount study of mRNA-3927 has been dosed. mRNA-3927 uses the same LNP formulation as mRNA-1944. This is the Company's first development candidate in its systemic intracellular therapeutics modality to enter the clinic. Moderna owns worldwide commercial rights to mRNA-3927.

- **Methylmalonic acidemia (MMA) (mRNA-3705):** Moderna received rare pediatric designation for its next generation MMA candidate (mRNA-3705). The Company plans to file new IND and CTA applications for mRNA-3705 and will focus development efforts on that candidate going forward. mRNA-3705 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-3705.
- **Phenylketonuria (PKU) (mRNA-3283):** Individuals with PKU have a deficiency in phenylalanine hydroxylase (PAH) resulting in a reduced or complete inability to metabolize the essential amino acid phenylalanine into tyrosine. mRNA-3283 encodes human PAH to restore the deficient or defective intracellular enzyme activity in patients with PKU. mRNA-3283 is in preclinical development. Moderna owns worldwide commercial rights to mRNA-3283.
- **Glycogen storage disease type 1a (GSD1a) (mRNA-3745):** Individuals with GSD1a have a deficiency in glucose-6-phosphatase resulting in pathological blood glucose imbalance. mRNA-3745 is an IV-administered mRNA encoding human G6Pase enzyme, designed to restore the deficient or defective intracellular enzyme activity in patients with GSD1a. mRNA-3745 is in preclinical development. Moderna owns worldwide commercial rights to mRNA-3745.

Information about each development candidate in Moderna's pipeline can be found on the investor relations page of its website: investors.modernatx.com.

First Quarter 2021 Financial Results

- **Revenue:** Total revenue was \$1.9 billion for the three months ended March 31, 2021 compared to \$8 million for the same period in 2020. Total revenue increased in the first quarter of 2021, resulting from a full quarter of commercial sales of the Company's COVID-19 vaccine in the U.S. and an initial ramp up of international sales. A total of 102 million doses were recognized as revenue. Product sales were \$1.7 billion for the three months ended March 31, 2021 from sales of the Company's COVID-19 vaccine. The increase in grant revenue of \$190 million was primarily driven by an increase in revenue from BARDA related to the Company's COVID-19 vaccine development.
- **Cost of Sales:** Costs of sales were \$193 million, or 11%, of product sales the three months ended March 31, 2021, including third-party royalties of \$84 million. A portion of the inventory costs associated with the Company's products sales for the three months ended March 31, 2021 was expensed as pre-launch inventory costs in 2020. If inventory sold in the three months ended March 31, 2021 was valued at cost, the Company's cost of sales for the quarter would have been \$377 million, or 22% of product sales.
- **Research and Development Expenses:** Research and development expenses were \$401 million for the three months ended March 31, 2021 compared to \$115 million for the same period in 2020. The growth in spending was mainly due to increases in clinical trial expenses, manufacturing expenses, personnel related costs, and consulting and outside services, largely driven by mRNA-1273 clinical development and increased headcount.
- **Selling, General and Administrative Expenses:** Selling, general and administrative expenses were \$77 million for the three months ended March 31, 2021 compared to \$24 million for the same period in 2020. The growth in spending was mainly due to increases in consulting and outside services, personnel-related costs, legal and other licensing expenses, and marketing and other expenses, primarily attributable to increased headcount and the Company's COVID-19 vaccine commercialization-related activities.
- **Net Income (Loss):** Net income was \$1.2 billion for the three months ended March 31, 2021 compared to a net loss of \$(124) million for the same period in 2020.

- **Cash Position:** Cash, cash equivalents and investments as of March 31, 2021 and December 31, 2020 were \$8.2 billion and \$5.2 billion, respectively.
- **Net Cash Provided by (Used in) Operating Activities:** Net cash provided by operating activities was \$3.0 billion for the three months ended March 31, 2021 compared to \$(106) million used in operating activities for the same period in 2020. Net cash provided by operating activities increased significantly in 2021, mainly due to net income of \$1.2 billion and additional customer deposits received in the first quarter for supply of the Company's COVID-19 vaccine.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was \$35 million for the three months ended March 31, 2021 compared to \$6 million for the same period in 2020.

2021 Updated Financial Framework

- **Advance Purchase Agreements (APAs):** The Company has already signed APAs for scheduled delivery in 2021, for a total of \$19.2 billion in anticipated product sales, including sales already recorded in the three months ended March 31, 2021.
- **Q2 Delivered Doses:** The Company expects doses delivered in the second quarter 2021 to be in the range of 200-250 million doses.
- **Cost of Sales:** Cost of sales as percentage of product sales are expected to be approximately 20% for fiscal year 2021.
- **2021 Research & Development (R&D) and Selling, General & Administrative (SG&A) Expenses:** Expect quarter over quarter cost increases in R&D and SG&A expenses during 2021 as commercial and research and development activities and expenses ramp up.
- **Tax Rate:** Effective tax rate expected in the low-teens as a result of the forecasted global sales mix and utilization of the accumulated net operating loss carry-forward of \$2.3 billion, based on current tax rates.
- **Capital Expenditures:** \$450-550 million of capital investments currently planned for 2021 including the planned capacity expansion.

2022 and 2023 Vaccine Access Discussions

- The Company has already signed APAs with Israel and Switzerland for 2022, and Switzerland has options for further deliveries in 2023. Through its recent agreement with COVAX, the Company has committed up to 466 million doses to COVAX for 2022. The Company is having ongoing discussions for 2022 APAs with all governments that have 2021 APAs. The Company is also having ongoing discussions to supply new geographies in Asia, Latin America and Africa in 2022 that it could not supply in 2021 due to manufacturing supply constraints. In response to feedback from governments for their desire to procure more high efficacy mRNA vaccines, the Company recently announced manufacturing investments to facilitate supply of up to 3 billion doses in 2022. The Company is also engaged in discussions with some governments for supply in 2023.

Management Updates

- Shannon Thyme Klinger will join the Company as Chief Legal Officer and Corporate Secretary, effective June 1, 2021. Ms. Klinger joins Moderna from Novartis (NYSE: NVS), where she served as Chief Legal Officer and a member of the Novartis Executive Committee since 2018. Previously, she served as Chief Ethics, Risk & Compliance Officer. During her ten-year tenure at Novartis, she held other roles of increasing responsibility, including as Chief Ethics and Compliance Officer and Global Head of Litigation, General Counsel and Global Head of Legal at Sandoz, a Novartis division.

Corporate Updates

- **Full-Time Employees:** Over the last year, the Company nearly doubled the size of its workforce. As of March 31, 2021, Moderna had approximately 1,500 employees, compared to approximately 830 employees as of March 31, 2020.
- **Vaccines Day:** Moderna hosted its annual Vaccines Day on April 14, 2021.
- **Corporate Social Responsibility (CSR):** Moderna CEO Stéphane Bancel published a letter on the Company's commitment to CSR on April 27, 2021.
- **Company Recognition:** Moderna was named as a top company on Fast Company's annual list of the World's Most Innovative Companies for 2021 and was named to TIME's inaugural list of the TIME100 Most Influential Companies.

Key 2021 Investor and Analyst Event Dates

- Science Day – May 27
- R&D Day – September 9

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Thursday, May 5, 2021. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 7487119. A webcast of the call will also be available under "Events and Presentations" in the Investors section of the Moderna website at 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 one year 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 the Company the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune and inflammatory diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense; 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) and the Coalition for Epidemic Preparedness Innovations (CEPI). Moderna has been named a top biopharmaceutical employer by *Science* for the past six years. To learn more, visit www.modernatx.com.

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in millions, except per share data)

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Product sales	\$1,733	\$ —
Grant revenue	194	4
Collaboration revenue	10	4
Total revenue	<u>1,937</u>	<u>8</u>
Operating expenses:		
Cost of sales	193	—
Research and development	401	115
Selling, general and administrative	77	24
Total operating expenses	<u>671</u>	<u>139</u>
Income (loss) from operations	1,266	(131)
Interest income	4	8
Other expense, net	(10)	(1)
Income (loss) before income taxes	1,260	(124)
Provision for income taxes	39	—
Net income (loss)	<u>\$1,221</u>	<u>\$ (124)</u>
Earnings per share		
Basic	\$ 3.05	\$(0.35)
Diluted	\$ 2.84	\$(0.35)
Weighted average common shares used in calculation of earnings per share		
Basic	400	353
Diluted	430	353

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

	March 31, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 8,203	\$ 5,247
Total assets	12,694	7,337
Total liabilities	8,856	4,776
Total stockholders' equity	3,838	2,561
Total liabilities and stockholders' equity	12,694	7,337
	Three Months Ended	
	March 31,	
	2021	2020
Net cash provided by (used in) operating activities	\$ 2,971	\$ (106)
Cash used for purchases of property and equipment	(35)	(6)

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: the Company's development of the Moderna COVID-19 Vaccine (mRNA-1273); the number of doses of the Moderna COVID-19 Vaccine that the Company anticipates being able to manufacture in 2021 and 2022 and on a quarterly basis, and investments to facilitate that manufacturing; the Company's efforts to continue developing vaccines against COVID-19, including efforts to develop vaccines against variant strains of SARS-CoV-2 and for booster doses, and the anticipated efficacy of those vaccines; the Company's plans to submit for a Biologics License Application for mRNA-1273; the Company's plans to share additional data regarding its COVE Study of the Moderna COVID-19 Vaccine and the conduct of ongoing and future clinical trials; the development of additional COVID-19 vaccine candidates that may be refrigerator stable; the conditions under which mRNA-1273 or future vaccine candidates can be shipped and stored; the efficacy of mRNA vaccines and their potential for regulatory approval or authorization; the ability of the Moderna COVID-19 Vaccine to provide protection against COVID-19 over time; the Company's investments in increased research and development for infectious diseases and other therapeutic areas; the potential efficacy of vaccines against RSV and CMV and future clinical trials for those vaccines; the status of developments for programs in the Company's pipeline, including with respect to the timing, enrollment and potential results of clinical trials; future growth prospects for the Company; the Company's commercial rights to its development candidates; future research and development expenses; future sales, general and administrative expenses, and capital expenditures, as well as other expenses; orders for the Company's Moderna COVID-19 Vaccine, both inside and outside the U.S.; anticipated doses to be delivered under advance purchase agreement in 2021 and 2022 and the associated dollar amounts to be received, which should not be construed as expected 2021 or 2022 revenue; the anticipated cost of sales associated with the Moderna COVID-19 Vaccine; the Company's future tax rate; and personnel recruitment efforts. 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 press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks,

uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: 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; the Moderna COVID-19 Vaccine may prove less effective against variants of the SARS-CoV-2 virus, or the Company may be unsuccessful in developing future versions of its vaccine against these variants; despite having ongoing interactions with the 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 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

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