

**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): February 25, 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

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 (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 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 February 25, 2021, 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, 2020. 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 February 25, 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.

Date: February 25, 2021

MODERNA, INC.

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

Moderna Reports Fourth Quarter and Fiscal Year 2020 Financial Results and Provides Business Updates

2021 Vaccine Manufacturing: Raises lower end of global manufacturing plan for 2021 from 600 million doses to 700 million doses; manufacturing is still working to supply up to 1 billion doses for 2021

2022 Vaccine Manufacturing: Based on the high demand from around the world for our COVID-19 vaccine and variant-based boosters, making new capital investments to increase capacity up to 1.4 billion doses in 2022

Commercial Subsidiaries: Company established 8 commercial subsidiaries in 2020 in North America and Europe and plans to expand in 2021 to Japan, South Korea and Australia

CAMBRIDGE, Mass., February 25, 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 fourth quarter and fiscal year 2020 and highlighted pipeline progress.

“2020 was a historic year for Moderna. The team rose to the challenge to address the devastating COVID-19 pandemic in less than one year with our authorized vaccine. It is encouraging and humbling that more than 32 million doses of our vaccine have been administered in the U.S. and that millions of people around the world have been vaccinated with our vaccine to date. 2020 demonstrated the power of harnessing mRNA to make medicines and demonstrated the speed and scalability of the Moderna platform that we have built over the last 10 years,” said Stéphane Bancel, Chief Executive Officer of Moderna. “I believe that 2021 will be an inflection year for Moderna. We previously believed that mRNA would lead to approved medicines, and we were limited in our ambitions by the need for regular capital raises and keeping several years of cash to manage financing risk. We now know that mRNA vaccines can be highly efficacious and authorized for use, and we are a cash-flow generating commercial company. We opened commercial subsidiaries in 8 countries in 2020 and plan to add Japan, South Korea and Australia in 2021. We plan to accelerate and significantly increase our investments in science and grow our development pipeline faster. By executing on our 2021 priorities, we will advance our mission of delivering on the promise of mRNA science to create a new generation of transformative medicines for patients. This is just the beginning.”

New updates and recent progress include:

COVID-19 Vaccine Development

- Raises lower end of global manufacturing plan for 2021 from 600 million doses to 700 million doses; making capital investments to increase capacity up to an expected 1.4 billion doses in 2022
- Phase 2/3 study of mRNA-1273 in adolescents has completed enrollment of 3,000 participants

Infectious Diseases

- First cohort in the Phase 1 study of hMPV/PIV3 vaccine candidate (mRNA-1653) fully enrolled
- First older adult in the Phase 1 study of RSV vaccine candidate (mRNA-1345) has been dosed
- First 3 cohorts in age de-escalation study of RSV vaccine candidate (mRNA-1345) for the pediatric population fully enrolled

Rare Diseases

- Study start-up activities for Phase 1/2 study of PA candidate (mRNA-3927) ongoing

Cardiovascular Diseases

- Regained all rights to the Relaxin development candidate from AstraZeneca

Moderna currently has 24 mRNA development programs in its portfolio with 13 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:** On December 30, 2020, interim safety and primary efficacy results from the Phase 3 trial of the Moderna COVID-19 Vaccine (mRNA-1273) were published in the *New England Journal of Medicine*. Safety data continues to accrue, and the study continues to be monitored by an independent Data Safety Monitoring Board (DSMB) appointed by the National Institutes of Health (NIH). All participants in the COVE study will be monitored for two years after their second dose to assess long-term protection and safety. Today, the Company is sharing an update on the Phase 3 COVE study. An updated total of adjudicated COVID-19 cases among baseline seronegative participants in the COVE study starting two weeks following the second dose showed 690 cases to date, of which 639 cases of COVID-19 were observed in the placebo group versus 51 cases observed in the Moderna COVID-19 Vaccine group. Participants in the Phase 3 COVE study are in the process of being unblinded and cases will continue to accrue. On December 18, 2020, the U.S. Food and Drug Administration (FDA) authorized the emergency use of mRNA-1273, Moderna's vaccine against COVID-19, in individuals 18 years of age and older. 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 and Qatar. Moderna is working with additional health agencies and with the World Health Organization 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.
- **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:** Letter to the editor in the *New England Journal of Medicine* published February 17, 2021, showed vaccination with the Moderna COVID-19 Vaccine produced neutralizing titers against all key emerging variants tested, including B.1.1.7 and B.1.351, first identified in the UK and Republic of South Africa, respectively. The study showed no significant impact on neutralizing titers against the B.1.1.7 variant relative to prior variants. A six-fold reduction in neutralizing titers was observed with the B.1.351 variant relative to prior variants.

- **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 of 3,000 participants in the U.S.
- **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 will start in the near-term.
- **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.
- **Next-generation vaccine against COVID-19 (mRNA-1283):** 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 interim data from the Phase 2 study assessing the safety, reactogenicity, and immunogenicity of different dose levels of mRNA-1647 were presented at Moderna’s annual R&D Day. 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. On January 11, Moderna announced its plan to amend the protocol to include evaluation of mRNA-1345 in older adults (greater than 50 years), in addition to the pediatric population, who are also at risk of significant RSV disease. In the pediatric population, the first three cohorts of younger adults in the Phase 1 age de-escalation study of mRNA-1345 are fully enrolled. The age range of toddlers in this de-escalation Phase 1 study has been amended to 12-59 months (from 12-36 months). In the older adult population, the first participant in the Phase 1 study of mRNA-1345 in the adult RSV vaccine has been

dosed. 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 WHO estimates globally about 3,000,000-5,000,000 severe cases of flu each year, and 290,000-650,000 flu-related respiratory deaths. Approximately 8% of the U.S. population experiences symptoms from flu each year, with 140,000-810,000 hospitalizations and 12,000-61,000 deaths per year. Peak flu activity is seen in temperate climates from fall to winter and is reflected in increases in outpatient visits, urgent care visits, and hospitalizations. In the U.S., the estimated average economic burden of seasonal influenza is approximately \$11 billion per year. 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 Phase 1 clinical trials for this 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 (BMGF), 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 new 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 new 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):** Study start-up activities for the Phase 1/2 study of PA candidate (mRNA-3927) have resumed following COVID-19 related pause and protocol amendment. mRNA-3927 uses the same LNP formulation as mRNA-1944. 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.

Fourth Quarter and Full Year 2020 Financial Results (Unaudited)

- **Cash Position:** Cash, cash equivalents and investments as of December 31, 2020 and 2019 were \$5.25 billion and \$1.26 billion, respectively.
- **Net Cash Provided by (Used in) Operating Activities:** Net cash provided by operating activities was \$2.03 billion for the year ended December 31, 2020 compared to net cash used in operating activities of \$(459) million for the year ended December 31, 2019.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was \$67 million for the year ended December 31, 2020 compared to \$32 million for the same period in 2019.
- **Revenue:** Total revenue was \$571 million for the fourth quarter of 2020 compared to \$14 million for the fourth quarter of 2019. Total revenue was \$803 million for the year ended December 31, 2020 compared to \$60 million for the year ended December 31, 2019. The increases in both periods in 2020 were driven by increases in grant revenue and product sales. The increase in grant revenue was primarily due to the BARDA award to accelerate development of our COVID-19 vaccine. We began to recognize revenue in December 2020 from our COVID-19 vaccine subsequent to its authorization for emergency use by the FDA and Health Canada.
- **Cost of Sales:** Costs of sales were \$8 million, or 4% of Moderna's product sales, in 2020, primarily comprised of third-party royalties as the associated inventory costs were expensed previously. If inventory sold during 2020 was valued at cost, Moderna's cost of sales for 2020 would have been \$62 million, or 31% of Moderna's product sales.
- **Research and Development Expenses:** Research and development expenses were \$759 million for the fourth quarter of 2020 compared to \$118 million for the fourth quarter of 2019. Research and development expenses were \$1.37 billion for the year ended December 31, 2020 compared to \$496 million for the year ended December 31, 2019. The increases in 2020 were largely attributable to mRNA-1273 clinical development, pre-launch inventory buildup prior to the emergency use authorization from the FDA and to a lesser extent, an increase in personnel related costs, primarily driven by an increase in the number of employees supporting our mRNA-1273 development activities.
- **Selling, General and Administrative Expenses:** Selling, general and administrative expenses were \$79 million for the fourth quarter of 2020 compared to \$26 million for the fourth quarter of 2019. Selling, general and administrative expenses were \$188 million for the year ended December 31, 2020 compared to \$110 million for the year ended December 31, 2019. The increases in 2020 were mainly due to an increase in personnel costs, and outside services, primarily attributable to increased headcount and mRNA-1273 vaccine candidate commercialization-related activities.
- **Net Loss:** Net loss was \$272 million for the fourth quarter of 2020 compared to \$123 million for the fourth quarter of 2019. Net loss was \$747 million for the year ended December 31, 2020 compared to \$514 million for the year ended December 31, 2019.

Moderna's COVID-19 Vaccine Supply Agreements & Regulatory Updates

Moderna has confirmed the following supply agreements of committed orders:

- **United States:** 300 million doses with options to purchase an additional 200 million doses; the U.S. Food and Drug Administration (FDA) has authorized emergency use in individuals 18 years of age and older

- **European Union:** 310 million doses with option to purchase an additional 150 million doses in 2022; the European Commission has granted a conditional marketing authorization (CMA) for COVID-19 Vaccine Moderna in individuals 18 years of age and older¹
- **Japan:** 50 million doses
- **Canada:** 44 million doses; Health Canada authorized COVID-19 Vaccine Moderna for the immunization of people 18 years of age and older under an Interim Order
- **Republic of Korea:** 40 million doses
- **United Kingdom:** 17 million doses; the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved the COVID-19 Vaccine Moderna for use under Regulation 174, a temporary authorization
- **Switzerland:** 13.5 million doses; Swissmedic, the Swiss Agency for Therapeutic Products, authorized the COVID-19 Vaccine Moderna in Switzerland
- **Colombia:** 10 million doses
- **Israel:** 6 million doses; Israel’s Ministry of Health (MOH) has given authorization to import the COVID-19 Vaccine Moderna
- **Taiwan:** 5 million doses
- **Singapore:** (undisclosed); the Singapore Health Sciences Authority (HSA) approved the interim authorization of the COVID-19 Vaccine Moderna for use under the Pandemic Special Access Route (PSAR)
- **Qatar** (undisclosed); the Qatar Ministry of Public Health issued an emergency use authorization for the COVID-19 Vaccine Moderna

Management Updates

- Moderna’s Chief Medical Officer (CMO), Tal Zaks, M.D., Ph.D., will be leaving the Company in late September after six years of service. The Company has retained Russell Reynolds to recruit for a new CMO with global and commercial experience as the Company scales up the launch of its COVID-19 Vaccine and prepares to file several biologics license applications (BLAs) over the next few years.

“I would like to thank Tal for his tremendous impact on Moderna’s success over the last six years. Tal joined us when we were a pre-clinical company. His guidance and contributions were important in helping Moderna get to where we are today. Through his leadership over the past year in Moderna’s response to the COVID-19 pandemic, Tal has made a contribution that extends beyond Moderna to all of society. I have enjoyed having him as my partner and wish him all the best as he embarks on the next leg of his career,” said Stéphane Bancel.

- Corinne Le Goff, Pharm.D., M.B.A., joined Moderna as the Company’s first Chief Commercial Officer on January 19, 2021. Dr. Le Goff previously served as SVP and President U.S. Business Organization at Amgen (Nasdaq: AMGN). During her nearly 6-year tenure at Amgen, she also served as SVP of the Europe Region and oversaw 48 markets. Dr. Le Goff was actively engaged with the policy community and advocates for innovative, high-quality and affordable healthcare.

2020 Commercial Network

The Company started to build a global commercial network. This infrastructure will enable Moderna’s entire portfolio, which means that Moderna can commercialize its entire pipeline without a large pharmaceutical partner. The Company now has subsidiaries, distributors or partners in the following geographies:

- Moderna USA
- Moderna Canada

¹ On February 18, 2021, the European Commission advised Moderna it had successfully tendered for the provision of 150 million doses of COVID-19 Vaccine Moderna in 2021 and an option to purchase an additional 150 million doses in 2022; this tender is subject to execution of the Purchase Agreement, which is expected February 26, 2021, following an opt out period for individual Member States.

- Moderna France
- Moderna Germany
- Moderna Italy
- Japan (Partner: Takeda)
- Moderna Spain
- Moderna UK
- Moderna Switzerland

Corporate Updates

- **Shareholder letter:** Moderna CEO Stéphane Bancel published a letter to shareholders on January 4, 2021.
- **Annual Meeting of Shareholders:** The Moderna Annual Meeting of Shareholders will be held on April 28, 2021 at 8:00 a.m. ET. The meeting will be held virtually at www.virtualshareholdermeeting.com/MRNA2021. The record date for voting or attendance as a stockholder is 4:00 p.m. ET on March 1, 2021.

2021 Financial Considerations

- **Advance Purchase Agreements (APAs):** Already signed APAs for scheduled delivery in 2021, reflecting a total of \$18.4 billion in anticipated product sales. Additional discussions ongoing with several governments relating to APAs for scheduled deliveries in 2021 and 2022. Moderna responded to a tender to UNICEF to supply COVAX in 2021 and 2022 and discussions are ongoing with COVAX/UNICEF.
- **Cost of Sales:** Expected at approximately 20% of product sales for fiscal year 2021.
- **2021 Research & Development (R&D) and Selling, General & Administrative (SG&A) Expenses:** For the first quarter 2021, expect low double-digit percent increase versus adjusted fourth quarter 2020 results of \$0.5 billion. The fourth quarter 2020 reported expense was \$0.8 billion. Adjusted Q4 expense, totaling \$0.5 billion, excludes \$0.3 billion of reported expenses, which are now capitalized and expensed through cost of sales, based on our change from a research and development to a commercial organization.
- **Tax Rate:** Effective tax rate expected in the mid-teen percentage level as a result of the forecasted global sales mix and utilization of the accumulated net operating loss carry-forward of \$2.3 billion.
- **Capital Expenditures:** \$350-400 million of capital investments currently planned for 2021.

2021 New Commercial Networks

In 2021, the Company plans to further expand its commercial network to enable Moderna's entire portfolio.

- Moderna Australia
- Moderna Japan
- Moderna South Korea

Key 2021 Investor and Analyst Event Dates

- Vaccines Day – April 14
- 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, February 25, 2021. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 4066945. 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 thousands)

	<u>Three Months Ended December 31,</u>		<u>Years Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue:				
Grant revenue	\$ 341,370	\$ 3,502	\$ 528,905	\$ 12,173
Product sales	199,872	—	199,872	—
Collaboration revenue	29,503	10,553	74,618	48,036
Total revenue	<u>570,745</u>	<u>14,055</u>	<u>803,395</u>	<u>60,209</u>
Operating expenses:				
Cost of sales	7,933	—	7,933	—
Research and development	758,860	117,954	1,370,339	496,309
Selling, general and administrative	78,990	25,707	188,267	109,620
Total operating expenses	<u>845,783</u>	<u>143,661</u>	<u>1,566,539</u>	<u>605,929</u>
Loss from operations	(275,038)	(129,606)	(763,144)	(545,720)
Interest income	4,200	7,984	24,715	38,530
Other expense, net	(174)	(1,837)	(6,084)	(7,526)
Loss before provision for (benefit from) income taxes	(271,012)	(123,459)	(744,513)	(514,716)
Provision for (benefit from) income taxes	1,473	(169)	2,551	(695)
Net loss	<u>\$ (272,485)</u>	<u>\$ (123,290)</u>	<u>\$ (747,064)</u>	<u>\$ (514,021)</u>
Net loss per share, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.37)</u>	<u>\$ (1.96)</u>	<u>\$ (1.55)</u>
Weighted average common shares used in net loss per share, basic and diluted	<u>396,697,168</u>	<u>334,392,128</u>	<u>381,333,059</u>	<u>330,802,136</u>

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

	<u>December 31,</u>	
	<u>2020</u>	<u>2019</u>
Cash, cash equivalents and investments	\$5,246,456	\$1,262,987
Total assets	7,336,750	1,589,422
Total liabilities	4,775,375	414,612
Total stockholders' equity	2,561,375	1,174,810
	<u>Years Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Net cash provided by (used in) operating activities	\$2,026,971	\$(458,968)
Cash used for purchases of property and equipment ⁽¹⁾	(67,448)	(31,554)

(1) Includes \$41.7 million and \$14.6 million for the years ended December 31, 2020 and 2019, respectively, related to our Moderna Technology Center facilities.

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; the Company's establishment of additional subsidiaries and development of its commercial network; 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 efficacy of mRNA vaccines and their potential for regulatory approval or authorization; expected timing of execution of the Purchase Agreement by the European Commission for additional vaccine doses; future research and development expenses; 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 agreements in 2021 and the associated dollar amounts to be received, which should not be construed as expected 2021 revenue; the anticipated cost of sales associated with the Moderna COVID-19 Vaccine; and 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 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.

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