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

November 4, 2021

Q3 total revenue of $5.0 billion, net income of $3.3 billion and diluted EPS of $7.70

U.S. FDA granted Priority Review to the Biologics License Application for Moderna's COVID-19 vaccine

Interim data from Phase 2/3 KidCOVE study of mRNA-1273 in children ages 6 to under 12 years shows vaccine efficacy of 100% two weeks after first dose of mRNA-1273 at 50 µg dose level

First participants dosed in Phase 3 study of cytomegalovirus (CMV) vaccine candidate (mRNA-1647)

Introducing inhaled pulmonary therapeutics modality: Vertex and Moderna cystic fibrosis mRNA therapeutic (VXc-522) IND-enabling first-in-human studies ongoing

Company continues to scale with 37 programs in development, including 21 in ongoing clinical studies

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 4, 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 third quarter of fiscal year 2021.

"We are humbled to have helped hundreds of millions of people around the world with our COVID-19 vaccine and yet we know our work is not done. We will not rest until our vaccine is available to anyone who needs it, and we are working hard to ensure our vaccine is available in low-income countries with approximately 10% of our 2021 volume and significantly more of our 2022 volume going to low-income countries. It is promising to see the real-world evidence showing that the Moderna COVID-19 vaccine shows sustainably high, durable efficacy," said Stéphane Bancel, Chief Executive Officer of Moderna. "Looking ahead, we are focused on advancing the many other programs in our pipeline. We recently dosed the first participants in the Phase 3 study of our CMV vaccine. CMV is a latent virus that remains in the body for life after infection and can lead to lifelong medical conditions. We are also focused on addressing respiratory viruses in addition to COVID-19, including seasonal flu and RSV. We look forward to sharing data from the Phase 1 study of our flu vaccine candidate soon and we are preparing to start our Phase 2 study. We are also preparing to start the Phase 2/3 study of our RSV vaccine candidate. RSV causes hospitalizations and deaths in our most vulnerable populations of young children and older adults. In addition, we continue to progress our therapeutics pipeline and we look forward to clinical proof of concept data. I would like to thank the Moderna team for their scientific passion and commitment to our mission. I am more energized than ever by the impact our mRNA platform will have on human health."

Updates and recent progress include:

COVID-19 Vaccine Development

- Moderna COVID-19 Vaccine (Spikevax™): Received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (U.S. FDA), and approvals by the European Commission and Swissmedic for a booster dose of the Moderna COVID-19 vaccine at the 50 µg dose level
- U.S. FDA granted Priority Review to the Biologics License Application (BLA) for the Moderna COVID-19 vaccine
- New data from Phase 2/3 KidCOVE study of mRNA-1273 in children ages 6 to under 12 years shows vaccine efficacy of 100% two weeks after first dose of mRNA-1273 at 50 µg dose level, using the Phase 3 COVE study primary case definition for COVID-19
- The Phase 1 study of next-generation vaccine candidate against COVID-19 (mRNA-1283) is fully enrolled; Moderna expects to begin Phase 2 study of mRNA-1283 soon; mRNA-1283 is being developed as a potential refrigerator-stable mRNA vaccine

Respiratory Vaccines

- Phase 1 portion of the Phase 1/2 study of quadrivalent seasonal flu vaccine candidate (mRNA-1010) fully enrolled, preparations for Phase 2 portion of the study are ongoing
- Pivotal Phase 2/3 study of respiratory syncytial virus (RSV) vaccine candidate (mRNA-1345) in older adults expected to begin in 2021; study expected to enroll approximately 34,000 participants, subject to agreement with regulatory authorities
- New combination respiratory vaccines: Moderna COVID-19 vaccine + flu vaccine candidate (mRNA-1073) and pediatric RSV + hMPV vaccine candidate (mRNA-1365)

Latent Vaccines

- First participants dosed in Phase 3 study of cytomegalovirus (CMV) vaccine candidate (mRNA-1647)
- Phase 1 study of EBV vaccine candidate (mRNA-1189) expected to start soon
- New EBV therapeutic vaccine candidate (mRNA-1195)

Therapeutics

- Phase 2 randomized, placebo-controlled study of personalized cancer vaccine (PCV) (mRNA-4157) in combination with Merck's pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma is fully enrolled; data readout expected in the fourth quarter of 2022
- Enrollment of the first cohort in Propionic Acidemia candidate (mRNA-3927) Phase 1/2 Paramount study is complete
- First patient dosed in Phase 1 study of Methylmalonic Acidemia (MMA) candidate (mRNA-3705)
- Investigational New Drug application (IND) open and Orphan Drug Designation granted by U.S. FDA for GSD1a program (mRNA-3745)
- Providing investigational mRNA Crigler-Najjar Syndrome Type 1 (CN-1) therapy (mRNA-3351) to Institute for Life Changing Medicines (ILCM) free of charge; CN-1 is an ultra-rare disease
- Introducing inhaled pulmonary therapeutics modality; IND-enabling first-in-human studies of Vertex and Moderna mRNA cystic fibrosis (CF) therapeutic (VXc-522) are ongoing in new pulmonary modality

Moderna continues to scale, now with 37 programs in development across 34 development candidates[1], including 21 in ongoing clinical studies. The Company's updated pipeline can be found at www.modernatx.com/pipeline. Moderna and collaborators have published nearly 100 peer reviewed manuscripts.

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, vaccines against latent viruses, and 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.*

Vaccines against acute respiratory infections

COVID-19 vaccine development

- **Moderna COVID-19 Vaccine (mRNA-1273[2], Spikevax™):** The U.S. FDA granted Priority Review to the BLA for mRNA-1273. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is in April 2022. The World Health Organization (WHO) and health agencies in more than 60 countries have granted emergency use authorization or emergency use listing for the use of the Moderna COVID-19 vaccine in adults.
    - **Booster Dose of mRNA-1273:** The U.S. FDA, EMA, Swissmedic and other health agencies around the world have authorized a booster dose of the Moderna COVID-19 vaccine at the 50 µg dose level.
    - **Addressing Variants of Concern:** Moderna has four development candidates against SARS-CoV-2 variants of concern, including three which have been administered in a Phase 2/3 clinical trial. The Company's strategy is to develop booster vaccines against current variants of concern and against potential future variants of concern.
        - mRNA-1273.351: Variant-specific candidate against the Beta variant
        - mRNA-1273.617: Variant-specific candidate against the Delta variant
        - mRNA-1273.211: Multivalent candidate combining the Beta-specific variant and mRNA-1273
        - mRNA-1273.213: Multivalent candidate combining the Beta-specific and Delta-specific candidates
- **Further Clinical Studies of mRNA-1273**
    - **Phase 2/3 "TeenCOVE" study of mRNA-1273 in adolescents:** mRNA-1273 is authorized for use in adolescents ages 12 to 17 in the United Kingdom, European Union, Japan, Canada, Switzerland, Taiwan, Saudi Arabia, Australia and the Philippines. The U.S. FDA notified the Company that it will require additional time to complete its assessment of Moderna's EUA request for the use of mRNA-1273 at the 100 µg dose level in adolescents 12 to 17 years of age.
    - **Phase 2 "KidCOVE" study of mRNA-1273 in young children:** The Phase 2 study of mRNA-1273 in pediatric population ages 6 months to under 12 years is ongoing. Moderna is sharing new data from the KidCOVE study of mRNA-1273 in children ages 6 years to under 12 years. Vaccine efficacy of 100% using the P301 primary case definition for COVID-19 was observed two weeks after the first dose of mRNA-1273 at the 50 µg dose level. Additionally, for asymptomatic infection two weeks after the first dose, vaccine efficacy was 65% (95% CI: .16, .85). For SARS-CoV-2 infection regardless of symptoms, vaccine efficacy was 80% (95% CI: .62, .90) two weeks after the first dose. On October 24, the Company announced positive top line top line data from the Phase 2/3 study of mRNA-1273 in children 6 to under 12 years of age. Geometric mean ratio (GMR) comparing the response in children to the response in young adults from the Phase 3 COVE study was 1.5 (95% CI: 1.3, 1.8), with a seroresponse rate of 99.3%. Two 50 µg doses of mRNA-1273 were generally well tolerated. Moderna plans to submit results to the EMA and regulatory agencies around the world soon. Dose selection studies are underway for

the 2 to under 6 years and 6 months to under 2 years age groups.

  - **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, including the offer of a third vaccine dose to these immunocompromised participants.

- **Next-generation vaccine candidate against COVID-19 (mRNA-1283):** The Phase 1 study of mRNA-1283 is fully enrolled and ongoing. An interim analysis of data from the Phase 1 study of mRNA-1283 at three dose levels indicate that a lower dose of mRNA-1283 achieved similar neutralizing antibody responses compared to a primary series of mRNA-1273. mRNA-1283 had an acceptable tolerability profile. The Company expects to start a Phase 2 booster study in the near term. 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.

Additional vaccines against acute respiratory infections

- **Seasonal influenza vaccine (mRNA-1010):** The Phase 1 study evaluating the safety and reactogenicity of three different dose levels of mRNA-1010 in adults over age 18 is fully enrolled (N=180). mRNA-1010 encodes for hemagglutinin (HA) glycoproteins of four flu strains and targets lineages recommended by the WHO for the prevention of influenza, including seasonal influenza A H1N1, H3N2 and influenza B Yamagata and Victoria.

- **COVID-19 and flu combination vaccine (mRNA-1073):** mRNA-1073 encodes for the COVID-19 spike protein and the Flu HA glycoproteins. Moderna owns worldwide commercial rights to mRNA-1073.

- **Respiratory syncytial virus (RSV) vaccine (mRNA-1345):** At its annual R&D Day on September 9, the Company shared positive Phase 1 interim data from the older adult cohort. Moderna is preparing for a Phase 2/3 study of RSV in older adults (ages older than 60 years) and expects to begin this study by the end of 2021. The Company expects this Phase 2/3 study will be a global study conducted in locations influenced by the epidemiology of RSV and expects to enroll approximately 34,000 participants, subject to agreement with regulatory authorities. The FDA has granted Fast Track designation for mRNA-1345 in adults older than 60 years of age. RSV is the leading cause of severe respiratory illness in young children and older adults (65+). The Phase 1 study of mRNA-1345 to evaluate the tolerability and reactogenicity of mRNA-1345 in younger adults, women of child-bearing potential, older adults and seropositive toddlers is ongoing. All four cohorts of younger adults (ages 18-49 years) and all four cohorts of older adults (ages 65-79 years) are fully enrolled. There is no approved vaccine to prevent RSV. Moderna owns worldwide commercial rights to mRNA-1345.

- **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 is fully enrolled. Moderna owns worldwide commercial rights to mRNA-1653.

- **Pediatric RSV and hMPV combination vaccine (mRNA-1365):** mRNA-1365 encodes for the RSV prefusion F glycoprotein and the hMPV F protein. Moderna owns worldwide commercial rights to mRNA-1365.

Vaccines against latent viruses

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** The first participants have been dosed in the Phase 3 study, known as CMVictory, which is evaluating the safety and efficacy of mRNA-1647 against primary CMV infection in women ages 16-40 years. The Company will seek to enroll up to approximately 8,000 participants in the study, including 6,900 women of child-bearing potential, at approximately 150 sites globally, beginning in the U.S. Moderna has set a goal of enrolling a diverse group of U.S. participants into the study, including approximately 42% of participants who are Persons of Color. Based on the interim analysis of the Phase 2 study, the 100 µg dose has been chosen for the Phase 3 pivotal study. The ClinicalTrials.gov identifier is NCT05085366. To learn more about eligibility, visit www.CMVictory.com. Moderna owns worldwide commercial rights for mRNA-1647.

- **Epstein-Barr virus (EBV) vaccine (mRNA-1189):** The Phase 1 study of mRNA-1189 is expected to begin soon. EBV is a member of the herpesvirus family and is spread through bodily fluids (e.g., saliva) and contracted primarily by young children and adolescents. It is a major cause of infectious mononucleosis (IM), and associated risks to other long-term medical conditions, including an increased risk of developing multiple sclerosis by approximately 4 to 10-fold, certain lymphoproliferative disorders and cancers, and autoimmune diseases[3,4]. While EBV infection in early childhood is predominantly asymptomatic, primary infection in adolescence can lead to IM, which can debilitate patients for weeks to

months, sometimes requiring hospitalization for serious complications. mRNA-1189 is a vaccine being developed to prevent IM, and potentially EBV infection. Similar to Moderna's CMV vaccine (mRNA-1647), mRNA-1189 contains four mRNAs that encode EBV envelope glycoproteins (gH, gL, gp42, gp220). There is currently no approved vaccine for EBV or IM. Moderna owns worldwide commercial rights to mRNA-1189.

- **Epstein-Barr virus (EBV) therapeutic vaccine candidate (mRNA-1195):** mRNA-1195 is being developed to prevent longer term sequelae of EBV infection, which are associated with loss of immune control of EBV latent infection, creating longer-term complications. mRNA-1195 is in pre-clinical development and encodes for additional antigens than mRNA-1189. The Company expects to initially test the vaccine in post-transplant lymphoproliferative disorder (PTLD) because at least 80% of PTLD in transplant patients is associated with EBV. The Company expects to also pursue other longer-term potential indications for this vaccine, including multiple sclerosis.

- **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. 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.

Public health vaccines

- **Zika virus vaccine (mRNA-1893):** The Phase 2 study of mRNA-1893 is ongoing in the U.S. and Puerto Rico. mRNA-1893 is being developed in collaboration with BARDA. Moderna owns worldwide commercial rights to mRNA-1893.

- **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).

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):** The Phase 1 study evaluating escalating doses of mRNA-1944 has completed. The Company anticipates publication of the full results of the Phase 1 study soon. At this time, the Company does not have plans to advance to a Phase 2 study.

- **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 first participant in the Phase 1 study of mRNA-6231 in healthy adult participants (between 18 and 50 years of age) has been dosed. 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 (mRNA-0184):** mRNA-0184 encodes for the relaxin fusion protein. The mRNA sequence of mRNA-0184 is engineered to increase protein expression and prolong half-life. Moderna is planning for a Phase 1 study in participants

with chronic heart failure. The Company expects that mRNA-0184 will be administered after heart failure decompensation to bridge patients through the vulnerable period. Moderna owns worldwide commercial rights to mRNA-0184.

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, placebo-controlled 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 fully enrolled (n=150). The Company expects the Phase 2 data readout to occur in the fourth quarter of 2022. The primary endpoint of the Phase 2 study is recurrence-free survival at 12 months. The Phase 1 in multiple cohorts is ongoing and the expanded head and 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/IL-23/IL-36γ (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 fully enrolled. Enrollment in additional cohorts is ongoing. Moderna owns worldwide commercial rights to mRNA-2752.
    - **Presentation of Note:** Moderna will share a poster presentation at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting on November 12.

- **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 surgery with moderately impaired systolic function, led by AstraZeneca, has completed recruitment after enrollment of the low dose cohort (n=11). Moderna has licensed worldwide commercial rights to AZD8601 to AstraZeneca.
    - **Presentation of Note:** AstraZeneca to present on the VEGF-A program on November 15 at the American Heart Association's Scientific Sessions 2021 annual meeting.

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 Phase 1/2 Paramount study of mRNA-3927 is ongoing and the first cohort is fully enrolled. mRNA-3927 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-3927.

- **Methylmalonic acidemia (MMA) (mRNA-3705):** The Phase 1/2 Landmark study to evaluate the safety and pharmacology of mRNA-3705 in patients 1 year of age and older with MMA is ongoing and the first participant has been dosed. Moderna received rare pediatric designation for mRNA-3705. 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):** The U.S. FDA has granted mRNA-3745 Orphan Drug Designation and completed its review of the IND application allowing it to proceed to clinic. 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. Moderna owns worldwide commercial rights to mRNA-3745.

- **Crigler-Najjar Syndrome Type 1 (CN-1) (mRNA-3351):** mRNA-3351 encodes for the human UGT1A1 and is designed to restore the missing or dysfunctional proteins that causes Crigler-Najjar Syndrome Type 1. mRNA-3351 has been granted Rare Pediatric Disease designation by the U.S. FDA. Moderna will provide investigational mRNA-3351 to the nonprofit Institute for Life Changing Medicines (ILCM) free of charge. ILCM will be responsible for the clinical development of mRNA-3351 and plans to initiate clinical studies of mRNA-3351 in 2022.

Inhaled Pulmonary Therapeutics

- **Cystic Fibrosis (CF) (VXc-522):** VXc-522 is an mRNA therapeutic being designed in collaboration with Vertex Pharmaceuticals. It is designed to treat the underlying cause of CF by enabling cells in the lungs to produce functional cystic fibrosis transmembrane conductance regulator (CFTR) protein for the treatment of the 10% of patients who do not produce any CFTR protein. IND-enabling studies are underway, and Vertex expects to submit an IND for this program in 2022. VXc-522 is being advanced by Vertex.

Information about each development candidate in Moderna's pipeline can be found at investors.modernatx.com.

Third Quarter 2021 Financial Results

- **Revenue:** Total revenue was $5.0 billion for the three months ended September 30, 2021, compared to $157 million for the same period in 2020. Total revenue was $11.3 billion for the nine months ended September 30, 2021, compared to $232 million for the same period in 2020. Total revenue increased in 2021 as a result of commercial sales of the Company's COVID-19 vaccine, and to a lesser extent, grant revenue. Product sales for the three and nine months ended September 30, 2021 were $4.8 billion and $10.7 billion, respectively, from sales of 208 million and 510 million doses of the Company's COVID-19 vaccine for the three and nine months ended September 30, 2021, respectively. The increase in grant revenue of $286 million for the nine months ended September 30, 2021 was primarily driven by an increase in revenue from BARDA related to the Company's COVID-19 vaccine development. Grant revenue for the three months ended September 30, 2021 was relatively flat compared to the same period in 2020.

- **Cost of Sales:** Cost of sales was $722 million, or 15%, of product sales for the three months ended September 30, 2021, including third-party royalties of $168 million. Cost of sales was $1.7 billion, or 16%, of the Company's product sales, for the nine months ended September 30, 2021, including third-party royalties of $400 million. A portion of the inventory costs associated with the Company's product sales for the nine months ended September 30, 2021 was expensed as pre-launch inventory costs in 2020. At the end of the first quarter of 2021, the Company's zero-cost COVID-19 vaccine inventory was substantially utilized. If inventory sold for the nine months ended September 30, 2021 was valued at cost, the Company's cost of sales for the period would have been $1.9 billion, or 17% of product sales.

- **Research and Development Expenses:** Research and development expenses were $521 million for the three months ended September 30, 2021, compared to $344 million for the same period in 2020. Research and development expenses were $1.3 billion for the nine months ended September 30, 2021, compared to $611 million for the same period in 2020. The growth in spending in 2021 was mainly due to increases in clinical trial expenses and personnel-related costs, largely driven by increased mRNA-1273 clinical development and headcount.

- **Selling, General and Administrative Expenses:** Selling, general and administrative expenses were $168 million for the three months ended September 30, 2021, compared to $48 million for the same period in 2020. Selling, general and administrative expenses were $366 million for the nine months ended September 30, 2021, compared to $109 million for the same period in 2020. The growth in spending in 2021 was mainly due to increases in consulting and outside services, personnel-related costs, marketing expenses and distributor fees, primarily attributable to the Company's COVID-19 vaccine commercialization-related activities and increased headcount.

- **Net Income (Loss):** Net income was $3.3 billion for the three months ended September 30, 2021, compared to a net loss of $(233) million for the same period in 2020. Net income was $7.3 billion for the nine months ended September 30, 2021, compared to a net loss of $(474) million for the same period in 2020.

- **Cash Position:** Cash, cash equivalents and investments as of September 30, 2021 and December 31, 2020 were $15.3 billion and $5.2 billion, respectively.

- **Net Cash Provided By Operating Activities:** Net cash provided by operating activities was $10.3 billion for the nine months ended September 30, 2021, compared to $763 million for the same period in 2020. Net cash provided by operating

activities increased significantly in 2021, mainly due to net income of $7.3 billion and additional customer deposits received during the period for the Company's future COVID-19 vaccine supply.

- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was $164 million for the nine months ended September 30, 2021, compared to $44 million for the same period in 2020.

2021 Updated Financial Framework

- **For Expected Delivery in Fiscal Year (FY) 2021:** Expected to realize product sales for FY 2021 between $15 billion and $18 billion.
    - **Key Variables Impacting FY 2021 Revenues:** Fewer doses for delivery in 2021, shifted to early 2022; prioritization of deliveries to low-income countries through COVAX and African Union
- **Vaccine Dose Deliveries for FY 2021:** The Company expects deliveries of its COVID-19 vaccine in FY 2021 to be between 700 million and 800 million doses at the 100 µg dose level. Key variables impacting output include longer delivery lead times for international shipments and exports that may shift deliveries to early 2022, temporary impact from expansion of fill/finish capacity and ramp up of product release to market.
- **Cost of Sales:** Cost of sales as percentage of product sales are expected to be between 16-17% for FY 2021.
- **2021 Research & Development (R&D) and Selling, General & Administrative (SG&A) Expenses:** Continue to 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:** The Company now expects the effective tax rate for 2021 to be in the high single digit range 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:** Expect approximately $0.4 billion of capital investments for 2021.
- **Share Repurchase Program:** The Board of Directors has authorized a share repurchase program of up to $1 billion over a two-year period to return excess capital to shareholders. No shares were repurchased through the end of the third quarter.

2022 Revenue Drivers

We expect several dynamics will drive 2022 revenues:

- **APAs Signed:** The Company has signed approximately $17 billion of advance purchase agreements (APAs) for delivery in 2022.
- **APAs with Options:** The Company anticipates the exercise of options under 2022 APAs of up to $3 billion.
- **U.S. Fall 2022 Booster Market:** Subject to receipt of a BLA or sBLA for boosters prior to the fall booster season, the Company anticipates commercial booster market sales could be up to $2 billion.

Based on these three revenue drivers, the Company believes 2022 sales could be in the range of $17 billion to $22 billion. The Company continues to have discussions for 2022 APAs with governments and international organizations, including COVAX, the Pan American Health Organization (PAHO) and the African Union.

Corporate Social Responsibility

- **Sustainability:** Moderna announced a pledge to achieve net-zero carbon emissions globally by 2030.
- **Global Vaccine Access Strategy:** Moderna CEO Stéphane Bancel published a letter on Moderna's commitment to global vaccine access on October 8.
- **COVID-19 Vaccine Doses to the African Union:** Moderna recently announced a new Memorandum of Understanding (MoU) to make up to 110 million doses of the Moderna COVID-19 vaccine available to the African Union. The Company is prepared to deliver the first 15 million doses in the fourth quarter of 2021, 35 million doses in the first quarter of 2022, and up to 60 million doses in second quarter 2022. All doses are offered at Moderna's lowest tiered price, in line with the Company's global access commitments.
- **COVID-19 Vaccine Doses to COVAX:** Moderna also announced an agreement with Gavi, the Vaccine Alliance to supply

up to 116.5 million doses of Moderna's COVID-19 vaccine to be delivered in the second quarter of 2022. The exercise of these options for additional doses represents an increase from an earlier agreement for 60 million doses of Moderna's COVID-19 vaccine that was communicated earlier this year. As per the advance purchase agreement signed on behalf of the COVAX Facility, Gavi continues to retain the option to procure 233 million additional doses in 2022 for a potential total of 500 million doses between 2021 and 2022 under the agreement. All doses are offered at Moderna's lowest tiered price, in line with the Company's global access commitments.

- **mRNA Facility in Africa:** Moderna announced that it will build a state-of-the-art mRNA facility in Africa with the goal of producing up to 500 million doses of vaccines each year at the 50 µg dose level. The Company anticipates investing up to $500 million in this new facility, which is expected to include drug substance manufacturing with the opportunity for fill/finish and packaging capabilities at the site.

- **Moderna Fellowship Program:** Moderna announced the launch of the Moderna Fellowship Program to support the next generation of scientists and healthcare professionals as they innovate in the field of mRNA research towards improving patient care and population health.

Corporate Updates

- **Full-Time Employees:** As of September 30, 2021, Moderna had approximately 2,400 employees, compared to approximately 1,200 employees as of September 30, 2020.

- **Moderna Genomics (mGx):** Moderna announced a new collaboration with Metagenomi in genomics around novel gene editing enzymes.

- **Company Recognition:** Moderna was named a top employer by *Science and Science Careers* for the seventh consecutive year and was named the number one company on *Fast Company*'s 2021 Best Workplaces for Innovators list.

- **Moderna Science Center:** Moderna announced that it is investing in a new science center, known as the Moderna Science Center, at 325 Binney Street in Cambridge, MA to support the Company's next chapter of discovery. This 462,000 square foot state-of-the-art building is targeting LEED Zero certification and is being designed to be the most sustainable commercial lab building in Cambridge.

- **Collaboration to Bring mRNA Manufacturing to Canada:** Moderna announced an MoU with the government of Canada to build a state-of-the-art mRNA vaccine manufacturing facility in Canada, including access to Moderna's mRNA development engine. The goals of this MoU are to build the foundation to support Canada with direct access to rapid pandemic response capabilities and to provide access to Moderna's vaccines in development for respiratory viruses.

- **R&D Day:** Moderna hosted its fifth annual R&D Day on September 9.

Key 2022 Investor and Analyst Event Dates

- Vaccines Day: March 24
- Science Day: May 17
- R&D Day: September 8

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Thursday, November 4, 2021. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 9177025. 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

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has

allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by *Science* for the past seven 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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product sales	$ 4,810	$ —	$ 10,740	$ —
Grant revenue	140	145	473	187
Collaboration revenue	19	12	47	45
Total revenue	4,969	157	11,260	232
Operating expenses:				
Cost of sales	722	—	1,665	—
Research and development	521	344	1,343	611
Selling, general and administrative	168	48	366	109
Total operating expenses	1,411	392	3,374	720
Income (loss) from operations	3,558	(235)	7,886	(488)
Interest income	4	6	11	21
Other expense, net	(10)	(3)	(22)	(6)
Income (loss) before income taxes	3,552	(232)	7,875	(473)
Provision for income taxes	219	1	541	1
Net income (loss)	$ 3,333	$ (233)	$ 7,334	$ (474)
Earnings (loss) per share:				
Basic	$ 8.27	$ (0.59)	$ 18.25	$ (1.26)
Diluted	$ 7.70	$ (0.59)	$ 17.00	$ (1.26)

Weighted average common shares used in calculation of earnings (loss) per share:				
Basic	404	395	402	376
Diluted	434	395	431	376

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS AND STATEMENTS OF CASH FLOWS DATA

(Unaudited, in millions)

	September 30, 2021	**December 31, 2020**
Cash, cash equivalents and investments	$ 15,348	$ 5,247
Total assets	20,923	7,337
Total liabilities	10,799	4,776
Total stockholders' equity	10,124	2,561
Total liabilities and stockholders' equity	20,923	7,337

	Nine Months Ended September 30,	
	2021	**2020**
Net cash provided by operating activities	$ 10,310	$ 763
Cash used for purchases of property and equipment	(164)	(44)

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 regarding: the Company's development of the Moderna COVID-19 Vaccine (mRNA-1273); its 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 ability of the Moderna COVID-19 vaccine to provide protection against COVID-19 over time and to trigger an antibody response against variants of concern; the Company's plans to submit results from its ongoing KidCOVE study to regulatory agencies; the development of additional COVID-19 vaccine candidates that may be refrigerator stable; the conduct and timing of clinical trials for programs in the Company's pipeline, including its vaccine candidates against seasonal flu, CMV, RSV, HIV, Nipah virus and EBV, as well as the Company's personalized cancer vaccine candidate; expected enrollment in the Company's Phase 3 study of its CMV vaccine; anticipated timing for the submission of an IND for the Company's partnered cystic fibrosis program with Vertex; the potential to combine different vaccines into a single dose; the number of doses of the Moderna COVID-19 vaccine that the Company anticipates being able to manufacture and deliver in 2021 and 2022, and investments to facilitate that manufacturing; 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; potential exercises for options to deliver vaccines, entry into the booster market for COVID-19 vaccine and the outcome of discussions for future sales of vaccine with governments and international organizations; anticipated deliveries to the African Union and COVAX in 2021 and 2022; the construction of manufacturing facilities in Canada and Africa; the anticipated cost of sales associated with the Moderna COVID-19 vaccine; 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; the Company's future tax rate; and the Company's efforts to achieve net-zero carbon emissions. 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 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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[1]Includes separate COVID-19 Vaccine (mRNA-1273) programs in development for adults, pediatrics & adolescents and separate RSV vaccine (mRNA-1345) programs in development for adults and pediatrics

[2]BARDA, part of ASPR within the U.S. HHS is supporting the continued research and development of the Company's COVID-19 vaccine development efforts with federal funding under contract no. 75A50120C00034 BARDA is reimbursing Moderna for 100 percent of the allowable costs incurred by the Company for conducting the program described in the BARDA contract. The U.S. government has agreed to purchase supply of mRNA-1273 under U.S. Department of Defense contract no. W911QY-20-C-0100.

[3] Saade A et al, Infect Dis Now (2021), https://doi.org/10.1016/j.idnow.2021.07.005

[4] Jacobs M et al, Mult Scler. (2020), https://doi.org/10.1177/1352458520907901

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