



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

August 5, 2021

*Moderna COVID-19 Vaccine mRNA-1273: Final blinded analysis of Phase 3 COVE study shows 93% efficacy; Efficacy remains durable through six months after second dose*

*Moderna booster candidates demonstrate robust antibody responses to COVID-19 variants of concern in Phase 2*

*Dosing started in Phase 1 studies for quadrivalent seasonal flu vaccine candidate (mRNA-1010) and IL-2 mRNA program for autoimmune disorders (mRNA-6231)*

*Moderna has mRNA candidates in clinical development across five therapeutic areas: infectious disease, cardiovascular, oncology, rare disease and autoimmune disorders*

*Q2 total revenue of \$4.4 billion, net income of \$2.8 billion and diluted earnings per share of \$6.46*

*Moderna establishes new Charitable Foundation to promote public health, healthcare and educational opportunities, particularly in underserved populations*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 5, 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 second quarter of fiscal year 2021.

"I am proud of the progress our teams at Moderna have made in the past quarter in advancing our development pipeline while addressing a global pandemic and quickly establishing global manufacturing and commercial organizations," said Stéphane Bancel, Chief Executive Officer of Moderna. "We now have mRNA candidates in clinical trials across five therapeutic areas including infectious diseases, cardiovascular, oncology, rare disease and autoimmune disorders. We are pleased that our COVID-19 vaccine is showing durable efficacy of 93% through six months, but recognize that the Delta variant is a significant new threat so we must remain vigilant."

Looking forward, Bancel said, "We have begun preparing late stage studies for our flu vaccine and RSV vaccine, which received fast track designation from the FDA a few days ago and are looking forward towards our vision of a single dose annual booster that provides protection against COVID-19, flu and RSV for adults. I look forward to the start of our Phase 3 trial for CMV this year and to clinical proof of concept data in the coming quarters from our therapeutics pipeline. We believe this is just the beginning."

### Updates and recent progress include:

#### *COVID-19 Vaccine Development*

- Robust antibody responses have been observed from existing Moderna booster candidates against COVID-19 in Phase 2 studies
- The Conditional Marketing Authorization (CMA) for Spikevax™ (Moderna's COVID-19 Vaccine) in the European Union (EU) and authorization in Japan by the Ministry of Health, Labor and Welfare have been expanded to include adolescents 12 years of age and older
- Moderna has initiated the rolling submission process for a Biologics License Application (BLA) for our vaccine in the U.S. and expects to complete its submission in August
- Enrollment has completed for the Phase 1 study of mRNA-1283, Moderna's next-generation COVID-19 vaccine, which is a potential refrigerator-stable vaccine that could facilitate easier distribution and storage

#### *Infectious Diseases*

- Phase 3 study of cytomegalovirus (CMV) vaccine candidate (mRNA-1647) to begin in 2021
- Dosing started in Phase 1/2 study of quadrivalent seasonal flu vaccine candidate (mRNA-1010)
- Started dosing in Phase 2 study of Zika virus vaccine candidate (mRNA-1893)
- Received Fast Track designation from U.S. Food and Drug Administration (FDA) for respiratory syncytial virus (RSV) vaccine candidate (mRNA-1345) for older adults (60 years of age and above)

#### *Autoimmune Disorders*

- First participant dosed in the Phase 1 study of IL-2 mRNA program for autoimmune disorders (mRNA-6231)

#### *Oncology*

- Discontinued further development of mRNA-2416, our standalone OX40L candidate; focus shifted to the development of mRNA-2752, which comprises mRNAs for OX40L plus two cytokines, IL23 + IL36γ.

Moderna currently has 23 mRNA development programs in its portfolio with 15 having entered clinical studies. The Company's updated pipeline can be found at [www.modernatx.com/pipeline](http://www.modernatx.com/pipeline). Moderna and collaborators have published more than 80 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, 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:** Moderna has received emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine in adults from health agencies in more than 50 countries and an Emergency Use Listing (EUL) from the World Health Organization (WHO), as well as authorization for use of its COVID-19 vaccine in adolescents age 12 and up in the European Union and Japan. On June 1, 2021, the Company [initiated](#) the rolling submission process for a Biologics License Application (BLA) for the vaccine in the U.S. and expects to complete its submission in August. Moderna is working with additional health agencies on the authorization and/or approval 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.
  - **Six months durability data:** In final analysis of Phase 3 COVE study data, the Moderna COVID-19 Vaccine showed 93% efficacy, with the efficacy remaining durable through six months after administration of the second dose.
  - **Addressing Variants of Concern:** In a Phase 2 study, vaccination with 50 µg of three different Moderna mRNA booster candidates induced robust antibody responses against the wildtype D614G COVID-19 strain and against important variants of concern including Gamma (P.1); Beta (B.1.351); and Delta (B.1.617.2). The booster candidates included mRNA-1273, investigational mRNA-1273.351, and investigational mRNA-1273.211. Neutralizing antibody levels following the boost approached those observed after primary vaccination with two doses of 100 µg of mRNA-1273. These data have been submitted to a peer-reviewed journal for publication.
- **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 completed enrollment in the U.S. An [initial analysis](#) of 3,732 participants randomized 2:1 in TeenCOVE Study showed a vaccine efficacy rate of 93% in seronegative participants who received at least one injection in a secondary analysis. The analysis included 15 cases (13 in the placebo group and 2 in the mRNA-1273 group) reported 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. The median duration for follow-up in this initial analysis was 53 days following the second dose. mRNA-1273 was generally well tolerated. The majority of adverse events were mild or moderate in severity. 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 Conditional Marketing Authorization (CMA) for Spikevax<sup>1</sup> in the European Union (EU) has been expanded to include adolescents 12 years of age and older. In addition, the Japanese Ministry of Health, Labor and Welfare also approved Moderna Inc.'s COVID-19 vaccine for ages 12 to 17. Moderna has [filed](#) for an emergency use authorization (EUA) for adolescents with the U.S. Food and Drug administration as well as with additional regulatory agencies around the world.
  - **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 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 against COVID-19 (mRNA-1283):** The Phase 1 study of mRNA-1283 is fully enrolled and 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.

#### *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. Based on the interim analysis of the Phase 2 study, the 100 µg dose has been chosen for the Phase 3 pivotal study. The Company expects the Phase 3 study 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. The Phase 1 study of mRNA-1345 to evaluate the tolerability and reactogenicity of mRNA-1345 in younger adults, women of child-bearing age, older adults and seropositive toddlers 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 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. The FDA has granted Fast Track designation for mRNA-1345 in adults older than 60 years of age. 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. 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. 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 sentinel cohorts in the [Phase 1/2 study](#) of mRNA-1010 have been dosed.

#### *Public health vaccines*

- **Zika virus vaccine (mRNA-1893):** The Phase 2 study of mRNA-1893 is enrolling participants. 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).

**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 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 (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/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 ongoing. 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 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 [Phase 1/2 Paramount study](#) of mRNA-3927 is ongoing. 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 at [investors.modernatx.com](https://investors.modernatx.com).

## Second Quarter 2021 Financial Results

- **Revenue:** Total revenue was \$4.4 billion for the three months ended June 30, 2021, compared to \$67 million for the same period in 2020. Total revenue was \$6.3 billion for the six months ended June 30, 2021, compared to \$75 million for the same period in 2020. Total revenue increased in 2021, resulting from commercial sales of the Company's COVID-19 vaccine, and to a lesser extent, grant revenue. Product sales for the three and six months ended June 30, 2021 was \$4.2 billion and \$5.9 billion, respectively, from sales of 199 million and 302 million doses of the Company's COVID-19 vaccine. The increases in grant revenue of \$101 million and \$291 million for the three and six months ended June 30, 2021, respectively, were primarily driven by increases in revenue from BARDA related to the Company's COVID-19 vaccine development.
- **Cost of Sales:** Cost of sales was \$750 million, or 18%, of product sales for the three months ended June 30, 2021, including third-party royalties of \$148 million. Cost of sales was \$943 million, or 16%, of the Company's product sales, for the six months ended June 30, 2021, including third-party royalties of \$232 million. A portion of the inventory costs associated with the Company's product sales for the six months ended June 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 six months ended June 30, 2021 was valued at cost, the Company's cost of sales for the period would have been \$1.1 billion, or 19% of product sales.
- **Research and Development Expenses:** Research and development expenses were \$421 million for the three months ended June 30, 2021, compared to \$152 million for the same period in 2020. Research and development expenses were \$822 million for the six months ended June 30, 2021, compared to \$267 million for the same period in 2020. The growth in spending in 2021 was mainly due to increases in clinical trial expenses, and to a lesser extent, personnel-related costs, manufacturing expenses, and consulting and outside services, largely driven by increased mRNA-1273 clinical development and headcount.
- **Selling, General and Administrative Expenses:** Selling, general and administrative expenses were \$121 million for the three months ended June 30, 2021, compared to \$37 million for the same period in 2020. Selling, general and administrative expenses were \$198 million for the six months ended June 30, 2021, compared to \$61 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, and marketing expenses, primarily attributable to the Company's COVID-19 vaccine commercialization-related activities and increased headcount.
- **Net Income (Loss):** Net income was \$2.8 billion for the three months ended June 30, 2021, compared to a net loss of

\$(117) million for the same period in 2020. Net income was \$4.0 billion for the six months ended June 30, 2021, compared to a net loss of \$(241) million for the same period in 2020.

- **Cash Position:** Cash, cash equivalents and investments as of June 30, 2021 and December 31, 2020 were \$12.2 billion and \$5.2 billion, respectively.
- **Net Cash Provided By (Used In) Operating Activities:** Net cash provided by operating activities was \$7.0 billion for the six months ended June 30, 2021, compared to \$(130) 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 \$4.0 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 \$65 million for the six months ended June 30, 2021, compared to \$25 million for the same period in 2020.

#### 2021 Updated Financial Framework

- **For Expected Delivery in Fiscal Year (FY) 2021:** Advance Purchase Agreements (APAs) signed for anticipated product sales of \$20 billion, including sales already recorded in the six months ended June 30, 2021.
- **Dose Capacity for FY 2021:** The Company expects dose capacity for its COVID-19 vaccine in FY 2021 to be between 800 million and 1 billion doses.
- **For Expected Delivery in FY 2022:** The Company has already signed APAs for product sales of approximately \$12 billion and options of approximately \$8 billion. Numerous additional negotiations are still ongoing for 2022 APAs.
- **For Expected Delivery in 2023:** The Company has also started to sign APAs for 2023 as forward-looking countries prepare for the endemic phase of COVID-19.
- **Dose Capacity for FY 2022:** The Company expects dose capacity for its COVID-19 vaccine in FY 2022 to be between 2 billion to 3 billion doses, subject to dose level.
- **Cost of Sales:** Cost of sales as percentage of product sales are expected to be between 18-20% for fiscal year 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 approximately 10% 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:** Continue to expect \$450-550 million of capital investments for 2021 including the [planned capacity expansion](#) announced in April 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.
- **Further Investments:** The Company plans to continue to invest in its technology platform and in potential new modalities. The Company will also consider attractive strategic opportunities that further enable and complement our platform.

#### Management Updates

- Shannon Thyme Klinger joined the Company as [Chief Legal Officer and Corporate Secretary](#) on June 1, 2021. Ms. Klinger joined 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.
- Paul Burton M.D., Ph.D., F.A.C.C, M.R.C.S joined the Company as [Chief Medical Officer](#) on July 6, 2021. Dr. Burton joined Moderna after spending sixteen years with Johnson & Johnson. Since March 2020, he served as Chief Global Medical Affairs Officer of Janssen Pharmaceuticals where he was responsible for Janssen's worldwide medical affairs strategy and execution. Previously, he served as Janssen's Vice President and Head, Cardiovascular and Metabolic Medical Affairs.
- Kate Cronin joined Moderna as [Chief Brand Officer](#) on July 12, 2021. Ms. Cronin joined Moderna from Ogilvy Health, part of WPP plc., where she served as Global CEO and led the full spectrum of Ogilvy Health's core capabilities including public relations and influence, brand strategy, advertising, medical education, market access, and patient and consumer engagement. Additionally, Ms. Cronin grew Ogilvy's business in the health and wellness arena, encompassing a broad portfolio including pharmaceuticals, consumer health, insurance, hospitals, health technology and medical devices.

#### Corporate Updates

- **Full-Time Employees:** As of June 30, 2021, Moderna had approximately 1,800 employees, compared to approximately 930 employees as of June 30, 2020.
- **Moderna Charitable Foundation:** Moderna announced it is establishing a [new charitable foundation](#) with an initial endowment of \$50 million to promote public health, healthcare and educational opportunities, particularly in underserved populations.

- **Moderna International Business Services (MIBS) Center:** Moderna announced plans to [establish](#) an international business services hub in Warsaw, Poland, as the Company continues to build out a global infrastructure.
- **Science Day:** Moderna hosted its fourth annual [Science Day](#) on May 27.
- **Job Creation in Massachusetts:** Moderna reaffirmed its [commitment](#) to job creation in Massachusetts.
- **S&P 500:** Moderna was added to the Standard & Poor's (S&P) 500 index on Wednesday, July 21.
- **Company Recognition:** Moderna was named number one on *Fast Company's* 2021 Best Workplaces for Innovators list and number three on the Axios/Harris 2021 Poll of Corporate Reputation Rankings.

#### Key 2021 Investor and Analyst Event Dates

- 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, August 5, 2021. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 5749439. 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](https://investors.modernatx.com). The webcast and slides are available directly at: <https://investors.modernatx.com/events/event-details/moderna-2q-2021-earnings-call>. 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. Today, 23 development programs are underway across these therapeutic areas, with 15 programs having entered the clinic. Moderna has been named a top biopharmaceutical employer by *Science* for the past six years. To learn more, visit [www.modernatx.com](http://www.modernatx.com).

#### MODERNA, INC.

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in millions, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	\$ 4,197	\$ —	\$ 5,930	\$ —
Grant revenue	139	38	333	42
Collaboration revenue	18	29	28	33
Total revenue	4,354	67	6,291	75
Operating expenses:				
Cost of sales	750	—	943	—
Research and development	421	152	822	267

Selling, general and administrative	121	37	198	61
Total operating expenses	1,292	189	1,963	328
Income (loss) from operations	3,062	(122)	4,328	(253)
Interest income	3	7	7	15
Other expense, net	(2)	(2)	(12)	(3)
Income (loss) before income taxes	3,063	(117)	4,323	(241)
Provision for income taxes	283	—	322	—
Net income (loss)	\$ 2,780	\$ (117)	\$ 4,001	\$ (241)

Earnings (loss) per share:

Basic	\$ 6.93	\$ (0.31)	\$ 9.98	\$ (0.66)
Diluted	\$ 6.46	\$ (0.31)	\$ 9.30	\$ (0.66)

Weighted average common shares used in calculation of earnings (loss) per share:

Basic	402	381	401	367
Diluted	431	381	430	367

**MODERNA, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS AND STATEMENTS OF CASH FLOWS DATA**

**(Unaudited, in millions)**

	<b>June 30,</b>	<b>December 31,</b>
	<b>2021</b>	<b>2020</b>
Cash, cash equivalents and investments	\$ 12,197	\$ 5,247
Total assets	16,153	7,337
Total liabilities	9,449	4,776
Total stockholders' equity	6,704	2,561
Total liabilities and stockholders' equity	16,153	7,337



**Six Months Ended June 30,**

	<b>2021</b>	<b>2020</b>
Net cash provided by (used in) operating activities	\$ 7,034	\$ (130)
Cash used for purchases of property and equipment	(65)	(25)

**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 for a Biologics License Application for mRNA-1273; 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; 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 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; 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; plans to conduct a share repurchase program; plans to establish a charitable foundation; and plans to establish the Moderna International Business Services Center. 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](http://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.

<sup>1</sup>[Spikevax](#) is the trade name authorized by the European Medicines Agency (EMA) for the Moderna COVID-19 vaccine.

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