



NEWS RELEASE

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

2/24/2022

Q4 2021 revenues of \$7.2 billion; GAAP net-income of \$4.9 billion and GAAP diluted EPS of \$11.29

Full year 2021 revenues of \$18.5 billion; GAAP net-income of \$12.2 billion and GAAP diluted EPS of \$28.29

Moderna increased its 2022 signed advance purchase agreements to approximately \$19 billion, with additional signed options of approximately \$3 billion; numerous discussions ongoing with governments for the fall of 2022 and 2023

Moderna received full U.S. FDA approval for COVID-19 vaccine, Spikevax

Moderna announces new bivalent booster candidate (mRNA-1273.214) combining Omicron-specific booster candidate (mRNA-1273.529) and the Moderna COVID-19 vaccine (mRNA-1273)

Company now has 44 programs in development

Moderna announces a new \$3 billion share repurchase plan

CAMBRIDGE, MA / ACCESSWIRE / February 24, 2022 / **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 of fiscal year 2021.

"Spikevax is now approved in more than 70 countries around the world protecting hundreds of millions of people and real-world evidence from multiple independent studies has confirmed its strong effectiveness," said Stéphane Bancel, Chief Executive Officer of Moderna. "In 2021, we delivered 807 million doses with approximately 25% of those doses going to low- and middle-income countries, and we will continue to scale in 2022 to help end the COVID-19 pandemic. Moderna has experienced exponential growth and we have more than doubled the size of our team over the last year with a global team of 3,000. We also have announced plans to scale to 21 commercial subsidiaries across the world, including four new locations in Asia and six new locations in Europe. We continue to expand and advance our industry-leading mRNA pipeline with 44 programs in development. We look forward to clinical readouts from our therapeutics development candidates later in 2022 in rare genetic diseases and oncology. We are entering 2022 with a remarkable team and strategic priorities to continue advancing mRNA vaccines and therapeutics to impact human health."

Updates and recent progress include:

#### COVID-19 Vaccine Development

- Therapeutic Goods Administration (TGA) in Australia has granted provisional registration for the use of Spikevax® in a 50 µg dose, two-dose series, for active immunization to prevent COVID-19 caused by SARS-CoV-2 in children aged 6-11 years
- U.S. Food and Drug Administration (U.S. FDA) approved the Biologics License Application (BLA) for Spikevax® (COVID-19 Vaccine, mRNA-1273) to prevent COVID-19 in individuals in the U.S. 18 years of age and older; Spikevax approved or authorized in more than 70 countries
- Pivotal studies are underway for Omicron-specific booster candidate (mRNA-1273.529)
- Moderna announces bivalent booster candidate (mRNA-1273.214) combining mRNA-1273.529 and the Moderna COVID-19 vaccine (mRNA-1273)

#### Respiratory Vaccines

- Pivotal Phase 3 study of respiratory syncytial virus (RSV) vaccine candidate (mRNA-1345) has begun
- Seasonal flu vaccine candidate (mRNA-1010) successfully boosted hemagglutination inhibition (HAI) assay geometric mean titers against all strains 29 days after vaccination at all doses tested in younger and older adults in Phase 1 study and no significant safety concerns were observed through day 29; Phase 2 study of mRNA-1010 is fully enrolled; preparation for the Phase 3 study is underway

#### Latent Vaccines

- Announcing new Herpes simplex virus (HSV) therapeutic vaccine candidate (mRNA-1608), a vaccine candidate

to prevent incidence of herpes lesions due to HSV-2

- Announcing a new Varicella-zoster virus (VZV) vaccine candidate (mRNA-1468) designed to reduce the rate of herpes zoster (shingles)
- Enrollment in Phase 1 study of Epstein-Barr virus (EBV) vaccine candidate (mRNA-1189) is ongoing
- Enrollment in Phase 3 pivotal registration study of cytomegalovirus (CMV) vaccine candidate (mRNA-1647) is ongoing

#### Cancer Vaccines

- Announcing new checkpoint cancer vaccine (mRNA-4359) to expand naturally occurring T cells that counteract the impact of immune checkpoints Indoleamine 2,3 -dioxygenase (IDO) and programmed death-ligand 1 (PD-L1)
- Moderna has regained all rights to mutant KRAS vaccine (mRNA-5671) from Merck; Moderna is evaluating next steps for the program

#### Therapeutics

- Enrollment of the first cohort in Phase 1/2 Paramount study of Propionic Acidemia candidate (mRNA-3927) is complete; enrollment in additional dose level cohorts is continuing
- Enrollment of the first cohort in Phase 1/2 Landmark study of Methylmalonic Acidemia candidate (mRNA-3705) is complete; enrollment for additional cohorts expected to begin soon

Moderna now has 44 programs in development across 41 development candidates 1, of which 25 are currently in active clinical trials. 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 100 peer reviewed manuscripts.

#### Summary of Program Highlights by Modality 2

##### Core Modalities

**Prophylactic Vaccines:** Moderna is developing vaccines against viral diseases where there is an unmet medical need, including vaccines against respiratory infections and vaccines against latent viruses.

##### Vaccines against acute respiratory infections

##### COVID-19 vaccine development

- Moderna COVID-19 Vaccine (mRNA-1273 3 , Spikevax ® ): The U.S. Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for SPIKEVAX (COVID-19 Vaccine, mRNA) to prevent COVID-19

in individuals 18 years of age and older. 807 million doses of Moderna's COVID-19 vaccine shipped globally in 2021; approximately 25% of those doses shipped to low- and middle-income countries.

- **Booster Dose of mRNA-1273:** The U.S. FDA, European Medicines Agency (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 for adults ages 18 years and older.
- **Omicron-specific booster candidate (mRNA-1273.529):** Moderna's Omicron-specific booster candidate is being studied to evaluate the immunogenicity, safety, and reactogenicity of mRNA-1273.529 as a single booster dose in adults aged 18 years and older in two cohorts: individuals who previously received the two-dose primary series of mRNA-1273 with the second dose being at least six months ago (cohort 1), or who have received the two-dose primary series and a 50 µg booster dose of mRNA-1273 with the booster dose being at least three months ago (cohort 2). Participants in both cohorts will receive a single booster dose of mRNA-1273.529.
- **Bivalent booster candidate (mRNA-1273.214):** Today, Moderna is announcing a new bivalent candidate that combines Moderna's Omicron-specific candidate and mRNA-1273.
- **Moderna COVID-19 Vaccine for adolescents and children:** Moderna has received regulatory authorizations for the use of the 100 µg Moderna COVID-19 vaccine primary series for adolescents 12 to 17 years of age in the European Union, UK, Australia, Canada, Switzerland and other countries. At this point, the U.S. FDA has not concluded on the benefit-risk profile of the 100 µg primary series for adolescents 12 to 17 years of age. Moderna made the decision to **evaluate** the potential of a 50 µg two-dose primary series to meet regulatory guidance for immunogenicity in adolescents and children ages 6 to 11 years. The Company is also evaluating a heterologous booster dose in adolescents after a two-dose primary series of 50 µg, 100 µg, or BNT162b2 and is preparing to submit data to regulators. The Company received authorization for a two-dose 50 µg primary series of the Moderna COVID-19 vaccine in children ages 6 to 11 in Australia and has submitted additional applications for the 6 to 11 age group. In the U.S., Moderna is also studying a two-dose 25 µg primary series for the 6 to 11 age group. In the 6 months to 5 years age group, Moderna is studying a two-dose 25 µg primary series, and expects data in the first quarter of 2022. The Company plans to submit these data to regulators. Additionally, the Company is evaluating lower doses in the U.S. for this age group.
- **Next-generation vaccine candidate against COVID-19 (mRNA-1283):** The Phase 1 study of mRNA-1283 is fully enrolled and ongoing. The Phase 2 study of a booster dose of mRNA-1283 is ongoing. mRNA-1283 is a next-generation vaccine candidate against COVID-19 that encodes for the portions of the SARS-CoV-2 spike protein critical for neutralization, specifically the Receptor Binding Domain (RBD) and N-terminal Domain (NTD). The encoded mRNA-1283 antigen is shorter than mRNA-1273 and is being developed as a potential refrigerator-stable mRNA vaccine that will facilitate easier distribution and administration by healthcare providers.

Additional vaccines against respiratory infections

- Seasonal influenza vaccine (mRNA-1010): On December 10, 2021, Moderna **announced** positive interim data from the Phase 1 study of mRNA-1010. mRNA-1010 successfully boosted hemagglutination inhibition (HAI) assay geometric mean titers against all strains 29 days after vaccination at all doses tested in both younger and older adults and no significant safety concerns were observed through day 29. The Phase 2 study of mRNA-1010 is fully enrolled and preparation for the Phase 3 study is underway. mRNA-1010 encodes for hemagglutinin (HA) glycoproteins of four flu strains and targets lineages recommended by the World Health Organization (WHO) for the prevention of influenza, including seasonal influenza A H1N1, H3N2 and influenza B Yamagata and Victoria.
- Seasonal Influenza vaccines with expanded coverage (mRNA-1011 and mRNA-1012) and broader immunologic coverage (mRNA-1020 and mRNA-1030): On December 10, 2021, Moderna **announced** two development candidates which the Company believes may expand coverage against seasonal influenza strains. mRNA-1011 will have one additional hemagglutinin (HA) antigen and mRNA-1012 will have two additional HA antigens. Moderna is also developing two next-generation flu candidates that incorporate neuraminidase antigens to potentially improve immunity by increasing immunologic breadth targeting more conserved antigens (mRNA-1020, mRNA-1030).
- COVID-19 and flu combination vaccine (mRNA-1073): mRNA-1073 encodes for the COVID-19 spike protein and the Flu HA glycoproteins.
- Respiratory syncytial virus (RSV) vaccine (mRNA-1345): The pivotal Phase 3 study of RSV in older adults (ages older than 60 years) is ongoing. This is a global study conducted in locations influenced by the epidemiology of RSV and the Company expects to enroll approximately 34,000 participants. 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.
- Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653): The Phase 1 study of mRNA-1653 in children 12-59 months of age is fully enrolled.
- Pediatric RSV and hMPV combination vaccine (mRNA-1365): mRNA-1365 encodes for the RSV prefusion F glycoprotein and the hMPV F protein.

#### Vaccines against latent viruses

- Cytomegalovirus (CMV) vaccine (mRNA-1647): The **Phase 3** pivotal registration study of mRNA-1647, known as CMVVictory, is ongoing. The study 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 6,900 women of child-bearing age, 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. The [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05085366) identifier is **NCT05085366**. To learn more about eligibility, visit [www.CMVictory.com](https://www.CMVictory.com).

- Epstein-Barr virus (EBV) vaccine (mRNA-1189): The **Phase 1 study** of mRNA-1189 ongoing. EBV 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, certain lymphoproliferative disorders and cancers, and autoimmune diseases 4,5 . 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.
- 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 60-80% of PTLD cases are associated with EBV infection. The Company expects to also pursue other longer-term potential indications for this vaccine, including multiple sclerosis.
- HIV vaccine (mRNA-1644 & mRNA-1574): The first participant has been dosed in the ongoing **Phase 1 study** of mRNA-1644, which is using iterative human testing to validate the approach and antigens and multiple novel antigens will be used for germline-targeting and immuno-focusing. mRNA-1644, a collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill & Melinda Gates Foundation, is a novel approach to HIV vaccine strategy in humans designed to elicit broadly neutralizing HIV-1 antibodies (bNAbs). A second approach, mRNA-1574, is being evaluated in collaboration with the National Institutes of Health (NIH) and includes multiple native-like trimer antigens.
- Herpes simplex virus (HSV) therapeutic vaccine candidate (mRNA-1608): Moderna recently announced a new development candidate, mRNA-1608, a vaccine candidate against herpes. In the U.S., approximately 18.6 million adults ages 18 to 49 years are living with HSV-2. Moderna is developing mRNA-1608 to reduce the burden of HSV lesions.
- Varicella-zoster virus (VZV) vaccine candidate (mRNA-1468): Moderna recently announced a new mRNA vaccine candidate (mRNA-1468) designed to express varicella-zoster virus (VZV) glycoprotein E (gE) to reduce the rate of herpes zoster (shingles). Herpes zoster occurs in one of three adults in their lifetime and incidence dramatically increases at approximately 50 years of age. Declining immunity in older adults decreases cell-mediated immunity against VZV, allowing reactivation of the virus from latently infected neurons, causing painful and itchy lesions. Serious herpes zoster complications include postherpetic neuralgia (10-13% of herpes zoster cases), bacterial coinfections, and cranial and peripheral palsies; 1-4% of herpes zoster cases are hospitalized for complications.

## 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.
- 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. 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.

- 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 Phase 1 study of mRNA-6231 in healthy adult participants (between 18 and 50 years of age) is ongoing.
- 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.
- Relaxin (mRNA-0184): mRNA-0184 encodes for the relaxin protein which has been engineered to increase 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.

## 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 including in the expanded head and neck cohort. Moderna shares worldwide commercial

rights to mRNA-4157 with Merck.

- Mutant KRAS vaccine (mRNA-5671 or V941): Moderna has regained all rights to mutant KRAS vaccine (mRNA-5671) from Merck and Moderna is evaluating next steps for the program. 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.
- Checkpoint cancer vaccine (mRNA-4359): Moderna recently announced a new checkpoint cancer vaccine (mRNA-4359) expresses Indoleamine 2,3 -dioxygenase (IDO) and programmed death-ligand 1 (PD-L1) antigens. Moderna designed mRNA-4359 with the goal of stimulating effector T-cells that target and kill suppressive immune and tumor cells that express these checkpoints. Moderna is planning to explore initial indications for advanced or metastatic cutaneous melanoma and non-small cell lung carcinoma (NSCLC).

**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.
- 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): **Positive data** from the AstraZeneca-led Phase 2 (EPICURE) study evaluating the use of VEGF-A (AZD8601) in patients undergoing coronary artery bypass grafting (CABG) were presented at the American Heart Association's Scientific Sessions 2021 annual meeting. The Phase 2 study met the primary endpoint of safety and tolerability of AZD8601. In the study of 11 patients, seven were treated with AZD8601 VEGF-A mRNA and four received placebo injections. Numerical trends were observed in endpoints in the heart failure efficacy domains compared with placebo, including increase in left ventricular ejection fraction (LVEF) and patient reported outcomes. In addition, all seven patients treated with AZD8601 had NT-proBNP levels below heart failure (HF) limit at 6 months follow-up compared to one of four patients treated with placebo. These results support further investigation of AZD8601 for efficacy and safety in future studies.

**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. Moderna is enrolling participants into additional cohorts.
- 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. Moderna received rare pediatric designation for mRNA-3705.
- 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.
- 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.
- 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.

#### 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](https://investors.modernatx.com).

#### Fourth Quarter and Full Year 2021 Financial Results

##### Fourth Quarter 2021

- Revenue: Total revenue was \$7.2 billion for the fourth quarter of 2021, compared to \$571 million for the same period in 2020. The increase in 2021 was driven by increased product sales. Product sales for the fourth quarter of 2021 were \$6.9 billion from sales of 297 million doses of the Company's COVID-19 vaccine,

compared to \$200 million in the fourth quarter of 2020 from sales of 13 million doses of the Company's COVID-19 vaccine. The Company began to record product sales for the Company's COVID-19 vaccine subsequent to its authorization for emergency use by the FDA and Health Canada in December 2020.

- **Cost of Sales:** Cost of sales was \$952 million, or 14% of the product sales for the fourth quarter of 2021, including third-party royalties of \$241 million. Cost of sales was \$8 million, or 4% of product sales, for the fourth quarter of 2020, comprised of third-party royalties and shipping and handling costs only as the associated inventory costs were expensed previously as pre-launch inventory.
- **Research and Development Expenses:** Research and development expenses were \$648 million for the fourth quarter of 2021, compared to \$759 million for the same period in 2020. The decrease in spending in 2021 was mainly due to a decrease in pre-launch inventory costs, partially offset by an increase in clinical trial expenses.
- **Selling, General and Administrative Expenses:** Selling, general and administrative expenses were \$201 million for the fourth quarter of 2021, compared to \$79 million for the same period in 2020. The growth in spending was driven by the commercialization of our COVID-19 vaccine globally with continued investments in personnel and outside services in support of the accelerated company buildout.
- **Provision for Income Taxes:** The effective tax rate was 10.0% for the fourth quarter of 2021, which included tax benefits from the utilization of the cumulative net operating loss carry-forward of \$2.3 billion, the foreign-derived intangible income deduction and stock-based compensation. Income taxes were \$542 million for the fourth quarter of 2021, compared to \$1 million for the same period in 2020. The increase was due to pre-tax income recognized in 2021, compared to a loss in 2020.
- **Net Income (Loss):** Net income was \$4.9 billion for the fourth quarter of 2021, compared to a net loss of \$(272) million for the same period in 2020.
- **Earnings (Loss) Per Share:** Diluted EPS was \$11.29 for the fourth quarter of 2021, compared to \$(0.69) for the same period in 2020.

#### Full Year 2021

- **Revenue:** Total revenue was \$18.5 billion for the full year 2021, compared to \$803 million in 2020. Total revenue increased in 2021, primarily due to commercial sales of the Company's COVID-19 vaccine. Product sales for the full year 2021 were \$17.7 billion from sales of 807 million doses of the Company's COVID-19 vaccine.
- **Cost of Sales:** Cost of sales was \$2.6 billion, or 15% of the product sales for full year 2021, including third-party royalties of \$641 million. A portion of the inventory costs associated with the Company's product sales for the full year 2021 was expensed as pre-launch inventory costs in 2020. The Company's pre-launch inventory was fully utilized in the first half of 2021. If inventory sold for the full year 2021 was valued at cost, the Company's cost of sales for the period would have been \$2.8 billion, or 16% of product sales.
- **Research and Development Expenses:** Research and development expenses were \$2.0 billion for the full year

2021, compared to \$1.4 billion in 2020. The growth in spending in 2021 was mainly due to increases in clinical trial expenses, personnel-related costs, 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 \$567 million for the full year 2021, compared to \$188 million in 2020. The growth in spending in 2021 was mainly due to increases in consulting and outside services, personnel-related costs, marketing expense and distributor fees, primarily attributable to the Company's COVID-19 vaccine commercialization-related activities and increased headcount.
- **Provision for Income Taxes:** The effective tax rate was 8.1% for the full year 2021 which included tax benefits from the utilization of the cumulative net operating loss carry-forward of \$2.3 billion, the foreign-derived intangible income deduction and stock-based compensation. Income taxes were \$1.1 billion for the full year 2021, compared to \$3 million in 2020. The increase was due to pre-tax income recognized in 2021, compared to a loss in 2020.
- **Net Income (Loss):** Net income was \$12.2 billion for the full year 2021, compared to a net loss of \$(747) million in 2020.
- **Earnings (Loss) Per Share:** Diluted EPS was \$28.29 for the full year 2021, compared to \$(1.96) in 2020.
- **Cash Position:** Cash, cash equivalents and investments as of December 31, 2021 and December 31, 2020 were \$17.6 billion and \$5.2 billion, respectively.
- **Net Cash Provided by Operating Activities:** Net cash provided by operating activities was \$13.6 billion for the full year 2021, compared to \$2.0 billion in 2020. Net cash provided by operating activities increased significantly in 2021, mainly due to net income of \$12.2 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 \$284 million for the full year 2021, compared to \$68 million in 2020. The increase was primarily driven by the Company's business expansion.

## 2022 Financial Framework

- **Advanced Purchase Agreements (APAs):** Moderna has signed 2022 APAs for product sales of approximately \$19 billion and approximately \$3 billion in options (probabilized) including for any potential updated COVID-19 vaccine booster candidates. The Company is currently in active discussions for additional orders in 2022. Moderna believes that the SARS-CoV-2 virus will evolve to an endemic phase in 2022 and as a result, the Company expects sales to be larger in the second half of 2022 than in the first half.
- **Cost of Sales:** Cost of sales as percentage of product sales are expected to be in the low-to-mid 20s percentage range.
- **Research & Development (R&D) and Selling, General & Administrative (SG&A) Expenses:** Full year expenses expected to be approximately \$4 billion.

- Tax Rate: The Company expects an Effective Tax Rate for the full year in the mid-teen percentage range.
- Capital Expenditures: Expect capital investments for 2022 in the range of \$0.6-\$0.8 billion.
- Share Repurchase Program: The Board of Directors has authorized a new share repurchase program for \$3 billion to return excess capital to shareholders. The previous program of \$1 billion announced in August 2021 has been fully utilized as of the end of January 2022.

#### Commercial Outlook in 2023 & Beyond

- Spikevax ® 2023 commercial outlook: Moderna has received firm orders for delivery in 2023 from the United Kingdom, Canada, Taiwan, and Kuwait. The Company is currently in active discussions for additional orders in 2023.
- Supply agreements with strategic countries: Moderna is committed to expanding its partnerships with governments to equip countries with access to innovative vaccines against respiratory viruses, and domestic access to rapid pandemic response capabilities. To date, Moderna has announced in principle agreements with **Australia** and **Canada** and the Company is in discussions with additional countries for similar partnerships.

#### Moderna's Capital Allocation Priorities

- Reinvest in the base business and accelerating investments in R&D, manufacturing infrastructure, digital, automation, and our global commercial operations.
- Seek attractive external investment and collaboration opportunities (licenses and/or M&A) to further expand the reach of Moderna's technology and capabilities.
- After evaluating internal and external investment opportunities, return excess capital to shareholders through share repurchases.

#### 2021 Commercial Network

Moderna is building a global commercial network to enable Moderna's entire portfolio, which will facilitate the commercialization of its pipeline without a large pharmaceutical partner. The Company now has active commercial subsidiaries in the following geographies - in the Americas: Canada, the United States; Europe: France, Germany, Italy, Spain, Switzerland, and the United Kingdom; Asia Pacific: Australia, Japan, and South Korea. In addition, Moderna works with distributors or partners in other geographies.

#### 2022 New Commercial Networks

In 2022, the Company plans to further expand its commercial network to enable Moderna's entire portfolio by establishing or activating commercial subsidiaries in the following geographies - in Asia: Hong Kong, Malaysia,

Singapore and, Taiwan; and in Europe: Belgium, Denmark, Netherlands, Norway, Poland, and Sweden. In addition, Moderna will continue to work with distributors or partners in other geographies.

### Corporate Social Responsibility

- **Global Access:** Approximately 807 million doses of the Moderna COVID-19 vaccine were shipped around the world during 2021 ; approximately 25% of all doses delivered in 2021 went to low- and middle-income countries through direct sales by Moderna and facilitated donations from high-income countries. The more than 200 million doses delivered to low- and middle-income countries in 2021 are more than Moderna delivered to any other country or multinational group last year, other than the United States. Gavi has exercised its option to purchase 293 million doses for delivery in 2022 under the agreement to purchase up to 650 million doses across 2021 and 2022, in addition to the 34 million doses delivered in 2021.
- **mRNA Facility in Africa:** Moderna **announced** that it will build a state-of-the-art mRNA facility in Africa, in part to ensure future access to mRNA vaccines in future pandemics, and is in the final stages of country selection with assistance from the United States government.
- **Sustainability:** Moderna announced a **pledge** to achieve **net-zero carbon emissions** globally by 2030.
- **Moderna Charitable Foundation:** Moderna announced it is establishing a **new charitable foundation** to promote public health, healthcare and educational opportunities, particularly in underserved populations.

### Corporate Updates

- **Continued Growth:** Moderna now has approximately 3,000 full time employees. Moderna ended 2020 with approximately 1,300 full time employees.
- **Expanding Manufacturing Partnerships:** Moderna announced an expanded long-term collaboration with Rovi for the manufacture of mRNA medicines over the next ten years in Madrid, Spain. Moderna announced an expanded long-term collaboration with Thermo Fisher for the manufacture of mRNA vaccines over the next 15 years in the U.S.
- **AI Academy:** In December 2020, Moderna launched its Artificial Intelligence (AI) Academy, an innovative initiative that will bring to life an immersive learning experience for Moderna employees, in partnership with **Carnegie Mellon University (CMU)**.
- **Shareholder Letter:** Moderna CEO Stéphane Bancel published a **letter to shareholders** on January 4, 2022.
- **Company Recognition:** Moderna was named a **top employer** by Science and Science Careers for the seventh consecutive year and was **ranked** the number one employer in BioSpace's **2022 Best Places to Work in Biopharma** report.
- **Juan Andres Elected to the National Academy of Engineering:** Juan Andres, Chief Technical Operations and Quality Officer has been elected to the National Academy of Engineering. Moderna's Co-founder and Chairman, Noubar Afeyan, was also elected to the Academy.

- Annual Meeting of Shareholders: The Moderna Annual Meeting of Shareholders will be held on Thursday, April 28, 2022 at 8:00 a.m. ET. The meeting will be held virtually at [www.virtualshareholdermeeting.com/MRNA2022](http://www.virtualshareholdermeeting.com/MRNA2022). The record date for voting or attendance as a stockholder is 4:00 p.m. ET on March 1, 2022.

#### Key 2022 Investor and Analyst Event Dates

- Vaccines Day: March 24
- Science Day: May 17
- R&D Day: September 8
- ESG Day: November 10

#### Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Thursday, February 24, 2022. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 5682797. 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](http://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 over 10 years since its inception, Moderna has transformed from a 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 seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. 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 and approval 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](http://www.modernatx.com).

MODERNA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in millions, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product sales	\$ 6,935	\$ 200	\$ 17,675	\$ 200
Grant revenue	262	341	735	529
Collaboration revenue	14	30	61	74
Total revenue	<u>7,211</u>	<u>571</u>	<u>18,471</u>	<u>803</u>
Operating expenses:				
Cost of sales	952	8	2,617	8
Research and development	648	759	1,991	1,370
Selling, general and administrative	<u>201</u>	<u>79</u>	<u>567</u>	<u>188</u>
Total operating expenses	<u>1,801</u>	<u>846</u>	<u>5,175</u>	<u>1,566</u>
Income (loss) from operations	5,410	(275)	13,296	(763)
Interest income	7	4	18	25
Other expense, net	<u>(7)</u>	<u>-</u>	<u>(29)</u>	<u>(6)</u>
Income (loss) before income taxes	5,410	(271)	13,285	(744)
Provision for income taxes	<u>542</u>	<u>1</u>	<u>1,083</u>	<u>3</u>
Net income (loss)	<u>\$ 4,868</u>	<u>\$ (272)</u>	<u>\$ 12,202</u>	<u>\$ (747)</u>
Earnings (loss) per share:				
Basic	\$ 12.03	\$ (0.69)	\$ 30.31	\$ (1.96)
Diluted	\$ 11.29	\$ (0.69)	\$ 28.29	\$ (1.96)
Weighted average common shares used in calculation of earnings (loss) per share:				
Basic	405	397	403	381
Diluted	431	397	431	381

MODERNA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS AND STATEMENTS OF CASH FLOWS DATA

(Unaudited, in millions)

December 31, December 31,

15

	2021	2020
Cash, cash equivalents and investments	\$ 17,570	\$ 5,247
Total assets	24,669	7,337
Total liabilities	10,524	4,776
Total stockholders' equity	14,145	2,561
Total liabilities and stockholders' equity	24,669	7,337

	Years Ended December 31,	
	2021	2020
Net cash provided by operating activities	\$ 13,620	\$ 2,027
Cash used for purchases of property and equipment	(284)	(68)
Cash used for repurchase of common stock	(857)	-

## Forward-Looking Statements

This presentation 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 vaccines against COVID-19, including efforts to develop variant-specific and multivalent vaccines against variant strains of SARS-CoV-2 and for booster doses; the ability of the Moderna COVID-19 Vaccine and booster doses to provide protection against COVID-19 and variants of concern, including Omicron; the need for boosters against COVID-19; the Company's plan to submit for EUA for at-risk adolescents; the Company's plan to submit data regarding use of its COVID-19 vaccine in adolescents and pediatrics to regulators; the conduct and timing of clinical trials for programs in the Company's pipeline, including its vaccine candidates against seasonal flu, combination flu and COVID-19, hMPV + PIV3, RSV + hMPV, CMV, RSV, HIV, Zika virus, Nipah virus, EBV, triplet, IL-12, KRAS, VEGF-A, IL-2, PA, MMA, the Company's checkpoint cancer vaccine, as well as the Company's personalized cancer vaccine candidate; the ability of the Company's next-generation flu candidates to potentially improve immunity; the ability of an mRNA vaccine against HSV-2 to deliver similar efficacy as existing treatments and to improve compliance and quality of life; the potential for the Company's HSV-2 vaccine candidate to provide cross protection against HSV-1; the commercial opportunity for an HSV-2 vaccine; the potential market associated with commercial vaccines; the Company's capital allocation priorities, including its intention to reinvest in the business, accelerate investment, seek external investment opportunities and return capital to shareholders; anticipated vaccine deliveries under advance purchase agreements and options in 2022 and the associated dollar amounts to be received, which should not be construed as expected 2022 revenue and the anticipated timing for those deliveries; contracts for COVID-19 vaccine sales in 2023; the likelihood that options for purchases of the Company's COVID-19 vaccine will be



exercised; expected cost of sales as a percentage of product sales for fiscal year 2022; expected full year operating expenses and capital investments in 2022; the Company's expected effective tax rate for 2022; new manufacturing and commercial capacity expected to come online in 2022, including the Company's plans to expand its commercial network globally through the establishment of subsidiaries in new locations; anticipated deliveries of COVID-19 vaccine to the COVAX facility in 2022; the Company's plans to build a facility in Africa; the Company's pledge to achieve net-zero carbon emissions by 2030; and the Company's commercial rights to its development candidates. 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 presentation 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, those 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 presentation 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 Unless otherwise specified, Moderna owns commercial worldwide rights to each of the programs described here.

3 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.

4 Saade A et al, Infect Dis Now (2021), <https://doi.org/10.1016/j.idnow.2021.07.005>

5 Jacobs M et al, Mult Scler. (2020), <https://doi.org/10.1177/1352458520907901>

6 Consisting of 50 µg and 100 µg doses, equivalent to approximately 790 million doses at the 100 µg dose level

SOURCE: Moderna, Inc.

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