



NEWS RELEASE

# Moderna Reports First Quarter 2022 Financial Results and Provides Business Updates

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First quarter 2022 revenues of \$6.1 billion; GAAP net-income of \$3.7 billion and GAAP diluted EPS of \$8.58

Moderna reiterates its 2022 signed advance purchase agreements of approximately \$21 billion

Company expects to have four programs in Phase 3 in the second quarter: Omicron-containing bivalent COVID booster, flu, RSV, CMV

CAMBRIDGE, MA / ACCESSWIRE / May 4, 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 first quarter of fiscal year 2022.

"The Moderna team delivered a strong Q1 performance and I am thankful for the progress our team continues to make as we advance our pipeline of mRNA medicines. Today, we are reiterating our signed advanced purchase agreements for 2022 of \$21 billion. In the second quarter, we expect to have four programs in late-stage Phase 3 studies including our Omicron-containing bivalent COVID booster, seasonal flu, RSV and CMV vaccine candidates. Beginning in the fall of 2022, our robust Phase 3 pipeline could lead to three respiratory commercial launches over the next two to three years. We also look forward to advancing our therapeutic programs and sharing proof-of-concept readouts on our rare genetic disease programs for propionic acidemia and methylmalonic acidemia, and on our personalized cancer vaccine program this year," said Stéphane Bancel, Chief Executive Officer of Moderna. "I would like to thank the global Moderna team for their commitment to our mission. mRNA has changed the future of medicine and I look forward to continuing our impact on human health. This is just the



beginning."

Recent progress includes:

#### Respiratory Vaccines

- Submitted a EUA request to U.S. FDA for a 25 µg two-dose primary series of mRNA-1273 in children 6 months to under 6 years of age; similar requests underway with international regulatory authorities
- Positive initial data on booster dose of bivalent candidate based on the wild-type and Beta variant (mRNA-1273.211)
- Positive Phase 2 interim analysis of seasonal flu vaccine candidate (mRNA-1010); Phase 3 study in the Southern Hemisphere expected to begin in the second quarter
- Moderna continues to progress respiratory vaccine pipeline with positive Phase 1 data on next-generation, refrigerator-stable COVID vaccine candidate (mRNA-1283), a new combination respiratory vaccine candidate (mRNA-1230) against SARS-CoV-2 virus, influenza virus and RSV and a new vaccine candidate (mRNA-1287) against the four endemic human coronaviruses (HCoV-229E, -NL63, -OC43 and -HKU1)

#### Latent Vaccines

- First participants dosed in Phase 1 study of HIV vaccine candidate with germline targeting approach (mRNA-1644)
- First participants dosed in Phase 1 study of HIV trimer mRNA vaccine candidate (mRNA-1574)

#### Public Health Vaccines

- The U.S. FDA completed its review of the investigational new drug (IND) application of Moderna's Nipah virus vaccine candidate (mRNA-1215), allowing it to proceed to clinic

#### Therapeutics

- The first cohort of the **Phase 1/2 Paramount study** of propionic acidemia candidate (mRNA-3927) is fully enrolled. Moderna is enrolling patients into additional cohorts. All five patients eligible for the Open Label Extension (OLE) study have elected to participate.
- The first cohort of the **Phase 1/2 Landmark study** of methylmalonic acidemia candidate (mRNA-3705) is fully enrolled. Moderna is enrolling patients into additional cohorts. The one patient eligible to participate in the OLE study has elected to participate.

Moderna now has 46 programs in development across 43 development candidates<sup>1</sup>, of which 29 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 115 peer reviewed manuscripts.

## First Quarter 2022 Financial Results

- **Revenue:** Total revenue was \$6.1 billion for the first quarter of 2022, compared to \$1.9 billion for the same period in 2021. The increase in 2022 was primarily due to increased product sales. Product sales for the first quarter of 2022 were \$5.9 billion from sales of the Company's COVID vaccine, compared to \$1.7 billion in the first quarter of 2021.
- **Cost of Sales:** Cost of sales was \$1.0 billion, or 17%, of product sales for the first quarter of 2022, including third-party royalties of \$207 million. Cost of sales was \$193 million, or 11%, of product sales, for the first quarter of 2021. The increase in cost of sales as a percentage of product sales in 2022 was mainly driven by the lack of the pre-launch inventory benefit (that impacted the first quarter of 2021), coupled with inventory write-downs and a current period expense related to firm purchase commitments. The increase was partially offset by a favorable customer mix, and benefits from the scale up of our manufacturing processes. If inventory sold for the three months ended March 31, 2021 was valued at cost, Moderna's cost of sales for the period would have been \$377 million, or 22%, of the Company's product sales.
- **Research and Development Expenses:** Research and development expenses were \$554 million for the first quarter of 2022, compared to \$401 million for the same period in 2021. The increase in spending in 2022 was mainly due to increases in personnel-related costs, clinical trial expenses, technology and facility-related costs, and consulting and outside services.
- **Selling, General and Administrative Expenses:** Selling, general and administrative expenses were \$268 million for the first quarter of 2022, compared to \$77 million for the same period in 2021. The growth in spending in 2022 was mainly due to an endowment to the Moderna Charitable Foundation and increases in distributor fees, personnel-related costs, and consulting and outside services.
- **Provision for Income Taxes:** The effective tax rate was 14% for the first quarter of 2022, compared to 3% for the same period in 2021. Income taxes were \$572 million for the first quarter of 2022, compared to \$39 million for the same period in 2021. The increase in income tax provision was primarily due to an increase in pre-tax income and a higher effective tax rate in 2022, as 2021 included tax benefits related to the release of the valuation allowance on the majority of our deferred tax assets.
- **Net Income:** Net income was \$3.7 billion for the first quarter of 2022, compared to \$1.2 billion for the same period in 2021.
- **Earnings Per Share:** Diluted EPS was \$8.58 for the first quarter of 2022, compared to \$2.84 for the same period in 2021.
- **Cash Position:** Cash, cash equivalents and investments as of March 31, 2022 and December 31, 2021 were \$19.3 billion and \$17.6 billion, respectively.
- **Net Cash Provided by Operating Activities:** Net cash provided by operating activities was \$2.8 billion for the

three months ended March 31, 2022, compared to \$3.0 billion for the same period in 2021. Net cash provided by operating activities decreased in 2022, primarily attributable to revenue recognized from deferred revenue in excess of customer deposits received, partially offset by increased product sales and higher collection of receivables.

- Cash Used for Purchases of Property and Equipment: Cash used for purchases of property and equipment was \$132 million for the three months ended March 31, 2022, compared to \$35 million for the same period in 2021. The increase was primarily driven by the Company's business expansion.
- Cash Used for Repurchase of Common Stock: Cash used for repurchases of common stock was \$623 million for the three months ended March 31, 2022. Moderna did not conduct share repurchases prior to the fourth quarter of 2021. From the end of the third quarter of 2021 to the end of the first quarter of 2022, the Company repurchased 7 million shares, reducing the number of common shares outstanding from 405 million to 400 million, more than offsetting 2 million shares of common stock issued in connection with equity compensation over this period.

## 2022 Financial Framework

- Advanced Purchase Agreements (APAs): Moderna's 2022 APAs for product sales are approximately \$21 billion. Moderna believes that COVID market dynamics will result in sales slightly 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: As announced last quarter, the Board of Directors authorized a share repurchase program for \$3 billion in February 2022 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.

## Management Updates

- Jorge Gomez will join Moderna as **Chief Financial Officer** effective May 9, 2022. He will serve on Moderna's Executive Committee and report to Chief Executive Officer, Stéphane Bancel. Mr. Gomez joins Moderna from Dentsply Sirona, Inc. (Nasdaq: XRAY) where he served as Executive Vice President & Chief Financial Officer since August 2019. At Dentsply Sirona, he was responsible for leading the global finance organization, including strategic finance, FP&A, Accounting, Treasury, Tax, Corporate Audit and Investor Relations, and the Information Technology function. In addition, Mr. Gomez was responsible for leading Dentsply Sirona's

sustainability and ESG program. David Meline, Moderna's current CFO, has decided to retire and will remain with the Company as a consultant to ensure a smooth transition of the CFO role to Mr. Gomez.

"I am very thankful to David for having decided to come out of retirement for two years in the spring of 2020 to help us get Moderna ready for commercialization in record time. Moderna was an early-stage development, U.S. focused company when David joined us. He goes back into retirement after having helped transform Moderna into a global commercial company. He has built a great team and strong financial business processes. It has been a pleasure to work with him, and I wish him and his wife a wonderful time," said Stéphane Bancel.

- Arpa Garay will join Moderna as **Chief Commercial Officer** effective May 31, 2022. She will serve on Moderna's Executive Committee and report to Chief Executive Officer, Stéphane Bancel. Ms. Garay joins Moderna from Merck & Co., Inc. (MRK) where she most recently served as Chief Marketing Officer for Merck's Human Health business; she reported to Merck's Chief Executive Officer and was a member of Merck's Executive Committee. Additionally, she was responsible for data & analytics, digital marketing, and precision medicine worldwide. She also served as President of Global Pharmaceuticals, Analytics, and Digital Marketing; SVP & Head of U.S. Vaccines; and General Manager of Merck & Co. in Norway.

"I am very pleased to welcome Arpa to Moderna as our Chief Commercial Officer and to the Executive Committee. Arpa brings extensive experience leading commercial teams at global biopharmaceutical companies in an evolving global healthcare environment. Arpa is an innovative thinker with digital expertise and broad international experience, having lived in many countries. I look forward to partnering with Arpa as we advance our mission of delivering on the promise of mRNA medicines for people around the world."

## Corporate Updates

- Continued Growth: Moderna now has approximately 3,200 full time employees, compared to approximately 1,500 employees as of March 31, 2021.
- Moderna Enterprise Solutions Hub in Atlanta: Moderna **announced** plans to establish an Enterprise Solutions Hub in Atlanta, Georgia. Moderna's Atlanta office will initially host finance, human resources, procurement, and digital functions.
- mRNA Manufacturing Facility in Canada: Moderna **announced** plans to build a state-of-the-art mRNA vaccine manufacturing facility in Quebec that will support a long-term strategic partnership with the Government of Canada to enhance pandemic preparedness.
- mRNA Facility in Australia: Moderna **announced** the finalization of a strategic partnership with the Australian Federal Government to establish a state-of-the-art, domestic mRNA vaccine manufacturing facility in Australia.
- mRNA Manufacturing Facility in Kenya: Moderna **announced** it has entered into a Memorandum of

Understanding with the Government of the Republic of Kenya to establish Kenya as the location for the Company's mRNA manufacturing facility.

- Global Public Health Strategy: Moderna **announced** its global public health strategy through four new initiatives aimed at advancing mRNA vaccines for the prevention of infectious diseases, including a new program, **mRNA Access**, that will offer researchers use of Moderna's mRNA technology to explore new vaccines against emerging or neglected infectious disease
- Company Recognition: Moderna was named one of TIME Magazine's **most influential companies** of 2022.

#### Key 2022 Investor and Analyst Event Dates

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

#### Summary of Program Highlights by Modality<sup>2</sup>

##### 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

- Moderna COVID Vaccine (mRNA-12733, Spikevax<sup>®</sup>): The U.S. Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for SPIKEVAX (COVID-19 Vaccine, mRNA) to prevent COVID in individuals 18 years of age and older.
  - Booster Dose of mRNA-1273: The U.S. FDA approved an **amendment** to the emergency use authorization (EUA) to allow for a second booster dose of its COVID vaccine (mRNA-1273) at the 50 µg dose level in adults 50 years of age and older who have received an initial booster of any of the authorized or approved COVID vaccines and adults 18 years of age and older with certain kinds of immunocompromise.
  - Beta-specific bivalent booster (mRNA-1273.211): mRNA-1273.211 includes mutations found in the Beta variant of concern, several of which have been persistent in more recent variants of concern, including Omicron. A 50 µg booster dose of mRNA-1273.211 **demonstrated** superiority compared to a 50 µg booster dose of mRNA-1273 against Beta, Delta and Omicron variants of concern one month after administration. Superiority continued six months after administration for Beta and Omicron variants of concern as well. A 50 µg booster dose of mRNA-1273.211 was generally well tolerated with a reactogenicity profile comparable to a booster dose of mRNA-1273 at the 50 µg dose level.

- Omicron-specific booster (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 the U.S and the UK. The **Phase 2 study** of mRNA-1273.529 is ongoing.
- Bivalent booster (mRNA-1273.214): mRNA-1273.214 is a bivalent candidate that combines Moderna's Omicron-specific candidate and mRNA-1273. mRNA-1273.214 is being evaluated in a Phase 2/3 study. The Company expects initial data on mRNA-1273.214 in June to inform selection of its candidate for the Northern Hemisphere fall 2022 booster.
- Moderna COVID Vaccine for adolescents and children: Moderna has received regulatory authorizations for the use of the 100 µg Moderna COVID vaccine primary series for adolescents 12 to 17 years of age in more than 40 countries. The Company has received authorization for a two-dose 50 µg primary series of mRNA-1273 in children ages 6 to 11 in more than 35 countries. Moderna **submitted** a request for emergency use authorization (EUA) for a 25 µg two-dose primary series of mRNA-1273 in children 6 months to 6 years of age to the U.S. FDA; similar requests are underway with international regulatory authorities. The Company has initiated an EUA submission with the U.S. FDA for a 50 µg two-dose primary series of mRNA-1273 in children 6-11 years of age. For the adolescent age group, Moderna recently expanded its previous EUA submission for a two-dose 100 µg primary series of mRNA-1273 with a follow-up of clinical safety and efficacy data at FDA's request, which is now under review. These submissions will be completed in approximately 2 weeks with the submission of the statistical packages.
- Next-generation vaccine against COVID (mRNA-1283): In a Phase 1 study of mRNA-1283, preliminary results indicate that when administered as primary series at lower doses levels (10 µg, 30 µg), mRNA-1283 elicits a robust anti-SARS-CoV-2 neutralizing antibody response comparable to the 100 µg mRNA-1273 primary series. The frequency of local and systemic solicited adverse reactions of the mRNA-1283 primary series administered at lower dose levels (10 µg, 30 µg) was overall comparable to mRNA-1273. Enrollment is complete in a Phase 2 study evaluating booster doses of mRNA-1283, mRNA-1283.211, and mRNA-1283.529. mRNA-1283 is a next-generation vaccine candidate against COVID 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.
- Seasonal influenza vaccine (mRNA-1010): In a positive interim analysis of a Phase 2 study of mRNA-1010, no significant safety concerns were identified, and the immunogenicity data was consistent with a potential for superiority to standard dose vaccine for influenza A strains, which drive the majority of disease in adults. The interim data is consistent with potential for non-inferiority to standard dose vaccine in influenza B strains (primarily a concern in pediatrics). Moderna expects to begin its Phase 3 safety and immunogenicity trial in

the Southern Hemisphere in the second quarter of 2022 to support potential accelerated approval. Moderna is preparing for a Phase 3 efficacy study in Fall 2022 if needed. 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): Moderna is developing vaccine candidates that 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). Moderna started its **Phase 1/2 study** of mRNA-1020 and mRNA-1030 in April 2022.
- COVID and flu combination vaccine (mRNA-1073): mRNA-1073 encodes for the COVID spike protein and the influenza 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 one of the leading causes 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 cohorts are fully enrolled except the RSV seropositive children cohort, which is ongoing.
- Combination respiratory vaccine (mRNA-1230): mRNA-1230 is a combination respiratory vaccine candidate against SARS-CoV-2 virus, influenza virus and respiratory syncytial virus (RSV). This vaccine targets three of the most significant viruses causing respiratory disease in older adults and is envisioned as an annual booster targeting SARS-CoV-2 virus, influenza virus and respiratory syncytial virus (RSV).
- Endemic coronavirus vaccine (mRNA-1287): mRNA-1287 is a vaccine candidate against the four endemic human coronaviruses (HCoV-229E, -NL63, -OC43 and -HKU1). While less-well known than other coronaviruses, HCoVs are a significant cause of respiratory disease worldwide. The targeted HCoVs are endemic globally, accounting for approximately 10% to 30% of upper respiratory tract infections in adults.
- 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 CMVictory, 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 expects 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** identifier is **NCT05085366**. To learn more about eligibility, visit **www.CMVictory.com**. In a Phase 2 study, mRNA-1647 was observed to be generally well tolerated and seven-month interim data demonstrates strong immunogenicity in both CMV-seronegative and CMV-positive participants.
- Epstein-Barr virus (EBV) vaccine to prevent long-term sequelae (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 compared to mRNA-1189. The Company expects to test the vaccine in patients with multiple sclerosis, and in transplant patients to prevent post-transplant lymphoproliferative disorder (PTLD).
- Herpes simplex virus (HSV) therapeutic vaccine (mRNA-1608): mRNA-1608 is a vaccine candidate against recurrent genital herpes. In the U.S., approximately 18.6 million adults aged 18 to 49 years are living with HSV-2. Moderna is developing mRNA-1608 to reduce the burden of recurrent genital lesions caused by HSV. Preclinical studies are underway for mRNA-1608.
- Epstein-Barr virus (EBV) vaccine to prevent infectious mononucleosis (mRNA-1189): The **Phase 1 study** of mRNA-1189 is 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<sup>4,5</sup>. 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.
- HIV vaccine (mRNA-1644 & mRNA-1574): The ongoing **Phase 1 study** of mRNA-1644 is the first study in a series of planned iterative clinical trials with the primary aim to validate a novel vaccination approach i.e., to elicit specific broadly neutralizing antibodies against HIV using an antigen guided antibody germline targeting. mRNA-1644, a collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill & Melinda Gates Foundation. A second study, mRNA-1574, is being evaluated in collaboration with IAVI, SCRIPPS and the National Institutes of Health (NIH) to test and compare multiple native-like HIV env trimer antigens. This Phase 1 study of mRNA-1574 is **ongoing**.
- Varicella-zoster virus (VZV) vaccine (mRNA-1468): mRNA-1468 is 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. Preclinical studies are underway for mRNA-1468.

#### 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): The U.S. FDA has completed its review of the IND application of mRNA-1215 allowing it to proceed to clinic. 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.

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 12 month-recurrence-free survival. The Phase 1 study is ongoing. 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) that 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): Dose escalation for 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 expansion cohorts in combination with durvalumab 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.
- Publication of Note: AstraZeneca presented **Phase 1 data** at the American Association for Cancer Research (AACR) in April 2022. MEDI1191 combined with durvalumab was safe and the combination showed preliminary evidence of clinical benefit, with 29% of patients exhibiting partial responses (PRs) or stable disease (SD) ≥12 weeks as best overall response.

**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 2 study of AZD8601 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 patients into additional cohorts. All five patients eligible for the Open Label Extension (OLE) study have elected to participate.
- Methylmalonic acidemia (MMA) (mRNA-3705): The first cohort of the **Phase 1/2 Landmark study** of mRNA-3705 is fully enrolled. The study is now open in the UK, Canada and the U.S. Moderna is enrolling patients into additional cohorts. The one patient eligible to participate in the OLE study has elected to participate.
- 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): In collaboration with Vertex Pharmaceuticals, this mRNA therapeutic program 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 approximately 5,000 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.

Information about each development candidate in Moderna's pipeline can be found at [investors.modernatx.com](https://investors.modernatx.com).

#### Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Wednesday, May 4, 2022. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 2083116. 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 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 INCOME  
(Unaudited, in millions, except per share data)

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Revenue:		
Product sales	\$ 5,925	\$ 1,733
Grant revenue	126	194
Collaboration revenue	<u>15</u>	<u>10</u>
Total revenue	<u>6,066</u>	<u>1,937</u>
Operating expenses:		
Cost of sales	1,017	193
		13

Research and development	554	401
Selling, general and administrative	<u>268</u>	<u>77</u>
Total operating expenses	<u>1,839</u>	<u>671</u>
Income from operations	4,227	1,266
Interest income	15	4
Other expense, net	<u>(13)</u>	<u>(10)</u>
Income before income taxes	4,229	1,260
Provision for income taxes	<u>572</u>	<u>39</u>
Net income	<u>\$ 3,657</u>	<u>\$ 1,221</u>

Earnings per share:

Basic	\$ 9.09	\$ 3.05
Diluted	\$ 8.58	\$ 2.84

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

Basic	402	400
Diluted	426	430

MODERNA, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(Unaudited, in millions, except per share data)

	<u>March 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,048	\$ 6,848
Investments	5,067	3,879
Accounts receivable	3,173	3,175
Inventory	1,942	1,441
Prepaid expenses and other current assets	<u>1,120</u>	<u>728</u>
Total current assets	16,350	16,071
Investments, non-current	9,171	6,843
Property and equipment, net	1,341	1,241
Right-of-use assets, operating leases	132	142
Restricted cash, non-current	12	12
Deferred tax assets	521	326
Other non-current assets	<u>82</u>	<u>34</u>
Total assets	<u>\$ 27,609</u>	<u>\$ 24,669</u>

Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 199	\$ 302
Accrued liabilities	1,608	1,472
Deferred revenue	5,599	6,253
Income taxes payable	1,592	876
Other current liabilities	<u>240</u>	<u>225</u>
Total current liabilities	9,238	9,128
Deferred revenue, non-current	464	615
Operating lease liabilities, non-current	95	106
Financing lease liabilities, non-current	646	599
Other non-current liabilities	<u>91</u>	<u>76</u>
Total liabilities	10,534	10,524
Stockholders' equity:		
Additional paid-in capital	3,644	4,211
Accumulated other comprehensive loss	(184)	(24)
Retained earnings	<u>13,615</u>	<u>9,958</u>
Total stockholders' equity	<u>17,075</u>	<u>14,145</u>
Total liabilities and stockholders' equity	<u>\$ 27,609</u>	<u>\$ 24,669</u>

MODERNA, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited, in millions)

	Three Months Ended March 31,	
	<u>2022</u>	<u>2021</u>
Operating activities		
Net income	\$ 3,657	\$ 1,221
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	44	30
Depreciation and amortization	79	15
Amortization/accretion of investments	18	5
Deferred income taxes	(146)	(50)
Changes in assets and liabilities:		
Accounts receivable	1	(1,819)
Prepaid expenses and other assets	(414)	(12)
Inventory	(501)	(448)
Right-of-use assets, operating leases	10	2
Accounts payable	(35)	(15)
Accrued liabilities	114	285
		15

Deferred revenue	(805)	3,666
Income taxes payable	716	90
Operating lease liabilities	(10)	(2)
Other liabilities	<u>35</u>	<u>3</u>
Net cash provided by operating activities	2,763	2,971
Investing activities		
Purchases of marketable securities	(5,572)	(726)
Proceeds from maturities of marketable securities	441	339
Proceeds from sales of marketable securities	1,377	242
Purchases of property and equipment	(132)	(35)
Investment in convertible notes	<u>(35)</u>	<u>-</u>
Net cash used in investing activities	(3,921)	(180)
Financing activities		
Proceeds from issuance of common stock through equity plans	12	28
Repurchase of common stock	(623)	-
Changes in financing lease liabilities	<u>(31)</u>	<u>(2)</u>
Net cash (used in) provided by financing activities	<u>(642)</u>	<u>26</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,800)	2,817
Cash, cash equivalents and restricted cash, beginning of year	<u>6,860</u>	<u>2,636</u>
Cash, cash equivalents and restricted cash, end of period	<u>\$ 5,060</u>	<u>\$ 5,453</u>
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 64	\$ 21
Right-of-use assets obtained through finance lease modifications and reassessments	\$ -	\$ 51
Right-of-use assets obtained in exchange for financing lease liabilities	\$ 94	\$ -

## Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: anticipated sales under advanced purchase agreements in 2022 and the associated dollar amounts to be received, which should not be construed as expected 2022 revenue; Moderna's ongoing discussions with countries regarding additional advanced purchase agreements; COVID market dynamics and anticipated timing of sales in 2022; the number of programs Moderna expects to have in Phase 3 studies in the second quarter of 2022; timing of new data on Moderna's therapeutics development candidates in rare genetic diseases and oncology; timing of initial data on mRNA-1273.214; timing of submissions to regulators and review periods with respect to Moderna's COVID-19 vaccine; the ability of mRNA-1283 to elicit a robust anti-SARS-CoV-2 neutralizing antibody response; Moderna's 2022 financial framework; Moderna's appointments of executive officers; Moderna's plans to construct mRNA manufacturing facilities in Kenya, Canada and Australia; Moderna's mRNA Access initiative to allow researchers access to Moderna's mRNA platform; the potential for superiority of mRNA-1010 to standard dose vaccine for influenza A strains and non-inferiority to standard dose vaccine in influenza B strains; the potential for the Company's seasonal flu vaccine candidates to



provide broader coverage of protection and to improve immunity against seasonal flu; expected enrollment in Moderna's pivotal Phase 3 study of RSV in older adults; Moderna's plans to pursue longer-term potential indications for mRNA-1195; Moderna's expectations regarding the administration of mRNA-0184; and timing of the Phase 2 data readout for mRNA-4157. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others, 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 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 of this press release.

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1 Includes separate COVID 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 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>

SOURCE: Moderna, Inc.

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<https://www.accesswire.com/700021/Moderna-Reports-First-Quarter-2022-Financial-Results-and-Provides-Business-Updates>