



Moderna Reports First Quarter 2020 Financial Results and Provides Business Updates

May 7, 2020

Progress on novel coronavirus vaccine (mRNA-1273) includes FDA clearance to proceed with Phase 2 study

Finalizing protocol for Phase 3 study of mRNA-1273, expected to begin in early summer of 2020

Awarded up to \$483 million funding from BARDA for accelerated development of mRNA-1273

Entered strategic collaboration with Lonza Ltd. to manufacture up to one billion doses of mRNA-1273 per year

Up to \$2.4 billion to invest, including cash and investments of \$1.7 billion and up to \$0.7 billion in potentially available grants and awards; reconfirms 2020 guidance that net cash used in operating activities and for purchases of property and equipment is expected to be approximately \$500 million

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 7, 2020-- Moderna, Inc. (Nasdaq: MRNA), a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today reported financial results and provided business updates for the first quarter of 2020 and highlighted pipeline progress.

"The imminent Phase 2 study start is a crucial step forward as we continue to advance the clinical development of mRNA-1273, our vaccine candidate against SARS-CoV-2. With the goal of starting the mRNA-1273 pivotal Phase 3 study early this summer, Moderna is now preparing to potentially have its first BLA approved as soon as 2021. We are accelerating manufacturing scale-up and our partnership with Lonza puts us in a position to make and distribute as many vaccine doses of mRNA-1273 as possible, should it prove to be safe and effective," said Stéphane Bancel, Moderna's Chief Executive Officer. "We also are continuing to progress our development pipeline and invest in our future. We are very pleased with Vertex's decision, based on our preclinical progress, to extend our strategic collaboration working to develop the technology to allow for delivery of mRNA in the lung."

New updates and recent progress include:

Infectious Diseases

- The U.S. Food and Drug Administration (FDA) completed its review of the Company's Investigational New Drug (IND) application for its novel coronavirus (SARS-CoV-2 or COVID-19) vaccine candidate (mRNA-1273) allowing it to proceed to Phase 2 study, expected to begin shortly; finalizing protocol for Phase 3 study of mRNA-1273, expected to begin in early summer of 2020
- Positive interim results announced from Phase 1 Zika vaccine candidate (mRNA-1893) study

Oncology

- Positive data from the monotherapy arm of the Phase 1/2 study of OX40L (mRNA-2416) [presented](#) at the American Association for Cancer Research (AACR) Virtual Annual Meeting

Rare Diseases

- Due to COVID-19, enrollment and new site initiation paused for methylmalonic acidemia (MMA; mRNA-3704) and propionic acidemia (PA; mRNA-3927) clinical trials. During the pause, the Company is implementing changes that the Company believes will ultimately help to accelerate clinical development
- Given current strategic priorities, the Fabry disease program (mRNA-3630) is being discontinued

Research Update

- In March 2020, based on promising preclinical data generated to date, Vertex Pharmaceuticals, Inc. extended the conduct of the initial cystic fibrosis (CF) research plan for an additional 18 months by making an additional payment to Moderna

Moderna currently has 23 mRNA development candidates in its portfolio with 13 in clinical studies. Across Moderna's pipeline, more than 1,900 participants have been enrolled in clinical studies. The Company's updated pipeline can be found at www.modernatx.com/pipeline. Moderna and collaborators have published more than 45 peer-reviewed papers.

Summary of Program Highlights by Modality

Core Modalities

Prophylactic Vaccines: Moderna is developing vaccines against viral diseases where there is unmet medical need – including complex vaccines with multiple antigens for common diseases, as well as vaccines against threats to global public health. The Company's global public health portfolio is focused on epidemic and pandemic diseases for which funding has been sought from governments and non-profit organizations.

Infections transmitted from mother to baby

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** In March, Moderna [announced](#) completion of enrollment for the Phase 2

dose-confirmation study of mRNA-1647. The first Phase 2 interim analysis is expected in the third quarter of 2020. Manufacturing and planning are underway for the pivotal Phase 3 study, which is designed to evaluate the efficacy of mRNA-1647 against primary CMV infection in women of childbearing age and is expected to start in 2021. Moderna owns worldwide commercial rights for mRNA-1647.

- **Zika virus vaccine (mRNA-1893):** The 10 µg, 30 µg and 100 µg cohorts in the Phase 1 study of mRNA-1893 have completed enrollment. In April 2020, Moderna [announced](#) positive interim Phase 1 data showing the 10 µg and 30 µg dose levels of mRNA-1893 induced a neutralizing antibody response in both flavivirus infection-naïve (seronegative) participants and in participants with pre-existing flavivirus antibodies (seropositive) following a two-dose vaccination schedule given 28 days apart. The 10 µg and 30 µg dose levels were both generally well-tolerated, and there were no vaccine-related serious adverse events (SAEs) or adverse events of special interest (AESI). The most frequent solicited adverse reaction was local pain at the injection site. The safety profile did not appear affected by the second vaccination nor a flavivirus-positive baseline serostatus. mRNA-1893 is being developed in collaboration with the U.S. Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. Moderna owns worldwide commercial rights to mRNA-1893.

Vaccines against respiratory infections

- **Novel coronavirus (SARS-CoV-2) vaccine (mRNA-1273):** The U.S. Food and Drug Administration (FDA) completed its review of the Company's Investigational New Drug (IND) application for its novel coronavirus (SARS-CoV-2 or COVID-19) vaccine candidate (mRNA-1273) allowing it to proceed to the Phase 2 study. A 600 participant Phase 2 study is expected to begin shortly. The Company is finalizing the protocol for the Phase 3 study, which is expected to begin in the early summer of 2020.
- **Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653):** Due to the pandemic, the Company previously decided to pause new enrollment of participants in the ongoing hMPV/PIV3 study (mRNA-1653), which had been actively enrolling seropositive pediatric participants (12-36 months of age). The Company intends to work with appropriate medical and site personnel to determine when to resume new enrollment. Moderna owns worldwide commercial rights to mRNA-1653.
- **Pediatric respiratory syncytial virus (RSV) vaccine (mRNA-1345):** mRNA-1345 is a vaccine against RSV in young children encoding for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state. The Company intends to combine mRNA-1345 with mRNA-1653, its vaccine against hMPV and PIV3, to create a combination vaccine against RSV, hMPV and PIV3. There is no approved vaccine for RSV. Moderna owns worldwide commercial rights to the combined mRNA-1345/mRNA-1653 vaccine.
- **RSV vaccine (mRNA-1172 or V172):** The Phase 1 study of mRNA-1172 led by Merck is ongoing. Moderna has licensed worldwide commercial rights to mRNA-1172 to Merck.
- **Influenza H7N9 vaccine (mRNA-1851):** Discussions regarding funding the Company's influenza H7N9 vaccine program through approval are ongoing.

Vaccines against highly prevalent viral infections

- **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. There is no approved vaccine for EBV. Moderna owns worldwide commercial rights to mRNA-1189.

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):** Moderna has been notified that the enrollment of further subjects in the Phase 1 study of mRNA-1944 has been paused by the site due to the impact of COVID-19. Moderna owns worldwide commercial rights to mRNA-1944.
- **IL-2 (mRNA-6231):** mRNA-6231 is an mRNA encoding for a long-acting tolerizing IL-2. This new autoimmune development candidate is designed to preferentially activate and expand the regulatory T cell population. The Company plans to conduct a Phase 1 study of mRNA-6231 in healthy adult volunteers. mRNA-6231 uses the same LNP formulation as mRNA-1944. The Phase 1 study of mRNA-6231 will be the first clinical demonstration of subcutaneous administration of this delivery technology. Moderna owns worldwide commercial rights to mRNA-6231.
- **PD-L1 (mRNA-6981):** mRNA-6981 is an mRNA encoding for PD-L1. This new autoimmune development candidate is

designed to augment cell surface expression of PD-L1 on myeloid cells to provide co-inhibitory signals to self-reactive lymphocytes. As an initial step to addressing a range of autoimmune indications, the Company intends to pursue proof-of-concept in a Phase 1 study of mRNA-6981 in type 1 autoimmune hepatitis (AIH), a condition that involves liver inflammation and can lead to cirrhosis and liver failure. mRNA-6981 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-6981.

- **Relaxin (AZD7970):** Partnered with AstraZeneca, AZD7970 is in preclinical development for the treatment of heart failure. Under the terms of the collaboration, AstraZeneca would sponsor the Phase 1 trial to assess safety, tolerability and duration of systemic exposure to the Relaxin protein. Moderna shares worldwide commercial rights to AZD7970 with AstraZeneca.
- **Fabry disease (mRNA-3630):** Given current strategic priorities, the Fabry disease program (mRNA-3630) is being discontinued.
- **Publication of note:** In April, in collaboration with Seattle Children's Research Institute, Moderna published preclinical data in [Molecular Therapy Nucleic Acids](#) showing administration of mRNA encoding the factor VIII (FVIII) protein led to rapid and prolonged FVIII expression in mouse models of Hemophilia A. This work is part of Moderna's research to explore the potential of mRNA therapy across various rare diseases.

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. The Phase 1 study is ongoing. The Company is evaluating the impact of COVID-19 related challenges that are leading to delays in enrollment. Moderna shares worldwide commercial rights to mRNA-4157 with Merck.
- **KRAS vaccine (mRNA-5671 or V941):** The Phase 1 open-label, multi-center study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with pembrolizumab, led by Merck, is ongoing. Moderna shares worldwide commercial rights to mRNA-5671 with Merck.

Intratumoral Immuno-Oncology: *These programs aim to drive anti-cancer T cell responses by injecting mRNA therapies directly into tumors.*

- **OX40L (mRNA-2416):** The Phase 1/2 study of mRNA-2416 alone and in combination with durvalumab (IMFINZI[®]) is ongoing. The Company is evaluating the impact of COVID-19-related challenges that are leading to delays in enrollment. Moderna owns worldwide commercial rights to mRNA-2416.
- **Presentation of Note:** Data from the monotherapy arm of the Phase 1/2 study of OX40L (mRNA-2416) were [presented](#) at the AACR Virtual Annual Meeting showing that mRNA-2416 was well-tolerated at all dose levels studied with the majority of adverse events reported as grade 1 and 2; no grade 3 adverse events were reported. Best overall response observed was stable disease in 14/39 patients with 6 of these patients at stable disease for >14 weeks. Patients treated with monotherapy mRNA-2416 showed increased OX40L protein expression, upregulation of PD-L1 levels and evidence of increased pro-inflammatory activity demonstrating proof of mechanism and supporting the evaluation of intratumoral mRNA-2416 with the anti-PD-L1 inhibitor durvalumab in solid tumors, which is ongoing in Part B of this study with a focus on advanced ovarian carcinoma.
- **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. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators. The Company is evaluating the impact of COVID-19-related challenges that are leading to delays in enrollment. 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 for VEGF-A for ischemic heart disease in patients undergoing

coronary artery bypass grafting (CABG) surgery with moderately impaired systolic function, led by AstraZeneca, is ongoing at one site. 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.*

- **Methylmalonic acidemia (MMA) (mRNA-3704):** Due to the COVID-19 pandemic, Moderna previously decided to pause new enrollment and new site initiation for its Phase 1/2 study of mRNA-3704 to ensure the safety of these pediatric patients and their caregivers. No patients have been dosed to date. During the pause, the Company is implementing changes that the Company believes will ultimately help to accelerate clinical development. mRNA-3704 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-3704.
- **Propionic acidemia (PA) (mRNA-3927):** Due to the COVID-19 pandemic, Moderna previously decided to pause new enrollment and new site initiation for its Phase 1/2 study of mRNA-3927 to ensure the safety of these pediatric patients and their caregivers. No patients have been dosed to date. During the pause, the Company is implementing changes that the Company believes will ultimately help to accelerate clinical development. mRNA-3927 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-3927.
- **MMA and PA Natural History Study (MaP):** This is a global, multi-center, non-interventional study for patients with confirmed diagnosis of MMA due to MUT deficiency or PA and is designed to identify and correlate clinical and biomarker endpoints for these disorders. Enrollment in the study has been completed.
- **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, including those discussed in this press release, can be found on the investor relations page of its website: investors.modernatx.com.

Research Update

- **Vertex cystic fibrosis research collaboration:** In July 2016, Moderna and Vertex announced an exclusive research [collaboration](#) and licensing agreement aimed at the discovery and development of mRNA therapeutics for the treatment of CF. In July 2019, Vertex elected to extend the initial research period by six months. Based on promising preclinical work to date, in March 2020 Vertex extended this collaboration through August 2021 with options to extend further based on future progress. Pulmonary mRNA delivery represents a potential new route of administration for Moderna.

Management Updates

- Moderna's Chief Financial Officer, Lorence Kim, M.D., will be leaving the Company in August after six years of service. The Company has retained Russell Reynolds to recruit for a new CFO with public company, global and commercial experience as the Company scales up to file several biologics license applications (BLAs) over the next few years with the Company's first potential launch, for its SARS-CoV-2 vaccine, as soon as 2021.

"I would like to thank Lorence for his tremendous impact on Moderna's success over the last six years. Lorence brought unique skills with a medical degree and financial market experience, which has helped us build our financial foundation. His leadership and contributions were vital in helping Moderna get to where we are today. I have enjoyed having him as my partner and wish him all the best as he embarks on the next leg of his successful career," said Stéphane Bancel.

- Charbel Haber, M.P.H., Ph.D. joined Moderna on April 21 as SVP, Regulatory Affairs joining from Biogen where he served as Vice President, Global Safety and Regulatory Sciences since 2017. Prior to Biogen, Dr. Haber was Head, Global Regulatory Affairs-Immunology and Neurology at EMD Serono, Inc. Dr. Haber brings significant global regulatory experience and led numerous successful regulatory development and registration of drugs in different modalities and disease areas.
- Jacqueline Miller, M.D., FAAP will join Moderna on May 11 as SVP, Infectious Disease Development. Dr. Miller joins the Company from GlaxoSmithKline where she held a variety of leadership roles since 2005. Most recently, Dr. Miller was the Vice President and Head, Clinical R&D and Epidemiology where she built and led the clinical and epidemiology research

teams at the first GSK vaccines research and development center in the U.S.

- Patrick Bergstedt will join Moderna on June 1 as SVP, Commercial Vaccines. Prior to Moderna, Mr. Bergstedt held various progressive leadership positions with the Infectious Diseases and Global Human Health groups at Merck & Co, Inc. since 2001. Mr. Bergstedt most recently served as Head of Global Marketing & Commercial Operations: Vaccines at Merck where he led global initiatives with a focus on revenue growth and access expansion, and played a pivotal role in the transformation of the vaccines business.

“We are excited to welcome these three new senior leaders, who bring extensive clinical development, regulatory and commercial experience, as we begin to pivot towards late-stage development and commercialization,” said Stéphane Bancel.

Corporate Updates

- The Company hosted its first [Vaccines Day](#) on April 14, 2020.

Financial Guidance

- The Company has up to \$2.4 billion to invest, including cash and investments of \$1.7 billion and up to \$0.7 billion in potentially available grants and awards.
- In 2020, the Company expects net cash used in operating activities and for purchases of property and equipment to be approximately \$500 million.
- While the Company expects to incur significant expenses this year in relation to the BARDA award for the development of mRNA-1273 to FDA licensure and manufacturing process scale-up, the Company expects in general a close matching of expenses and reimbursements for those expenses covered by the BARDA award.

Key 2020 Investor and Analyst Event Dates

- Science Day – June 2 (virtual)
- R&D Day – September 17

First Quarter 2020 Financial Results (Unaudited)

- **Cash Position:** Cash, cash equivalents and investments as of March 31, 2020 and December 31, 2019 were \$1.7 billion and \$1.3 billion, respectively.
- **Net Cash Used in Operating Activities:** Net cash used in operating activities was \$106.2 million for the three months ended March 31, 2020 compared to \$144.3 million for the three months ended March 31, 2019. Net cash used in operating activities includes \$22.0 million for the three months ended March 31, 2019, of in-licensing payments to Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc., to sublicense certain patent rights. After the first quarter of 2019, the Company has no further in-licensing payment obligations to Cellscript and its affiliate.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was \$6.2 million for the three months ended March 31, 2020 compared to \$7.6 million for the three months ended March 31, 2019.
- **Revenue:** Total revenue was \$8.4 million for the three months ended March 31, 2020 compared to \$16.0 million for the three months ended March 31, 2019. The total revenue decrease in 2020 was mainly attributable to cumulative catch-up adjustments in revenue due to changes in estimated costs for our future performance obligations under the collaboration agreements with Merck and AstraZeneca, and a decrease in revenue from Merck, primarily driven by the timing of amortization of deferred revenue due to the satisfaction of the Company’s performance obligation.
- **Research and Development Expenses:** Research and development expenses were \$115.1 million for the three months ended March 31, 2020 compared to \$130.4 million for the three months ended March 31, 2019. The decrease was primarily attributable to decreases in lab supplies and materials, clinical trial and manufacturing costs, consulting and outside services, partially offset by increases in personnel related costs, depreciation and amortization and stock-based compensation.
- **General and Administrative Expenses:** General and administrative expenses were \$24.1 million for the three months ended March 31, 2020 compared to \$27.3 million for the three months ended March 31, 2019. The decrease was mainly due to a decrease in legal related costs and consulting and outside services.
- **Net Loss:** Net loss was \$124.2 million for the three months ended March 31, 2020 compared to \$132.6 million for the three months ended March 31, 2019.

MODERNA, INC.**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited, in thousands, except share and per share data)**

	Three Months Ended March 31,	
	2020	2019
Revenue:		
Collaboration revenue	\$ 4,457	\$ 14,115
Grant revenue	3,932	1,910
Total revenue	8,389	16,025
Operating expenses:		
Research and development	115,137	130,413
General and administrative	24,114	27,253
Total operating expenses	139,251	157,666
Loss from operations	(130,862)	(141,641)
Interest income	7,852	10,972
Other expense, net	(1,154)	(1,931)
Loss before income taxes	(124,164)	(132,600)
Provision for (benefit from) income taxes	66	(24)
Net loss	\$ (124,230)	\$ (132,576)
Net loss per share, basic and diluted	\$ (0.35)	\$ (0.40)
Weighted average common shares used in net loss per share, basic and diluted	353,105,021	328,809,986

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

	March 31,	December 31,
	2020	2019

Cash, cash equivalents and investments	\$ 1,720,180	\$ 1,262,987
Total assets	2,067,541	1,589,422
Total liabilities	426,667	414,612
Total stockholders' equity	1,640,874	1,174,810
Total liabilities and stockholders' equity	2,067,541	1,589,422

Three Months Ended March 31,

	2020	2019
Net cash used in operating activities	\$ 106,191	\$ 144,268
Cash used for purchases of property and equipment	6,223	7,595

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Thursday, May 7, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 6698719. 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. A replay of the webcast will be archived on Moderna's website for one year following the presentation.

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. Moderna's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing the Company the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune and inflammatory diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense; the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) and the Coalition for Epidemic Preparedness Innovations (CEPI). Moderna has been named a top biopharmaceutical employer by *Science* for the past five years. To learn more, visit www.modernatx.com.

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, but not limited to, statements concerning: the impact of the SARS-CoV-2 pandemic on the Company's clinical trials and operations, including mRNA-1653, mRNA-3704, mRNA-3927, mRNA-3630 and mRNA-1944; the status, timing and results of the Phase 1 trial of mRNA-1273 being conducted by the NIH; the timing of and proposed design for the planned Phase 2 study of mRNA-1273; the next steps, including the Phase 3 study design and the timing thereof, and ultimate commercial plan for mRNA-1273; the ability to scale dosing capacity for mRNA-1273; the size of the potential market opportunity for mRNA-1273; the timing and results of the Phase 2 dose confirmation study of mRNA-1647; the timing and design of the Phase 3 study of mRNA-1647; the Company's intention to create a combination therapy with mRNA-1345 and mRNA-1653 against RSV, hMPV and PIV3; the timing and status of the Phase 1 study of mRNA-6231 in healthy volunteers; the continuing success of the extended strategic collaboration with Vertex; the probability of success of the Company's vaccines individually and as a portfolio; and the ability of the Company to accelerate the research and development timeline for any individual product or the platform as a whole. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "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: whether the interim Phase 1 results for mRNA-1893 will be predictive of study results and any future clinical studies for mRNA-1893 or other development candidates; whether the interim Phase 1 results for mRNA-1944 will be predictive of any future clinical studies for mRNA-1944 or other development candidates with the same LNP formulation, including mRNA-3704 and mRNA-3927; preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no commercial product using mRNA technology has been approved, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with the Company's regulatory approval strategies, components of our filings, such as

clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the fact that the safety and efficacy of mRNA-1273 has not yet been established; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and 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. 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200507005478/en/): <https://www.businesswire.com/news/home/20200507005478/en/>

Media:

Colleen Hussey
Senior Manager, Corporate Communications
203-470-5620
Colleen.Hussey@modernatx.com

Dan Budwick
1AB
973-271-6085
Dan@1abmedia.com

Investors:

Lavina Talukdar
Head of Investor Relations
617-209-5834
Lavina.Talukdar@modernatx.com

Source: Moderna, Inc.