UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 18, 2020

MODERNA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38753**	**81-3467528**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Technology Square **Cambridge, MA**	**02139**
(Address of principal executive offices)	**(Zip code)**

(Registrant's telephone number, including area code): (617) 714-6500

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**MRNA**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On May 18, 2020, Moderna, Inc. issued a press release announcing interim data from the Phase 1 study of mRNA-1273, its vaccine candidate against the novel coronavirus (SARS-CoV-2). A copy of this press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Moderna, Inc. on May 18, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 18, 2020

MODERNA, INC.

By: /s/ Lori Henderson
Lori Henderson
General Counsel and Secretary

Moderna Announces Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus

After two doses all participants evaluated to date across the 25 µg and 100 µg dose cohorts seroconverted with binding antibody levels at or above levels seen in convalescent sera

mRNA-1273 elicited neutralizing antibody titer levels in all eight initial participants across the 25 µg and 100 µg dose cohorts, reaching or exceeding neutralizing antibody titers generally seen in convalescent sera

mRNA-1273 was generally safe and well tolerated

mRNA-1273 provided full protection against viral replication in the lungs in a mouse challenge model

Anticipated dose for Phase 3 study between 25 µg and 100 µg; expected to start in July

Conference call to be held on Monday, May 18 at 8:30 a.m. ET

CAMBRIDGE, Mass.—May 18, 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 announced positive interim clinical data of mRNA-1273, its vaccine candidate against novel coronavirus (SARS-CoV-2), from the Phase 1 study led by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Immunogenicity data are currently available for the 25 µg and 100 µg dose level (ages 18-55) after two doses (day 43) and at the 250 µg level (ages 18-55) after one dose (day 29). Dose dependent increases in immunogenicity were seen across the three dose levels, and between prime and boost within the 25 µg and 100 µg dose levels. All participants ages 18-55 (n=15 per cohort) across all three dose levels seroconverted by day 15 after a single dose. At day 43, two weeks following the second dose, at the 25 µg dose level (n=15), levels of binding antibodies were at the levels seen in convalescent sera (blood samples from people who have recovered from COVID-19) tested in the same assay. At day 43, at the 100 µg dose level (n=10), levels of binding antibodies significantly exceeded the levels seen in convalescent sera. Samples are not yet available for remaining participants.

At this time, neutralizing antibody data are available only for the first four participants in each of the 25 µg and 100 µg dose level cohorts. Consistent with the binding antibody data, mRNA-1273 vaccination elicited neutralizing antibodies in all eight of these participants, as measured by plaque reduction neutralization (PRNT) assays against live SARS-CoV-2. The levels of neutralizing antibodies at day 43 were at or above levels generally seen in convalescent sera.

mRNA-1273 was generally safe and well tolerated, with a safety profile consistent with that seen in prior Moderna infectious disease vaccine clinical studies. The sole incidence of a grade 3 adverse event in the 25 µg and 100 µg dose cohorts was a single participant at 100 µg who experienced grade 3 erythema (redness) around the injection site. To date, the most notable adverse events were seen at the 250 µg dose level, comprising three participants with grade 3 systemic symptoms, only following the second dose. All adverse events have been transient and self-resolving. No grade 4 adverse events or serious adverse events have been reported.

Preclinical results from a viral challenge study in mice conducted in collaboration with NIAID and its academic partners are also available. In this study, vaccination with mRNA-1273 prevented viral replication in the lungs of animals challenged with SARS-CoV-2. Neutralizing titers in Phase 1 clinical trial participants at the 25 µg and 100 µg dose levels were consistent with neutralizing titers that were protective in the mouse challenge model.

Based on the interim Phase 1 data, the Moderna-led Phase 2 study will be amended to study two dose levels, 50 µg and 100 µg, with the aim of selecting a dose for pivotal studies. The NIAID-led Phase 1 study is being amended to include a 50 µg dose level cohort across each of the three age groups. Moderna anticipates the dose for the Phase 3 study to be between 25 µg and 100 µg and expects Phase 3 trial initiation in July, subject to finalization of the clinical trial protocol.

“These interim Phase 1 data, while early, demonstrate that vaccination with mRNA-1273 elicits an immune response of the magnitude caused by natural infection starting with a dose as low as 25 µg,” said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. “When combined with the success in preventing viral replication in the lungs of a pre-clinical challenge model at a dose that elicited similar levels of neutralizing antibodies, these data substantiate our belief that mRNA-1273 has the potential to prevent COVID-19 disease and advance our ability to select a dose for pivotal trials.”

“With today’s positive interim Phase 1 data and the positive data in the mouse challenge model, the Moderna team continues to focus on moving as fast as safely possible to start our pivotal Phase 3 study in July and, if successful, file a BLA,” said Stéphane Bancel, Chief Executive Officer at Moderna. “We are investing to scale up manufacturing so we can maximize the number of doses we can produce to help protect as many people as we can from SARS-CoV-2.”

Funding from 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), supported the planning for the Phase 2 and Phase 3 studies of mRNA-1273 and will also support the execution of these studies, as well as the scale-up of mRNA-1273 manufacturing both at the Company’s facilities and that of its strategic collaborator, Lonza Ltd.

Conference Call and Webcast Information

Moderna will host a live conference call and webcast at 8:30 a.m. ET on Monday, May 18, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 2186342. A webcast of the call will also be available under “Events and Presentations” in the Investors section of the Moderna website at investors.modernatx.com. The archived webcast will be available on Moderna’s website approximately two hours after the conference call.

About mRNA-1273

mRNA-1273 is an mRNA vaccine against SARS-CoV-2 encoding for a prefusion stabilized form of the Spike (S) protein, which was selected by Moderna in collaboration with investigators from Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of the NIH. The first clinical batch, which was funded by the Coalition for Epidemic Preparedness Innovations, was completed on February 7, 2020 and underwent analytical testing; it was shipped to NIH on February 24, 42 days from sequence selection. The first participant in the NIAID-led Phase 1 study of mRNA-1273 was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing.

On May 6, the U.S. Food and Drug Administration (FDA) completed its review of the Company's Investigational New Drug (IND) application for mRNA-1273 allowing it to proceed to a Phase 2 study, which is expected to begin shortly. On May 12, the FDA granted mRNA-1273 Fast Track designation. Moderna is finalizing the protocol for a Phase 3 study, expected to begin in July 2020. A summary of the company's work to date on SARS-CoV-2 can be found here.

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. More than 1,400 participants have been enrolled in Moderna's infectious disease vaccine clinical studies under health authorities in the U.S., Europe and Australia. Clinical data demonstrate that Moderna's proprietary vaccine technology has been generally well-tolerated and can elicit durable immune responses to viral antigens. Based on clinical experience across Phase 1 studies, the company designated prophylactic vaccines a core modality and is working to accelerate the development of its vaccine pipeline.

The potential advantages of an mRNA approach to prophylactic vaccines include the ability to combine multiple mRNAs into a single vaccine, rapid discovery to respond to emerging pandemic threats and manufacturing agility derived from the platform nature of mRNA vaccine design and production. Moderna has built a fully integrated manufacturing plant which enables the promise of the technology platform.

Moderna currently has nine development candidates in its prophylactic vaccines modality, including:

Vaccines against respiratory infections

- Respiratory syncytial virus (RSV) vaccine for older adults (mRNA-1777 and mRNA-1172 or V172 with Merck)
- RSV vaccine for young children (mRNA-1345)
- Human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) vaccine (mRNA-1653)
- Novel coronavirus (SARS-CoV-2) vaccine (mRNA-1273)
- Influenza H7N9 (mRNA-1851)

Vaccines against infections transmitted from mother to baby

- Cytomegalovirus (CMV) vaccine (mRNA-1647)
- Zika vaccine (mRNA-1893 with BARDA)

Vaccines against highly prevalent viral infections

- Epstein-Barr virus (EBV) vaccine (mRNA-1189)

To date, Moderna has demonstrated positive Phase 1 data readouts for seven prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3, CMV and Zika). Moderna's CMV vaccine is currently in a Phase 2 dose-confirmation study. Moderna's investigational Zika vaccine (mRNA-1893), currently in a Phase 1 study, was granted FDA Fast Track designation in August 2019.

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. The company's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing Moderna 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 and cardiovascular 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, and 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). Moderna has been ranked in the top ten of *Science's* list of top biopharma industry employers for the past five years. To learn more, visit www.modernatx.com.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding the Company's development of a potential vaccine against the novel coronavirus, the parameters and timing of the Phase 1 and planned Phase 2 and 3 studies of mRNA-1273, the Company's investment in manufacturing, and the Company's intentions regarding vaccine dose production. 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: the fact that there has never been a commercial product utilizing mRNA technology approved for use; 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 other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

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