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): March 16, 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
(Address of principal executive offices)

02139
(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 203.425)

☐ 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 7.01. Regulation FD Disclosure.

On March 16, 2020, Moderna, Inc. (the "Company") posted to its website a summary and FAQ relating to the Company's activities with respect to development of an mRNA vaccine (mRNA-1273) against the novel coronavirus (SARS-CoV-2). A copy of this document is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 to this Current Report on Form 8-K, and in Exhibit 99.1 furnished herewith, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On March 16, 2020, the Company issued a press release announcing that the first participant has been dosed in the Phase 1 study of the Company's mRNA vaccine (mRNA-1273) against the novel coronavirus (SARS-CoV-2). A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Summary and FAQ dated March 16, 2020
99.2	Press Release issued by Moderna, Inc. on March 16, 2020

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: March 16, 2020

MODERNA, INC.

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

moderna

Moderna's Work on a Potential Vaccine Against COVID-19

Moderna is proud to be among the many groups working to respond to this continuing global health emergency. This page summarizes key milestones in our work to advance our vaccine candidate (mRNA-1273) and responds to frequently asked questions.

Timeline of our response through March 16, 2020

- On January 11, 2020, the Chinese authorities shared the genetic sequence of the novel coronavirus.
- On January 13, 2020, the U.S. National Institutes of Health (NIH) and Moderna's infectious disease research team finalized the sequence for mRNA-1273, the Company's vaccine against the novel coronavirus. At that time, the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, disclosed their intent to run a Phase 1 study using the mRNA-1273 vaccine in response to the coronavirus threat and Moderna mobilized toward clinical manufacture. Manufacture of this batch was funded by the Coalition for Epidemic Preparedness Innovations (CEPI).
- On February 7, 2020, the first clinical batch, including fill and finishing of vials, was completed, a total of 25 days from sequence selection to vaccine manufacture. The batch then proceeded to analytical testing for release.
- On February 24, 2020, the clinical batch was shipped from Moderna to the NIH for use in their Phase 1 clinical study.
- On March 4, 2020, the U.S. Food and Drug Administration (FDA) completed its review of the Investigational New Drug (IND) application filed by the NIH for mRNA-1273 and allowed the study to proceed to begin clinical trials.
- On March 16, 2020, the NIH announced that the first participant in its Phase 1 study for mRNA-1273 was dosed, a total of 63 days from sequence selection to first human dosing.

This Phase 1 study will provide important data on the safety and immunogenicity of mRNA-1273. Immunogenicity means the ability of the vaccine to induce an immune response in participants. The open-label trial is expected to enroll 45 healthy adult volunteers ages 18 to 55 years over approximately six weeks.

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How well validated is your mRNA platform?

mRNA is an emerging platform. Over the past few years, we have demonstrated its potential in vaccines across more than 1,000 subjects in our clinical trials. This includes successful early-stage (Phase 1) clinical trials against five other respiratory viruses (two pandemic influenza strains, RSV, hMPV, and PIV3). Over the last four years, we have started 9 clinical trials for mRNA vaccines.

However, it is important to emphasize that we are still early in the story. Our most advanced vaccine program (CMV) is in Phase 2 clinical testing and we have no approved drugs to date.

Despite this, we are doing everything we can to help in the current emergency by working to develop a safe and effective vaccine for this novel coronavirus.

Have you ever worked on other coronaviruses?

We had previously collaborated with the NIH on a vaccine for MERS-CoV, which is a different type of coronavirus than the current pandemic. While the program was only at the research stage, it provided significant insights as we launched our efforts for mRNA-1273. Before the Phase 1 study for mRNA-1273, we had not previously tested a coronavirus vaccine in humans.

How was mRNA-1273 able to move so quickly?

mRNA is an information molecule and we design our mRNA vaccines using the sequence of the virus, not by working on the virus itself. Our mRNA platform provides significant advantages in speed and efficiency, across basic science, manufacturing, and clinical development.

Moderna currently has 9 development candidates in its prophylactic vaccines modality. To date, Moderna has demonstrated positive Phase 1 data readouts for 6 prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3 and CMV).

For mRNA-1273, we were able to leverage our experience in vaccines to move rapidly on design and manufacture of material for the Phase 1 clinical trial. This included our broad understanding of the safety of our platform to date across more than 1,000 subjects. We also benefited from the use of our well-established manufacturing capabilities, which produced over 100 batches of mRNA medicines for use in human clinical trials in just the last two years.

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What happens after the Phase 1?

Phase 1 safety and immunogenicity data from the trial being run by the NIH is expected to guide our next steps. Given the pandemic, we have started to work in parallel to responsibly accelerate further development.

The Company is actively preparing for a potential Phase 2 study under its own Investigational New Drug (IND) filing to build on data from the ongoing Phase 1 study being conducted by the NIH. To continue to progress this potential vaccine during the ongoing global public health emergency, Moderna intends to work with the FDA and other government and non-government organizations to be ready for a Phase 2 and any subsequent trials, which are anticipated to include a larger number of subjects and which will seek to generate additional safety and immunogenicity data. Manufacture of the mRNA-1273 material for the potential Phase 2 trial, which could begin in a few months, is underway. Moderna continues to prepare for rapid acceleration of its manufacturing capabilities that could allow for the future manufacture of millions of doses should mRNA-1273 prove to be safe and effective.

Our goal is to generate data that will demonstrate the safety and effectiveness of mRNA-1273 against infection caused by SARS-CoV-2.

Are you working on further supply of the vaccine?

Moderna has already started to prepare for rapid acceleration of its manufacturing capabilities that could allow for the future manufacture of millions of doses should mRNA-1273 prove to be safe and of expected benefit. We are working around-the-clock to make sure a vaccine is available as quickly and as broadly as possible. We will continue to work together, with government, industry and other third parties to enable the best chance for success.

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Related Resources

- January 23: Moderna Announces Funding Award from CEPI to Accelerate Development of Messenger RNA (mRNA) Vaccine Against Novel Coronavirus
- February 10: Moderna Announces Progress in Prophylactic Vaccines Modality with CMV Vaccine Phase 2 Study Data Now Expected in Third Quarter 2020 and Expands Investment in This Core Modality with Three New Development Candidates
- February 24: Moderna Ships mRNA Vaccine Against Novel Coronavirus (mRNA-1273) for Phase 1 Study
- March 16: Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus
- March 16: NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding the Company's development of a potential vaccine against the novel Coronavirus, the conduct and timing of the Phase I study of mRNA-1273, the planning, conduct and timing of a potential Phase 2 and any subsequent trials of mRNA-1273, and potential manufacturing capabilities. 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 summary and FAQ 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; and those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this summary and FAQ 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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Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus

63 days from sequence selection to Phase 1 study dosing

mRNA-1273 is Moderna's 10th infectious disease vaccine to begin a clinical trial

March 16, 2020 12:42 PM Eastern Daylight Time

CAMBRIDGE, Mass.—(BUSINESS WIRE)—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 that the first participant has been dosed in the Phase 1 study of the Company's mRNA vaccine (mRNA-1273) against the novel coronavirus (SARS-CoV-2). This Phase 1 study is being conducted by the National Institutes of Health (NIH) under its own Investigational New Drug (IND) application.

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 the Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of NIH. Manufacture of the first clinical batch was funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

The Phase 1 study is evaluating the safety and immunogenicity of three dose levels of mRNA-1273 (25, 100, 250 μg) administered on a two-dose vaccination schedule, given 28 days apart. A total of 45 healthy adults will be enrolled in the study. Participants will be followed through 12 months after the second vaccination. The primary objective is to evaluate the safety and reactogenicity of a two-dose vaccination schedule of mRNA-1273. The secondary objective is to evaluate the immunogenicity to the SARS-CoV-2 S protein.

"This study is the first step in the clinical development of an mRNA vaccine against SARS-CoV-2, and we expect it to provide important information about safety and immunogenicity. We are actively preparing for a potential Phase 2 study under our own IND," said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. "We are grateful to NIH for their ongoing collaboration and to CEPI for funding the initial manufacturing of mRNA-1273 and are proud to be included with the many companies, worldwide health agencies and NGOs working on a possible response to the novel coronavirus outbreak."

On January 11, 2020, the Chinese authorities shared the genetic sequence of the novel coronavirus. On January 13, 2020 the VRC and Moderna's infectious disease research team finalized the sequence for the SARS-CoV-2 vaccine and Moderna mobilized toward clinical manufacture. The first clinical batch was completed on February 7, 2020 and underwent analytical testing; it was shipped on February 24, 2020 from Moderna and delivered to NIH from the Company's manufacturing facility in 42 days from sequence selection.

Next Steps for mRNA-1273

The Company is actively preparing for a potential Phase 2 study under its own IND to build on data from the ongoing Phase 1 study being conducted by the NIH. In order to continue to progress this potential vaccine during the ongoing global public health emergency, Moderna intends to work with the FDA and other government and non-government organizations to be ready for a Phase 2 and any subsequent trials, which are anticipated to include a larger number of subjects and which will seek to generate additional safety and immunogenicity data. Manufacture of the mRNA-1273 material for the potential Phase 2 trial, which could begin in a few months, is underway. Moderna continues to prepare for rapid acceleration of its manufacturing capabilities that could allow for the future manufacture of millions of doses should mRNA-1273 prove to be safe and effective.

About Coronavirus

Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Coronaviruses can be transmitted between animals and people and evolve into strains not previously identified in humans. On January 7, 2020, a novel coronavirus (SARS-CoV-2) was identified as the cause of pneumonia cases in Wuhan, Hubei Province of China, and additional cases have been found in a growing number of countries.[1,2]

About Moderna's Prophylactic Vaccines Core 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. Based on clinical experience across six Phase 1 studies, the Company has designated prophylactic vaccines a core modality and intends to accelerate development of its infectious disease vaccine candidates.

The potential advantages of an mRNA approach to prophylactic vaccines include the ability to mimic natural infection to stimulate a more potent immune response, combining 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 in Norwood, MA 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 and parainfluenza virus type 3 (hMPV/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 the Biomedical Advanced Research and Development Authority (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 six prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3 and CMV). 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.

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, 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 ranked in the top ten of *Science's* list of top biopharma industry employers for the past four years. To learn more, visit www.modernatx.com.

Forward Looking Statement

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[1] "Coronavirus." *World Health Organization*, https://www.who.int/health-topics/coronavirus.

[2] "2019 Novel Coronavirus, Wuhan, China." *Centers for Disease Control and Prevention*, https://www.cdc.gov/coronavirus/2019-nCoV/index.html.

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