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 23, 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 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 22, 2020, Dr. Stephen Hoge, President of Moderna, Inc. (the "Company" or "Moderna"), appeared in an interview on the television program *60 Minutes* and discussed the Company and its work on mRNA-1273, a potential vaccine against the novel coronavirus ("SARS-CoV-2" or "COVID-19"). mRNA-1273 is currently in a Phase 1 study led by the National Institute of Health ("NIH") as previously announced by NIH and the Company. For more information on the Company's work on a potential vaccine against COVID-19, please see the Company's dedicated COVID-19 page on its website, at https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19.

On March 20, 2020, Stephane Bancel, CEO of Moderna, was interviewed by representatives of Goldman Sachs regarding the Company's work on COVID-19. During such interview, Mr. Bancel indicated that while a commercially-available vaccine is not likely to be available for at least 12-18 months, it is possible that under emergency use, a vaccine could be available to some people, possibly including healthcare professionals, in the fall of 2020. In addition, Mr. Bancel confirmed that the Company is scaling up manufacturing capacity toward the production of millions of doses per month, in the potential form of individual or multi-dose vials. As has previously been disclosed, the ability of the Company to make millions of doses per month is contingent on investments in the scale up and further buildout of the Company's existing manufacturing infrastructure.

Dr. Hoge's statements in the *60 Minutes* interview and Mr. Bancel's statements to Goldman Sachs may contain 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 SARS-CoV-2, the conduct and timing of the clinical trials of mRNA-1273, the timing of availability of mRNA-1273 for human use, the number of doses of mRNA-1273 that may be available for use, collaborations and interactions with NIH, the United States Food and Drug Administration ("FDA") and any other government or regulatory agency, and potential manufacturing capabilities relating to mRNA-1273. 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. Any forward-looking statements made by Dr. Hoge or Mr. Bancel 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 the Company'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 those identified above, as well as, 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 the Company is still being developed and implemented; and those other risks and uncertainties described under the heading "Risk Factors" in the Company'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 the Company with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements made by Dr. Hoge or Mr. Bancel in the event of new information, future developments or otherwise. These forward-looking statements are based on current expectations and speak only as of the date made.

The information in this Item 7.01 to this Current Report on Form 8-K 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.

The Company is providing the following business updates in light of the ongoing SARS-CoV-2 pandemic.

Update on Moderna's work on a potential vaccine against COVID-19

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, which dosed the first participant on March 16, 2020, 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.

As of the date hereof, the Phase 1 study is proceeding in accordance with the protocol under the direction of NIAID.

Risk Factors

The Company is supplementing the risk factors previously disclosed in its Annual Report on Form 10-K for the year ended December 31, 2019 with the following risk factor:

Our business may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus ("SARS-CoV-2") has evolved into a global pandemic. The coronavirus has spread to many regions of the world, including the United States and Europe. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Should the coronavirus continue to spread, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. As of March 23, 2020, we have 13 development candidates in clinical trials. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials, components, parts, and consumables, and to perform quality testing. We also manufacture our products and perform various services at our manufacturing facility. If either we or any third-party parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations.

In response to the pandemic, we have closed our offices with our administrative employees continuing their work outside of our offices, restricted on-site staff to only those required to execute their job responsibilities and limited the number of staff in any given research and development laboratory and in our manufacturing facility. In the event of a shelter-in-place order or other mandated local travel restrictions, our employees conducting research and development or manufacturing activities may not be able to access our laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

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 23, 2020

MODERNA, INC.

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