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): April 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**	**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 1.01. Entry into a Material Definitive Agreement.

On April 16, 2020, Moderna, Inc. (the "Company") entered into a contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. Under the BARDA Contract, the Company will receive an award of up to $483 million to accelerate the development of the Company's mRNA vaccine candidate (currently mRNA-1273) against the novel coronavirus (SARS-CoV-2). BARDA will fund the advancement of the mRNA vaccine candidate to potential licensure, including clinical studies of the candidate and the manufacture of the candidate for use in these studies.

The BARDA Contract could result in payments to the Company of up to approximately $483 million, and consists of an approximately two-year base period-of-performance and a total contract period-of-performance (base period plus option exercises) of up to approximately five years and six months (if necessary). Under the base period-of-performance, the Company will conduct activities intended to obtain licensure of mRNA-1273 through a biologics license application submission for mRNA-1273.

The BARDA Contract contains terms and conditions that are customary for government contracts of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

The foregoing is a brief description of the material terms of the BARDA Contract and does not purport to be a complete description of the rights and obligations of the parties thereunder. The foregoing description is qualified in its entirety by reference to the BARDA Contract, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2020.

Item 7.01. Regulation FD Disclosure.

On April 16, 2020, the Company issued a press release announcing its entry into the BARDA Contract, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Moderna, Inc. on April 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.

MODERNA, INC.

Date: April 16, 2020

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

Exhibit 99.1

Moderna Announces Award from U.S. Government Agency BARDA for up to $483 Million to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus

Award will fund development of mRNA-1273 to FDA licensure

Award will fund manufacturing process scale-up to enable large-scale production in 2020 for pandemic response

NIH-led Phase 1 study of mRNA-1273 has completed enrollment of 3 dose cohorts (25 µg, 100 µg and 250 µg); expanding to an additional 6 cohorts of older adults and elderly adults

Phase 2 study expected to begin in Q2 2020, following safety data from ongoing Phase 1 study

Moderna to hire up to 150 new team members to support efforts

Conference call to be held on Friday, April 17 at 8:00 a.m. ET

CAMBRIDGE, Mass., April 16, 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 an agreement for a commitment of up to $483 million 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), to accelerate development of the Company's mRNA vaccine candidate (mRNA-1273) against the novel coronavirus (SARS-CoV-2).

Under the terms of the agreement, BARDA will fund the advancement of mRNA-1273 to FDA licensure. A Phase 1 study of mRNA-1273 is being conducted by the National Institutes of Health (NIH). The Phase 1 open-label study, which began on March 16, 2020 has completed enrollment of the original study: 45 healthy adult volunteers ages 18 to 55 years in three dose cohorts (25 µg, 100 µg and 250 µg). The NIH recently amended the Phase 1 protocol to include an additional six cohorts: three cohorts of older adults (ages 51-70) and three cohorts of elderly adults (age 71 and above). Enrollment for these cohorts is ongoing.

If supported by safety data from the Phase 1 study, the Company intends to begin a Phase 2 study of mRNA-1273 under its own Investigational New Drug (IND) application in the second quarter of 2020. Subject to data from these studies and discussions with regulators, a Phase 3 study could begin as soon as fall, 2020. BARDA funding will support these late-stage clinical development programs, as well as the scale-up of mRNA-1273 manufacture in 2020 to enable potential pandemic response.

To support the scale-up, Moderna plans to hire up to 150 new team members in the U.S. this year. This includes a significant increase in its skilled manufacturing staff to expand manufacturing capacity from two shifts per day, 5 days per week to three shifts per day, 7 days per week, engineers to manage process scale-up, and clinical and regulatory staff to support clinical development.

"We are thankful for BARDA's support to fund the accelerated development of mRNA-1273, our vaccine candidate against SARS-CoV-2," said Stéphane Bancel, Moderna's Chief Executive Officer. "Time is of the essence to provide a vaccine against this pandemic virus. By investing now in our manufacturing process scale-up to enable large scale production for pandemic response, we believe that we would be able to supply millions of doses per month in 2020 and with further investments, tens of millions per month in 2021, if the vaccine candidate is successful in the clinic."

“Vaccines are a critical tool for saving lives and stopping the spread of the SARS-CoV-2 virus,” said BARDA Director Rick Bright, Ph.D. “Delivering a safe and effective vaccine for a rapidly spreading virus requires accelerated action. BARDA’s goal is to have vaccine available as quickly as possible and preparing now for advanced stage clinical trials and production scale-up while the Phase 1 is underway could shave months off development of COVID-19 vaccines.”

Conference Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Friday, April 17, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 5115809. 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 NIH-led Phase 1 study of mRNA-1273 was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing. 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 six 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, BARDA funding for the development and manufacture of mRNA-1273 and the sufficiency of such funding, the intention to file an IND related to mRNA-1273, the expected conduct and timing of Phase 2 and Phase 3 clinical trials of mRNA-1273, potential future supply of mRNA-1273, and future hiring plans. 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 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.

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