

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 3, 2019

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

Delaware
(State or other jurisdiction of
incorporation)

001-38753
(Commission File Number)

81-3467528
(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 (17CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

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

Item 1.01 Entry into a Material Definitive Agreement.

On May 3, 2019, ModernaTX, Inc. (the “Company”), a subsidiary of Moderna, Inc., entered into a Fifth Amendment to Collaboration and License Agreement (the “Collaboration Amendment”) with Merck Sharp & Dohme Corp. (“Merck”). The Collaboration Amendment amends the terms of that certain Master Collaboration and License Agreement by and between the Company and Merck, dated January 12, 2015 (as amended, the “2015 Merck Agreement”). Pursuant to the Collaboration Amendment, Merck has elected to establish a new development candidate for the prevention of respiratory syncytial virus (RSV) infection (mRNA-1172) as a new “Product Candidate”, and to conduct a Phase 1 clinical trial for mRNA-1172. The Company will be responsible for certain costs associated with the conduct of the Phase 1 clinical trial for mRNA-1172, and the Company is eligible to receive an additional milestone payment unless Merck elects not to continue with further clinical development of mRNA-1172. In addition, under the terms of the Collaboration Amendment, the Company will have the right to research, develop, and commercialize a development candidate for the prevention of a specific set of respiratory infections, including RSV, for the pediatric population. As a part of the Collaboration Amendment, the Company and Merck agreed to focus the collaboration activities on RSV and discontinue the collaboration as it relates to the development of development candidates for other viruses, including mRNA-1278 for the prevention of varicella zoster virus (VZV) infection. Further development of the original development candidate for the prevention of RSV pursuant to the 2015 Merck Agreement, mRNA-1777, has been paused and next steps will be determined based on data from the new mRNA-1172 Phase 1 clinical trial.

The Company and Merck are also parties to that certain Amended and Restated mRNA Cancer Vaccine Collaboration and License Agreement, dated as of April 17, 2018, to develop and commercialize cancer vaccines.

The foregoing descriptions of the Collaboration Amendment are only a summary and are qualified in their entirety by reference to the full and complete terms contained in the Collaboration Amendment, which Moderna, Inc. intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2019.

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, Moderna, Inc. issued a press release announcing its results of operations and financial condition for the first quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference. This information, including Exhibit 99.1, 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.

<u>Exhibit</u>	
<u>No.</u>	<u>Description</u>
99.1	Press release issued by Moderna, Inc. dated May 8, 2019

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: May 8, 2019

By: /s/ Lorence Kim, M.D.

Lorence Kim, M.D.
Chief Financial Officer

MODERNA REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATES

Rare Diseases: New development candidate announced for glycogen storage disease type 1a (GSD1a), a rare metabolic disorder; Company now has five rare disease programs in its pipeline

Immuno-Oncology: Two personalized cancer vaccine (PCV) abstracts to be presented at the 2019 ASCO Annual Meeting

Infectious Diseases: Merck submitted an IND for mRNA-1172, a more potent RSV vaccine development candidate; development paused for first RSV candidate, mRNA-1777

Ended quarter with \$1.55 billion in cash, cash equivalents and investments

CAMBRIDGE, Mass., May 8, 2019 -- 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 for the first quarter of 2019 and provided business updates.

“We continue to execute against our corporate objectives as we progress clinical studies across our development portfolio, introduce a new mRNA rare disease development candidate and focus on identifying additional modalities and disease targets,” said Stéphane Bancel, Moderna’s chief executive officer. “We are excited to pursue a treatment to potentially address the underlying cause of glycogen storage disease type 1a, and we believe this candidate also reflects the continued productivity of our mRNA platform. At yesterday’s annual Science Day event, we presented new insights into our mRNA and delivery science, including the potential delivery of mRNA to white blood cells. While our team has additional research to perform in this area, we look forward to being able to bring new candidates into development as we continue working to help patients with a wide range of serious diseases.”

Moderna currently has 21 mRNA development candidates in its portfolio with 11 in clinical studies. Across Moderna's pipeline, more than 1,000 subjects have been enrolled in clinical studies. The Company’s updated pipeline can be found at www.modernatx.com/pipeline.

Summary of Recent Highlights by Modality

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 epidemic and pandemic threats to global public health.

- **Respiratory syncytial virus (RSV) vaccine (mRNA-1777 and mRNA-1172):** Merck has filed an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) and plans to run a Phase 1 study for a follow-on development candidate (mRNA-1172), a vaccine for RSV which has shown enhanced potency in preclinical studies and uses a Merck proprietary formulation. As a result, further development of mRNA-1777 has been paused and next steps will be determined based on data from the new mRNA-1172 Phase 1 study.
- **Varicella zoster virus (VZV) vaccine (mRNA-1278):** Based on an assessment of the commercial opportunity, research priorities and other factors, Merck has discontinued preclinical development of mRNA-1278, an investigational vaccine for VZV (the virus that causes shingles). Merck has returned rights to Moderna, and the Company will not continue development at this time.
- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** The first three dose levels in Moderna’s ongoing study of mRNA-1647 are fully enrolled, and the study is currently enrolling subjects into the fourth (300µg) dose cohort. The Phase 1 study is randomized, observer-blind and placebo-controlled with the goal of evaluating the safety and immunogenicity of mRNA-1647, a vaccine against the pentamer and gB complexes of CMV.

- **Presentation of note:** Moderna presented data from its Phase 1 studies of vaccines against viruses that cause respiratory diseases at the European Society for Pediatric Infectious Disease (ESPID) meeting held in Ljubljana, Slovenia.

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 vaccines (PCVs) (mRNA-4157, NCI-4650):** Two abstracts for Moderna PCV programs were accepted for presentation at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. Moderna will present new updates to clinical data from the Company's Phase 1 study of mRNA-4157, a PCV being studied alone in patients with resected solid tumors and in combination with Merck's pembrolizumab in patients with unresectable solid tumors. The National Cancer Institute (NCI) will also present data from its Phase 1 study of PCV NCI-4650, a monotherapy for patients with advanced metastatic cancers. The two abstracts are:
 - Moderna: *A Phase 1 multi-center study to assess the safety, tolerability and immunogenicity of mRNA-4157 alone in patients with resected solid tumors and in combination with pembrolizumab in patients with unresectable solid tumors.* Selected for a Poster Discussion, Saturday, June 1, 1:15 PM-2:45 PM CST.
 - NCI: *Immunogenicity and tolerability of personalized mRNA vaccine mRNA-4650 encoding defined neoantigens expressed by the autologous cancer.* Selected for a Poster Session, Saturday, June 1, 8:00 AM-11:00 AM CST.

Moderna and NCI PCVs are designed and manufactured individually based on the DNA sequence of a patient's tumor, encoding for peptides containing mutations found in their cancer in order to deliver multiple unique and personalized neoantigens in a single vaccine. Moderna's PCV now includes up to 34 neoantigens, up from 20. The NCI program uses Moderna's mRNA technology but uses a different neoantigen selection process and study design.

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

- **OX40L (mRNA-2416):** Moderna continues to enroll patients in its Phase 1/2 trial evaluating mRNA-2416, an intratumoral injection of mRNA encoding OX40L, for the treatment of advanced relapsed/refractory solid tumor malignancies and lymphomas and is also preparing to start enrollment of a Phase 2 expansion cohort of the study in patients with advanced ovarian carcinoma.
- **OX40L + IL23 + IL36 γ (Triplet) (mRNA-2752):** Moderna continues to dose a second cohort (0.5 mg) of patients in its ongoing Phase 1 study evaluating the safety and tolerability of mRNA-2752 for the treatment of advanced or metastatic solid tumor malignancies or lymphoma. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators designed to activate the immune system to recognize and eradicate tumors that are resistant to checkpoint inhibitors. It is being studied both as a single agent and in combination with AstraZeneca's durvalumab or tremelimumab.
- **IL12 (MEDI1191):** At the American Academy of Cancer Research (AACR) Annual Meeting in March, Moderna's strategic collaborator AstraZeneca shared preclinical data that supported advancing MEDI1191 into a Phase 1 clinical study. MEDI1191 is an mRNA encoding for IL12, a potent immunomodulatory cytokine, which aims to enhance immune response in immunologically "cold" tumors. AstraZeneca is now leading an open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with a checkpoint inhibitor.

Systemic Secreted Therapeutics: *In this modality, mRNA is delivered systemically to create proteins that are secreted outside the cell with the aim of producing pharmaceutically active proteins with therapeutic effects across the human body.*

- **Antibody against the chikungunya virus (mRNA-1944):** Moderna has completed enrollment of the second dose level cohort (0.3 mg/kg) of its Phase 1 study evaluating the safety and tolerability of escalating doses of
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mRNA-1944 via intravenous infusion in healthy adults. This is the first monoclonal antibody encoded by mRNA to be dosed in a human and the first development candidate from the Company's systemic secreted therapeutics modality to start clinical testing. The formulation used for mRNA-1944 is also utilized in Moderna's MMA program.

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):** Site initiation activities are ongoing for the Phase 1 study of mRNA-3704, Moderna's program for the rare metabolic disease MMA.
- **Propionic acidemia (PA) (mRNA-3927):** The European Commission (EC) has adopted the recommendation from the Committee for Orphan Medicinal Products for orphan drug designation for mRNA-3927, a development candidate for propionic acidemia (PA).

Additionally, enrollment continues in the Company's global natural history study of MMA and PA (MaP study). This is a global, multi-center, non-interventional study for patients with confirmed diagnosis of MMA due to methylmalonyl-CoA mutase (MUT) deficiency or PA and is designed to identify and correlate clinical and biomarker endpoints for these disorders.

- **Glycogen storage disease type 1a (GSD1a) (mRNA-3745):** Moderna has selected a new development candidate for the rare inherited metabolic disease GSD1a. GSD1a results in a buildup of glycogen in tissues and an inability to regulate glucose, due to mutations within the enzyme glucose 6-phosphatase (G6Pase), leading to life-threatening hypoglycemia and long-term liver and kidney damage. Patients with this disease incur metabolite buildup associated with hepatomegaly (enlarged livers), which can lead to benign and malignant liver tumors. mRNA-3745 is an IV-administered mRNA encoding G6Pase enzyme, designed to restore deficient or defective intracellular enzyme activity. This is expected to increase blood glucose levels, while decreasing levels of uric acid, lactic acid and triglycerides. In a mouse model, Moderna has shown the ability to improve hypoglycemia and other metabolic abnormalities associated with GSD1a, and mice treated with G6Pase mRNA showed a dose-dependent improvement in fasting glycemia and a reduction in both serum triglycerides and liver weight. There are approximately 6,500 GSD1a patients in the United States and the European Union. Disease management requires a strict diet to maintain blood glucose levels with some patients requiring a liver transplant. Preclinical data from this program were shared at the 22nd Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT).
- **Other systemic therapeutic preclinical research:** Also at ASGCT 2019, Moderna and academic collaborators gave oral presentations and shared data from seven preclinical animal studies using mRNA-based therapies for several rare diseases including: ornithine transcarbamylase deficiency (OTC) and maple syrup urine disease (MSUD) (in collaboration with the Gene Therapy Program at the Perelman School of Medicine, University of Pennsylvania); arginase-1 (ARG1) deficiency (in collaboration with the University of California, Los Angeles Department of Surgery and Department of Molecular and Medical Pharmacology); factor VIII deficiency (hemophilia A) (in collaboration with the Seattle Children's Research Institute); adult-onset type II citrullinemia (CTLN2); and progressive familial intrahepatic cholestasis type 3 (PFIC3). These programs are early research initiatives and presently are not Moderna development candidates.
- **Publication of note:** In March, Moderna published data in the *American Journal of Human Genetics* that showed preclinical proof-of-concept for administering mRNA encoding human α -Gal, across species, as a potential systemic mRNA therapy for the treatment of Fabry disease.

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 <https://investors.modernatx.com/>.

First Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and investments as of March 31, 2019 and December 31, 2018 were \$1.55 billion and \$1.69 billion, respectively.
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- **Net Cash Used in Operating Activities:** Net cash used in operating activities was \$143.9 million for the three months ended March 31, 2019 compared to \$111.4 million for the three months ended March 31, 2018. Net cash used in operating activities includes \$22.0 million and \$25.0 million in the first quarter of 2019 and 2018, respectively, of in-licensing payments to Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc., to sublicense certain patent rights. After 2019, we have no further in-licensing payment obligation to Cellscript and its affiliate.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was \$7.6 million for the three months ended March 31, 2019 compared to \$31.9 million for the three months ended March 31, 2018.
- **Revenue:** Total revenue was \$16.0 million for the three months ended March 31, 2019 compared to \$29.0 million for the three months ended March 31, 2018. On January 1, 2019, we adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. The total revenue decrease was mainly attributable to the decrease in collaboration revenue from all of our strategic alliances, particularly AstraZeneca and Merck, largely driven by the adoption of ASC 606. Total revenues under the previous revenue recognition standard would have been \$37.9 million for the first quarter of 2019.
- **Research and Development Expenses:** Research and development expenses were \$130.6 million for the three months ended March 31, 2019 compared to \$90.1 million for the three months ended March 31, 2018. The increase was primarily due to an increase in personnel related costs, including stock-based compensation, mainly driven by an increase in the number of employees supporting research and development programs, an increase in clinical trial and manufacturing costs, an increase in lab supplies and materials for our preclinical studies and clinical trials, and an increase in consulting and outside services costs.
- **General and Administrative Expenses:** General and administrative expenses were \$27.3 million for the three months ended March 31, 2019 compared to \$16.3 million for the three months ended March 31, 2018. The increase was mainly attributable to an increase in personnel related costs, including stock-based compensation, primarily driven by an increase in the number of employees, and consulting and outside services costs, both of which were related to operating as a publicly traded company.
- **Net Loss:** Net loss was \$132.7 million for the three months ended March 31, 2019 compared to \$72.4 million for the three months ended March 31, 2018.

Other Corporate Updates

- **Moderna Annual Science Day:** On May 7, Moderna hosted its annual Science Day, which featured presentations from Stephen Hoge M.D., president and Melissa Moore Ph.D., chief scientific officer of Moderna's mRNA research platform, and focused on some of the Company's latest advances in basic and applied mRNA science. This included improvements in the potency and delivery of potential mRNA medicines, and a new research program focused on delivery of mRNA to the immune system. The archived webcast of Science Day is available under "Events & Presentations" on the Investors section of the Moderna website at <https://investors.modernatx.com/> and will be available there for approximately 30 days.
- **Company Management:**
 - Moderna's mRNA platform chief scientific officer, Dr. Melissa Moore, was recently elected to the American Academy of Arts and Sciences.
 - Moderna's chief human resources officer, Annie Drapeau, left the Company in April to return to a human resources leadership role in the technology industry.

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Wednesday, March 8, 2019. To access the call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 8273939. A webcast of the call will also be available under "Events & Presentations" in the Investors section of

the Moderna website at <https://investors.modernatx.com/>. The archived webcast will be available on Moderna's website approximately two hours after the conference call and will be available for 30 days following the call.

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 Moderna the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immunology, 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, 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 four 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, but not limited to, statements concerning: mRNA-3745 as a potential treatment for GSD1a; the continued productivity of the Company's mRNA platform; and plans by AstraZeneca to initiate a Phase 1 clinical trial for MEDI1191 an mRNA for IL12. 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 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, among others: preclinical and clinical development is lengthy and uncertain, especially for a new category 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 mRNA drug has been approved in this new potential category of medicines, 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 category of medicines; and those risks and uncertainties described under the heading "Risk Factors" and those described 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.

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands)

	Three Months Ended March 31,	
	2019	2018
Revenue:		
Collaboration revenue	\$ 14,115	\$ 27,460
Grant revenue	1,910	1,579
Total revenue	16,025	29,039
Operating expenses:		
Research and development	130,575	90,124
General and administrative	27,283	16,317
Total operating expenses	157,858	106,441
Loss from operations	(141,833)	(77,402)
Interest income	10,972	5,209
Other expense, net	(287)	(156)
Loss before benefit from income taxes	(131,148)	(72,349)
Benefit from income taxes	(24)	—
Net loss	\$ (131,124)	\$ (72,349)

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

	March 31, 2019	December 31, 2018
Cash, cash equivalents and investments	\$ 1,546,583	\$ 1,694,417
Total assets	1,806,207	1,962,149
Total liabilities	360,174	431,908
Total stockholders' equity	1,446,033	1,530,241

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	\$ (143,927)	\$ (111,385)
Cash used for purchases of property and equipment	(7,595)	(31,909)

Contacts

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