

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): August 7, 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 (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 (§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.

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2019, Moderna, Inc. issued a press release announcing its results of operations and financial condition for the second quarter ended June 30, 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.

Exhibit No.	<u>Description</u>
99.1	Press release issued by Moderna, Inc. dated August 7, 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: August 7, 2019

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

Lorence Kim, M.D.
Chief Financial Officer

**MODERNA PROVIDES BUSINESS UPDATES AND REPORTS SECOND QUARTER 2019
FINANCIAL RESULTS**

Phase 2 Personalized Cancer Vaccine (mRNA-4157) study initiated, with first patient consented
Phase 1 CMV vaccine (mRNA-1647) study fully enrolled
Four new Phase 1 studies have begun, two in immuno-oncology and two in infectious diseases
Vertex Pharmaceuticals extended the companies' CF research collaboration
Ended quarter with \$1.44 billion in cash, cash equivalents and investments

CAMBRIDGE, Mass., August 7, 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 second quarter of 2019 and provided business updates.

New updates announced today include:

Infectious Diseases

- Enrollment complete for Phase 1 CMV vaccine (mRNA-1647) study
- Second planned interim analysis of Phase 1 hMPV and PIV3 vaccine (mRNA-1653) study showed antibody titers remained above baseline at all dose levels at seven months
- First subject dosed in Phase 1 RSV vaccine (mRNA-1172 or Merck V172) study
- First subject dosed in Phase 1 Zika vaccine (mRNA-1893) study

Immuno-Oncology

- First patient consented in Phase 2 PCV (mRNA-4157) study in patients with resected melanoma
- First patient dosed in Phase 1 KRAS cancer vaccine (mRNA-5671 or Merck V941) study
- First patient dosed in Phase 1 study of mRNA encoding IL12 (MEDI1191) injected intratumorally

Rare Diseases

- Six of eight subjects dosed in the third cohort (0.6 mg/kg) of the Phase 1 antibody against chikungunya virus (mRNA-1944) study; the lipid nanoparticle (LNP) formulation used for mRNA-1944 is also utilized in Moderna's MMA program
- Three clinical sites actively recruiting for Phase 1/2 MMA (mRNA-3704) study

Research

- Vertex Pharmaceuticals extended the companies' research collaboration in cystic fibrosis (CF)

“Since our last quarterly update, our personalized cancer vaccine program with Merck has advanced into Phase 2, the cytomegalovirus vaccine Phase 1 study has completed enrollment and four new Phase 1 trials in immuno-oncology and infectious diseases have begun,” said Stéphane Bancel, Moderna’s chief executive officer. “We are pleased by the advancement of our programs and look forward to sharing new clinical data in the near term. Additionally, we are excited that Vertex extended our research collaboration based on the teams’ progress to date. Our balance sheet remains strong, and we continue to deploy our capital toward the advancement and expansion of our development pipeline and the creation of potential new modalities.”

Moderna currently has 21 mRNA development candidates in its portfolio with 13 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. Moderna and collaborators have published more than 35 peer-reviewed papers, including 23 over the last 12 months.

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-1172 or V172):** The first subject has been dosed in the Phase 1 study of mRNA-1172 led by Merck. mRNA-1172 has shown enhanced potency in preclinical studies compared with the companies' first RSV candidate (mRNA-1777).
- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** The Phase 1 study of mRNA-1647 has been fully enrolled, at a top dose of 300µg. This randomized, observer-blind and placebo-controlled study is designed to evaluate the safety and immunogenicity of mRNA-1647, a vaccine encoding the gB and pentamer complexes of CMV. CMV is a common human pathogen and a leading cause of birth defects.
- **Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653):** Topline data from a second planned interim analysis of an ongoing Phase 1 randomized, observer-blind, placebo-controlled and dose-ranging study in healthy adults showed that hMPV and PIV3 serum neutralizing antibody titers remained above baseline through seven months and the vaccine was generally well-tolerated. Topline data from the study's first interim analysis, [announced](#) in February 2019, showed that mRNA-1653 boosted antibody titers one month after vaccination at all dose levels and was generally well-tolerated. Data from the study will be presented at IDWeek on October 2 - 6, 2019 in Washington, D.C. In a recent type C meeting with the U.S. Food and Drug Administration (FDA), the Company discussed a potential path forward to evaluate protection against both hMPV and PIV3 in a single Phase 3 study. Consistent with this development path, Moderna is planning to initiate a Phase 1b study of mRNA-1653 in seropositive toddler subjects as the next step.
- **Zika virus vaccine (mRNA-1893):** The first subject has been dosed in the Phase 1 study of mRNA-1893. This development candidate is being developed in collaboration with the U.S. Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.
- **Publications of note:** In May, Moderna published its clinical data in *Vaccine* from two Phase 1 studies showing that mRNA vaccines against H10N8 and H7N9 influenza viruses were well-tolerated and elicited robust immune responses. In July, Moderna published preclinical data in the *Journal of Infectious Diseases* demonstrating the ability of mRNA vaccines to protect against congenital Zika virus infection in mice.

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):** The first patient has been consented for the randomized Phase 2 study investigating Merck's pembrolizumab (KEYTRUDA[®]) in combination with a 1 mg dose of mRNA-4157, compared to pembrolizumab alone, for the adjuvant treatment of high-risk resectable melanoma. Additionally, the protocol for the ongoing Phase 1 trial has been amended to include a cohort of 17 patients who are refractory to PD-1 inhibitors.
- **KRAS vaccine (mRNA-5671 or V941):** The first patient was dosed in the Phase 1 open-label, multi-center study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with pembrolizumab. The study, led by Merck, will enroll patients with KRAS mutant advanced or metastatic non-small cell lung cancer, colorectal cancer or pancreatic adenocarcinoma, and centrally confirmed Human Leukocyte Antigen (HLA) HLA-A*1101 and/or HLA-C*0802 allele expression. mRNA-5671 is designed to

generate and present the four most prevalent KRAS mutations as neoantigens to the immune system. These four mutations comprise an estimated 80-90 percent of KRAS mutations in the study indications.

- **Presentations of note:** Moderna presented interim data from its ongoing Phase 1 study of PCV candidate mRNA-4157, demonstrating safety, tolerability and immunogenicity of mRNA-4157 alone and in combination with pembrolizumab, at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. Additionally, the National Cancer Institute (NCI) also presented data at ASCO from its Phase 1 study of PCV mRNA-4650 as a monotherapy for patients with advanced metastatic cancers. The NCI program uses Moderna's mRNA technology but uses a different neoantigen selection process and study design than Moderna's Phase 1 mRNA-4157 study.

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

- **OX40L (mRNA-2416):** Dosing is ongoing at the highest levels (8 mg) in the Phase 1/2 open-label, multi-center, dose escalation and efficacy study of intratumoral injections of mRNA-2416 in patients with advanced malignancies. A Phase 2 expansion cohort in patients with advanced ovarian carcinoma is preparing to start enrollment; this will include the combination of intratumoral mRNA-2416 with durvalumab (IMFINZI®).
- **OX40L + IL23 + IL36γ (Triplet) (mRNA-2752):** The first patient was dosed in the combination arm of the Phase 1 trial of mRNA-2752. This study is evaluating mRNA-2752 as a single agent and in combination with durvalumab in patients with accessible solid tumors and lymphomas. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators.
- **IL12 (MEDI1191):** The first patient was dosed with MEDI1191 monotherapy in the Phase 1 open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with a checkpoint inhibitor in patients with advanced solid tumors, being led by AstraZeneca. MEDI1191 is an mRNA encoding for IL12, a potent immunomodulatory cytokine.

***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):** Six of eight subjects have been dosed in the third cohort (0.6 mg/kg) of the Phase 1 antibody against chikungunya virus (mRNA-1944) study. This study is evaluating the safety and tolerability of escalating doses of mRNA-1944 via intravenous infusion in healthy adults. mRNA-1944 is the first monoclonal antibody encoded by mRNA to be dosed in a human and the first development candidate from Moderna's systemic secreted therapeutics modality to start clinical testing. The lipid nanoparticle (LNP) formulation used for mRNA-1944 is also utilized in Moderna's MMA program.
- **Publication of note:** In May, Moderna published preclinical data in *Science Immunology* showing mRNA encoding an antibody against the chikungunya virus (mRNA-1944) was well-tolerated, resulted in linear dose-dependent protein expression and provided complete protection in preclinical species.

***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):** Three clinical trial sites are open and actively recruiting patients for the Phase 1/2 open-label, dose escalation study evaluating mRNA-3704 for the treatment of MMA. The objectives of the study are to evaluate safety and tolerability, assess the pharmacodynamic response and characterize the pharmacokinetic profile of mRNA-3704. Moderna recently updated the study protocol to widen the age bracket of the first cohort for this trial to allow for the enrollment of pediatric patients (now includes patients 8 years and older, a modification from adolescents aged 12-18.) This is Moderna's first rare disease program to advance into clinical testing.

- **MMA and propionic acidemia (PA) Natural History Study (MaP):** As of July 15, 2019, a total of 71 patients have been enrolled in the study (35 MMA, 36 PA). 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.
- **Publication of note:** In July, Moderna published preclinical data in *EBioMedicine*, a *Lancet* publication, showing mRNA therapy demonstrated long-term efficacy and safety, with dose-dependent and reproducible biomarker responses, in mouse models of MMA.

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/>.

Research Update

- **Vertex CF research collaboration:** In July 2016, Moderna and Vertex announced an exclusive research [collaboration](#) and licensing agreement aimed at the discovery and development of mRNA therapeutics for the treatment of CF. Based on preclinical work to date, Vertex has extended this collaboration through the first quarter of 2020 with options to extend further based on future progress. Pulmonary mRNA delivery represents a potential new route of administration for Moderna.

Annual R&D Day

- Moderna will host its annual R&D Day in New York City on September 12, 2019.

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Wednesday, August 7, 2019. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international), and refer to conference ID 4799277. A webcast of the call will also be available under "Events and 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.

Second Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and investments as of June 30, 2019 and December 31, 2018 were \$1.44 billion and \$1.69 billion, respectively.
- **Net Cash Used in Operating Activities:** Net cash used in operating activities was \$256.1 million for the six months ended June 30, 2019 compared to \$159.6 million for the six months ended June 30, 2018. Net cash used in operating activities includes \$22.0 million and \$25.0 million for the six months ended June 30, 2019 and 2018, respectively, of in-licensing payments to Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc., to sublicense certain patent rights. After the first quarter of 2019, we have no further in-licensing payment obligations to Cellscript and its affiliate.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was \$18.2 million for the six months ended June 30, 2019 compared to \$66.0 million for the six months ended June 30, 2018.
- **Revenue:** Total revenue was \$13.1 million for the three months ended June 30, 2019 compared to \$28.9 million for the three months ended June 30, 2018. Total revenue was \$29.1 million for the six months ended June 30, 2019 compared to \$57.9 million for the six months ended June 30, 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 decreases in 2019 were due to decreases in collaboration revenue across all our strategic alliances, particularly AstraZeneca and Merck, largely driven by our adoption

of ASC 606. Total revenue under the previous revenue recognition standard would have been \$16.9 million and \$55.5 million for the three months and six months ended June 30, 2019, respectively.

- **Research and Development Expenses:** Research and development expenses were \$128.5 million for the three months ended June 30, 2019 compared to \$104.5 million for the three months ended June 30, 2018. The increase was primarily attributable to an increase in personnel related costs including stock-based compensation, an increase in lab supplies and materials, and an increase in clinical trial and manufacturing costs. Research and development expenses were \$259.1 million for the six months ended June 30, 2019 compared to \$194.6 million for the six months ended June 30, 2018. The increase was primarily attributable to an increase in personnel related costs including stock-based compensation, an increase in clinical trial and manufacturing costs, an increase in lab supplies and materials, and an increase in consulting and outside services.
- **General and Administrative Expenses:** General and administrative expenses were \$28.5 million for the three months ended June 30, 2019 compared to \$21.4 million for the three months ended June 30, 2018. The increase was mainly due to an increase in personnel related costs including stock-based compensation, and an increase in consulting and outside services. General and administrative expenses were \$55.8 million for the six months ended June 30, 2019 compared to \$37.7 million for the six months ended June 30, 2018. These increases were mainly due to the additional costs of operating as a publicly traded company, including an increase in personnel related costs and stock-based compensation, an increase in consulting and outside services, and an increase in information technology, facility and insurance related costs.
- **Net Loss:** Net loss was \$135.1 million for the three months ended June 30, 2019 compared to \$90.6 million for the three months ended June 30, 2018. Net loss was \$267.7 million for the six months ended June 30, 2019 compared to \$163.0 million for the six months ended June 30, 2018.

2019 Expected Cash Position

- Moderna reiterated its expectation for cash, cash equivalents and investments at December 31, 2019 to be in the range of \$1.15 billion to \$1.20 billion.

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, 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: sharing new clinical data in the near term; the advancement and expansion of Moderna's development pipeline and the creation of potential new modalities; the anticipated commencement of Moderna's clinical studies, including the Phase 1b study of

mRNA-1653 in seropositive toddler subjects and the Phase 2 expansion cohort of mRNA-2416 in patients with advanced ovarian carcinoma; whether mRNA-5671 will generate and present KRAS neoantigens from the four most prevalent KRAS mutations; and the Company's expected cash, cash equivalents, and investments at December 31, 2019. 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 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: preclinical and clinical development is lengthy and uncertain, especially for a new class 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 class 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 class of medicines; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with our regulatory approval strategies, components of our or filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; and those 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.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. IMFINZI is a registered trademark of AstraZeneca AB.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	\$ 10,030	\$ 25,831	\$ 24,145	\$ 53,291
Grant revenue	3,053	3,020	4,963	4,599
Total revenue	13,083	28,851	29,108	57,890
Operating expenses:				
Research and development	128,496	104,479	259,071	194,603
General and administrative	28,523	21,387	55,806	37,704
Total operating expenses	157,019	125,866	314,877	232,307
Loss from operations	(143,936)	(97,015)	(285,769)	(174,417)
Interest income	10,322	6,401	21,294	11,610
Other (expense) income, net	(1,764)	171	(3,584)	(12)
Loss before income taxes	(135,378)	(90,443)	(268,059)	(162,819)
(Benefit from) provision for income taxes	(324)	158	(348)	158
Net loss	\$ (135,054)	\$ (90,601)	\$ (267,711)	\$ (162,977)

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

	June 30,	December 31,
	2019	2018
Cash, cash equivalents and investments	\$ 1,435,378	\$ 1,694,417
Total assets	1,685,279	1,962,149
Total liabilities	346,725	431,908
Total stockholders' equity	1,338,554	1,530,241

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	\$ (256,147)	\$ (159,634)
Cash used for purchases of property and equipment	(18,181)	(65,989)