



Moderna Reports Third Quarter 2020 Financial Results and Provides Business Updates

October 29, 2020

Phase 3 study of COVID-19 vaccine candidate (mRNA-1273) fully enrolled with 30,000 participants, including 37% from diverse communities and 42% at high-risk of severe disease (>65 years or co-morbid risk factors)

Positive interim data from Phase 2 study of CMV vaccine candidate (mRNA-1647) announced during R&D Day; pivotal Phase 3 trial expected to begin in 2021

Received \$1.1 billion of customer deposits for supply of mRNA-1273 in Q3 2020, recorded as deferred revenue

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 29, 2020-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today reported financial results and provided business updates for the third quarter of 2020 and highlighted pipeline progress.

"The Moderna team continued to execute on our plan in the third quarter. We now have four programs in Phase 2 studies, in addition to the Phase 3 study of our COVID-19 vaccine, mRNA-1273, which is fully enrolled. Our CMV vaccine showed positive interim Phase 2 data and we are now preparing for the Phase 3 start in 2021. We are actively preparing for the launch of mRNA-1273 and we have signed a number of supply agreements with governments around the world. Moderna is committed to the highest data quality standards and rigorous scientific research as we continue to work with regulators to advance mRNA-1273," said Stéphane Bancel, Chief Executive Officer of Moderna. "I believe that if we launch our COVID-19 vaccine, 2021 could be the most important inflection year in Moderna's history. We will have the resources to scale Moderna to maximize the impact we can have on patients in the next 10 years through numerous new medicines."

New updates and recent progress include:

Infectious Diseases

- Phase 3 COVE study of COVID-19 vaccine candidate (mRNA-1273) conducted in collaboration with NIH and BARDA fully enrolled with 30,000 participants, including 37% from diverse communities
- Positive interim data from Phase 2 study of CMV vaccine candidate (mRNA-1647) announced during R&D Day on September 17; Moderna preparing for pivotal Phase 3 study expected to begin in 2021
- First cohort of Phase 1 study of RSV vaccine candidate (mRNA-1345) fully enrolled
- Resumed dosing pediatric participants in Phase 1b age de-escalation study of hMPV/PIV3 vaccine candidate (mRNA-1653) following COVID-19 disruptions

Oncology

- First patients dosed in Phase 2 dose expansion study of OX40L (mRNA-2416) in combination with durvalumab for ovarian cancer

Rare Diseases

- Rare pediatric disease designation received for next generation MMA candidate (mRNA-3705)
- Study start-up activities for Phase 1/2 study of PA candidate (mRNA-3927) have resumed following COVID-19 related pause and protocol amendment

Moderna currently has 21 mRNA development candidates in its portfolio with 13 in clinical studies. Across Moderna's pipeline, more than 32,000 healthy volunteers and patients have been enrolled in clinical studies, including the Phase 3 study of mRNA-1273. The Company's updated pipeline can be found at www.modernatx.com/pipeline. Moderna and collaborators have [published](#) more than 55 peer-reviewed papers.

Summary of Program Highlights by Modality

Core Modalities

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 threats to global public health. The Company's global public health portfolio is focused on epidemic and pandemic diseases for which funding has been sought from governments and non-profit organizations.

Infections transmitted from mother to baby

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** [Positive interim data](#) from the Phase 2 study assessing the safety, reactogenicity, and immunogenicity of different dose levels of mRNA-1647 were presented at Moderna's annual R&D Day. Based on the interim analysis of the Phase 2 study, the 100 µg dose has been chosen for the Phase 3 pivotal study, which is expected to begin in 2021. Moderna owns worldwide commercial rights for mRNA-1647.
- **Zika virus vaccine (mRNA-1893):** All dose cohorts (10, 30, 100 and 250 µg) in the Phase 1 study of mRNA-1893 have

completed enrollment. Moderna is preparing for a Phase 2 study of mRNA-1893. mRNA-1893 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. Moderna owns worldwide commercial rights to mRNA-1893.

Vaccines against respiratory infections

- **COVID-19 vaccine (mRNA-1273):** On October 22, the Phase 3 COVE study of COVID vaccine candidate (mRNA-1273) being conducted with NIH and BARDA [completed enrollment](#) with approximately 37% of participants from diverse communities; 25% were older (>65 years) and 17% had co-morbid risk factors. The Phase 1 interim analysis, [published](#) in *The New England Journal of Medicine* on July 14, showed that mRNA-1273 was generally well-tolerated across all age groups and induced rapid and strong immune responses against SARS-CoV-2. In the 18-55 age group, neutralizing antibody titers were observed in 100% of evaluated participants and at the 100 µg dose level selected for Phase 3, the geometric mean titers were above those seen in convalescent sera. Similarly, the second interim analysis of mRNA-1273, [published](#) in *The New England Journal of Medicine* on September 29, showed that mRNA-1273 induced consistently high levels of neutralizing antibody titers in all participants in the 56-70 and 71+ age groups. In addition, vaccination with mRNA-1273 elicited Th1-biased CD4 T cell responses in all age groups. The ongoing Phase 3 COVE study is a case-driven analysis with two planned interim analyses. At the first interim analysis, three potential outcomes include: the study meets the statistical hurdle (>74%) and the Company will be unblinded and will evaluate whether to proceed with a regulatory submission; the study does not meet the statistical hurdle and the study continues; or the study is determined to be futile. Moderna is committed to full transparency and will share the outcome of each interim analysis. BARDA, part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), partially supported the research and development of mRNA-1273 with federal funding under Contract no. 75A50120C00034. A summary of the Company's work to date on COVID-19 can be found [here](#). Moderna retains worldwide rights to develop and commercialize mRNA-1273.
- **Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653):** Sites have resumed dosing seropositive pediatric participants (12-36 months of age) in the Phase 1 study of hMPV/PIV3 study (mRNA-1653) following the COVID-19 related study disruption. Moderna owns worldwide commercial rights to mRNA-1653.
- **Pediatric respiratory syncytial virus (RSV) vaccine (mRNA-1345):** The first cohort of the Phase 1 study of mRNA-1345 is fully enrolled. This Phase 1 study includes initial dosing in adults, followed by age de-escalation into children. mRNA-1345 is a vaccine against RSV in young children encoding for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state. The Company intends to combine mRNA-1345 with mRNA-1653, its vaccine against hMPV and PIV3, to create a combination vaccine against RSV, hMPV and PIV3. There is no approved vaccine for RSV. Moderna owns worldwide commercial rights to mRNA-1345.
- **Seasonal influenza (flu):** At Moderna's annual R&D Day, the Company [announced](#) that it is entering the seasonal flu business. Seasonal flu (type A and type B) epidemics occur seasonally and vary in severity each year, causing respiratory illnesses and placing substantial burden on healthcare systems. Currently approved vaccines are 40-60% effective and face significant challenges from strain mismatch¹; high-risk groups would benefit from higher efficacy, which the Company believes its mRNA platform may be capable of delivering.
- **Pandemic influenza/H7N9 vaccine (mRNA-1851):** Discussions regarding funding the Company's pandemic influenza/H7N9 vaccine program through approval are ongoing.

Vaccines against highly prevalent viral infections

- **Epstein-Barr virus (EBV) vaccine (mRNA-1189):** mRNA-1189 is a vaccine against EBV containing five mRNAs that encode viral proteins (gp350, gB, gp42, gH and gL) in EBV. Similar to Moderna's CMV vaccine (mRNA-1647), the viral proteins in mRNA-1189 are expressed in their native membrane-bound form for recognition by the immune system. There is no approved vaccine for EBV. Moderna owns worldwide commercial rights to mRNA-1189.

Systemic Secreted & Cell Surface Therapeutics: *In this modality, mRNA is delivered systemically to create proteins that are either secreted or expressed on the cell surface.*

- **Antibody against the chikungunya virus (mRNA-1944):** Positive interim data from the Phase 1 study evaluating escalating doses of mRNA-1944 in the 0.6 mg/kg dose with steroid premedication cohort and two doses of 0.3 mg/kg (without steroid premedication) given one week apart cohort were presented at [Moderna's annual R&D Day](#) and demonstrated dose-dependent increases in levels of antibody against chikungunya. Safety and increased CHKV-IgG production in the two-dose regimen shows the platform's ability for repeat dosing.
- **IL-2 (mRNA-6231):** mRNA-6231 is an mRNA encoding for a long-acting tolerizing IL-2. This new autoimmune development

candidate is designed to preferentially activate and expand the regulatory T cell population. The Company plans to conduct a Phase 1 study of mRNA-6231 in healthy adult volunteers. mRNA-6231 uses the same LNP formulation as mRNA-1944. The Phase 1 study of mRNA-6231 will be the first clinical demonstration of subcutaneous administration of this delivery technology. Moderna owns worldwide commercial rights to mRNA-6231.

- **PD-L1 (mRNA-6981):** mRNA-6981 is an mRNA encoding for PD-L1. This new autoimmune development candidate is designed to augment cell surface expression of PD-L1 on myeloid cells to provide co-inhibitory signals to self-reactive lymphocytes. As an initial step to addressing a range of autoimmune indications, the Company intends to pursue proof-of-concept in a Phase 1 study of mRNA-6981 in type 1 autoimmune hepatitis (AIH), a condition that involves liver inflammation and can lead to cirrhosis and liver failure. mRNA-6981 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-6981.
- **Relaxin (AZD7970):** Partnered with AstraZeneca, AZD7970 is in preclinical development for the treatment of heart failure. Under the terms of the collaboration, AstraZeneca would sponsor the Phase 1 trial to assess safety, tolerability and duration of systemic exposure to the Relaxin protein. Moderna shares worldwide commercial rights to AZD7970 with AstraZeneca.

Exploratory Modalities

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 vaccine (PCV) (mRNA-4157):** The randomized Phase 2 study investigating a 1 mg dose of mRNA-4157 in combination with Merck's pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma is ongoing. The Phase 1 study is ongoing. Moderna shares worldwide commercial rights to mRNA-4157 with Merck.
- **Mutant KRAS vaccine (mRNA-5671 or V941):** 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, led by Merck, is ongoing. Moderna shares worldwide commercial rights to mRNA-5671 with Merck.

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

- **OX40L (mRNA-2416):** The Phase 1/2 study of mRNA-2416 alone and in combination with durvalumab (IMFINZI®) is ongoing. The Phase 2 dose expansion study of mRNA-2416 in combination with durvalumab in ovarian cancer patients is enrolling and the first patients have been dosed. Moderna owns worldwide commercial rights to mRNA-2416.
- **OX40L/IL-23/IL-36γ (Triplet) (mRNA-2752):** The Phase 1 trial evaluating mRNA-2752 as a single agent and in combination with durvalumab in patients with advanced solid tumor malignancies and lymphoma is ongoing. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators. Moderna owns worldwide commercial rights to mRNA-2752.
- **IL-12 (MEDI1191):** The Phase 1 open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with durvalumab in patients with advanced solid tumors, led by AstraZeneca, is ongoing. MEDI1191 is an mRNA encoding for IL-12, a potent immunomodulatory cytokine. Moderna shares worldwide commercial rights to MEDI1191 with AstraZeneca.

Localized Regenerative Therapeutics: *Localized production of proteins has the potential to be used as a regenerative medicine for damaged tissues.*

- **VEGF-A (AZD8601):** The Phase 2a study of AZD8601 VEGF-A, which is being developed for patients with ischemic heart disease undergoing coronary artery bypass grafting (CABG) surgery with moderately impaired systolic function, led by AstraZeneca, is ongoing. Moderna has licensed worldwide commercial rights to AZD8601 to AstraZeneca.

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-3705):** Moderna received rare pediatric designation for its next generation MMA candidate (mRNA-3705). The Company plans to file new IND and CTA applications for mRNA-3705 and will focus development efforts on that candidate going forward. mRNA-3705 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-3705.
- **Propionic acidemia (PA) (mRNA-3927):** Study start-up activities for the Phase 1/2 study of PA candidate (mRNA-3927) have resumed following COVID-19 related pause and protocol amendment. mRNA-3927 uses the same LNP formulation as mRNA-1944. Moderna owns worldwide commercial rights to mRNA-3927.
- **Publication of Note:** Publication in [Nature](#) shows mRNA therapy (mRNA-3927) restores functional PCC enzyme and metabolic function in long term repeat dose studies in mice.

- **MMA and PA Natural History Study (MaP):** This is a global, multi-center, non-interventional study for patients with confirmed diagnosis of MMA due to MUT deficiency or PA and is designed to identify and correlate clinical and biomarker endpoints for these disorders. Enrollment in the study has been completed.
- **Phenylketonuria (PKU) (mRNA-3283):** Individuals with PKU have a deficiency in phenylalanine hydroxylase (PAH) resulting in a reduced or complete inability to metabolize the essential amino acid phenylalanine into tyrosine. mRNA-3283 encodes human PAH to restore the deficient or defective intracellular enzyme activity in patients with PKU. mRNA-3283 is in preclinical development. Moderna owns worldwide commercial rights to mRNA-3283.
- **Glycogen storage disease type 1a (GSD1a) (mRNA-3745):** Individuals with GSD1a have a deficiency in glucose-6-phosphatase resulting in pathological blood glucose imbalance. mRNA-3745 is an IV-administered mRNA encoding human G6Pase enzyme, designed to restore the deficient or defective intracellular enzyme activity in patients with GSD1a. mRNA-3745 is in preclinical development. Moderna owns worldwide commercial rights to mRNA-3745.

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: investors.modernatx.com.

Research Updates

- **New collaboration with Vertex to treat cystic fibrosis using gene editing:** On September 16, Moderna and Vertex announced a new strategic research [collaboration](#) and licensing agreement aimed at the discovery and development of therapeutics that leverage Moderna's lipid nanoparticles (LNPs) and mRNA platform to deliver gene-editing therapies for the treatment of cystic fibrosis. The three-year research collaboration initially will focus on the discovery and optimization of novel LNPs and mRNAs that can deliver gene-editing therapies to cells in the lungs, enabling functional cystic fibrosis transmembrane conductance regulator (CFTR) protein to be produced.
- **Collaboration with Chiesi Group for mRNA therapeutics to treat pulmonary arterial hypertension (PAH):** On September 16, Moderna and Chiesi Group [announced](#) a mRNA therapeutics for the treatment of pulmonary arterial hypertension (PAH), a rare disease with an incidence of 2-5 per million adults².
- **New award from DARPA:** On October 8, the Defense Advanced Research Projects Agency (DARPA) [awarded](#) Moderna up to \$56 million to enable small-scale, rapid mobile manufacturing of nucleic acid vaccines and therapeutics as part of DARPA's Nucleic Acids On-Demand World-Wide (NOW) initiative to develop a medical countermeasure manufacturing platform.

Management Updates

- Moderna's General Counsel and Corporate Secretary, Lori Henderson, J.D., has announced her decision to retire in 2021. Moderna will begin the search for a new General Counsel as the Company continues on the path toward commercialization. Lori will remain with Moderna well into 2021 to ensure a smooth transition with Moderna's next General Counsel.

"I would like to thank Lori for her significant contributions during her time at Moderna, including helping us transition Moderna from a private to a public company and building a legal team to support the company during its rapid growth and expansion. She has been a great partner and champion of our people and our mission for patients. On behalf of Moderna, I thank Lori for her continued leadership and wish her all the best on her new life in retirement," said Stéphane Bancel.

- John Lepore [joined](#) Moderna as Senior Vice President, Government Engagement on August 10.
- Moderna [named](#) Michael Mulette Vice President, North America Commercial Operations on September 10.

COVID-19 Vaccine Supply Agreements & Regulatory Filings

- **North America:** On August 11, Moderna announced a [supply agreement](#) with the U.S. government for an initial 100 million doses of mRNA-1273. On September 22, Canada exercised an [increased option](#) for 20 million doses of mRNA-1273. On October 13, Moderna announced the initiation of a [rolling submission](#) to Health Canada for mRNA-1273.
- **Europe:** On August 24, Moderna confirmed [advanced discussions](#) with the European Commission to supply Europe with 80 million doses of mRNA-1273. On October 14, Moderna received confirmation of eligibility for submission of Marketing Authorization Application to the European Medicines Agency for mRNA-1273. On September 16, Moderna [announced](#) its first commercial organization outside of North America in Switzerland. Additionally, the Swiss Federal Government concluded an [agreement](#) with the Company for the procurement of 4.5 million doses of mRNA-1273. On October 27, the Company [announced](#) that the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom started the rolling review process of mRNA-1273.
- **Asia-Pacific:** On October 29, Moderna [confirmed](#) that the Ministry of Health, Labour and Welfare of Japan and Takeda Pharmaceutical Co., Ltd (NYSE: TAK) have agreed to purchase and distribute 50 million doses of mRNA-1273.
- **Middle East:** On June 17, the government of Israel [confirmed](#) a supply agreement with Moderna for mRNA-1273. On October 25, Moderna [announced](#) a supply agreement with the Ministry of Public Health of Qatar for mRNA-1273.

- **COVAX:** Discussions are ongoing with COVAX on a tiered pricing proposal for purchasing mRNA-1273.

Corporate Update

- On September 17, Moderna [hosted](#) its annual R&D Day

2020 Financial Update

- Moderna updates 2020 outlook, and now expects positive net cash provided by operating activities and used for purchases of property and equipment to be between \$0.1 billion and \$0.3 billion, driven by customer deposits of approximately \$1.2 billion received year-to-date as of September 30, 2020.
- The Company expects net cash provided by operating activities and purchases of property and equipment in 2020 to continue to evolve as it receives additional customer deposits.

Third Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and investments as of September 30, 2020 and December 31, 2019 were \$3.97 billion and \$1.26 billion, respectively.
- **Net Cash Provided by Operating Activities:** Net cash provided by operating activities was \$762.7 million for the nine months ended September 30, 2020 compared to \$(359.9 million) used in operating activities for the same period in 2019. Net cash provided by operating activities increased significantly in 2020 mainly due to an increase in deferred revenue attributable to deposits of \$1.17 billion received based on the supply agreements with the U.S. Government and several international government agencies for our future mRNA-1273 vaccine supply.
- **Cash Used for Purchases of Property and Equipment:** Cash used for purchases of property and equipment was \$44.1 million for the nine months ended September 30, 2020 compared to \$24.9 million for the same period in 2019.
- **Revenue:** Total revenue was \$157.9 million for the three months ended September 30, 2020 compared to \$17.0 million for the same period in 2019. Total revenue was \$232.7 million for the nine months ended September 30, 2020 compared to \$46.2 million for the same period in 2019. Total revenue increased for both the three month and nine month periods in 2020, due to increases in grant revenue, primarily due to our BARDA agreement related to our mRNA-1273 vaccine candidate development.
- **Research and Development Expenses:** Research and development expenses were \$344.5 million for the three months ended September 30, 2020 compared to \$119.6 million for the same period in 2019. Research and development expenses were \$611.5 million for the nine months ended September 30, 2020 compared to \$378.4 million for the same period in 2019. The increases for both the three month and nine month periods in 2020 were mainly due to increases in clinical trial expenses, an increase in raw materials and manufacturing costs, an increase in personnel related costs, and an increase in consulting and outside services, largely driven by increased headcount and mRNA-1273 clinical development.
- **General and Administrative Expenses:** General and administrative expenses were \$48.5 million for the three months ended September 30, 2020 compared to \$28.2 million for the same period in 2019. General and administrative expenses were \$109.3 million for the nine months ended September 30, 2020 compared to \$83.9 million for the same period in 2019. The increases were mainly due to an increase in personnel related costs, an increase in legal related costs, and an increase in consulting and outside services. The increases were primarily attributable to increased headcount and mRNA-1273 vaccine candidate development and commercialization activities.
- **Net Loss:** Net loss was \$233.6 million for the three months ended September 30, 2020 compared to \$123.2 million for the same period in 2019. Net loss was \$474.6 million for the nine months ended September 30, 2020 compared to \$390.7 million for the same period in 2019.

Investor Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Thursday, October 29, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 1938847. 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. A replay of the webcast will be archived on Moderna's website for one year following the presentation.

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 the Company 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, cardiovascular diseases, and autoimmune and inflammatory 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; 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 named a top biopharmaceutical employer by *Science* for the past five years. To learn more, visit www.modernatx.com.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Grant revenue	\$ 145,694	\$ 3,708	\$ 187,535	\$ 8,671
Collaboration revenue	12,216	13,338	45,115	37,483
Total revenue	157,910	17,046	232,650	46,154
Operating expenses:				
Research and development	344,486	119,637	611,479	378,355
General and administrative	48,541	28,173	109,277	83,913
Total operating expenses	393,027	147,810	720,756	462,268
Loss from operations	(235,117)	(130,764)	(488,106)	(416,114)
Interest income	5,571	9,252	20,515	30,546
Other expense, net	(3,226)	(1,881)	(5,910)	(5,689)
Loss before income taxes	(232,772)	(123,393)	(473,501)	(391,257)
Provision for (benefit from) income taxes	864	(178)	1,078	(526)
Net loss	\$ (233,636)	\$ (123,215)	\$ (474,579)	\$ (390,731)
Net loss per share, basic and diluted	\$ (0.59)	\$ (0.37)	\$ (1.26)	\$ (1.19)
Weighted average common shares used in net loss per share, basic and diluted	394,682,744	330,769,341	376,174,283	329,592,322

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CONDENSED CONSOLIDATED BALANCE SHEETS AND STATEMENTS OF CASH FLOWS DATA

(Unaudited, in thousands)

	September 30,	December 31,
	2020	2019
Cash, cash equivalents and investments	\$ 3,968,271	\$ 1,262,987
Total assets	4,650,873	1,589,422
Total liabilities	1,891,075	414,612
Total stockholders' equity	2,759,798	1,174,810
Total liabilities and stockholders' equity	4,650,873	1,589,422

Nine Months Ended September 30,

	2020	2019
Net cash provided by (used in) operating activities	\$ 762,682	\$ (359,946)
Cash used for purchases of property and equipment (44,147)		(24,892)

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 statements regarding: anticipated clinical next steps and catalysts for each of our development programs; the potential for mRNA-1273 to generate binding and neutralizing antibodies, as well as the safety and tolerability of mRNA-1273; expected timing for the Phase 3 pivotal trial of mRNA-1647; the timing of the first interim analysis and safety data for mRNA-1273, the disclosure of those events and subsequent actions to be taken by the Company; plans to create a combination vaccine; plans to enter the seasonal flu business and the ability for the Company to produce an effective flu vaccine; the ability for the Company's platform to facilitate repeat dosing; the potential for collaborations with strategic partners to produce new therapies; sales and supply agreements with governments for mRNA-1273 and the terms of such agreements; plans and timing for requesting regulatory approval for the use mRNA-1273 in the U.S. and other jurisdictions; and anticipated financial results for 2020, including with respect to net cash to be provided by operating activities and used for purchases of property and equipment and the receipt of cash deposits under mRNA-1273 supply agreements. 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: 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 commercial product using mRNA technology has been approved 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 the Company's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; 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 clinical trials, preclinical work, overall operations, regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q 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.

¹ Centers for Disease Control and Prevention. Vaccine Effectiveness: How Well Do the Flu Vaccines Work? Available at: <https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm>.

² Lancet Resp Medicine, Vol. 4, issue 4, p. 306-322, 2016

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