UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _ to _
Commission File Number: 001-38753

Moderna, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**81-3467528**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
200 Technology Square Cambridge, Massachusetts	**02139**
(Address of Principal Executive Offices)	(Zip Code)

(617) 714-6500
(Registrant's Telephone Number, Including Area Code)

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**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☑ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** ☐ **No** ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☑ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☑ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. **Yes** ☑ **No** ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). **Yes** ☐ **No** ☑

As of June 30, 2021, the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $80.8 billion based on the closing sale price on that date of $234.98. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the Registrant have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of February 18, 2022, there were 402,872,986 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to its 2022 Annual Meeting of Stockholders to be filed hereafter are incorporated by reference into Part III of this

Annual Report on Form 10-K where indicated.

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SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

- We may encounter difficulties producing, shipping or successfully commercializing our COVID-19 vaccine consistent with our existing or potential contractual obligations, including due to delays or difficulties experienced by our commercial partners;
- The pharmaceutical market is intensely competitive. We may be unsuccessful in competing effectively in the market for existing products, new treatment methods, and new technologies, including for COVID-19 vaccines;
- We may be delayed or prevented from receiving full regulatory approval of our COVID-19 vaccine in certain jurisdictions or for certain demographics;
- We may be unsuccessful in developing future versions of our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, or booster doses of our vaccine may not protect against such variants, and a market for vaccines and boosters against these variants may not develop;
- Preclinical 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 the clinic, any of which may have a material adverse impact on our platform or our business;
- Clinical development is lengthy and uncertain, especially with a new class of medicines such as mRNA medicines. Clinical trials of our investigational medicines may be delayed and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which could have a material adverse impact on our platform or our business;
- mRNA drug development has substantial clinical development and regulatory risks due to the novel nature of this new class of medicines, and the negative perception of the efficacy, safety, or tolerability profile of any investigational medicines that we or others develop could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals;
- Our mRNA products, including our COVID-19 vaccine, development candidates and investigational medicines are based on novel technologies and are complex and difficult to manufacture. We or our third-party manufacturers may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management, or shipping for any of our medicines;
- As our drug development pipeline increases and matures, the increased demand for clinical and commercial supplies from our facilities and third parties may impact our ability to operate. We rely on many service providers, all of whom have inherent risks in their operations that may adversely impact our operations;
- We are subject to significant regulatory oversight with respect to manufacturing our COVID-19 vaccine and our mRNA investigational medicines. Our manufacturing facilities or the manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by the FDA, EMA, and other global health authorities could result in significant delays in any approval of and costs of our products;
- We have in the past entered into, and in the future may enter into, strategic alliances with third parties for the development and commercialization of our and their products, development candidates and investigational medicines. If these strategic alliances are not successful, our business could be adversely affected;
- We may seek to establish additional strategic alliances and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our strategic alliance agreements may restrict our ability to develop certain products;
- If we are not able to obtain and enforce patent protection for our discoveries, or protect the confidentiality of our trade secrets, our ability to effectively compete using our development candidates will be harmed;
- Our reliance on government funding and collaboration from governmental and quasi-governmental entities for certain of our programs adds uncertainty to our research and development efforts with respect to those programs and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs;
- We have limited sales, distribution, and marketing experience, and have only recently invested significant financial and management resources to establish these capabilities. If we cannot effectively establish such capabilities or enter into agreements with third parties to market and sell our products or to help ensure compliance with local regulatory requirements, our ability to generate revenues may be adversely affected;
- Certain of our customers for our COVID-19 vaccine prepay us for a portion of the product payment for the vaccine doses that they expect to receive from us, and under the terms of certain of our supply agreements, we may be required to refund some or all of those prepayments if a customer reduces its purchase commitment or if we fail to deliver the purchased volume;
- We have a limited history of recognizing revenue from product sales and may not be able to achieve or maintain long-term sustainable profitability;

- We may encounter difficulties in managing the development and expansion of our company, which could disrupt our operations;
- Our internal computer systems and physical premises, or those of third parties with which we share sensitive data or information, may fail or suffer security breaches, which could materially disrupt our product development programs and manufacturing operations;
- We are subject to various and evolving laws and regulations governing the privacy and security of personal data, and our failure to comply could adversely affect our business, result in fines and/or criminal penalties, and damage our reputation;
- The price of our common stock has been volatile and fluctuates substantially, which could result in substantial losses for stockholders; and
- Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition, or results of operations.

You should consider carefully the risks and uncertainties described below, in the section entitled "Risk Factors" and the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, before you decide whether to purchase our common stock. The risks described above are not the only risks that we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our activities with respect to our COVID-19 vaccine, and our plans and expectations regarding future generations of our COVID-19 vaccine that we may develop in response to variants of the SARS-CoV-2 virus, ongoing clinical development, manufacturing and supply, pricing, commercialization, if approved, regulatory matters and third-party and governmental arrangements and potential arrangements;
- our ability to contract with third-party suppliers, distributors and manufacturers and their ability to perform adequately, particularly with respect to the timely production and delivery of our COVID-19 vaccine, including any variant booster vaccine candidates, if authorized;
- our ability and the ability of third parties with whom we contract to successfully manufacture our commercial products at scale, as well as drug substances, delivery vehicles, development candidates, and investigational medicines for preclinical and clinical use;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our commercial products, investigational medicines and technology;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- risks related to the direct or indirect impact of the COVID-19 pandemic or any future large-scale adverse health event, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, material delays in diagnoses, initiation or continuation of treatment for diseases that may be addressed by our development candidates and investigational medicines, or in patient enrollment in clinical trials, potential clinical trials, regulatory review or supply chain disruptions, and other potential impacts to our business, the effectiveness or timeliness of steps taken by us to mitigate the impact of the pandemic, and our ability to execute business continuity plans to address disruptions caused by the COVID-19 pandemic or future large-scale adverse health event;
- our anticipated next steps for our development candidates and investigational medicines that may be slowed down due to the impact of the COVID-19 pandemic, including our resources being significantly diverted towards our COVID-19 vaccine efforts, particularly if the federal government seeks to require us to divert such resources;

- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop development candidates and investigational medicines, including by applying learnings from one program to our other programs and from one modality to our other modalities;
- our ability to obtain and maintain regulatory approval of our investigational medicines;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our medicines, if approved;
- the implementation of our business model, and strategic plans for our business, investigational medicines, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our investigational medicines and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory, and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our investigational medicines, if approved;
- the size and growth potential of the markets for our investigational medicines, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our investigational medicines;
- legal and regulatory developments in the United States and foreign countries;
- our ability to produce our products or investigational medicines with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel; and
- developments relating to our competitors and our industry.

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on forward-looking statements. Factors that may cause actual results or events to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies

generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified the information contained in such sources.

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms “Moderna,” the “Company,” “we,” “us,” and “our” in this Annual Report on Form 10-K refer to Moderna, Inc. and its consolidated subsidiaries.

TRADEMARKS

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business

Moderna is pioneering a new class of medicines made of messenger RNA, or mRNA. The potential implications of using mRNA as a drug are significant and far-reaching and could meaningfully improve how medicines are discovered, developed, manufactured and administered.

Since our founding in 2010, we have transformed from a research-stage company advancing programs in the field of mRNA to a commercial enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle (LNP) formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna has established relationships with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of our manufacturing capabilities. Most recently, Moderna's capabilities have come together to allow the authorization and approval of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

In 2020, mRNA technology emerged as a new class of medicine. In under a year, we designed our vaccine against COVID-19 (mRNA-1273) using mRNA-based technology, conducted clinical trials, which demonstrated that the vaccine was highly effective at preventing COVID-19, and obtained an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and authorizations from other regulators around the world. During 2021, we shipped more than 800 million doses of our COVID-19 vaccine to countries around the globe to help fight the pandemic, with approximately 25% of those doses going to low- and middle-income countries. In January 2022, the FDA approved the Biologics License Application (BLA) for our COVID-19 vaccine, Spikevax®, for individuals 18 years of age and older in the United States.

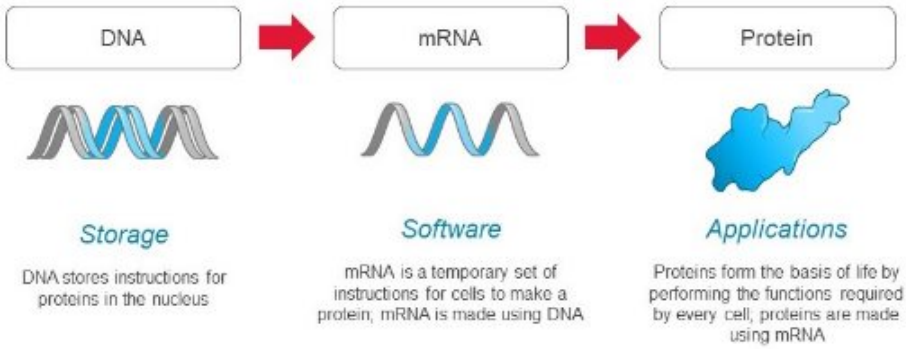
THE mRNA OPPORTUNITY

mRNA, the software of life

mRNA transfers the information stored in our genes to the cellular machinery that makes all the proteins required for life. Our genes are stored as sequences of DNA which contain the instructions to make specific proteins. DNA serves as a hard drive, safely storing these instructions in the nucleus until they are needed by the cell.

When a cell needs to produce a protein, the instructions to make that protein are copied from the DNA to mRNA, which serves as the template for protein production. Each mRNA molecule contains the instructions to produce a specific protein with a distinct function in the body. mRNA transmits those instructions to cellular machinery, called ribosomes, that make copies of the required protein.

We see mRNA functioning as the "software of life." Every cell uses mRNA to provide real time instructions to make the proteins necessary to drive all aspects of biology, including in human health and disease. This was codified as the central dogma of molecular biology over 50 years ago, and is exemplified in the schematic below.

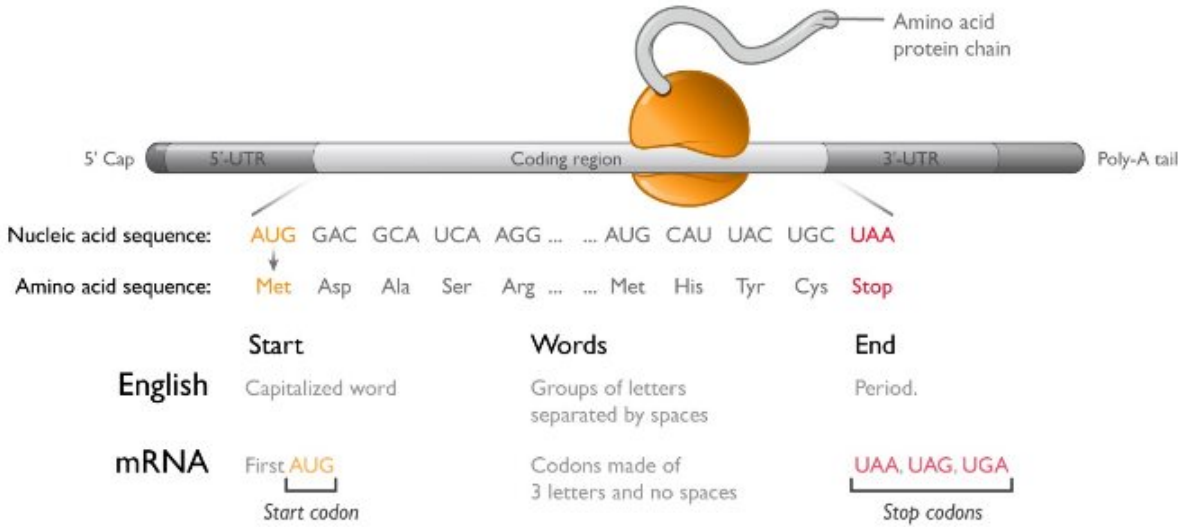


The structure of mRNA

Messenger RNA is a linear polymer comprising four monomers called nucleotides: adenosine (A), guanosine (G), cytosine (C), and uridine (U). Within the region of the molecule that codes for a protein, or the coding region, the sequence of these four nucleotides forms a language made up of three-letter words called codons. The first codon, or start codon (AUG), signals where the ribosome should start protein synthesis. To know what protein to make, the ribosome then progresses along the mRNA one codon at a time, appending the appropriate amino acid to the growing protein. To end protein synthesis, three different codons (UAA, UAG, and UGA)

serve as stop signals, telling the ribosome where to terminate protein synthesis. In total, there are 64 potential codons, but only 20 amino acids that are used to build proteins; therefore, multiple codons can encode for the same amino acid.

The process of protein production is called translation because the ribosome is reading in one language (a sequence of codons) and outputting in another language (a sequence of amino acids). The coding region is analogous to a sentence in English. Much like a start codon, a capitalized word can indicate the start of a sentence. Codons within the coding region resemble groups of letters representing words. The end of the sentence is signaled by a period in English, or a stop codon for mRNA.



In every cell, hundreds of thousands of mRNAs make hundreds of millions of proteins every day. A typical protein contains 200-600 amino acids; therefore, a typical mRNA coding region ranges from 600-1,800 nucleotides. In addition to the coding region, mRNAs contain four other key features: (1) the 5' untranslated region or 5'-UTR; (2) the 3' untranslated region or 3'-UTR; (3) the 5' cap; and (4) a 3' polyadenosine, or poly-A, tail. The sequence of nucleotides in the 5'-UTR influences how efficiently the ribosome initiates protein synthesis, whereas the sequence of nucleotides in the 3'-UTR contains information about which cell types should translate that mRNA and how long the mRNA should last. The 5' cap and 3' poly-A tail enhance ribosome engagement and protect the mRNA from attack by intracellular enzymes that digest mRNA from its ends.

The intrinsic advantages of using mRNA as a medicine

mRNA possesses inherent characteristics that we believe provide it with a strong foundation as a new class of medicines. These characteristics include:

- **mRNA is used by every cell to produce all proteins:** mRNA is used to make every type of protein, including secreted, membrane, and intracellular proteins, in varying quantities over time, in different locations, and in various combinations. Given the universal role of mRNA in protein production, we believe that mRNA medicines could have broad applicability across human disease.
- **Making proteins inside one's own cells mimics human biology:** Using a person's own cells to produce protein therapeutics or vaccine antigens provides certain advantages over existing technologies such as recombinant proteins, which are manufactured using processes that are foreign to the human body.
- **mRNA has a simple and flexible chemical structure:** Each mRNA molecule comprises four chemically similar nucleotides to encode proteins made from up to 20 chemically different amino acids. To make the full diversity of possible proteins, only simple sequence changes are required in mRNA.
- **mRNA has classic pharmacologic features:** mRNA possesses many of the attractive pharmacologic features of most modern medicines, including reproducible activity, predictable potency, and well-behaved dose dependency; mRNA also provides the ability to adjust dosing based on an individual patient's needs, including stopping or lowering the dose, to seek to ensure safety and tolerability.

mRNA as a new class of medicines

Unlike traditional approaches to medicine, where a protein or chemical is introduced to the body, we send tailored mRNA into cells to instruct them to produce specific proteins. Instead of starting from scratch for each new vaccine or therapy, our mRNA approach

leverages the technology and fundamental components that we have been researching and developing since our founding. Our success in developing, manufacturing and commercializing the Moderna COVID-19 vaccine further supports our belief that mRNA-based medicines as a class have the potential to help patients in far-reaching ways that could exceed the impact of traditional approaches to medicine.

We have developed four core beliefs about the value drivers of mRNA as a new class of medicines:

1. **mRNA has the potential to create an unprecedented abundance and diversity of medicines.** mRNA's breadth of applicability has the potential to create an extraordinary number of new mRNA-based medicines that are currently beyond the reach of recombinant protein technology.

2. **Advances in the development of our mRNA medicines reduce risks across our portfolio.** mRNA medicines share fundamental features that can be used to learn quickly across a portfolio. We believe that once safety and proof of protein production has been established in one program, the technology and biology risks of related programs that use similar mRNA technologies, delivery technologies, and manufacturing processes will decrease significantly.

3. **mRNA technology can accelerate discovery and development.** The software-like features of mRNA enable rapid *in silico* design and the use of automated high-throughput synthesis processes that permit discovery to proceed in parallel rather than sequentially. We believe these mRNA features can also accelerate drug development by allowing the use of shared manufacturing processes and infrastructure.

4. **The ability to leverage shared processes and infrastructure can drive significant capital efficiency over time.** We believe the manufacturing requirements of different mRNA medicines are similar and that at commercial scale, a portfolio of mRNA medicines will benefit from shared capital expenditures.

OUR STRATEGY

We believe that the development of mRNA as a new class of medicines, as evidenced by the development of mRNA-based vaccines during 2020, represents a significant breakthrough for patients and our industry. Our success in developing a highly effective vaccine against COVID-19, going from sequence selection, conducting clinical trials and to receipt of regulatory authorization for emergency use, all in less than a year, provides a visible example of the promise of mRNA-based medicine. The Moderna COVID-19 Vaccine/Spikevax has been authorized for use or approved in over 70 countries. In January 2022, the FDA approved the BLA for Spikevax for individuals 18 years of age and older in the United States. From the beginning of the pandemic through December 31, 2021, we delivered 824 million doses of our vaccine, helping to vaccinate millions of people worldwide and combat the pandemic. We believe our success in developing this vaccine has positive implications beyond infectious disease vaccines and across our entire pipeline. We currently have 44 programs in development, and our pipeline spans five therapeutic areas: infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and autoimmune diseases.

In order to deliver on the full scope of the mRNA opportunity and maximize long-term value for patients and investors, we have developed four pillars underlying our product strategy that guide our near-term and long-term goals:

1. **Continue to advance our COVID-19 program and bring to market a pan-respiratory annual booster vaccine.** Our long-term vision is to develop, and seek regulatory approval for, a convenient, annual, single-dose booster against as many respiratory viruses as possible. mRNA vaccines have the ability to combine multiple different antigens into one vaccine. We believe a single-dose booster would provide significant value to patients and healthcare systems, as compliance and convenience would increase and there would be a reduction in vaccine administration costs.

   This vision includes a single-dose booster vaccine against COVID-19, seasonal flu and respiratory syncytial virus (RSV). We are developing vaccines against each of these diseases individually, while also pursuing parallel development of combination vaccines. We are committed to bringing COVID-19 booster shots (variant-specific, if needed) to the market until the pandemic is under control. We have announced positive Phase 1 data for both our flu vaccine (mRNA-1010) and RSV vaccine (mRNA-1345). mRNA-1010 is preparing for a Phase 3 trial to start in 2022 and mRNA-1345 has started the Phase 3 portion of a pivotal Phase 2/3 study. We are also exploring agreements with governments around the world to establish local manufacturing capabilities in their countries, which would provide those governments with access to these annual vaccines, as well as future pandemic preparedness capabilities.

2. **Bring to market first-in-class vaccines against latent viruses.** Latent viruses, such as cytomegalovirus (CMV), Epstein-Barr virus (EBV) and human immunodeficiency virus (HIV), cause acute infections and significant long-term effects, or sequelae. CMV infection is the leading infectious cause of birth defects in children in the U.S. and is a major driver of immune dysfunction with aging, including cardiovascular diseases, cancer and cognitive impairment. EBV infection is a

major cause of infectious mononucleosis (IM), has been tied to increased risk of developing multiple sclerosis, and is associated with certain lymphoproliferative disorders, higher risk of developing cancer/autoimmune diseases and long-COVID. Untreated HIV infection causes impairment of the immune system, leading to acquired immunodeficiency syndrome (AIDS).

Our CMV vaccine (mRNA-1647) is in an ongoing pivotal Phase 3 study to evaluate the safety and efficacy of mRNA-1647 against primary CMV infection in women ages 16-40 years. Our prophylactic EBV vaccine (mRNA-1189) is in an ongoing Phase 1 study. We have two partnered HIV programs, one that is in an ongoing Phase 1 study (mRNA-1644) and another that is preparing to enter the clinic (mRNA-1547). In February 2022, we announced two new development candidates against herpes simplex virus (HSV) and varicella-zoster virus (VZV). Both of these candidates are in preclinical development.

3. **Bring to market therapeutics based on mRNA-encoded proteins.** We believe that mRNA medicines have the potential to provide patients with any therapeutic protein, including those targeting intracellular or membrane proteins. Across our therapeutics pipeline, we have 15 development programs across four therapeutic areas: oncology, cardiovascular, rare disease and autoimmune diseases.

   We have had positive, early signals in clinical studies in oncology, cardiovascular and rare diseases, demonstrating early proof-of-concept. However, we are still waiting to advance these programs through full clinical development and regulatory review, as we have done with our COVID-19 vaccine.

4. **Expand our portfolio through strategic investments that leverage or enhance our platform.** As we advance our existing technologies in mRNA and LNP delivery as well as our biology expertise, we believe we can expand our portfolio through collaborations. This strategy includes bringing forward novel nucleic acid editing capabilities through Moderna Genomics (MGX), which is our effort to expand the use of our platform to create more innovative drugs to help patients through complex gene editing. We are committed to advancing this research responsibly and are working toward identifying the right combinations of technologies that can leverage our platform and lead to further breakthroughs in this area.

   In December 2021, we announced a collaboration with Metagenomi, Inc., a genetic medicines company with a versatile portfolio of next-generation gene editing tools, focused on advancing new gene editing systems for *in vivo* human therapeutic applications. In January 2022, we announced a collaboration with Carisma Therapeutics, Inc. to discover, develop and commercialize *in vivo* engineered chimeric antigen receptor monocyte (CAR-M) therapeutics for the treatment of cancer.

The strategic principles that guide our approach are:

- **We seek to discover and develop a large pipeline in parallel.** Our goal is to address or prevent as many human diseases as our technology, talent, capital, and other resources permit. We do so as rapidly as we can, understanding both the urgency for patients and the need to be disciplined in our approach.

- **We undertake sustained, long-term investment in technology creation.** We aim to improve the performance of mRNA medicines in our current modalities, and to unlock new modalities, through investments within basic and applied science.

- **We focus on the pace and scale of our learning.** We seek to accelerate our progress by solving numerous technical problems in parallel rather than in sequence. We make significant investments in digital assets and research infrastructure to accelerate the pace and scale of our learning.

- **We integrate across the most critical parts of our value chain.** mRNA is a complex multicomponent system and we believe it demands integration. We believe that we must be directly engaged in research, drug discovery, drug development, process and analytical development, and manufacturing to accelerate our learning, reduce our risk, and protect our critical know-how.

- **We forward invest in core enabling capabilities and infrastructure.** To execute across a broad pipeline, we need to invest at risk before we have all the answers. Our forward investments focus on areas where lead times are long and where early investments can reduce execution risk and accelerate future progress. We proactively invested in a dedicated manufacturing facility, the Moderna Technology Center (MTC), in Norwood, Massachusetts, to support the anticipated growth of our pipeline, and this early investment greatly facilitated our ability to respond to the COVID-19 pandemic by allowing us to begin production of our vaccine even before we received regulatory authorization for its distribution.

OUR PLATFORM

Overview of our platform

Our mRNA "platform" refers to our accumulated knowledge and capabilities in basic and applied sciences. There are three key components to our platform: mRNA, delivery, and the manufacturing process. Our platform incorporates advances across all three of these areas as we advance our medicines. It is the integration of these components that allows us to make our medicines and we combine different versions of mRNA delivery and process into each of our medicines.

There are common features between groups of medicines, which we call "modalities." These modalities are the application of our platform – the groupings have common features in mRNA or delivery technology or in the process by which they are made. This strategy allows us to manage risk across development programs as well as to understand, in cases of success, where we can rapidly expand and build on success with similar programs.

The primary goal of our platform is to identify new modalities and to expand the utility of our existing modalities. Programs within a modality often have correlated technology risk, but because they pursue diverse diseases, they often have uncorrelated biology risk. Each time we add a modality and a new medicine to our portfolio, we create a network effect because each incremental program can help us gain additional insight into the other the programs in our pipeline.

We have created seven modalities to date:

- Prophylactic vaccines
- Systemic secreted and cell surface therapeutics
- Cancer vaccines
- Intratumoral immuno-oncology
- Localized regenerative therapeutics
- Systemic intracellular therapeutics
- Inhaled pulmonary therapeutics

Our platform: mRNA science advancements

We continue to invest in both basic and applied research, seeking to advance both the state of our technology and the state of the scientific community's understanding of mRNA. Examples of advances in mRNA science that combine nucleotide chemistry, sequence engineering, and targeting elements are described below.

mRNA chemistry: Modified nucleotides to mitigate immune system activation: The innate immune system has evolved to protect cells from foreign RNA, such as viral RNA, by inducing inflammation and suppressing mRNA translation once detected. Many cells surveil their environment through sensors called toll-like-receptors (TLRs). These include types that are activated by the presence of double-stranded RNA (TLR3) or uridine containing RNA fragments (TLR7, TLR8). Additionally, all cells have cytosolic double-stranded RNA, sensors, including retinoic acid inducible gene-I (RIG-I) that are sensitive to foreign RNA inside the cell.

The immune and cellular response to mRNA is complex, context specific, and often linked to the sensing of uridine. To minimize undesired immune responses to our potential mRNA medicines, our platform employs chemically-modified uridine nucleotides to minimize recognition by both immune cell sensors such as TLR3/7/8, and broadly-distributed cytosolic receptors such as RIG-I.

mRNA sequence engineering: Maximizing protein expression: mRNA exists transiently in the cytoplasm, during which time it can be translated into thousands of proteins before eventually being degraded. Our platform applies bioinformatic, biochemical, and biological screening capabilities, most of which have been invented internally that aim to optimize the amount of protein produced per mRNA. We have identified proprietary sequences for the 5'-UTR that have been observed to increase the likelihood that a ribosome bound to the 5'-end of the mRNA transcript will find the desired start codon and reliably initiate translation of the coding region. We additionally design the nucleotide sequence of the coding region to maximize its successful translation into protein.

Targeting elements: Enabling tissue-targeted translation: All nucleated cells in the body are capable of translating mRNA, resulting in pharmacologic activity in any cell in which mRNA is delivered and translated. To minimize or prevent potential off-target effects, our platform employs technologies that regulate mRNA translation in select cell types. Cells often contain short RNA sequences, called microRNAs or miRNAs, that bind to mRNA to regulate protein translation at the mRNA level. Different cell types have different concentrations of specific microRNAs, in effect giving cells a microRNA signature. microRNA binding directly to mRNA effectively silences or reduces mRNA translation and promotes mRNA degradation. We design microRNA binding sites into the 3'-UTR of our potential mRNA medicines so that if our mRNA is delivered to cells with such microRNAs, it will be minimally translated and rapidly degraded.

Our platform: Delivery science

Our mRNA can, in specific instances, such as our VEGF therapeutic, be delivered by direct injection to a tissue in a simple saline formulation without LNPs to locally produce small amounts of pharmacologically active protein. However, the blood and interstitial fluids in humans contain significant RNA degrading enzymes that rapidly degrade any extracellular mRNA and prevent broader distribution without LNPs. Additionally, cell membranes tend to act as a significant barrier to entry of large, negatively-charged molecules such as mRNA. We have therefore invested heavily in delivery science and have developed LNP technologies to enable delivery of larger quantities of mRNA to target tissues.

LNPs are generally composed of four components: an amino lipid, a phospholipid, cholesterol, and a pegylated-lipid (PEG-lipid). Each component, as well as the overall composition, or mix of components, contributes to the properties of each LNP system. LNPs containing mRNA injected into the body rapidly bind proteins that can drive uptake of LNPs into cells. Once internalized in endosomes within cells, the LNPs are designed to escape the endosome and release their mRNA cargo into the cell cytoplasm, where the mRNA can be translated to make a protein and have the desired therapeutic effect. Any mRNA and LNP components that do not escape the endosome are typically delivered to lysosomes where they are degraded by the natural process of cellular digestion. Examples of tools we developed by using our platform include proprietary LNP formulations that address the steps of mRNA delivery, including cell uptake, endosomal escape, and subsequent lipid metabolism, and for avoidance of counterproductive interactions with the immune system.

Chemistry: Novel lipid chemistry to potentially improve safety and tolerability: We initially used LNP formulations that were based on known lipid systems, which we refer to as "legacy LNPs." A recognized limitation of these legacy LNPs is the potential for inflammatory reactions upon single and repeat administration that can impact tolerability and therapeutic index. Our later-developed, proprietary LNP systems are therefore designed to be highly tolerated and minimize any LNP vehicle-related toxicities with repeat administration *in vivo*. The changes we made have included engineering amino lipids to avoid the immune system and to be rapidly biodegradable relative to prior lipids.

Composition: Proprietary LNPs enhance delivery efficiency: Our platform includes extensive in-house expertise in medicinal chemistry, which we have applied to design large libraries of novel lipids. Using these libraries in combination with our discovery biology capabilities, we have conducted high throughput screens for desired LNP properties and believe that we have made fundamental discoveries in preclinical studies about the relationships between structural motifs of lipids and LNP performance for protein expression.

Surface properties: Novel LNP design to avoid immune recognition: We have designed our proprietary LNP systems for sustained pharmacology upon repeat dosing by eliminating or altering features that activate the immune system. These are based on insights into the surface properties of LNPs. Upon repeated dosing, surface features on traditional LNPs such as amino lipids, phospholipids, and PEG-lipids, can be recognized by the immune system, leading to rapid clearance from the bloodstream, a decrease in potency upon repeat dosing, and an increase in inflammation. Based on our insights into these mechanisms, we have engineered our LNP systems to reduce or eliminate undesirable surface features. In preclinical studies in non-human primates for our systemic therapeutic development candidates that use our novel LNP systems, we have been able to repeat dose with negligible or undetectable loss in potency, liver damage, and immune system activation.

Our platform: Manufacturing process science

We invest significantly in manufacturing process science to impart more potent features to our mRNA and LNPs, and to invent the technological capabilities necessary to manufacture our mRNA medicines at scales ranging from micrograms to kilograms, as well as achieve pharmaceutical properties such as solubility and shelf life. We view developing these goals of manufacturing and pharmaceutical properties as appropriate for each program, based on its stage of development.

mRNA manufacturing process: Improving pharmacology: Our platform creates mRNA using a cell-free approach called *in vitro* transcription in which an RNA polymerase enzyme binds to and transcribes a DNA template, adding the nucleotides encoded by the DNA to the growing RNA strand. Following transcription, we employ proprietary purification techniques to ensure that our mRNA is free from undesired synthesis components and impurities that could activate the immune system in an indiscriminate manner. Applying our understanding of the basic science underlying each step in the manufacturing process, we have designed proprietary manufacturing processes to impart desirable pharmacologic features, for example increasing potency in a vaccine.

LNP manufacturing process: Improving pharmacology: Our platform technology includes synthetic processes to produce LNPs. Traditionally LNPs are assembled by dissolving the four molecular components, amino lipid, phospholipid, cholesterol, and PEG-lipid, in ethanol and then mixing this with mRNA in an aqueous buffer. The resulting mixture is then purified to isolate LNPs from impurities. Such impurities include molecular components that have not been incorporated into particles, un-encapsulated mRNA that could activate the immune system, and particles outside of the desired size range. Going beyond optimization of traditional manufacturing processes, we have invested in understanding and measuring the various biochemical and physical interactions during LNP assembly and purification. We have additionally developed state-of-the-art analytical techniques necessary to characterize our LNPs and biological systems to analyze their *in vitro* and *in vivo* performance. With these insights, we have identified manufacturing process parameters that drive LNP performance, for example, the potency in a secreted therapeutic setting. These insights have allowed us to make significant improvements in the efficiency of our processing and the potency of our LNPs.

Manufacturing facilities and scale: One of the key aspects of our mRNA platform is that a single manufacturing facility can be used to manufacture any of our mRNA medicines. In 2016, following positive Phase 1 data, we decided to build our clinical manufacturing site in Norwood, Massachusetts. This facility produces not only mRNA medicines for all of our preclinical experiments and clinical trials, but has also produced millions of doses of our COVID-19 vaccine for commercial use. We have also partnered with Lonza and additional contract manufacturing organizations (CMOs) to scale up our manufacturing capabilities globally in an effort to combat the COVID-19 pandemic. We are currently working with governments in different geographies to build additional manufacturing facilities, with a view toward being able to combat future pandemics.

Demonstrations of our platform

Since our founding in 2010, we have made considerable advancements across our platform. Several examples are described below.

Dose-dependent protein expression in the clinic: We have demonstrated in the clinic the ability to generate consistent dose dependent levels of protein (antibodies) as well as the ability to safely repeat dose. For example, we demonstrated the ability to safely repeat dosing in the Phase 1 study of our Chikungunya Antibody program (mRNA-1944), which demonstrated dose-dependent increases in levels of antibodies against chikungunya.

Reproducible pharmacology, including upon repeated dosing: By combining advances in mRNA, delivery, and manufacturing process science, we have demonstrated in preclinical studies sustained and reproducible pharmacology. An example is seen in a mouse model that recapitulates metabolic defects in propionic acidemia (PA). In this rare disease, a defect in one or both of two different subunits (PCCA and PCCB) of the mitochondrial enzyme propionyl-CoA carboxylase results in accumulation of toxic metabolites such as 2-methylcitrate (2MC). In mice hypomorphic for the PCCA subunit, monthly intravenous (IV) administration of mRNAs encoding PCCA and PCCB formulated in our proprietary LNP (mRNA-3927) resulted in a significant and sustained lowering of 2MC throughout the duration of the 6-month study compared to control (luciferase) mRNA (1 mg/kg, n=6/group).

Decreased immune activation upon repeat dosing in non-human primates: We have observed decreased immune activation which enables repeat dosing in non-human primates. Published data indicates serum concentration of human erythropoietin (hEPO) with repeat dosing of mRNA encoding hEPO in our proprietary LNPs with weekly IV administration at 0.2 mg/kg in non-human primates.

Pharmacologic activity in the target tissue and cell: While some of our modalities, such as systemic secreted therapeutics, can leverage many different cell types to make therapeutic proteins, others such as systemic intracellular therapeutics, may require delivery of our mRNA into specific tissues and cell types, for instance hepatocytes in certain liver metabolic diseases. Combining our proprietary mRNA, delivery, and manufacturing process technologies we have observed on-target pharmacologic activity in hepatocytes in non-human primates. The on-target potency of this approach contrasts with traditional delivery technologies. In published data, we have shown one of our proprietary LNPs with increased hepatocyte transfecting properties result in protein expression in liver hepatocytes in non-human primates (demonstrated with a reporter protein detected by immunohistochemistry at 6 hours after IV infusion at 2 mg/kg). Additionally, this LNP results in extended expression of a secreted reporter protein in non-human primates as compared to one of our other proprietary LNPs after IV delivery at 0.1mg/kg.

Our platform's future: Improving and expanding our modalities

We are committed to sustaining investment in our platform, both in basic science to elucidate new mechanistic insights, and in applied science to discover new technologies that harness these insights. Our platform investments have enabled seven modalities to date, most of which have already led to multiple development candidates and investigational medicines in our pipeline. We believe that sustaining our investment in platform research and development will enable further improvements in the current modalities and will lead to the creation of new modalities, both of which will benefit our clinical pipeline in the years ahead.

OUR MODALITIES

Our approach to developing modalities

Within our platform, we develop technologies that enable the development of mRNA medicines for diverse applications. When we identify technologies that we believe could enable a new group of potential mRNA medicines with shared product features, we call that group a "*modality*." While the programs within a modality may target diverse diseases, they share similar mRNA technologies, delivery technologies, and manufacturing processes to achieve shared product features. The programs within a modality will also generally share similar pharmacology profiles, including the desired dose response, the expected dosing regimen, the target tissue for protein expression, safety and tolerability goals, as well as pharmaceutical properties.

Illustrating our approach: From our first modality to today

We started with prophylactic vaccines as our first modality because we believed this modality faced lower technical hurdles, relative to other areas. Our early formulations of mRNA tended to stimulate the immune system, which would present a challenge to therapeutics but was a desired feature for vaccines. In addition, many potential prophylactic vaccine antigens are well-characterized, allowing us to reduce biology risk. Lastly, the dosing regimens for vaccines require as few as one or two administrations, and generally involve relatively low doses.

For our first programs in this modality we chose our H10N8 and H7N9 pandemic influenza vaccines, each requiring expression of a single membrane protein. We chose to pursue two programs in separate, but parallel, clinical trials to establish the flexibility of our platform. When both programs met our goals for safety, tolerability, and pharmacology, we accelerated and expanded our vaccine pipeline to include multiple commercially meaningful and increasingly complex vaccines.

These included a combination vaccine, designed to protect against two unrelated respiratory viruses, human metapneumovirus (hMPV) and human parainfluenza 3 (PIV3), and a vaccine that combines six different mRNAs, our CMV vaccine, to express a complex pentameric antigen. We also sought strategic alliances with the Defense Advanced Research Projects Agency (DARPA), the Biomedical Advanced Research Development Authority (BARDA) and Merck & Co. (Merck), to allow us to rapidly expand our pipeline and complement our capabilities with their expertise. This early work in the prophylactic vaccines modality led to the ability to introduce our COVID-19 vaccine during 2020 in response to the ongoing pandemic.

Over time, we have taken on more challenging applications and technological hurdles with each successive modality, but we have also tried to build upon our prior experiences to manage risk. For example, in our cancer vaccines modality, we are now applying our technology to elicit T cell responses to potentially recognize and eradicate cancer as a logical extension of our prophylactic vaccines modality. Having demonstrated local expression of protein in our vaccines, we expanded into local therapeutic applications. For example, in our intra-tumoral immuno-oncology modality, we are seeking to use local expression to drive anti-cancer T cell responses by transforming tumor microenvironments. We can also use local expression to drive regenerative processes as in our Vascular Endothelial Growth Factor A (VEGF-A) program. We expanded into two new modalities that use systemic delivery of mRNA to encode secreted and cell surface or intracellular proteins. Most recently, following a breakthrough in pulmonary delivery stemming from our partnership with Vertex Pharmaceuticals (Vertex), we expanded into the inhaled pulmonary therapeutics modality with our cystic fibrosis (CF) program.

Expanding within our designated core modalities

In 2020, we designated the prophylactic vaccines and systemic secreted and cell surface therapeutics modalities as "core modalities" following positive Phase 1 data from our CMV vaccine and chikungunya antibody program, respectively. We believed that this data reduced the risk of these modalities, and our strategy is to invest in additional development candidates within these modalities.

We believe our portfolio of modalities—each with distinct technological and biological risk profiles—allows us to maximize long-term value for patients and investors. We see our seven current modalities as seven distinct product pipelines that represent different risk profiles and benefit from common infrastructure and a shared platform technology. We believe the high technology correlation within a modality allows us to rapidly accelerate the expansion of the pipeline in that modality based on learnings from the initial programs. We believe the lower technology correlation between modalities allows us to compartmentalize the technology risks. We believe our ongoing investments in our platform will lead to the identification of additional new modalities in the future, and will expand the diversity of our pipeline.

Modality descriptions

We currently have seven modalities, described in more detail below:

- **Prophylactic vaccines**: The goal of any vaccine is to safely pre-expose the immune system to a small quantity of a protein from a pathogen, called an antigen, so that the immune system is prepared to fight the pathogen if exposed in the future, and prevent infection or disease.

  We believe mRNA vaccines have several advantages: (1) ability to mimic many aspects of natural viral infections, (2) multiplexing of mRNA for more compelling product profiles, (3) rapid discovery and advancement of mRNA programs into the clinic, and (4) capital efficiency and speed from shared manufacturing processes and infrastructure.

- **Cancer vaccines:** The goal of a cancer vaccine is to safely expose the patient's immune system to tumor related antigens, known as neoantigens, to enable the immune system to elicit a more effective antitumor response. Our cancer vaccines modality is focused on the use of mRNA to express neoantigens found in a particular tumor in order to elicit an immune response via T cells that recognize those neoantigens, and therefore the tumor. These neoantigens can either be unique to a patient or can be related to a driver oncogene found across subsets of patients. Recent breakthroughs in cancer immunotherapy, such as checkpoint inhibitors and chimeric antigen receptor T cell therapies, have demonstrated that powerful antitumor responses can be achieved by activating antigen specific T cells. We believe one approach to improve the efficacy of checkpoint inhibitors is to develop vaccines that increase both the number and antitumor activity of a patient's T cells that recognize tumor neoantigens.

  We believe that mRNA technology is an attractive approach for cancer vaccines: (1) mRNA vaccines can deliver multiple neoantigens concatenated in a single mRNA molecule, (2) mRNA encoding for neoantigens is translated and processed by patients' endogenous cellular mechanisms for presentation to the immune system, and (3) mRNA vaccines can be efficiently personalized.

- **Intratumoral immuno-oncology:** The goal of this modality is to treat or cure cancer by transforming the tumor microenvironment to drive anti-cancer T cell responses against tumors. The outlook for any patients with advanced cancer remains poor, especially in tumors that have little immune system engagement (sometimes termed immunologically "cold"). In conjunction with a checkpoint inhibitor, we aim to activate the immune system against these otherwise immunologically cold tumors. Intratumoral administration allows for localized effect of these therapeutics that could be toxic if administered systemically.

  We believe our approach to immuno-oncology using mRNA medicines could complement checkpoint inhibitors and has several advantages over recombinant protein-based drugs: (1) mRNA focuses and limits exposure of immune stimulatory proteins, (2) mRNA can produce membrane associated immune stimulatory proteins, (3) multiplexing of mRNA allows access to multiple immune stimulatory pathways, (4) mRNA sequences can be engineered to reduce off-target effects, and (5) local administration of mRNA can create a concentration gradient for encoded proteins.

- **Localized regenerative therapeutics:** The goal of this modality is to develop mRNA medicines to address injured or diseased tissues by locally producing proteins that provide a therapeutic benefit in the targeted tissue. There are multiple applications for tissue regeneration and our initial focus is on cardiovascular diseases.

  We believe our approach to localized regenerative therapeutics using mRNA has several advantages over alternative approaches: (1) mRNA can be administered locally to produce the desired protein for an extended duration, (2) local administration of mRNA allows for focused activity, and (3) mRNA allows for dose-dependent and repeated production of the encoded protein.

- **Systemic secreted and cell surface therapeutics:** The goal of this modality is to provide secreted proteins, such as antibodies or enzyme replacement therapies across a wide range of diseases, such as heart failure, infectious diseases, and rare genetic diseases. Our mRNA medicines instruct various cells of the human body to secrete proteins for therapeutic effect. Systemically delivered, secreted and cell surface therapeutics, we believe, would allow us to target areas of biology that cannot be addressed using recombinant proteins.

  Our potential advantages in this area include: (1) mRNA can produce hard-to-make or complex secreted proteins, (2) mRNA can produce membrane associated proteins, (3) native post-translational modifications are possible through intracellular protein production using mRNA, (4) mRNA can sustain production of proteins, which can increase exposure to proteins with short half-lives, and (5) mRNA allows for desirable pharmacology in rare genetic diseases currently addressed by enzyme replacement therapies.

- **Systemic intracellular therapeutics:** The goal of this modality is to provide intracellular proteins, such as intracellular enzymes and organelle-specific proteins, as safe, tolerable, and efficacious therapies. Our mRNA medicines aim to increase levels of intracellular proteins to achieve a therapeutic effect in one or more tissues or cell types and our initial focus is on rare genetic diseases. Intracellular therapeutics are not currently addressable with recombinant proteins, which are typically administered systematically and cannot reach inside of the cell.

  Our potential advantages in these areas include: (1) using mRNA to encode for intracellular and organelle-specific proteins; mRNA can produce hard-to-make or complex proteins, (2) native post-translational modifications are possible through intracellular protein production using mRNA, (3) mRNA can sustain production of proteins, which can increase exposure to proteins with short half-lives, and (4) mRNA allows for desirable pharmacology in complex metabolic diseases.

- **Inhaled pulmonary therapeutics:** The goal of this modality is to develop mRNA medicines that can be delivered to the lung as safe, tolerable and efficacious therapies. We are developing nebulized NLP formulations that can transfect airway epithelial cells to deliver mRNA into the lungs of patients in order to express proteins coded in the mRNA. We aim to leverage our technology for pulmonary diseases in patients for whom there are no existing effective therapies.

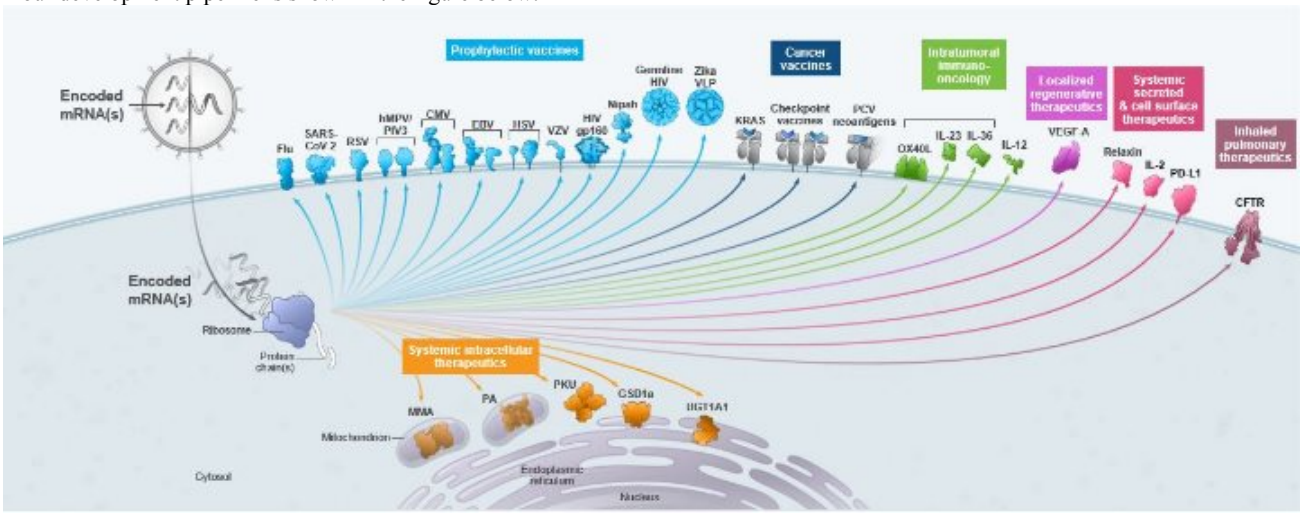
Our potential advantages in these areas include: (1) mRNA can produce hard-to-make or complex proteins, (2) mRNA can replace defective genes, and (3) LNP delivery allows for repeat dosing.

OUR PIPELINE

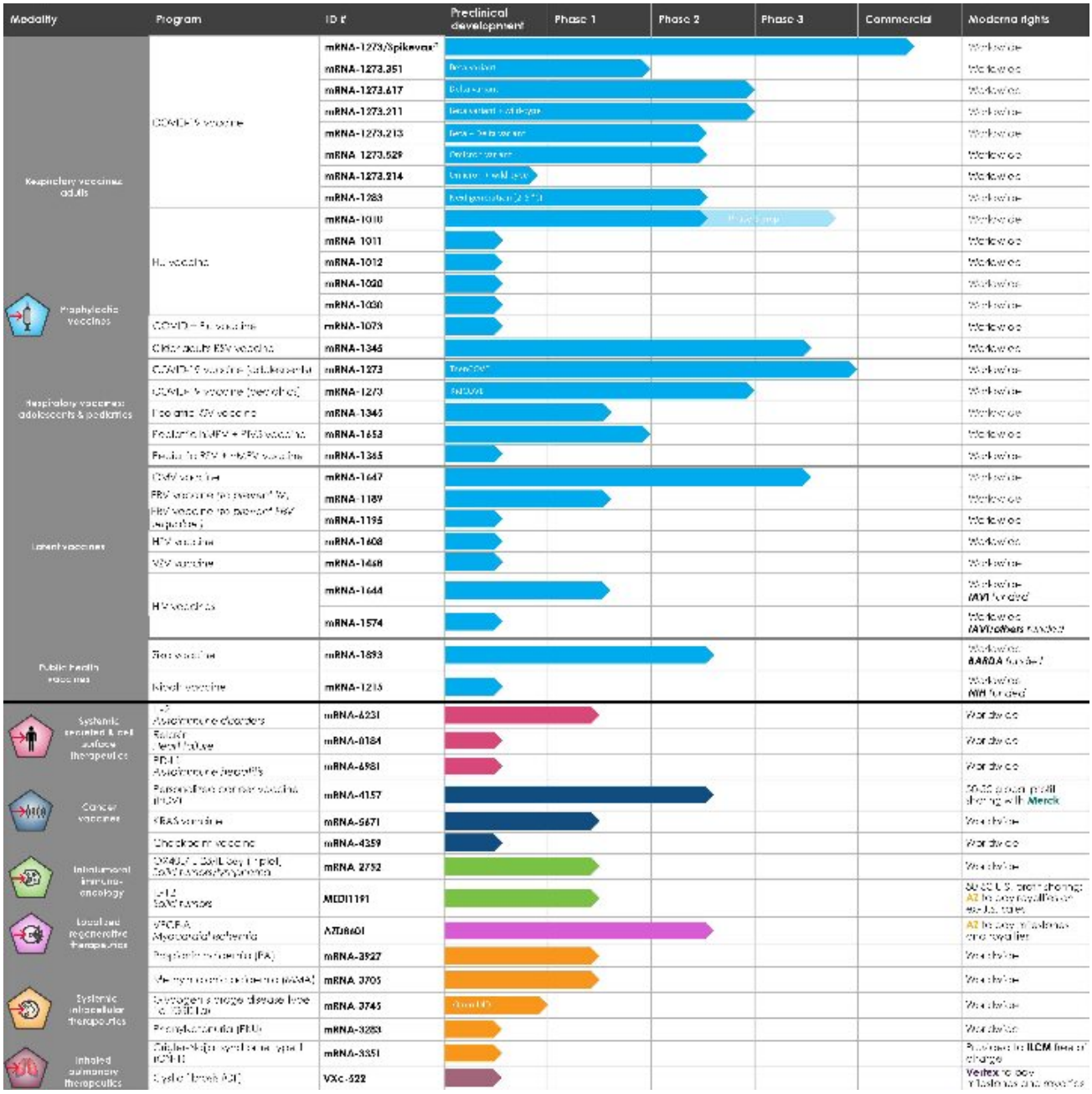
Since we nominated our first program in late 2014, we and our strategic collaborators have advanced in parallel a diverse development pipeline which currently consists of 44 development program across our 41 development candidates, with 25 having entered the clinic and one development candidate subject to an open investigational new drug application (IND). In the third quarter of 2021, we refined the way we track our development programs and now separately track each indication of our COVID-19 and RSV vaccine candidates, which resulted in an increase in the number of our development programs. We have entered seven other development candidates into the clinic that are no longer being pursued for further clinical development. Aspects of our pipeline have been supported through strategic alliances, including with AstraZeneca, Merck, and Vertex, and government-sponsored organizations and private foundations focused on global health initiatives, including BARDA, DARPA, the National Institutes of Health (NIH), and the Bill & Melinda Gates Foundation.

Our selection process for advancing new development candidates reflects both program-specific considerations as well as portfolio-wide considerations. Program-specific criteria include, among other relevant factors, the severity of the unmet medical need, the biology risk of our chosen target or disease, the feasibility of clinical development, the costs of development, and the commercial opportunity. Portfolio-wide considerations include the ability to demonstrate technical success for our platform components within a modality, thereby increasing the probability of success and learnings for subsequent programs in the modality and in some cases in other modalities.

The breadth of biology addressable using mRNA technology is reflected in our current development pipeline of 44 programs. The diversity of proteins made from mRNA within our development pipeline is shown in the figure below.



Our full pipeline, grouped by modalities, is shown in the figure below:



PROPHYLACTIC VACCINES MODALITY

We have 29 different prophylactic vaccine programs, of which 17 have entered the clinic. We separate our prophylactic vaccines modality into three categories: (1) vaccines against respiratory viruses, (2) vaccines against latent viruses, and (3) other vaccines (such as public health programs).

Prophylactic vaccines: Vaccines against respiratory viruses

COVID-19 vaccine (mRNA-1273)

Moderna's COVID-19 Vaccine/Spikevax is approved or authorized for use in more than 70 countries

The Moderna COVID-19 Vaccine, which is also marketed under the brand name Spikevax, is our first commercial product. From the beginning of the COVID-19 pandemic through December 31, 2021, we delivered approximately 824 million doses of our vaccine globally, with approximately 807 million of those doses shipped in 2021.

Coronaviruses are a large family of viruses that can cause illness in animals or humans. In humans there are several known coronaviruses that cause respiratory infections. These coronaviruses range from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and COVID-19. SARS-CoV-2 is the novel coronavirus first identified in humans in December 2019 and is the cause of COVID-19. COVID-19 is the most severe global pandemic since the influenza pandemic of 1918. According to the Johns Hopkins Coronavirus Resource Center, since the identification of SARS-CoV-2 in 2020, there have been over 430 million confirmed cases and over 5.9 million global deaths from COVID-19. The risk of mortality increases with age and the risk of severe disease and mortality increase for persons with pre-existing diseases or comorbid conditions (e.g. cardiovascular disease, diabetes, chronic lung disease, obesity).

Our vaccine against COVID-19, mRNA-1273, was designed, subject to Phase 1, Phase 2 and Phase 3 clinical trials, delivered clinical trial results, and received emergency use and other conditional authorizations in less than a year, and has been and continues to be a key tool in fighting the global COVID-19 pandemic. The SARS-CoV-2 virus continues to evolve, and certain variants of the virus have proven to be more transmissible and to cause more severe cases of COVID-19 than the ancestral strain that first emerged in Wuhan, China. As part of our strategy to combat the COVID-19 pandemic, we have continued to develop and assess variant-specific versions of our COVID-19 vaccine, including versions aimed at targeting the Beta, Delta and Omicron variants of the virus. Forward-looking references to our COVID-19 vaccine in this Annual Report on Form 10-K may include future modifications to mRNA-1273 or other development candidates that are designed to provide protection against variants of the SARS-CoV-2 virus.

We continue to study the use of our COVID-19 vaccine (mRNA-1273) in adolescent and pediatric populations, and for boosting and other indications. In addition to our original COVID-19 vaccine, we have advanced multiple other variant-specific vaccines into the clinic as part of effort to fight the global COVID-19 pandemic. As of the date of this Annual Report on Form 10-K, these programs include:

Spikevax/mRNA-1273 Programs

- Moderna COVID-19 vaccine/Spikevax: Approved/authorized in individuals 18 years and older in more than 70 countries (100 µg dose).
    - In January 2022, the U.S. FDA approved the Biologics License Application (BLA) for Spikevax (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 18 years of age and older.
- Adolescent COVID-19 vaccine/Spikevax: Authorized in individuals 12-17 years in the European Union, UK, Australia, Canada, Switzerland and other countries (100 µg dose); authorization by the U.S. FDA is pending.
    - The U.S. FDA notified us that it will require additional time to complete its assessment of our EUA request for the use of mRNA-1273 at the 100 µg dose level in adolescents 12 to 17 years of age. In early December 2021, we also decided to evaluate the potential of a lower 50 µg dose for primary vaccination.
- Pediatric COVID-19 vaccine/Spikevax: In clinical trials in children from 6 months to 11 years old; authorized in individuals 6-11 years in Australia, and subject to a positive recommendation from the European Medicines Agency's Committee for Medicinal Products for Human Use in individuals from 6-11 years (50 µg dose).
    - The Phase 2 study of mRNA-1273 in pediatric populations is ongoing. We selected the 50 µg dose for expanded enrollment in the 6 to 11 years old cohort, which is now fully enrolled (N=4,000). Dose selection studies are underway for 2 years to 5 years old and 6 months to <2 years old groups. In early December 2021, we also decided to evaluate the potential of a lower dose of 25 µg to meet regulatory guidance for immunogenicity in children 6-11 years of age. We expect to report data in children 2-5 years of age in March 2022.
- Booster dose of COVID-19 vaccine/Spikevax: Authorized in individuals 18 years and older in the United States, the European Union, Switzerland and other countries (50 µg dose).
    - For immunocompromised individuals, a booster dose of 100 µg is authorized.

Other COVID-19 Vaccine Programs

- Next-generation COVID-19 vaccine (mRNA-1283) is in an ongoing Phase 2 trial.
  - mRNA-1283 is a next-generation COVID-19 vaccine candidate that encodes for the portions of the SARS-CoV-2 spike protein critical for neutralization, specifically the Receptor Binding Domain (RBD) and Nterminal Domain (NTD). The encoded mRNA-1283 antigen is shorter than mRNA-1273 and is being developed as a potential refrigerator-stable mRNA vaccine that will facilitate easier distribution and administration by healthcare providers.
- Variant-specific or multi-valent COVID-19 vaccines: As SARS-CoV-2 has continued to evolve, we have proactively made new mRNA candidates in the case they are needed for an escape variant. In the event that mRNA-1273 proves ineffective at protecting against these variants, we have developed the variant vaccines listed below, which may be utilized to the extent necessary as the virus continues to evolve:
  - mRNA-1273.351: Vaccine against the Beta variant. Phase 2 clinical trial ongoing.
  - mRNA-1273.617: Vaccine against the Delta variant. Phase 2 clinical trial ongoing.
  - mRNA-1273.529: Vaccine against the Omicron variant. Phase 2 clinical trial ongoing.
  - mRNA-1273.211: Vaccine against the Beta variant and wild-type. Phase 2 clinical trial ongoing.
  - mRNA-1273.213: Vaccine against the Beta variant and Delta variant. Phase 2 clinical trial ongoing.
  - mRNA-1273.214: Vaccine against the Omicron variant and wild-type.

Moderna COVID-19 Vaccine Clinical Trials

The final analysis of adjudicated cases from the Phase 3 clinical trial for mRNA-1273, which we refer to as the COVE Study, demonstrated efficacy of 93% through six months after the second dose of the vaccine. The final analysis also demonstrated greater than 98% efficacy against severe cases of COVID-19 and 100% efficacy against death caused by COVID-19 in the per protocol cohort. The final analysis also demonstrated consistency in our subgroup analysis, including analyses by gender, by race and by preexisting medical conditions. The safety profile for mRNA-1273 continues to be consistent with the Phase 3 data over the longer period of safety follow up and across population subgroups.

Variant-specific and multivalent vaccines and Omicron update

We are continuously advancing booster candidates to address emerging variants of concern (VOCs). The strategy involves evaluating the prototype vaccine (mRNA-1273) at the authorized booster dose (50 µg), an Omicron-specific booster candidate (mRNA-1273.529), and a bivalent booster candidate (mRNA-1273.214) combining mRNA-1273.529 and mRNA-1273. Booster candidates are being evaluated in ongoing Phase 2/3 studies of approximately 300-600 participants per arm. In December 2021, we announced that at day 29 post-boost, the authorized 50 µg booster of mRNA-1273 increased neutralizing geometric mean titers (GMT) against Omicron approximately 37-fold higher than pre-boost levels. At day 29 post-boost, the 100 µg dose booster of mRNA-1273 increased neutralizing GMTs approximately 83-fold higher than pre-boost levels. Multivalent candidates (mRNA-1273.211 and mRNA-1273.213) boosted Omicron specific neutralizing antibody levels to similarly high levels at both the 50 µg and 100 µg levels. Based on the strength of neutralizing titers generated by mRNA-1273, the rapid pace of Omicron expansion, and the increased complexity of deploying a new vaccine, we are focusing our near-term efforts to address Omicron on the mRNA-1273 booster.

However, given the long-term threat demonstrated by Omicron's immune escape, we are also developing an Omicron containing variant vaccine (mRNA-1273.529) and a bivalent vaccine that is tailored to Omicron and the wild-type virus (mRNA-1273.214). The first participant was dosed in the mRNA-1273.529 trial in January 2022 and this trial is ongoing.

COVID-19 Commercial, Manufacturing and Supply Updates

Commercial sales of our COVID-19 vaccine accounted for $17.7 billion in revenues for the year ended December 31, 2021, based upon the delivery of approximately 807 million doses of the vaccine, accounting for all of our commercial revenues. We anticipate that sales of our COVID-19 vaccine in 2022 will similarly provide all of our commercial revenues for the coming year. These sales, both for 2021 and 2022, have been and will primarily be made to governments and international organizations engaged in the purchase of vaccines to combat the COVID-19 pandemic. We are preparing for the fall 2022 booster season and, if marketing approval is received for boosters of our COVID-19 vaccine, we expect to initiate sales in the U.S. private market. As the COVID-19 pandemic evolves into an endemic phase, we anticipate greater seasonality for sales, with greater demand in the fall/winter season in each hemisphere as countries seek to boost their populations. For further information on the sales and manufacturing of our COVID-19 vaccine, see "Manufacturing" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

Seasonal influenza vaccine (mRNA-1010, mRNA-1011, mRNA-1012, mRNA-1020 and mRNA-1030)

We are developing five influenza vaccines. mRNA-1010 has reported positive Phase 1 data and is ongoing in a Phase 2 study and a Phase 3 study is planned to start soon.

Seasonal influenza viruses are estimated by the World Health Organization (WHO) to cause 3 to 5 million cases of severe illness and up to 650,000 deaths each year, resulting in a severe challenge to public health. Currently licensed seasonal influenza virus vaccines rarely exceed 60% overall effectiveness and can provide low effectiveness during years when the circulating viruses do not match the strains selected for the vaccine antigens. Our mRNA seasonal influenza vaccine program has three different approaches. Our first approach – Quadrivalent Vaccine – is developing a quadrivalent seasonal flu vaccine (mRNA-1010) targeting WHO recommendations, including A H1N1, H3N2 and influenza B Yamagata and Victoria lineages. Our second approach – Expanded Coverage – is to provide an enhanced antigen selection opportunity to public health authorities with the potential for regional variation. Our third approach – Immunologic Breadth – is to provide immunity by targeting more conserved antigens to provide the broadest coverage. We also aim to work with the WHO and other regulators to make vaccines closer to the flu season and potentially choose strains closer to the ones circulating in the hemisphere.

mRNA-1010 is a single investigational vaccine consisting of four distinct mRNA sequences that encode the A H1N1, H3N2 and influenza B Yamagata and Victoria lineages in our proprietary LNP. mRNA-1011 and mRNA-1012 are investigational vaccines that will include the four WHO recommended strains and aim to add additional Hemagglutinin (HA) antigens (e.g. H3N2, H1N1). mRNA-1020 and mRNA-1030 are investigational vaccines that will aim to add Neuraminidase (NA) antigens.

Latest data and next steps

mRNA-1010 is ongoing in a Phase 2 study and a Phase 3 efficacy study is planned to start in 2022. In December 2021, we announced positive Phase 1 data, and that mRNA-1010 successfully boosted hemagglutination inhibition (HAI) assay geometric mean titers against all strains 29 days after vaccination at all doses tested in both younger and older adults. In the Phase 1 study, mRNA-1010 was evaluated at 50 µg, 100 µg and 200 µg dose levels in younger adult (age 18-49) and older adult (age 50+) cohorts. No significant safety findings were observed through day 29. Adverse reactions (ARs) were generally reported more frequently in younger adults compared to older adults, and at higher dose levels. Minimal differences in dose response was observed between the 50 µg, 100 µg and 200 µg dose levels, suggesting the potential to explore even lower doses.

Our expanded coverage influenza vaccines (mRNA-1011 & mRNA-1012) and immunologic breadth influenza vaccines (mRNA-1020 & mRNA-1030) are in preclinical studies.

RSV vaccine (mRNA-1345)

We are developing an RSV vaccine for children and older adults. In older adults, mRNA-1345 is ongoing in a pivotal Phase 3 study; in pediatrics, mRNA-1345 is ongoing in a Phase 1 study.

Respiratory syncytial virus (RSV) is one of the most common causes of respiratory disease in children under the age of five and also in older adults. Most children are infected at least once by two years of age. In the United States, it is estimated that over two million children younger than five years of age receive medical attention and more than 86,000 are hospitalized due to RSV infection annually. RSV also causes a substantial burden of respiratory illness in older adults. RSV infection causes an estimated 177,00 hospitalizations and 14,000 deaths per year in adults aged >65 years in the United States.

mRNA-1345 encodes an engineered form of the RSV F protein stabilized in the prefusion conformation and is formulated in our proprietary LNP. We believe that neutralizing antibodies elicited by mRNA-1345 may lead to an efficacious RSV vaccine.

Latest data and next steps

The Phase 1 study of mRNA-1345 to evaluate the tolerability, reactogenicity and immunogenicity of mRNA-1345 in younger adults, older adults, older adults of Japanese descent, women of child-bearing age and children with serologic evidence of prior RSV exposure is ongoing. The age range of children in this de-escalation Phase 1 study is 12-59 months. Enrollment in the pediatric and older adult Japanese descent cohorts are ongoing, whereas the other cohorts are fully enrolled. Phase 1 interim data from the older adult cohort showed that a single mRNA-1345 vaccination at 50 µg, 100 µg or 200 µg boosted neutralizing antibody titers against RSV-A by approximately 14-fold and against RSV-B by approximately 10-fold.

The Phase 3 portion of the pivotal global Phase 2/3 study of mRNA-1345 with approximately 34,000 participants and testing the 50 µg is currently enrolling. The FDA has granted Fast Track designation for mRNA-1345 in adults older than 60 years of age.

hMPV/PIV3 vaccine (mRNA-1653)

We are developing a combination vaccine to address two viruses that are leading causes of respiratory infection

Human metapneumovirus (hMPV) and human parainfluenza virus 3 (PIV3) are significant causes of respiratory tract infections in children. hMPV has been detected in 4% to 15% of patients with acute respiratory infections. hMPV causes disease primarily in young children but can also infect adults, the elderly, and immunocompromised individuals. Infections from parainfluenza virus (PIV) account for up to 7% of acute respiratory infections among children younger than 5 years. Of the four PIV types identified, PIV3 most frequently results in infections and leads to the more serious lower respiratory tract infections compared to the other three PIV types.

mRNA-1653 is a single investigational vaccine consisting of two distinct mRNA sequences that encode the membrane F proteins of hMPV and PIV3, co-formulated in our proprietary LNP.

Latest data and next steps

A first-in-human dose-ranging study, mRNA-1653-P101, in healthy adults (N=124) was completed in January 2020. This study evaluated the safety, reactogenicity, and immunogenicity of a range of dose levels (25, 75, 150 or 300 µg) administered on a 1-dose or 2-dose vaccination schedule (approximately 28 days apart) compared with a placebo control in healthy adult subjects (18 through 49 years of age) with a 13 month follow-up period. The mRNA-1653 vaccine was generally well-tolerated at all dose levels. A single dose of mRNA-1653 boosted serum neutralization titers against hMPV and PIV3, and the magnitude of the boost was similar at all dose levels. The Month 1 to baseline geometric mean ratio (GMR) for the pooled mRNA-1653 treatment groups was approximately 6 for hMPV and 3 for PIV3. A second vaccination did not impact the magnitude of hMPV or PIV3 neutralization titers measured at Month 2. The hMPV neutralizing antibody titers remained above baseline at all dose levels through Month 13, and the PIV3 neutralizing antibody titers remained above baseline at all dose levels through Month 7.

We are conducting a Phase 1b trial to evaluate mRNA-1653 in healthy adults and children aged 12-59 months. The Phase 1b trial is a randomized, observer-blinded, placebo-controlled, dose-ranging trial to evaluate the safety and immunogenicity of two dose levels of mRNA-1653 in healthy adults (18-49 years of age) and two dose levels in children (12-59 months of age) with serologic evidence of prior hMPV and PIV3 exposure. The study is fully enrolled.

Combination vaccines (mRNA-1073 & mRNA-1365)

Our vision is to develop a pan-respiratory annual booster vaccine (mRNA-1073) and a pediatric combination vaccine (mRNA-1365)

In September 2021, we announced two development candidates that build upon our combination strategy. mRNA-1073 is our COVID-19 and seasonal flu combination vaccine. mRNA-1073 encodes for the COVID-19 spike protein and the flu HA glycoproteins. mRNA-1365 is our pediatric RSV and hMPV combination vaccine. mRNA-1365 encodes for the RSV prefusion F glycoprotein and the hMPV F protein.

Prophylactic vaccines: Vaccines against latent viruses

CMV vaccine (mRNA-1647)

Our CMV program targets prevention of CMV infections, which could reduce the risk of birth defects

Human CMV is a common human pathogen and member of the herpes virus family. Congenital CMV results from infected mothers transmitting the virus to their unborn child and it is the leading infectious cause of birth defects in the United States, with approximately 25,000 newborns in the U.S. infected annually. There is currently no available vaccine for CMV and a vaccine that leads to durable immunity in women of child-bearing age would address a critical unmet need in the prevention of congenital CMV infection.

Our CMV vaccine, mRNA-1647, combines six mRNAs in one vaccine, which encode for two proteins located on the surface of CMV: five mRNAs encoding the subunits that form the membrane-bound pentamer complex and one mRNA encoding the full-length membrane-bound glycoprotein B (gB). Both the pentamer and gB are essential for CMV to infect barrier epithelial surfaces and gain access to the body, which is the first step in CMV infection. mRNA-1647 is designed to produce an immune response against both the pentamer and gB for the prevention of CMV infection.

Latest data and next steps

Phase 1 and 2 studies of mRNA-1647 demonstrated functional antigen-specific responses that support the vaccine candidate’s potential to prevent CMV infection. Interim, seven-month data from the Phase 2 study of mRNA-1647 at the 50 µg, 100 µg and 150 µg dose levels showed that mRNA-1647 was generally well tolerated. In CMV-seronegative participants in mRNA-1647 treatment groups after the third vaccination, neutralizing antibody GMTs against epithelial cell infection were at least 20-fold higher than the baseline GMT of the CMV seropositive group, and neutralizing antibody GMTs against fibroblast infection approximated the baseline

GMT of the CMV-seropositive group. In CMV positive participants in mRNA-1647 treatment groups after the third vaccination, neutralizing antibody GMTs against epithelial cell infection increased to at least 6.8-fold over baseline, and neutralizing antibody GMTs against fibroblast infection increased to approximately 2-fold over baseline.

Based on the interim analysis of the Phase 2 study, the 100 μg dose was chosen for the Phase 3 study. The first participant in the Phase 3 study, known as CMVictory, was dosed in October 2021. The study is evaluating the safety and efficacy of mRNA-1647 against primary CMV infection in women ages 16-40 years and seeks to enroll 6,900 women of child-bearing age.

EBV vaccine (mRNA-1189 & mRNA-1195)

We are developing two EBV vaccines – a vaccine to prevent infectious mononucleosis and another vaccine to prevent the longer term sequelae of EBV infection

Epstein-Barr virus (EBV) a member of the herpesvirus family that includes CMV, infects approximately 90% of people by adulthood, with primary infection typically occurring during childhood or late adolescence (approximately 50% and 89% seropositivity, respectively) in the U.S. EBV is the major cause of infectious mononucleosis in the U.S., accounting for over 90% of the approximately 1-2 million cases of infectious mononucleosis in the U.S. each year. Infectious mononucleosis can debilitate patients for weeks to months and, in some cases, can lead to hospitalization and splenic rupture. EBV infection is associated with the development and progression of certain lymphoproliferative disorders, cancers, and autoimmune diseases. In particular, EBV infection and infectious mononucleosis are associated with increased risk of developing multiple sclerosis, an autoimmune disease of the central nervous system.

Similar to our CMV vaccine (mRNA-1647) product concept, we believe that an effective EBV vaccine must generate an immune response to antigens that are required for viral entry in most of the susceptible cell types. We have thus designed our EBV vaccine, mRNA-1189, to elicit an immune response to EBV envelope glycoproteins gp220 as well as gp42, and the gH/gL complex, which are required for infection of both epithelial and B cells. mRNA-1189 contains four mRNAs encoding for these proteins encapsulated in our proprietary LNPs. mRNA-1195 encodes for additional antigens and the first indication it will focus on is post-transplant lymphoproliferative diseases (80% of PTLD can be attributed to EBV).

Latest data and next steps

We are conducting a Phase 1, randomized, observer-blind, placebo-controlled study of mRNA-1189. The primary purpose of the Phase 1 study is to assess safety, tolerability and immunogenicity of mRNA-1189 in healthy adults ages 18 to 30. We announced the dosing of the first participant in January 2022 and we expect to enroll approximately 270 participants. Our EBV therapeutic vaccine, mRNA-1195, is in preclinical studies.

HSV vaccine (mRNA-1608)

We are developing a herpes simplex virus (HSV) vaccine candidate against HSV-2 disease

Herpes simplex viruses (commonly known as herpes) are categorized into two types: HSV-1 infects the mouth, face and genitals, and HSV-2 primarily infects the genitals. Both viruses establish life-long latent infections within nearby sensory neurons from which they can reactivate and re-infect the skin. There is a significant burden of disease from HSV genital infections. Diagnosed, symptomatic genital herpes causes a reduction in quality of life, which antivirals (current standard of care) only partially restore. In the United States, approximately 18.6 million adults ages 18 to 49 years are living with HSV-2. Globally, approximately 5% of the population in the 18-to-49-year age range is HSV-2 seropositive.

We believe that an HSV vaccine could deliver similar efficacy as suppressive antiviral treatments and could improve compliance and quality of life. We aim to induce a strong antibody response with neutralizing and effector functionality combined with cell-mediated immunity.

Latest data and next steps

Our HSV vaccine (mRNA-1608) is currently in preclinical studies. In a preclinical study in mice, we demonstrated robust neutralizing response induced by an mRNA vaccine containing HSV-2 antigens against both HSV-2 infection, and cross-neutralization against HSV-1 infection. In addition, the sera also demonstrated high antibody-dependent cellular cytotoxicity (ADCC) activity. The immune responses induced by the HSV-2 mRNA vaccine are higher than the average observed in 80 randomly selected seropositive human sera.

VZV vaccine (mRNA-1468)

We are developing a varicella-zoster virus (VZV) vaccine candidate to reduce the rate of herpes zoster (shingles)

Herpes zoster occurs in one of three adults in their lifetime and incidence dramatically increases at approximately 50 years of age. Declining immunity in older adults decreases cell-mediated immunity against VZV, allowing reactivation of the virus from latently infected neurons, causing painful and itchy lesions. Serious herpes zoster complications include postherpetic neuralgia (10-13% of herpes zoster cases), bacterial coinfections, and cranial and peripheral palsies; 1-4% of individuals with herpes zoster cases are hospitalized for complications. Severity of disease and likelihood of complications, including postherpetic neuralgia (PHN) also increases with age. Immunocompromised patients, autoimmune disease patients using immunosuppressive therapies, HIV-infected patients, hematopoietic stem cell (HSCT) and organ transplant recipients have an increased risk of developing herpes zoster. The incidence of herpes zoster has been increasing throughout the world, from 0.76 per 1,000 person years from 1945 to 1949, to 7.2 per 1,000 person years in 2016. The current standard of care is Shingrix™, an FDA-approved vaccine for the prevention of shingles (herpes zoster) in adults 50 years and older. It is more than 90% effective against herpes zoster in adults aged 50-70 with only a slight reduction in efficacy for adults over age 70.

Our VZV vaccine (mRNA-1468) is designed to express VZV glycoprotein E (gE) to reduce the rate of herpes zoster.

Latest data and next steps

In partnership with Merck, we previously published preclinical data in *Vaccine* showing that an LNP formulated (Merck's proprietary LNP) mRNA encoding VZV gE antigen is highly immunogenic in non-human primates. Our VZV vaccine (mRNA-1468) using our proprietary LNP is currently in preclinical studies.

HIV vaccine (mRNA-1644 & mRNA-1574)

We are developing two HIV vaccines – one approach is to test a novel HIV vaccine strategy in humans for eliciting broadly neutralizing HIV-1 antibodies (bnAbs) and the second approach is to test novel HIV trimer designs in humans.

HIV is the virus responsible for acquired immunodeficiency syndrome (AIDS), a lifelong, progressive illness with no effective cure. Approximately 38 million people worldwide are currently living with HIV, with 1.2 million in the U.S. Approximately 1.5 million new infections of HIV are acquired worldwide every year and approximately 680,000 people die annually due to complications from HIV/AIDS. The primary routes of transmission are sexual intercourse and IV drug use, putting young adults at the highest risk of infection. From 2000 to 2015, a total of $562.6 billion globally was spent on care, treatment and prevention of HIV, representing a significant economic burden.

In collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill & Melinda Gates Foundation, mRNA-1644 is testing a novel HIV vaccine strategy in humans as delivered by mRNA to elicit broadly neutralizing HIV-1 antibodies (bnAbs) through sequential vaccination of novel prime and boost antigens that induce specific B-cell responses. In collaboration with IAVI and the HIV Vaccine Trials Network, mRNA-1574 is testing multiple native-like HIV trimer mRNAs in humans to improve our understanding of how to make stable and immunogenic native-HIV trimers.

Latest data and next steps

mRNA-1644 is in an ongoing Phase 1 clinical trial and mRNA-1574 is in preclinical studies.

Prophylactic vaccines: Public health vaccines

Zika vaccine (mRNA-1893)

In partnership with BARDA, we are in a Phase 2 clinical trial for our Zika vaccine

The Zika virus is a single stranded RNA virus of the flaviviridae family. Seroepidemiology data suggest that it is endemic to regions of Africa and Asia where the Aedes mosquito vectors are found. Zika virus is predominantly spread by mosquitos from the Aedes genus, but it can also be transmitted congenitally, sexually, and through blood donation. Zika infection is usually asymptomatic or mild in adults, leading to fever, rash, and conjunctivitis. However, infection of women during pregnancy can result in devastating microcephaly in newborns. Microcephaly is a birth defect characterized by an abnormally small head and brain, associated with lifelong neurodevelopmental delay, seizures, intellectual disability, balance problems, and dwarfism / short stature, resulting in significant disability and requiring lifelong support. In 2007, a Zika infection outbreak progressed across the Pacific islands. An outbreak observed in Brazil in 2015 soon spread across the Americas. This led to the WHO declaring it a public health emergency of international concern in 2016. During the period, there were tens of thousands of cases of microcephaly and congenital Zika syndrome reported in infants and of resulting neurological sequelae such as Guillain-Barré syndrome reported in adults.

Our Zika vaccine, mRNA-1893, encodes for the prME structural protein encapsulated in our proprietary LNP.

Latest data and next steps

In 2020, we announced positive data from our Phase 1 clinical trial, which enrolled four cohorts (10, 30, 100 and 250 µg). mRNA-1893 was safe and well tolerated at the 10 and 30 µg dose level. In the flavivirus-seronegative group, seroconversion rates after the second vaccination reached 94.4% at the 10 µg dose level and 100% in the 30 µg dose level ($PRNT_{50}$). In the flavivirus-seropositive group, the percentage of participants achieving a 4-fold boost in pre-existing $PRNT_{50}$ titers after the second vaccination reached 50% in the 10 µg dose level and 75% in the 30 µg dose level ($PRNT_{50}$). We are currently enrolling mRNA-1893 in a Phase 2 clinical study in the United States and Puerto Rico with approximately 800 participants. The randomized, placebo-controlled study aims to evaluate the safety, tolerability and reactogenicity of mRNA-1893 compared to placebo.

Nipah vaccine (mRNA-1215)

In collaboration with the NIH-VRC, we are preparing to start a Phase 1 study for our Nipah vaccine

Nipah virus (NiV) is a zoonotic virus transmitted to humans from animals, contaminated food, or through direct human-to-human transmission and causes a range of illnesses including fatal encephalitis. Severe respiratory and neurologic complications from NiV have no treatment other than intensive supportive care. The case fatality rate among those infected is estimated at 40-75%. NiV outbreaks cause significant economic burden to impacted regions due to loss of human life and interventions to prevent further spread, such as the slaughter of infected animals. NiV has been identified as the cause of isolated outbreaks in India, Bangladesh, Malaysia, and Singapore since 2000 and is included on the WHO R&D Blueprint list of epidemic threats needing urgent R&D action.

Latest data and next steps

mRNA-1215, our vaccine candidate against the Nipah virus (NiV), was co-developed along with the NIH's Vaccine Research Center. The Phase 1 clinical testing will be focused on pandemic preparedness.

SYSTEMIC SECRETED AND CELL SURFACE THERAPEUTICS MODALITY

Our systemic secreted and cell surface therapeutics modality currently has three active development programs, of which one has entered the clinic. We previously announced positive data from our Chikungunya Antibody program (mRNA-1944) within this modality. However, we do not expect to advance our Chikungunya Antibody program without outside funding, and we are not currently pursuing further development of it at this time.

IL-2 Mutein (mRNA-6231)

IL-2 is a critical cytokine for Treg activation and expansion and our product utilizes subcutaneous mRNA administration to produce a modified version of IL-2 in order to treat autoimmune diseases

IL-2-based therapeutics are being clinically evaluated for a wide range of immune-mediated disorders, including rheumatoid arthritis, systemic lupus erythematosus, graft versus host disease, inflammatory bowel diseases, and autoimmune hepatitis. IL-2 is a cytokine, which are potent modulators of the immune system, directing function and homeostasis. IL-2 is critically important to T cell survival and function. IL-2 acts through a receptor complex that can be dimeric, IL-2Rß (CD122) plus the common γ chain (CD132), or trimeric, which is formed through the addition of IL-2Rα (CD25) to the dimeric form. The trimeric form has 10-fold to 100-fold greater affinity for IL-2. Under low or homeostatic IL-2 conditions, those cells which preferentially express the trimeric receptor, or IL-2R, such as Tregs and very recently activated effector T cells, are activated.

We believe that our platform can be exploited to produce a modified IL-2 for the treatment of autoimmune conditions. Our modified IL-2 is engineered with mutations that selectively decrease binding to the dimeric IL-2 receptor present on CD4+ and CD8+ T effector cells and NK cells, and increase reliance upon CD25 of the trimeric IL-2 receptor complex to trigger the signaling cascade in regulatory T cells. Our modified IL-2 is also expressed as a fusion protein to extend its half-life in the serum. It is also the first demonstration of subcutaneous administration of the delivery technology that was also used our chikungunya antibody therapeutic, mRNA-1944.

Latest data and next steps

mRNA-6231 is ongoing in a Phase 1 clinical study. The trial is a Phase 1, first-in-human, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of mRNA-6231 in healthy adult participants (between 18-50 years of age), following subcutaneous administration of mRNA-6231.

PD-L1 (mRNA-6981)

PD-L1 is a co-inhibitory receptor that can induce anergy in programmed cell death protein 1 (PD-1)-expressing T cells and we intend to induce expression of PD-L1 on myeloid cells to send a tolerizing signal to immune cells in their environment in order to treat autoimmune diseases

The PD-L1/PD-1 pathway has a critical function in immune regulation and promotes development and function of Tregs. PD-L1 is a transmembrane protein expressed on antigen presenting cells, such as dendritic cells and macrophages, activated T cells, B cells, and monocytes as well as peripheral tissues. Its cognate receptor, PD-1, is a co-inhibitory transmembrane protein expressed on T cells, B cells, natural killer cells and thymocytes. Preclinical mouse models deficient in PD-1 spontaneously develop a variety of autoimmune diseases such as arthritis, myocarditis, lupus-like glomerulonephritis and type 1 diabetes, demonstrating the critical role of the PD-L1/PD-1 interaction in maintaining tolerance to self-antigens. Additionally, treatment of cancer patients with PD-1 or PD-L1 inhibitors sometimes results in immune-related adverse events, including the development of hepatitis, dermatitis and colitis, demonstrating the role of PD-1/PD-L1 in human autoimmune reactions.

We believe our PD-L1 therapy may augment PD-L1 expression on cell types similar to those that endogenously express it, and by reducing immune activation, potentially reduce the clinical manifestations of a variety of autoimmune diseases. Our intent is to use our platform to influence myeloid cells, including dendritic cells, to provide additional co-inhibitory signals by augmenting endogenous expression of PD-L1. We believe that this tolerizing signal to lymphocytes may limit autoreactivity in the context of ongoing autoimmune pathology without severe and global suppression of the immune system. Given that our platform allows us to modify myeloid cells *in situ*, our approach to the creation of a tolerogenic environment may provide unique benefits in treating autoimmune diseases by seeking to restore immune homeostasis.

Latest data and next steps

We have investigated mRNA-6981 in a range of preclinical models of autoimmune and related diseases, including arthritis, type 1 diabetes, colitis and graft-versus-host disease, and observed disease-modifying activity. We are currently in preclinical studies for mRNA-6981.

Relaxin (mRNA-0184)

Relaxin is a vasoactive peptide associated with cardiovascular remodeling and we intend to encode for a relaxin fusion protein to treat decompensated heart failure

Relaxin is a naturally occurring hormone, present in both men and women, that has been shown to promote vasodilation and angiogenesis, regulate extracellular matrix turnover, and suppress arrhythmias post myocardial infarction. Subsequent studies have implicated relaxin's role beyond pregnancy, through vasodilatory, antifibrotic, anti-inflammatory and protective effects on multiple organs. Relaxin activates a variety of pathways, contributing to the reduction of oxidative stress, fibrosis, and inflammation. There is a large body of evidence to support relaxin's clinical potential in several therapeutic areas, with its impact on cardiovascular diseases having been studied in both preclinical and clinical settings. Though prior studies have failed to demonstrate long-term benefit in clinical studies, we believe a novel approach can overcome potential flaws of previous approaches.

mRNA-0184 is being developed to treat decompensated heart failure. Acute heart failure (AHF) is defined as the new onset or worsening of symptoms and signs of heart failure (HF). In developed countries, HF has become a substantial public health problem, affecting 2% of the adult population and AHF is the most frequent cause of unplanned hospital admission in patients of >65 years of age. mRNA-0184 encodes for the relaxin fusion protein. The mRNA sequence of mRNA-0184 is engineered to increase protein expression and prolong half-life.

Latest data and next steps

In preclinical studies, we have shown preliminary protein expression data in nonhuman primates that supports the hypothesis of extended pharmacology relative to historical efforts with recombinant protein. We are planning for a Phase 1 study in participants with chronic heart failure. We expect that mRNA-0814 will be administered after heart failure decompensation to bridge patients through the vulnerable period.

CANCER VACCINES MODALITY

Our cancer vaccines modality currently has three development programs, two of which have entered the clinic. We have regained all rights to our KRAS vaccine (mRNA-5671) from Merck and we are evaluating next steps for the program.

Personalized Cancer Vaccine (PCV) (mRNA-4157)

PCV encodes for up to 34 neoantigens designed against an individual's patient tumor mutations and is ongoing in a Phase 1 and Phase 2 trial across a variety of indications

As tumors grow, they acquire mutations, some of which create new protein sequences, or neoantigens, that can be presented on human leukocyte antigen (HLA) molecules in the tumor and recognized as non-self by T cells. These neoantigens can be shared or are completely unique to an individual patient's tumor. In addition to the neoantigens being unique and patient specific, the presentation of those neoantigens is also dependent on a patient's specific HLA type. Identification of patient-specific HLA type and tumor neoantigens through next generation sequencing paired with our proprietary, *in silico* design of each patient's mRNA vaccine and rapid manufacturing for a specific patient allows us to rapidly deliver a completely unique and personalized medicine to patients.

Our personalized cancer vaccine program, mRNA-4157, consists of an mRNA that encodes up to 34 neoantigens, predicted to elicit both class I (CD8) and class II (CD4) responses, designed against each individual patient's tumor mutations and specific to their HLA type. The neoantigens are encoded in a single mRNA sequence and formulated in our proprietary LNPs designed for intramuscular injection. The mRNA sequence is then manufactured using an automated workflow to enable a rapid turnaround time.

Latest data and next steps

The Phase 1 trial is an open-label, multicenter study to assess the safety, tolerability, and immunogenicity of mRNA-4157 alone in subjects with resected solid tumors and in combination with the checkpoint inhibitor, pembrolizumab (marketed in the United States as KEYTRUDA®), in subjects with resected and unresected solid tumors. mRNA-4157 is administered on the first day of each 21-day cycle for a maximum of nine doses. mRNA-4157 is administered as monotherapy (Part A) or in combination with pembrolizumab (Parts, B, C, and D) in the United States. Studies have shown mRNA-4157 to be well tolerated at all dose levels. The majority of adverse events from mRNA-4157 have been low grade and reversible. Encouraging data emerging from an expansion arm in patients with head and neck cancer has recently caused us to increase the size of that cohort, which continues to recruit trial participants.

The randomized, placebo-controlled Phase 2 study is 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. This study was fully enrolled (N=150) in September 2021 and the primary endpoint of the Phase 2 study is recurrence-free survival at 12 months.

KRAS Vaccine (mRNA-5671)

The Phase 1 study, led by Merck, is ongoing; we have retained all rights to our KRAS vaccine (mRNA-5671) from Merck and we are evaluating next steps for the program.

Oncogenic driver mutations that encode targetable T cell neoantigens have considerable potential therapeutic implications: (1) driver mutations are subject to positive selection, as they confer survival advantages for the tumor, and (2) such neoantigens could be shared between patients, enabling an easier approach to developing and manufacturing such therapeutic or curative interventions.

KRAS is a frequently mutated oncogene in epithelial cancers, primarily lung, colorectal cancer (CRC) and pancreatic cancers. The four most prevalent KRAS mutations associated with these malignancies are G12D, G12V, G13D, and G12C, which constitute 80% to 90% of KRAS mutations.

Latest data and next steps

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. We have retained all rights to our KRAS vaccine (mRNA-5671) from Merck and we are evaluating next steps for the program.

Checkpoint cancer vaccine (mRNA-4359)

We are developing a checkpoint cancer vaccine that encodes antigens for Indoleamine ^{2,3}-dioxygenase (IDO) and programmed death-ligand 1 (PD-L1) antigens

Our checkpoint vaccine aims to stimulate effector T cells that target and kill suppressive immune and tumor cells that express IDO and PD-L1 antigens. Following vaccine-mediated activation, IDO- and PD-L1-specific T cells kill immunosuppressive (regulatory) immune cells and cancer cells. Cancer cell killing and the reduction of regulatory immune cells tip the balance towards productively

inflammatory immune cells with signaling molecules “heating up” the tumor microenvironment, which leads to additional tumor killing by vaccine-activated T cells. T cell priming leads to recognition of additional tumor-associated antigens and to more tumor killing by tumor-specific cytotoxic T cells. Systemic PD-1/PD-L1 blockade may further amplify the effect, leading to further immune activation and superior disease control.

Our initial indications for our checkpoint vaccine are advanced or metastatic cutaneous melanoma and non-small cell lung carcinoma (NSCLC). Melanoma is the fifth most common cancer diagnosis in the U.S. It accounts for approximately 5% of all new cancer diagnoses and 1.5% of all cancer-related deaths. Cutaneous melanoma is a cancer that starts in the melanocytes (pigment-producing cells) of the skin. If diagnosed at the local stage, the 5-year survival rate is approximately 95%. However, for regional or metastatic disease (stage IIIB+), 5-year survival rates decline to approximately 30 to 60%. Approximately 18,000 new patients are diagnosed with stage IIIB+ cutaneous melanoma in the U.S. Advanced melanoma, a rare and serious type of skin cancer, is responsible for most skin cancer-related deaths, despite representing only 1% of skin cancer cases. Current standard of care pembrolizumab, nivolumab or the combination of nivolumab + ipilimumab.

NSCLC frequently goes undetected, remaining asymptomatic until it has progressed to later stages. Approximately 115,000 people are diagnosed with metastatic NSCLC or progress to metastatic disease annually in the United States. The current approach to treatment of metastatic NSCLC treatment is dependent on the presence of PD-L1 expression. If tumor PD-L1 expression is greater than 50% pembrolizumab or atezolizumab monotherapy are preferred, while a combination of chemotherapy and pembrolizumab is preferred for patients with PD-L1 expression less than 50%.

Latest data and next steps

Our checkpoint vaccine is currently in preclinical studies.

INTRATUMORAL IMMUNO-ONCOLOGY MODALITY

Our intratumoral immuno-oncology modality currently has two development programs, both of which are in the clinic.

OX40L/IL-23/IL-36*γ* (Triplet) (mRNA-2752)

Triplet includes three mRNAs encoding human OX40L, interleukin 23 (IL-23) and interleukin 36 gamma (IL-36γ), that are encapsulated in our proprietary LNP and administered intratumorally

Despite recent advances in immune-mediated therapies for cancer, the outlook for many patients with advanced cancer is poor. We are developing Triplet (mRNA-2752) and other programs to drive anti-cancer T cell responses by transforming cold tumor microenvironments into productive, “hotter” immune landscapes with local intratumoral therapies. Triplet (mRNA-2752) utilizes the intrinsic advantage of mRNA to multiplex and to produce membrane and secreted proteins with mRNA in a single investigational medicine. Triplet (mRNA-2752) includes three mRNAs encoding human OX40L, IL-23 and IL-36γ that are encapsulated in our proprietary LNP and administered intratumorally. OX40L is a membrane protein, whereas IL-23 and IL-36γ are secreted cytokines. We believe our approach has the advantage of localized high concentration gradients of IL-23 and IL-36γ compared to recombinant proteins administered systemically or intratumorally. Additionally, the mRNA for OX40L encodes for the wild type membrane protein, which we believe recombinant protein technologies cannot enable.

We are developing Triplet (mRNA-2752) for the treatment of advanced or metastatic solid tumor malignancies or lymphoma as a single agent or in combination with checkpoint inhibitors.

Latest data and next steps

mRNA-2752 is ongoing in a Phase 1 open-label, multicenter, dose-escalation study. This study is evaluating the safety and tolerability of escalating intratumoral injections of mRNA-2752 alone and in combination with PD-L1 inhibitor (durvalumab) to define the maximum tolerated dose (MTD) or a recommended dose for expansion (RDE). The study consists of dose escalation and dose confirmation parts, which will occur in Arm A and Arm B, followed by a dose expansion part, which will occur in Arm B, and a Dose Exploration in Arm C as a neoadjuvant therapy for cutaneous melanoma. Enrollment in the dose expansion part of Arm B and Arm C is currently ongoing.

We previously announced the interim results of Part A in 2020. In 2021, we announced that the Phase 1 study demonstrates that Triplet given in combination with AstraZeneca’s durvalumab (IMFINZI®) was tolerated at all dose levels tested and elicited evidence of anti-tumor activity. The recommended dose for expansion (RDE) is up to of 4mg mRNA-2752 + durvalumab. The study also demonstrated evidence of immunomodulation and expected pharmacodynamics in the tumor immune microenvironment (TME) of both injected and un-injected lesions, in both monotherapy and combination cases, as indicated by increases in proliferating (activated)

T cells, PD-L1 levels (marker of interferon signaling), and T cell-inflamed (GEP) and DC transcriptional signature score, with greatest changes observed in patients with clinical benefit.

IL-12 (MEDI1191)

In collaboration with AstraZeneca, we are developing a mRNA that encodes for IL-12 encapsulated in our proprietary LNP delivered intratumorally

Another strategy for cancer patients with immunologically cold tumors is to transform the tumor microenvironment by introducing pro-inflammatory cytokines directly into tumors or draining lymph nodes. In collaboration with AstraZeneca, we are developing MEDI1191, which is an mRNA for IL-12 encapsulated in our proprietary LNP to be delivered intratumorally. Systemic administration of recombinant IL-12 protein was poorly tolerated in early clinical trials and exhibited generally low response rates. MEDI1191 can enhance the immune response by positively impacting both antigen presenting cells and T cells, and local, intratumoral expression of IL-12 can potentially improve tolerability compared to systemic protein treatments.

MEDI1191 is being developed for the treatment of advanced or metastatic solid tumors in combination with a checkpoint inhibitor. MEDI1191 consists of our proprietary LNP encapsulating an mRNA for human IL-12B (p40) and IL-12A (p35) subunits. The mRNA produces a single-chain fusion protein of the IL-12B and IL-12A subunits, with a linker between the subunits. The mRNA sequence has been engineered to enhance protein production and is designed to decrease the amount of protein that might be made in hepatocytes for better tolerability.

Latest data and next steps

In preclinical studies, treatment with IL-12 transformed the tumor microenvironment, with notable activation of natural killer and dendritic cells, and an increase in cytotoxic lymphocytes. AstraZeneca is leading the early clinical development and an open-label multicenter Phase 1 clinical trial of intratumoral injections of MEDI1191 alone and in combination with the checkpoint inhibitor, durvalumab, is ongoing. In 2021, we presented IL-12 data that show evidence of antitumor activity in injected and non-injected lesions as well as pharmacodynamic effects such as increased IL-12, Interferon gamma (IFNγ) and 12, and inflammatory transcriptome.

REGENERATIVE THERAPEUTICS MODALITY

Our regenerative therapeutics modality currently has one development program, which is in the clinic.

VEGF-A (AZD8601)

In collaboration with AstraZeneca, VEGF-A is a localized therapeutic encoding for the VEGF-A protein and addressing ischemic heart failure

Heart disease is the leading cause of death in the United States, accounting for one in every four deaths, and is often due to the inability of adults to regenerate heart tissue. Current approved therapies do not specifically address heart regeneration. Previous attempts at cardiac regeneration have included stem cell grafting and gene therapy, but have faced challenges with safety or efficacy. Several treatments are available for patients with ischemic heart failure. Current treatments include revascularization of the coronary arteries to relieve symptoms and improve cardiac function and therapies that reduce blood pressure or potentially help eliminate excess fluids in congested tissues, including: beta-blockers, angiotensin-converting enzyme inhibitors, angiotensin II inhibitors, and aldosterone receptor blockers as diuretics. However, adult humans are unable to regenerate myocardium tissue following injury and the treatment options described above cannot compensate for this.

Vascular Endothelial Growth Factor A (VEGF-A) is a potent angiogenic factor that promotes growth of blood vessels and acts as a powerful promoter of blood vessel growth. Systemic injection of VEGF-A protein increases VEGF-A exposure throughout the body, which can lead to side effects, but is very short-lived in circulation. Therefore, any therapy involving VEGF-A needs to be localized to elevate local protein concentration and drive revascularization while minimizing systemic side effects. AstraZeneca has opted to pursue the localized application of VEGF-A mRNA in a simple saline formulation in the heart muscle to elevate local protein concentration for longer periods due to increased local protein production. This potentially allows for an extended pharmacodynamic effect at the specific site of injection compared to systemic or local administration of a recombinant protein version of VEGF-A.

Latest data and next steps

Preclinical studies have been conducted at AstraZeneca in models of ischemic heart failure. In mouse, rat, and pig models of myocardial infarction, direct injection in the heart muscle (myocardium) of VEGF-A mRNA led to elevated cardiac VEGF-A protein levels and improved cardiac function. The Phase 1a/b study was a randomized, double-blind, placebo-controlled study in men with type 2 diabetes mellitus conducted in Europe. VEGF-A mRNA was administered by intradermal injection into the forearm skin in single ascending doses. Administration of AZD8601 demonstrated protein production and changes in local blood flow in diabetic patients. Tolerability of our mRNA injected intradermally was demonstrated for all dose levels. The only causally treatment-related adverse events were mild injection-site reactions, occurring in 32 of 33 participants receiving VEGF-A mRNA across both parts of the study design. All adverse events of injection-site reaction were of mild intensity. No deaths, serious adverse events, or adverse events leading to discontinuation occurred.

AstraZeneca has also progressed VEGF-A (AZD8601) to a randomized, placebo-controlled, double-blind, multicenter, 6-month, Phase 2a clinical trial of the safety, tolerability, and exploratory efficacy of epicardial injections of AZD8601 in patients with stable coronary artery disease and moderately decreased left ventricular ejection fraction (LVEF) who are undergoing coronary artery bypass graft surgery. Exploratory efficacy endpoints included LVEF, NT-proBNP (a biomarker which measures the level of a hormone which is elevated in patients with heart failure), and functional patient reported outcomes. In 2021, the Phase 2 study met the primary endpoint of safety and tolerability of AZD8601 for the 3 mg dose. In the study of 11 patients, seven were treated with AZD8601 VEGF-A mRNA and four received placebo injections. Numerical trends were observed in endpoints in the heart failure efficacy domains compared with placebo, including increase in LVEF and patient reported outcomes. In addition, all seven patients treated with AZD8601 had NT-proBNP levels below heart failure (HF) limit at 6 months follow-up compared to one of four patients treated with placebo. AstraZeneca has announced that they intend to move AZD8601 into further studies.

SYSTEMIC INTRACELLULAR THERAPEUTICS

Our systemic intracellular therapeutics modality currently has five development programs, two of which are in the clinic.

Propionic acidemia (PA) (mRNA-3927)

PA is an inherited metabolism disorder with significant morbidity and mortality and our mRNA therapy is ongoing in a Phase 1 trial, aiming to produce an intracellular, mitochondrial enzyme complex to treat the disorder

PA is a serious inborn error of metabolism disorder with significant morbidity and mortality. There are approximately 325-2,000 PA patients in the United States based on estimated birth prevalence (0.2-1.2:100,000 newborns) and mortality rates. The vast majority of patients present with life-threatening metabolic crises during the first few days or weeks of life, with mortality rates ranging from 13-53% during the neonatal period. The cardinal feature of the disorder is the occurrence of life-threatening acute metabolic decompensations that are more frequent in the first few years of life. Longer term sequelae include cardiac complications (cardiomyopathy, arrhythmias) and severe neurologic complications. The disorder is caused by a defect or deficiency in PCC, an enzyme that is one step upstream in the same metabolic pathway as the MUT enzyme that is deficient in MMA, as further described below. PCC is a complex hetero-dodecamer enzyme composed of six alpha subunits (PCCA) and six beta subunits (PCCB). The disorder is autosomal recessive, with PA patients generally having loss-of-function mutations in either PCCA or PCCB (and in rare instances, mutations in both PCCA and PCCB). The disorder is biochemically characterized by the accumulation of toxic metabolites such as 3-hydroxypropionic acid and 2-methylcitrate, among others, and these metabolites may be used as biomarkers of disease. There is no approved therapy for PA to treat the underlying defect, including no enzyme replacement therapy, due to the complexity of PCC and mitochondrial localization.

We are developing an IV-administered combination mRNA approach, which contains two mRNAs, one for each of the subunits of PCC (PCCA and PCCB) encapsulated in our proprietary LNP (the same LNP formulation as mRNA-1944). The intent is to potentially treat the entire PA population, regardless of whether an individual has a defect or deficiency in the PCC alpha or beta subunit. The mRNA sequences have been engineered to improve protein translation and encode enzymatically-active PCC with the proper subcellular localization in the mitochondria.

Latest data and next steps

We have demonstrated activity in a PA mouse model in a long-term repeat dose study. In the 6-month repeat dose study in PA mice, a significant and sustained lowering of additional disease biomarkers (e.g., 2-methylcitrate, or 2MC) was observed throughout the duration of the 6-month study. mRNA-3927 is ongoing in a Phase 1/2 study, the Paramount Study, and the first cohort is fully enrolled, and cohort 2 enrollment is ongoing. The study's objective is to evaluate the safety and pharmacology of mRNA-3927 in patients 1 year of age and older with PA. The primary endpoints are safety and pharmacokinetics and pharmacodynamics. Secondary endpoints include incidence and severity of adverse events (AEs) and change in plasma biomarkers: methylcitric acid (2-MC) and 3-Hydroxypropionic acid (3-HP). We have received Rare Pediatric Disease Designation, Orphan Drug Designation and Fast Track Designation from the FDA and Orphan Drug Designation from the European Commission for the PA program.

Methylmalonic acidemia (MMA) (mRNA-3705)

MMA is an inherited metabolism disorder with significant morbidity and mortality and our mRNA therapy is ongoing in a Phase 1 trial, aiming to produce an intracellular, mitochondrial enzyme complex to treat the disorder

There are an estimated 500-2,000 MMA MUT deficiency patients in the United States based on estimated birth prevalence (0.3-1.2:100,000 newborns) and mortality rates. Mortality is significant, with mortality rates of 50% for MMA patients with complete MUT deficiency (mut ^{0}) (median age of death 2 years) and 40% for MMA patients with partial MUT deficiency (mut $^{-}$) (median age of death 4.5 years) reported in a large European study. MMA mainly affects the pediatric population and usually presents in the first few days or weeks of life. The occurrence of acute metabolic decompensations is the hallmark of the disorder and decompensations are typically more frequent in the first few years of life. Each decompensation is life-threatening and often requires hospitalization and management at an intensive care unit. Surviving patients often suffer from numerous complications including chronic renal failure and neurologic complications such as movement disorders, developmental delays, and seizures. Consequently, the health-related quality of life for MMA patients and their families is significantly impaired.

The disorder is autosomal recessive and primarily caused by loss-of-function mutations in the gene encoding MUT, a mitochondrial enzyme that metabolizes certain proteins and fats, resulting in complete (mut ^{0}) or partial (mut $^{-}$) enzyme deficiency. There are currently no approved therapies that address the underlying defect for MMA.

We are developing an mRNA encoding human MUT encapsulated in our proprietary LNPs for IV administration for the treatment of isolated MMA associated with MUT deficiency. The sequence has been engineered to improve protein translation. To function, the mRNA-encoded MUT protein is translocated to its site of action in the mitochondria. mRNA-3705 is our second generation MMA development candidate.

Latest data and next steps

We previously demonstrated, in a series of *in vitro* and *in vivo* pharmacology studies, that human MUT mRNA effectively directs the biosynthesis of active MUT protein with physiologically correct mitochondrial localization in vitro, and improves survival and corrects biochemical abnormalities in two different mouse models of MMA representing the spectrum of MUT deficiency (mut0 and mut-). Technology and process improvements enabled the development of an updated drug product, mRNA-3705, which shows greater potency and better pharmacology compared to our prior candidate, mRNA-3704. mRNA-3705 is currently ongoing in a Phase 1/2 study, the Landmark Study. The study is an adaptive, open-label study is designed to evaluate the safety and tolerability of up to five different dosing regimens of mRNA-3705 administered via intravenous infusion in patients one year and older with isolated methylmalonic acidemia due to methylmalonyl-CoA mutase (hMUT). Upon establishment of an optimized dose based on safety and pharmacological data, additional patients may be enrolled in an optional expansion cohort.

Glycogen storage disease type 1a (GSD1a) (mRNA-3745)

GSD1a is an inherited metabolism disease and our approach is to use an mRNA encoding for intracellular human glucose 6-phosphatase

GSD1a is an inherited metabolic disorder caused by a deficiency in the catalytic activity of G6Pase. G6Pase catalyzes the hydrolysis of glucose-6-phosphate to glucose and inorganic phosphate, the final step of glycogenolysis and gluconeogenesis that mainly takes place in the liver and kidneys. GSD1a patients suffer from severe fasting hypoglycemia, hepatomegaly, nephromegaly, lactic acidemia, hypertriglyceridemia, hyperuricemia, hypercholesterolemia, hepatic steatosis, and growth retardation. In addition, hepatocellular adenomas occur in 70% to 80% of GSD1a patients by their third decade of life and carries risk of transformation into hepatocellular carcinomas. Proteinuria has been observed in over half of patients above 25 years of age. GSD1a occurs in approximately 1:100,000 live births in the United States and European Union but is more common in Ashkenazi Jews where the incidence is reported to be 1:20,000 live births. There are an estimated 2,500 people in the United States and over 4,000 people in the European Union with GSD1a. Although strict diet therapy, including frequent feeding with uncooked cornstarch, allows GSD1a patients to live into adulthood by preventing hypoglycemia, the underlying pathological processes remain uncorrected resulting in the development of many long-term complications including liver adenomas and hepatocellular carcinoma.

Our program, mRNA-3745, consists of an mRNA encoding for modified human G6Pase encapsulated in our proprietary LNPs. The human G6Pase sequence is modified for improved protein production and G6Pase activity. mRNA-3745 is designed to be administered intravenously and encodes G6Pase protein to restore this deficient or defective enzyme.

Latest data and next steps

We have conducted several *in vitro* and *in vivo* pharmacology studies to demonstrate preclinical proof-of-concept for GSD1a therapy. mRNA encoding for G6Pase introduced in human cells resulted in robust production of active G6Pase with subcellular localization into endoplasmic reticulum. mRNA-3745 has been granted Orphan Drug Designation by the U.S. FDA as well as the European Medicines Agency (EMA) and has an open IND. The Phase 1 study will evaluate the safety and pharmacology of mRNA-3745 in patients 18 years of age and older with GSD1a. The Phase 1 study, the Balance Study, is a single dose escalation study in adult participants diagnosed with GSD1a. The primary objective is to determine the safety and tolerability following a single dose of mRNA-3745. Secondary objectives are to evaluate pharmacokinetics and pharmacodynamics of mRNA-3745 in adult GSD1a patients.

Phenylketonuria (PKU) (mRNA-3283)

PKU is a rare inherited metabolic disease is and our approach is to use an mRNA encoding for intracellular phenylalanine hydroxylase (PAH)

Phenylketonuria (PKU) is a rare inherited metabolic disease resulting from a deficiency in the metabolism of phenylalanine (PHE) due to mutations within the enzyme phenylalanine hydroxylase (PAH). The most effective treatment is a restrictive diet of low protein, which controls PHE intake. Approximately 20-56% of PKU patients respond to sapropterin dihydrochloride (marketed as Kuvan in the United States), a synthetic BH4 cofactor for PAH which improves PHE metabolism, but does not fully cure patients. In addition, in May 2018, Biomarin received approval for pegylated phenylalanine lyase (PAL), marketed as Palynziq. Palynziq is a pegylated recombinant bacterial enzyme which metabolizes PHE in the blood. We believe the immune risk is, at least in part, driven by bacterial PAL. PKU occurs in approximately 1:10,000-15,000 live births in the United States. Based on current population estimates that would translate into approximately 21,000-32,000 PKU patients in the United States. Affected individuals have a deficiency in the enzyme PAH, resulting in a reduced or complete inability to metabolize the essential amino acid phenylalanine into tyrosine. Thus, PKU patients suffer from a phenylalanine intoxication and a subsequent deprivation of tyrosine, leading to severe mental disability if left untreated.

Our program mRNA-3283 consists of an mRNA encoding human PAH encapsulated in our proprietary LNPs. The mRNA sequence is optimized for protein synthesis and contains a microRNA binding site to reduce or potentially eliminate synthesis of protein outside of the target tissues. mRNA-3283 is designed to be administered intravenously to encode enzymatically-active PAH protein in liver to restore this deficient or defective enzyme.

Latest data and next steps

We have conducted several *in vitro* and *in vivo* pharmacology studies to demonstrate preclinical proof-of-concept for PAH therapy. A PKU mouse model demonstrated a significant reduction of blood PHE levels post dose. mRNA-3283 is ongoing in preclinical studies.

Crigler-Najjar Syndrome Type 1 (CN-1) (mRNA-3351)

CN-1 is a severe condition caused by the mutations in the UGT1A1 gene and our approach, in collaboration with the Institute of Life Changing Medicines (ILCM), is to encode for the human UGTA1A1 protein

Crigler-Najjar syndrome is a severe condition characterized by high levels of a toxic substance called bilirubin in the blood (hyperbilirubinemia). It is caused by the mutations in the UGT1A1 gene in which bilirubin, a substance made by the liver, cannot be broken down. Without this enzyme, bilirubin can build up in the body and lead to jaundice and damage to the brain, muscles and nerves. The symptoms become apparent shortly after birth and can be life-threatening. It is estimated that there are only approximately 70-100 known cases of CN-1 in the world. Affected individuals rely on current standard of care, phototherapy treatments of up to 12 hours a day, throughout life. The only definitive treatment is liver transplant that is associated with its own set of side effects and risk of death.

Our program, mRNA-3351, consists of an mRNA encoding human UGTA1 encapsulated in our proprietary LNPs. It is designed to restore the missing or dysfunctional proteins that causes CN-1.

Latest data and next steps

We have licensed mRNA-3351 to ILCM with no upfront fees and without any downstream payments. The goal of the collaboration is to make an mRNA therapy for the treatment of CN-1 available at no cost to patients. ILCM will be responsible for the clinical development of mRNA-3351.

INHALED PULMONARY THERAPEUTICS

Our inhaled pulmonary therapeutics modality currently has one development candidate.

Cystic Fibrosis (CF) (VXc-522)

CF is a multi-system disease caused by the mutations in the CFTR gene and our approach, in collaboration with Vertex, is to deliver mRNA to the lungs to provide functional CFTR protein expression that translates to transformative clinical benefit

CF is a rare genetic disease, which is progressive from birth and leads to multi-organ damage and early death due to lung dysfunction. It is caused by the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene which results in the loss of CFTR chloride ion channel function. This decreased function of CFTR at the cell surface leads to thick, sticky mucus in multiple organ systems but most pathologically the lungs. It is estimated that there are ~75,000 patients with cystic fibrosis in the world, with ~10% of these patients not addressable with the approved CFTR modulators.

Our program is designed to treat the underlying cause of CF by enabling cells in the lungs to produce functional CFTR protein for the treatment of the 10% of patients who do not produce any modulator-responsive CFTR protein.

Latest data and next steps

We are collaborating with Vertex on our CF candidate, VXc-522. Pre-clinical studies are ongoing and Vertex expects to submit an IND in 2022.

MANUFACTURING

Manufacturing plays a critical role in our value chain and our ability to develop a new class of medicines. Our manufacturing capabilities support every stage of the development of our products, from new product ideas to commercialization. During the research stage of product development, manufacturing provides mRNA drug substance and drug product for platform research and therapeutic area drug discovery. During early development of our investigational medicines, we manufacture mRNA and drug product for IND-enabling GLP toxicology studies and initial human clinical studies. For late clinical development, we produce mRNA and drug product for phase 3 studies. At the commercial stage of development, we manufacture drug substance and drug product in collaboration with our contract manufacturing organizations (CMOs), both in the U.S. and internationally.

Our approach to date has been to proactively invest and build manufacturing capacity internally and externally with our network of strategic partners in anticipation of demand. This capacity was immediately leveraged and expanded during our COVID-19 vaccine ramp-up into a commercial product in response to the ongoing pandemic. Our ability to rapidly accelerate our manufacturing capabilities in response to COVID-19 allowed us to ship 807 million doses of our COVID-19 vaccine globally in 2021, compared to 17 million doses in December 2020. We are committed to further increase our manufacturing capacity substantially in 2022.

Overview of our manufacturing operating model

Our manufacturing activities generally focus on the following:

- **Commercial Production:** Our manufacturing expertise includes state-of-the-art technologies for mRNA and drug product manufacturing, as well as quality control testing to attain a robust and consistent supply that matches target product profiles. Our manufacturing technology is built to scale-up and support industrialization of products for commercial approval.
- **Research and Development Support:** The product supply enables platform research and drug discovery in our therapeutic and vaccine areas, in addition to activities related to clinical studies of our investigational medicines.

Given our expectations for significant ongoing pipeline expansion and the long lead time required to build manufacturing infrastructure, we built a dedicated in-house manufacturing facility in Norwood, MA, the Moderna Technology Center (MTC), which we have since expanded to a multi-building campus. The MTC provides supply for our preclinical research, IND-enabling GLP toxicology study supplies, our Phase 1 and Phase 2 pipeline activities, later-stage clinical development activities (e.g., Phase 3 CMV vaccine clinical trials), as well as COVID-19 vaccine drug substance production.

The MTC campus has been designed with a high level of automation and state-of-the-art digital integration to handle manufacturing execution, product testing and release, and regulatory filings. In addition, substantial manufacturing capabilities are realized via CMO relationships in the United States and abroad, providing drug substance and fill-finish capacity for the COVID-19 vaccine. Much of the production for our COVID-19 vaccine supply for the U.S. market is completed at the MTC campus, with additional production by Lonza Ltd. (Lonza). We have also partnered with Lonza to complete production in Switzerland of our COVID-19 vaccine for markets outside the United States, as well as with National Resilience, Inc. to manufacture drug substance at its facility in Ontario, Canada for distribution worldwide. Fill-finish services for our COVID-19 vaccine are provided by Catalent Inc., Thermo Fisher Scientific, Sanofi and Baxter BioPharma Solutions in the United States, and by ROVI (in Spain), Recipharm (in France) and Samsung Biologics (in South Korea) outside the United States. We have also partnered with other CMOs for the production of and fill-finish services of our COVID-19 vaccine, and expect that we will enter into additional collaborations as we continue to scale. In April 2021, we announced additional investments in manufacturing to increase supply at our owned and partnered manufacturing facilities, with the goal of increasing our global 2022 capacity for COVID-19 vaccine production. In May 2021, we announced the planned expansion of the MTC, which we expect to more than double the space at the MTC and allow us to continue to optimize our mRNA products as we explore new pharmaceutical delivery forms such as prefilled syringes and lyophilized products. Additionally, in February 2022, we announced new collaborations with ROVI and Thermo Fisher Scientific (Thermo Fisher) for manufacturing capabilities. With ROVI, we agreed to a ten-year collaboration to increase manufacturing capacity at ROVI's facilities in Spain. In addition to producing our COVID-19 vaccine, we expect that ROVI's platform may be utilized to service other vaccine candidates in the future. With Thermo Fisher, we agreed to a fifteen-year collaboration to enable dedicated large-scale manufacturing in the United States of our COVID-19 vaccine and other investigational mRNA medicines in our pipeline.

In addition, during 2021 we announced agreements in principle with the governments of Canada and Australia to establish mRNA manufacturing facilities in those countries. These agreements are subject to final negotiation, but we envision entering into long-term supply agreements with these countries for the supply of mRNA vaccines. By establishing manufacturing facilities locally, we will also provide these governments with direct access to rapid pandemic response capabilities. We are in active discussions with other governments to provide similar manufacturing capabilities in other geographies.

We have further committed to building a state-of-the-art mRNA facility in Africa to provide a local source of mRNA medicines for the continent, in part to prepare for future pandemics. We expect to invest up to $500 million in this facility and anticipate that once fully operational, it will be capable of producing up to 500 million doses of vaccines annually at the 50 μg dose level.

Manufacturing technology development

To support our broad pipeline of products, which span multiple therapeutic areas and routes of administration (e.g., intramuscular, intratumoral, and intravenous), there is close collaboration between our platform research and technical development teams to facilitate rapid and seamless clinical translation of scientific breakthroughs. This, in turn, enables us to develop potential vaccines and therapies to serve a widening patient population.

Technical development encompasses the design and optimization of robust and consistent manufacturing processes, product characterization, fit-for-purpose formulations, and product presentations. For instance, our novel hardware platforms' automation and robotics, coupled with the flexibility of our in-house digital development systems, allows for thousands of experiments and process parameters across our projects, thus supporting our drug product pharmaceutical readiness. Moreover, our recent technical manufacturing advances have enabled internalization of new key capabilities, including DNA plasmids and small molecules.

In parallel, we have refined existing processes, resulting in increased manufacturing scale and more robust stability of our mRNA and drug product. These improvements allow us significant control over our supply chain, resulting in larger production yields and longer shelf life of our products. Furthermore, formulation development advancements have added new drug product images, including lyophilization, giving us a path from frozen to refrigerated storage conditions.

Our substantial investments in recent years in technical development has enabled the breadth and depth of our pipeline, and laid the foundation to help meet the needs and requirements associated with late stage development and the commercialization of the COVID-19 vaccine.

Supply of mRNA for All Stages of Product Development and Commercialization

Supply for Research

High-throughput automation and custom engineered equipment allow us to produce and deliver high quality mRNA and formulated constructs in a short period of time: our proprietary platform is capable of producing up to 1,000 lots of mRNA sequences and formulations per month with a turnaround time of a few weeks from sequence to final product. The typical scale of mRNA manufactured by this team is 1–1,000 mg. This has been possible, in part, thanks to the ability of researchers in the Moderna ecosystem to order constructs through an integrated digital portal that tracks materials end-to-end in less than 45 days. In addition, multiple integrated algorithms that leverage artificial intelligence and machine learning optimize manufacturability, reduce failures, and increase quality of mRNA sequences.

Supply for Early Development

We have established manufacturing capabilities that support the early development stage of product development in three key areas: GLP Tox, Clinical Studies, and Personalized Cancer Vaccines. We supply mRNA and formulated product to conduct IND-enabling GLP toxicology studies. In addition, human clinical studies rely on supply to meet required cGMP standards. This is achieved via internal manufacturing at the MTC and external manufacturing at well-established CMOs. We select specialized CMOs to support our portfolio. We will continue to selectively partner with CMOs to complement our capacity and provide supply contingency where needed. Our MTC facility is also suited to enable rapid technology development and scale-up for future needs. Our manufacturing also produces cGMP PCVs. Due to the specialized nature of personalized medicine (i.e., where a batch is specifically designed and manufactured for a single patient), the manufacturing Personalized Vaccine Unit (PVU) has unique requirements. We digitally integrate patient-specific data from sequencing tumor samples to automatically design PCVs for patients. We have developed proprietary bioinformatics designed algorithms linked to an automated manufacturing process for rapid production of formulated mRNA, with a typical turnaround time of a few weeks. We have operationalized PCV manufacturing at the MTC campus to meet our Phase 1 and 2 pipeline supply needs by using single-use systems with fast "needle-to-needle" turnaround times. Unlike traditional process development, each PCV batch is manufactured for a single patient and thus scaled-out (in parallel) with extensive use of automation and robotics to account for the larger number of patients involved in later phases of development and commercialization. We have shown consistent quality in our production of over 160 patient batches, each with unique mRNA sequences.

These capabilities have allowed us to build our broad pipeline of 44 development programs, including the output required to supply related toxicological and human clinical studies. While the technology that underpins these programs is the same, each program typically requires customization based on target product profiles. These custom features range from varying molecular architecture to different routes of administration, often requiring multivalent products. For example, our CMV vaccine (mRNA-1647) requires six different mRNA sequences to be manufactured for inclusion in an intramuscular mRNA medicine, whereas our COVID-19 vaccine (mRNA-1273) requires a single mRNA sequence for inclusion in an intramuscular mRNA medicine. All programs, with the exception of PCV, require that we progressively scale up supply to meet clinical demand requirements across development phases, in addition to

the necessary preparation for regulatory approval and commercial production, which demand larger batch sizes. In contrast, the PCV program seeks to develop a cancer vaccine that is designed and manufactured for a specific patient, thus increasing the number of unique batches. As we scale manufacturing output for each program, we plan to continuously improve yield, purity, and the pharmaceutical properties of our development candidates.

Supply for Late-Stage Development and Commercialization

As we continue to manufacture our COVID-19 vaccine, our development pipeline continues to advance to later-stage development and towards commercialization. Our platform approach allows us to continue to evolve our manufacturing suites and other capabilities at our MTC campus. Building expansions and enhancements have continued throughout scale-up of our COVID-19 vaccine manufacturing capabilities. The modular nature of the MTC suites permits us to manufacture multiple products in parallel. For instance, we can produce drug substance and drug product for our phase 3 CMV clinical trial while manufacturing COVID-19 drug substance in the same facilities.

Quality Unit

Quality is core to the way we operate. We seek to ensure quality at Moderna through a combination of a robust Quality Management System (QMS), our quality culture, and our people. In accordance with applicable regulations, we have established, documented, and implemented a QMS to assure continued compliance with the requirements therein. The QMS facilitates cGMP compliance by implementing practices that identify the various required processes, their application throughout the organization, and the sequence of interaction of these processes.

The primary mode of documenting these key practices is through policies, standard operating procedures (SOPs), forms, and other quality records, which include an overarching Quality Policy and Quality Manual. We have implemented measurement tools and metrics to monitor, measure, and analyze these practices to support cGMP operations, achieve planned results, and support continuous improvement. We monitor these quality metrics through formal governance processes, including Quality Management Review (QMR), to enable continuous improvement. We have also established an independent Quality Unit that fulfills quality assurance and quality control responsibilities.

Our Quality Unit grew into an international organization with the introduction of COVID-19 vaccine manufacturing. Quality drives our quality culture and ensures it is applied consistently and thoughtfully across the globe.

While the Quality Unit is ultimately accountable and responsible for quality, this is a shared responsibility. All cGMP personnel are empowered to ensure quality systems are appropriately maintained and executed.

We have established a culture that encourages transparency, accountability, and ownership of quality at all levels in the organization. As we scale the quality organization, we have focused on hiring the best talent with the required experience, training, and education.

Supply Chain Unit

We have established an international supply chain to enable supply of the raw materials used to produce our mRNAs and the components of our formulations, securing supply for COVID-19 vaccine alongside clinical and preclinical demands. We have worked with our supply chain vendors to characterize critical raw materials and to understand their impact on the quality of mRNA drug substance and formulated drug product. We also assess the quality system and performance of our supply chain vendors and work with them to comply with regulatory requirements.

DIGITAL INFRASTRUCTURE

We believe that digital technologies, such as robotics, automation, artificial intelligence (AI) and cloud computing, are critical to operationalize our strategy, accelerate our pace of learning and execute at scale. We aspire to digitize our operations wherever possible, with the goal of using the power of digital technology to maximize our impact on patients. Since our inception, we have invested heavily in our digital technologies, robotics/automation, analytics, data science and AI. To facilitate our growth, we will continue to invest in our digital infrastructure. Construction has begun on our new Moderna Science Center in Cambridge, which is designed to integrate digital-first scientific research and development labs. Our approach to bring these digital technologies into our workflows and processes has involved the following:

- utilization of a consistent set of digital building blocks;
- application of digital technologies in multiple business processes; and
- rapid iterations for maximum optimization.

We have seen several benefits from our investments in digitization, most importantly through the depth of our platform technology and breadth of our pipeline. Other benefits include:

- Quality: Reduction in human errors by enabling automation, repeatability, and seamless integration;
- Scalability: Growth in our pipeline to 44 development programs;
- Speed: Rapid manufacture of cGMP product, as exhibited by our first COVID-19 vaccine batch, and research-grade mRNA; and
- Cost efficiencies: Digital infrastructure utilized across our platform, drug discovery, clinical development, and manufacturing to maximize efficiencies.

Our digital building blocks

We utilize six building blocks for our digital infrastructure:

- *Cloud enablement* is a critical component of our digital infrastructure. We are at the forefront of mRNA technology. We generate complex data sets, and our scientists need computational power and agility to operate without being limited by traditional computing technology. Maintaining digital infrastructure in the cloud provides the benefits of lower costs by simplifying provisioning and administration, flexibility, scalability, ease of maintenance, disaster recovery, and information security.
- *Integration of business processes* enables us to streamline processes and bring data together in a consistent manner, avoiding caches of information and manual intervention. This efficient flow of data between systems enables the automation of our business processes.
- *Internet of things* allows for smart interconnected devices that provide real-time synchronization of operations. The data from equipment provides real-time guidance to our scientists and engineers and helps us in supply chain and manufacturing with compliance and traceability, including tracking material, controlling inventory and optimizing instrument usage.
- *Automation* allows us to scale our operations reliably and reproducibly. With the help of custom hardware solutions and state-of-the-art robotics, we can continue to increase our operating efficiency, reduce errors, and improve our quality and compliance.
- *Advanced analytics* enable us to draw insights from our data. We are constantly generating large data sets that can provide important insights if mined appropriately and regularly.
- *AI* is enabling key breakthroughs in predictive modeling. It will allow us to improve our mRNA design algorithms based on machine learning, and will provide us with critical insights into research, supply chain, manufacturing, and other processes.

Digital technologies to enable our drug discovery efforts

We have deployed multiple digital technologies to drive a rapid pace of learning, enable efficient workflows and business processes, and draw insights from vast amounts of data. Our aim is to provide our platform and discovery scientists with access to an environment that helps them through each step of their research cycle.

Drug Design Studio: Our proprietary in-house digital application suite contains a Sequence Designer module to tailor an entire mRNA, with ever-improving rule sets that contain our accumulated learning about mRNA design. Drug Design Studio utilizes cloud-based computational capacity to run various algorithms we have developed to design each mRNA sequence. The utility of cloud-based capacity allows us to provide flexible computational capacity on demand, allowing us to power parallel intake and design of multiple mRNA sequences. Once a sequence is designed, it can be ordered digitally using an internal order form application within Drug Design Studio.

Manufacture of research-grade mRNA: Once an order is optimized, the mRNA production process is triggered. We have developed proprietary interfaces that allow the manufacturing team to track production orders at every stage. We have automated several manufacturing steps using both off-the-shelf and custom automation. The equipment used in the manufacture of research-grade

mRNA is integrated with the digital interfaces to capture, extract, and interpret the data generated at each step of the manufacturing process, building digital traceability on each mRNA order. We have also embedded real-time algorithms and analytics tools to allow for automated decision-making at some stages, accelerate the quality control workflows, and provide for continuous improvement of manufacturing processes.

Dispatching and shipping mRNA: Because we produce large quantities of research-grade mRNA, we require digital tools to track their shipment to our scientists and to external contract research organizations (CROs) conducting *in vivo* studies. Our dispatching and shipping application automatically generates bar-coded labels, allowing for traceability of product.

Inventory and registry: Material used in research and created in production, including mRNA, cell lines, chemicals, and reagents, is tracked in our Inventory application. This application supports numerous workflow tools such as consumption, aliquoting, material transfer, and stock alerts. Critical material types are assigned unique registry identification by our Registry application.

Study design: Using our Drug Design Studio, our scientists can design their *in vivo* studies using our proprietary Study Design application. This application captures *in vivo* study protocol design parameters, including dose amount, number of doses, frequency, samples, and assays for each sample. This application serves two purposes. It allows our scientists to maintain and track their *in vivo* study designs and associated research grade mRNA. Our Study Design application also allows our *in vivo* pharmacology teams to track the various ongoing studies and leverage external CROs to manage the *in vivo* demand as needed.

Experiment management: We have deployed Electronic Lab Notebooks for experiment management, allowing our scientists to streamline documentation of their experiments and track it in a standardized, searchable repository. We have also integrated Electronic Lab Notebooks further with our other research tools to connect inventory, *in vivo* studies, and instrument data.

Advanced analytics and AI to accelerate the pace of learning: We utilize AI to enable various parts of our platform and drug discovery. Examples include:

- *Neural networks for protein engineering*: One way to optimize the efficacy of the proteins encoded by our mRNA is to engineer the sequence of the protein itself. We use neural networks to analyze and model protein sequences. We train these models by inputting orthologous sequences from thousands of organisms, from which we can generate potential protein sequences optimized for specific attributes.
- *Neural networks for mRNA engineering*: The redundancy in the genetic code allows for a large number of mRNA sequences that encode the same protein. mRNA sequence may impact translation, thereby impacting the amount of protein produced in circulation. We are developing AI tools to predict mRNA sequences that can enhance protein expression.
- *Automated Sanger sequencing analysis*: Sanger sequencing is used repeatedly to quality check (QC) our DNA templates and final mRNA; while the data contain every nucleotide in a sequence, it is very complex to analyze. A fully automated data pipeline starts processing raw data the moment it is saved to the cloud by the sequencers. The pipeline spawns numerous AWS computer servers to run an analysis algorithm and then shuts the servers down, minimizing costs. The results are viewable in a powerful, dynamic visualization tool. We have run over three million Sanger data files through this system. We have further improved our Sanger analysis with a convolutional neural network (CNN) to better analyze the tail sections of mRNA as well.

Digital technologies to enable our clinical trials

We have deployed multiple digital technologies to drive the rapid pace of advancement, in parallel, of our development candidates into the clinic.

Digital systems for cGMP manufacture: We are committed to having integrated systems connected with robotics to drive our manufacturing in a paperless environment, and have designed and deployed automation to drive efficient manufacturing operations. We have also deployed digital tools within manufacturing process development that give us the ability to track, analyze, and rapidly deploy manufacturing process improvements. Additionally, we have implemented several digital systems across manufacturing process development, quality, supply chain, and operations, including:

- enterprise Quality Management System (QMS) to electronically manage deviations, investigation, and correction and preventive actions;
- Laboratory Information Management System (LIMS) to manage our analytical development data and automate our manufacturing quality control;
- computerized maintenance management system to manage equipment maintenance and calibration; and
- SAP/S4 Hana system for enterprise resource planning (ERP), manufacturing execution system, and manufacturing control system to manage inventories, track raw material consumption, digitally integrate equipment with manufacturing recipes in batch records, and control automated equipment.

Digital systems for clinical development and clinical operations: In order to track the timelines of various development candidates, we have created a set of integrated applications. Workflows include timelines for regulatory filings, planning for IND-enabling GLP toxicology studies, scheduling for cGMP manufacturing, and clinical operations management. Below is a summary of our applications:

- Our portfolio application is a digital interface that maintains and tracks the timelines across multiple workstreams for each of our development candidates.
- The supply application manages the manufacturing schedule of IND-enabling GLP toxicology supplies and cGMP manufacture of clinical supplies to support our programs. This application helps us see how the manufacturing schedule changes over time, identifies supply/demand mismatches, and enables resource planning with real-time alerts should we have any issues.
- The GLP toxicology application tracks the planned and ongoing IND-enabling GLP toxicology studies and allows us to manage timelines with our external vendors.
- The regulatory application tracks timelines related to regulatory affairs including, pre-IND meetings, IND/CTA submission dates, and other planned regulatory interactions.
- Our clinical operations application allows us to track our ongoing trials by accessing clinical operations information in real-time from our CROs. It also has multiple tools and analytics to draw key insights, including, for example, enrollment by trial and enrollment by site to maintain our program timelines.

Digital systems for PCV: The PCV program aims to design, manufacture, and deliver a drug product that includes an mRNA sequence encoding for each patient's specific neoantigens. The personalized nature of the PCV program adds additional steps and complexity in the overall patient treatment process. We have addressed those additional steps and complexity by digitizing and automating steps within the process, as described below.

- Each patient is provided a unique identifier. We track the entire workflow using a single integrated tracker based on this unique identifier. This is one of many ways we ensure that each patient receives the specific drug product lot manufactured for them.
- We use neural networks to design the mRNA sequences for the PCV program. Our proprietary vaccine design algorithm selects the top twenty neoantigens to be used and determines their amino acid sequences to trigger the desired immune response.
- We utilize Monte Carlo simulations of PCV supply/demand to manage our capacity. Since each drug product lot is personalized to a patient, there is a need to manage supply and demand to avoid bottlenecks at any stage of the workflow.

Digital systems for commercialization: Our investment in our digital capabilities prepared us to rapidly scale our production of our COVID-19 vaccine in 2021 and 2022. We are continuing to build out our commercial capabilities to establish medical affairs engagements with doctors, support our sales and marketing capabilities and deliver a world-class patient experience. In addition to a patient- and doctor-centric view, our commercial capabilities will strengthen our supply chain demand forecasting and our compliance. We are looking at building a robust serialization process for regulatory requirements as well as anti-counterfeiting technologies to ensure safe, efficacious medicines to patients.

Digital technologies to support our business processes

We have deployed several digital systems across finance, manufacturing, and human resources to automate our business processes and drive efficiencies. We have implemented the SAP S4/Hana system for ERP. We have implemented various cloud-based solutions to improve business processes and drive efficiencies. For example, we have implemented the Workday system for human resource planning and management and integrated various applications across payroll, 401(k) services, equity plan management and expense reporting. Our class-leading integration platform, Dell Boomi, allows us to have a highly interconnected environment, moving us from simple cloud-to-cloud integrations to an evolving use of the integration platform for master data management, systems account management, and ultimately for cost savings and improved user experience.

COMMERCIAL

We have grown our U.S. and international commercial sales organization beginning in early 2020 as we prepared for the commercialization of our COVID-19 vaccine. We have active commercial subsidiaries in 11 countries, including the U.S., Canada, many European countries and the Asia Pacific region, providing us with local commercial teams in key markets around the world. This commercial presence is supported by the Moderna International Business Service center in Warsaw, Poland. Our commercial teams also work in conjunction with third-party distributors and other partners in countries where we do not have a presence. In February 2022, we announced our intention to establish a commercial presence in six additional markets in Europe and four additional markets in Asia.

To date, our COVID-19 vaccine has been sold to government customers and international purchasing organizations, such as Gavi, on behalf of the COVAX Facility, and the African Union. We anticipate that most of our COVID-19 vaccine sales in 2022 will continue

to be pursuant to government contracts and these international purchasing organizations. We expect future sales to private customers if and as we gain marketing approval in various jurisdictions.

In addition, during 2021, we announced agreements in principle with the Canadian and Australian governments to establish mRNA manufacturing facilities in those countries, pursuant to which we would enter into long-term supply agreements for mRNA vaccines. See "Manufacturing" above for further detail.

THIRD-PARTY STRATEGIC ALLIANCES

Strategic alliances

To accelerate the discovery and advancement of potential mRNA medicines across therapeutic areas, we have entered into, and intend to seek other opportunities to form, alliances with a diverse group of strategic collaborators. We have forged productive strategic alliances with pharmaceutical and biotechnology companies, government agencies, academic laboratories, foundations and research institutes with therapeutic area expertise and resources. Through our collaborations, we seek to advance our discovery and development programs, while leveraging our platform and our research and early development capabilities. We also seek to partner with and invest in companies developing other types of therapeutics, such as gene editing and cell-therapy, where we believe we can leverage our core mRNA and LNP capabilities to expand the reach of our technology.

Through certain of our strategic alliances, we share the rewards and risks of developing a new mRNA modality or program, where we may have early research data and desire a strategic collaborator to join us in advancing early development candidates within such modality into the clinic. Representative relationships and associated programs include those with:

- **AstraZeneca** for the VEGF-A program (AZD8601) in the localized regenerative therapeutics modality, and the IL-12 program (MEDI1191) in the intratumoral immuno-oncology modality;
- **Merck** for the personalized cancer vaccine program (mRNA-4157) in the cancer vaccines modality; and
- **Vertex** for the cystic fibrosis (CF) program (VXc-522) in the inhaled pulmonary therapeutics modality.

We view strategic alliances as important drivers for accelerating execution of our goal of rapidly developing mRNA medicines to treat patients across a wide range of medical and disease challenges. To maintain the integrity of our platform, the terms of our agreements with our strategic collaborators generally provide that either we receive rights to develop and commercialize potential mRNA medicines that we design and manufacture or our strategic collaborators receive rights to develop and commercialize potential mRNA medicines that we design and manufacture, as opposed to granting rights to our strategic collaborators to use our platform to generate new mRNA technologies, and that we generally own mRNA-related intellectual property arising from research activities performed under the strategic alliance. We plan to continue to identify potential strategic collaborators who can contribute meaningful technology and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

Below are brief descriptions of certain of our collaborations. For additional information on these relationships, including their ongoing financial and accounting impact on our business, please see *Note 5, Collaboration Agreements*, to our consolidated financial statements included in this Annual Report on Form 10-K.

AstraZeneca (Nasdaq: AZN)—Strategic Alliances in Cardiovascular and Oncology

We have two ongoing strategic alliances with AstraZeneca. Pursuant to the first collaboration, which was established in 2013 and amended and restated in 2018, we granted AstraZeneca certain exclusive rights and licenses to research, develop and commercialize potential mRNA medicines directed at certain targets for the treatment of cardiovascular and cardiometabolic diseases and cancer, and agreed to provide related services to AstraZeneca. Our localized VEGF-A program (AZD8601) is being developed by AstraZeneca pursuant to this alliance.

Pursuant to our second strategic alliance with AstraZeneca, which was established in 2016, we agreed to collaborate to discover, develop and commercialize potential mRNA medicines in a range of cancers. We and AstraZeneca have agreed to work together on an immune-oncology program focused on the intratumoral delivery of a potential mRNA medicine to make the IL-12 protein, and our IL-12 program (MEDI1191) is being developed in collaboration with AstraZeneca pursuant to this alliance.

Merck (NYSE: MRK)—Strategic Alliances in Infectious Diseases and Cancer Vaccines

We have established a multi-faceted relationship with Merck Sharp & Dohme Corp. (Merck) that includes distinct strategic alliances directed to the research, development, and commercialization of mRNA medicines for the prevention and treatment of viral infections and for the treatment of cancer.

2016 Cancer Vaccine Strategic Alliance—Personalized mRNA Cancer Vaccines with Merck

In June 2016, we entered into a personalized mRNA cancer vaccines (PCV) Collaboration and License Agreement with Merck (PCV Agreement) to develop and commercialize PCVs for individual patients using our mRNA vaccine and formulation technology. Under the strategic alliance, we identify genetic mutations present in a particular patient's tumor cells, synthesize mRNA for these mutations, encapsulate the mRNA in one of our proprietary LNPs and administer to each patient a unique mRNA cancer vaccine designed to specifically activate the patient's immune system against her or his own cancer cells.

Pursuant to the PCV Agreement, we are responsible for designing and researching PCVs, providing manufacturing capacity and manufacturing PCVs, and conducting Phase 1 and Phase 2 clinical trials for PCVs, alone and in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, all in accordance with an agreed upon development plan and budget.

2018 Expansion of the Cancer Vaccine Strategic Alliance with Merck—Shared Neoepitope Cancer Vaccines

In April 2018, we and Merck agreed to expand our cancer vaccine strategic alliance to include the development and commercialization of our KRAS vaccine development candidate, mRNA-5671, and potentially other shared neoantigen mRNA cancer vaccines (SAVs). We preclinically developed mRNA-5671 prior to its inclusion in the cancer vaccine strategic alliance and it is comprised of a novel mRNA construct designed by us and encapsulated in one of our proprietary LNPs. The PCV Agreement was amended and restated to include the new SAV strategic alliance (PCV/SAV Agreement). We have regained all rights to our KRAS vaccine (mRNA-5671) from Merck and we are evaluating next steps for the program.

Vertex (Nasdaq: VRTX)—2016 Strategic Alliance in Cystic Fibrosis

In July 2016, we entered into a Strategic Collaboration and License Agreement (Vertex Agreement) with Vertex Pharmaceuticals Incorporated, and Vertex Pharmaceuticals (Europe) Limited (together, Vertex). The Vertex Agreement is aimed at the discovery and development of potential mRNA medicines for the treatment of cystic fibrosis (CF) by enabling cells in the lungs of people with CF to produce functional cystic fibrosis transmembrane conductance regulator (CFTR) proteins.

Vertex —2020 Strategic Alliance in Cystic Fibrosis

In September 2020, we entered into a new Strategic Collaboration and License Agreement with Vertex (Vertex 2020 Agreement). The Vertex 2020 Agreement is aimed at the discovery and development of potential medicines to treat CF by delivering gene-editing therapies to lung cells to facilitate production of functional CFTR proteins.

The three-year research period of the Vertex 2020 Agreement will initially focus on the identification and optimization of novel LNPs and mRNAs that can deliver gene-editing therapies to cells in the lungs. Following the initial three-year period, Vertex is responsible for conducting development and commercialization activities for candidates and products that arise from the strategic alliance, including the costs associated with such activities. Vertex is also obligated to pay us for research services in connection with our performance of certain activities in accordance with a jointly agreed research plan. Subject to customary "back-up" supply rights granted to Vertex, under the agreement, we are the exclusive manufacturer of related mRNA and LNPs for preclinical, clinical, and commercialization purposes.

Other Collaborations

Chiesi—2020 Collaboration and License Agreement with Chiesi

In September 2020, we entered into a Collaboration and License Agreement (Chiesi Agreement) with Chiesi Farmaceutici S.P.A. (Chiesi). The Chiesi Agreement is aimed at the discovery and development of potential mRNA medicines for the treatment of pulmonary arterial hypertension (PAH), a rare disease characterized by high blood pressure in the arteries of the lungs.

Metagenomi—2021 Collaboration for Next-Generation In Vivo Gene Editing Therapeutics

In November 2021, we entered into a strategic research and development collaboration with Metagenomi, Inc. (Metagenomi) focused on advancing new gene editing systems for *in vivo* human therapeutic applications. The collaboration intends to utilize Metagenomi's novel gene editing tools and leverage our mRNA platform, as well as LNP delivery technologies, with the goal of developing curative therapies for patients with serious genetic diseases. Under the terms of the collaboration, we and Metagenomi have agreed to advance a series of *in vivo* gene editing therapeutics against undisclosed targets. We agreed to pay Metagenomi an up-front cash payment and make an equity investment in Metagenomi in the form of a convertible note. Metagenomi is eligible to receive certain target option exercise fees as well as certain milestone payments, plus tiered royalties on net sales of any products that are commercialized by us under the agreement.

Carisma Therapeutics—2022 Collaboration For In Vivo CAR-M Therapeutics

In January 2022, we entered into a new strategic collaboration agreement with Carisma Therapeutics, Inc. (Carisma) to discover, develop and commercialize *in vivo* engineered chimeric antigen receptor monocyte (CAR-M) therapeutics for the treatment of cancer, including solid tumors. Under the terms of the agreement, we agreed to pay Carisma an up-front cash payment and make an equity investment in Carisma in the form of a convertible note. Carisma will receive research funding and is eligible to receive certain milestone payments, plus tiered royalties on net sales of any products that are commercialized by us under the agreement. Carisma will be responsible for the discovery and optimization of development candidates while we will lead the clinical development and commercialization of therapeutics resulting from the agreement. We have the option to nominate up to twelve targets for development and commercialization.

Strategic alliances with government organizations and foundations

Defense Advanced Research Projects Agency (DARPA)

In October 2013, DARPA awarded us up to approximately $25 million under Agreement No. W911NF-13-1-0417 to research and develop potential mRNA medicines as a part of DARPA's Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program, which is focused on assisting with the development of technologies to rapidly identify and respond to threats posed by natural and engineered diseases and toxins. As of December 31, 2021, $20 million of the award amount has been funded. This award followed an initial award from DARPA given in March 2013 under Agreement No. W31P4Q-13-1-0007. The DARPA awards have been deployed primarily in support of our vaccine and antibody programs to protect against Chikungunya infection. Although our antibody against Chikungunya virus (mRNA-1944) had positive Phase 1 readouts, we do not have plans to advance to a Phase 2 study.

In September 2020, we entered into an agreement with DARPA for an award of up to $56 million to fund development of a mobile manufacturing prototype leveraging our existing manufacturing technology that is capable of rapidly producing vaccines and therapeutics. As of December 31, 2021, the committed funding, net of revenue earned was $2 million, with an additional $42 million available under Agreement No. HR0011-20-9-0118 if DARPA exercises additional contract options.

Biomedical Advanced Research and Development Authority (BARDA)

In September 2016, we received an award of up to approximately $126 million under Agreement No. HHSO100201600029C from BARDA, a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), to help fund our Zika vaccine program. Under the terms of the agreement with BARDA, an initial base award of approximately $8 million supported toxicology studies, a Phase 1 clinical trial, and associated manufacturing activities. Additionally, four contract options were awarded under the agreement with BARDA. Three out of four of these options have been exercised, bringing the total current award to approximately $117 million to support an additional Phase 1 study of an improved Zika vaccine candidate, Phase 2 and Phase 3 clinical studies, as well as large-scale manufacturing for the Zika vaccine.

In April 2020, we entered into an agreement with BARDA for an award of up to $483 million to accelerate development of mRNA-1273, our COVID-19 vaccine. In July 2020, we amended our agreement with BARDA to provide for an additional commitment of up to $472 million to support late-stage clinical development of mRNA-1273, including the execution of a 30,000 participant Phase 3 study in the U.S. We further amended the agreement in March 2021 to provide for an additional commitment of $63 million to further support late-stage clinical development, including Phase 2/3 mRNA-1273 pediatric studies. In April 2021, we entered into a further amendment to the BARDA agreement, increasing the amount of potential reimbursements by $236 million in connection with costs associated with the Phase 3 clinical trials for mRNA-1273 and pharmacovigilance efforts. In June 2021, the agreement was further amended to award additional funding of $144 million to support pediatric clinical trials for mRNA-1273. The maximum award from BARDA, inclusive of the 2020 and 2021 amendments, is $1.4 billion. Under the terms of the agreement, BARDA will fund the advancement of mRNA-1273 to FDA licensure. All contract options have been exercised. As of December 31, 2021, the remaining available funding net of revenue earned was $189 million.

Institute for Life Changing Medicines (ILCM)

In September 2021, we entered into a collaboration agreement with the ILCM to develop a new mRNA therapeutic (mRNA-3351) for CN-1. Under the terms of the agreement, we agreed to license mRNA-3351 to ILCM with no upfront fees, and without any downstream payments. ILCM will be responsible for the clinical development of mRNA-3351.

The Bill & Melinda Gates Foundation

In January 2016, we entered a global health project framework agreement with the Bill & Melinda Gates Foundation to advance mRNA-based development projects for various infectious diseases. The Bill & Melinda Gates Foundation has committed up to $20 million in grant funding to support our initial project related to the evaluation of antibody combinations in a preclinical setting as well as the conduct of a first-in-human Phase 1 clinical trial of a potential mRNA medicine to help prevent HIV infections. Follow-on projects, which could bring total potential funding under the framework agreement up to $100 million (including the HIV antibody project) to support the development of additional mRNA-based projects for various infectious diseases, can be proposed and approved until the sixth anniversary of the framework agreement, subject to the terms of the framework agreement, including our obligation to grant to the Bill & Melinda Gates Foundation certain non-exclusive licenses.

INTELLECTUAL PROPERTY

We rely on a combination of intellectual property laws, including patent, trademark, copyright and trade secret, as well as confidentiality and license agreements, to protect our intellectual property and proprietary rights.

Protecting our platform, modality, and program investments: Building an expansive, multi-layered IP estate

We have built a substantial IP estate that includes numerous patents and patent applications related to the development and commercialization of mRNA vaccine and therapeutic development candidates, including related platform technologies. Our platform IP protects advances in mRNA design and engineering, proprietary LNP components, delivery systems, processes for the manufacture and purification of drug substances and products, and analytical methods. A significant portion of our platform IP estate further provides multi-layered protection for our modalities and programs.

With respect to our IP estate, our solely-owned patent portfolio consists of more than 170 issued or allowed U.S. patents or patent applications and more than 110 granted or allowed patents in jurisdictions outside of the U.S. (including granted European patents that have been validated in numerous European countries) covering certain of our proprietary platform technology, inventions, and improvements, and covering key aspects of our clinical and most advanced development candidates. We have over 430 additional pending patent applications that, in many cases, are counterparts to the foregoing U.S. and foreign patents.

Most of the patents and applications (if issued) in our portfolio will not expire until 2033 at the earliest. Any patent that may issue from our most recently filed patent applications is projected to expire between 2042 and 2043, at the earliest. We file additional U.S. and foreign patent applications as necessary to protect our evolving intellectual property position.

We also rely on trademarks, copyright, trade secrets, and know-how relating to our proprietary technology and programs, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of mRNA therapeutic and vaccine technologies. We take additional steps, such as entering into confidentiality and license agreements, to protect our intellectually property and proprietary rights. We additionally plan to rely on data exclusivity, market exclusivity, and patent term extensions when available, and plan to seek and rely on regulatory protection afforded through orphan drug designations. We also possess substantial proprietary know-how associated with related manufacturing processes and expertise.

IP protecting our platform

We have a broad IP estate covering key aspects of our platform. This estate provides multiple layers of protection covering the making and use of the mRNA drug substance and delivery technologies.

With respect to our platform, we have a portfolio that includes U.S. and foreign patents or patent applications covering platform innovations that are directly related to the design, formulation and manufacturing of mRNA medicines. For example, these patents and patent applications include claims directed to:

- mRNA chemistry imparting improved properties for vaccine and therapeutic uses;
- methods for mRNA sequence optimization to enhance the levels and fidelity of proteins expressed from our mRNA medicines;
- methods for identifying epitopes having superior suitability in cancer vaccine contexts;
- engineering elements tailored to enhance stability and the *in vivo* performance of mRNA medicines;
- LNP delivery systems, including novel lipid components designed for optimal expression of both therapeutic and vaccine mRNAs, in particular, prophylactic infectious disease and cancer vaccine mRNAs, intratumoral immuno-oncology therapeutics, local regenerative therapeutics, systemic therapeutics, and inhaled pulmonary therapeutics; and
- innovative processes for the manufacture and analysis of mRNA drug substance and formulated drug product.

IP protection for modalities

Our IP estate provides protection for the multiple programs within our modalities both at the product-specific level and at various broader levels. For example, we have patent coverage for LNP-encapsulated mRNAs having specific chemical modification suited for vaccine and therapeutic mRNA use. Our estate also includes IP covering certain LNP-encapsulated mRNAs coding for infectious disease antigens for use in prophylactic vaccination. Our mRNA chemistry, formulation and manufacturing patent applications and related know-how and trade secrets may also provide us with additional IP protection relating to our development candidates.

Prophylactic vaccines

For programs within our prophylactic vaccines modality, we typically pursue patent protection featuring composition of matter and method of use claims. Our global patent protection strategy may vary based on the unique geographic prevalence of various infectious diseases.

We have filed several patent applications covering our COVID-19 vaccine program. Claims covering mRNA-1273, which is a LNP-encapsulated mRNA encoding prefusion-stabilized Spike protein antigen, and claims to methods of vaccinating subjects against SARS-CoV-2 infection using our vaccine are featured in several patent families that includes four pending PCT applications, a pending U.S. patent application, and foreign patent applications filed in Argentina and Taiwan. Priority dates for these applications span a period from late January through late May 2020. The U.S. government has rights in certain of the foregoing patent applications. A further pending PCT application includes claims covering our variant-specific COVID-19 vaccines. Protection for mRNA-1283 can be found in a PCT application and three pending U.S. provisional patent applications. Two additional U.S. provisional patent applications include claims covering our COVID-19 and seasonal flu combination vaccine.

Issued U.S. Patent No. 10,702,600 includes claims to LNP-encapsulated mRNA encoding betacoronavirus spike protein. Issued U.S. patent 10,933,127 includes claims to methods of using such compositions to elicit an immune response in subjects. Corresponding vaccine composition and method of use claims are also featured in a pending European patent application. These patents and applications enjoy an October 2015 priority date.

Further coverage for our COVID-19 vaccine and many of our other prophylactic vaccines is found in a broad, infectious disease vaccine patent family featuring claims to LNP-encapsulated mRNAs encoding infectious disease antigens and methods using such compositions for vaccination. This patent family includes two issued U.S. patents, two pending U.S. patent applications and pending patent applications in Europe, Canada, Australia, Brazil, China, Hong Kong, India, Japan, Russia, and Singapore. Issued U.S. Patent Nos. 10,022,435 and 10,709,779 feature claims directed to methods of vaccinating subjects against infection with LNP-encapsulated mRNAs encoding infectious disease antigens.

Patent coverage for our human CMV vaccine, which includes mRNAs encoding several surface glycoproteins of the CMV virus, can be found in pending applications in Australia, Canada, Europe and in both a granted patent and pending patent application in Japan. In the United States, our CMV vaccine is covered in a pending U.S. patent application and in issued U.S. Patent Nos. 10,064,935, 10,383,937 and 10,716,846. Two pending PCT applications and a pending U.S. patent application feature claims to clinical formulations of our CMV vaccine and methods of use.

Patent applications directed to our hMPV/PIV3 vaccine are pending in the United States, Europe and Hong Kong. Five U.S. patents have issued featuring hMPV/PIV3 vaccines with U.S. Patent No. 10,064,934 having claims covering LNP-encapsulated mRNA vaccines that encode the PIV3 and hMPV fusion proteins, U.S. Patent No. 10,272,150 having claims covering administration methods for these LNP-encapsulated mRNA vaccines, U.S. Patent No. 10,543,269 having claims covering vaccines that include HMPV-encoding mRNA formulated in LNPs, U.S. Patent No. 10,702,599 having claims covering vaccines that include PIV3-encoding mRNA formulated in LNPs, and U.S. Patent 11,103,578 having claims covering specific HMPV- and PIV3-encoding mRNAs for use as vaccines. A pending provisional patent application features claims to clinical aspects of our hMPV/PIV3 vaccine. A pending U.S. patent application features claims covering our hMPV/RSV vaccine.

Our Zika mRNA vaccine is covered in a series of patent families directed to mosquito-borne viruses. These patent families include four issued U.S. Patents that cover our Zika vaccines, U.S. Patent Nos. 10,449,244, 10,653,767, 11,007,260 and 11,207,398, and several pending U.S., European and Hong Kong patent applications, one of which is recently allowed and soon to be issued as a U.S. patent, and one of which is recently allowed and soon to be granted as a European patent.

We filed patent applications in several jurisdictions covering RSV vaccines. At least two U.S. and two European patent applications are pending, as are applications in Canada, Australia and several Asian jurisdictions. Also pending are two provisional applications featuring our pediatric RSV vaccine.

A pending PCT patent application and a pending U.S. provisional patent application includes claims covering our vaccine program for the prevention of human infection with seasonal influenza virus. The program also is protected by the broad, infectious disease

vaccine patent family described above, in particular, issued U.S. Patent No. 9,872,900 and granted European Patent EP 3134131, having claims to HA-encoding mRNA vaccine compositions.

Pending patent applications in the United States, Australia, Canada, Europe, and Japan include claims covering our EBV vaccines and methods of use.

We have pending patent applications in the United States and Europe that include claims covering our Nipah vaccine and methods of use, and pending applications in the United States and Europe that include claims covering our HIV vaccine and methods of use.

Cancer vaccines

Composition of matter and method claims also protect programs within our cancer vaccines modality. Proprietary methods around the making and therapeutic use of our personalized cancer vaccines (PCVs) and resulting vaccine compositions are described and claimed in six pending U.S. patent applications, five pending European patent applications, four pending patent applications in each of Australia, Canada, China and Japan, and several pending patent applications in New Zealand, South Africa, as well as other European, Asian and South American countries. Of these patent applications, a U.S. patent application and a Chinese patent application are allowed and soon to be issued. These applications also relate to various vaccine design formats, in particular, polyepitopic vaccine formats, and methods of treating cancer with such personalized cancer vaccines. We also possess substantial know-how and trade secrets relating to the development and commercialization of our cancer vaccine programs, including related manufacturing process and technology.

Likewise, our KRAS antigen cancer vaccine and methods of treating cancer featuring such vaccines are covered in issued U.S. Patent No. 10,881,730, which includes claims to LNP-encapsulated mRNA encoding mutant KRAS antigens, and in a pending U.S. patent application and pending applications in Australia, Canada, Europe, and Japan, as well as in several other European, South American, Asian and Middle Eastern jurisdictions.

Intratumoral immuno-oncology

To protect programs within our intratumoral immuno-oncology modality, we have filed numerous patent applications featuring claims to mRNAs encoding immune-stimulatory proteins and methods of treating cancer using such compositions.

Two of our immuno-oncology programs are designed to be administered intratumorally to alter the tumor microenvironment in favor of mounting an immune response against tumors. Our mRNA program that includes mRNAs that encode OX40L, IL-23 and IL-36γ are covered by a granted European Patent, EP 3394093, by eleven issued U.S. patents, U.S. Patent Nos. 10,143,723, 10,172,808, 10,285,950, 10,322,090, 10,322,091, 10,379,767, 10,383,951, 10,406,113, 11,003,366, 11,071,716 and 11,185,510, by several pending U.S. and European patent applications, two of which are allowed and soon to issue, and by several pending patent applications in foreign jurisdictions including Asian, South American and other jurisdictions. These applications feature claims to the mRNA therapeutics as compositions of matter, formulations that include such mRNAs and methods of reducing tumors and treating cancer featuring these development candidates. Similar claims cover our IL-12 development candidate which can be found in issued U.S. Patent No. 10,646,549, issued U.S. Patent No. 11,000,573, and in pending patent applications in the United States and Europe, two of which are allowed and soon to be issued, and in Australia, Canada, China and Japan, as well as several other jurisdictions in Asia, South America and the Middle East.

Localized regenerative therapeutics

Our localized regenerative therapeutics modality is focused on regenerative therapeutics. Our sole program, VEGF-A, is being developed in collaboration with AstraZeneca and is covered by a granted European patent EP 3464338, granted Japanese patent JP 6859369 and granted Russian patent RU 2756313, and by pending U.S. and European patent applications and by several national phase patent applications filed in South American, Asian and Middle Eastern jurisdictions. The VEGF patent applications are solely-owned by Moderna.

Systemic intracellular therapeutics

Within our systemic intracellular therapeutics modality, we have four programs featuring expression of intracellular enzymes for the treatment of rare diseases. For our rare disease programs, we generally pursue patent protection featuring composition of matter and method of use claims, for example, pharmaceutical composition and method of treatment claims. Our most advanced rare disease development candidate, MMA, is covered by a patent family that includes issued U.S. Patent No. 10,406,112, two pending U.S. patent applications, foreign patent applications filed in Australia, Canada, Japan, Europe and the Middle East, and two pending U.S. Provisional patent applications.

For our PA development candidate, we have patent applications pending in the United States, Canada, Europe, and Japan which cover mRNA encoding the alpha and beta subunits of the enzyme propionyl-CoA carboxylase (PCCA and PCCB, respectively), for the treatment of PA.

For our PKU development candidate, we have a pending PCT and pending patent applications in the U.S., Europe and Japan covering mRNA encoding phenylalanine hydroxylase (PAH) for the treatment of PKU.

For our Glycogen Storage Disorder, Type 1a (GSD1a) development candidate, we have pending U.S and European patent applications, as well as applications pending in Australia, Canada, China, Japan, Israel and several Middle Eastern jurisdictions, and a pending PCT and pending provisional patent applications covering mRNA encoding glucose 6-phosphatase (G6Pase) for the treatment of this disorder.

For our Crigler-Najjar Syndrome Type 1 (CN-1) development candidate, we have patent applications pending in the U.S., Europe, Australia, Canada and Japan.

Any U.S. and foreign patents that may issue from these patent families would be expected to expire in 2036 for the earliest of the MMA patents and 2038-2042 for the remaining MMA, PA, PKU, GSD1a and CN-1 patents, excluding any patent term adjustments and any patent term extensions.

As further described below, we have filed or intend to file patent applications on these and other aspects of our technology and development candidates, and as we continue the development of our intended products, we plan to identify additional means of obtaining patent protection that would potentially enhance commercial success, including protection for additional methods of use, formulation, or manufacture.

Systemic secreted and cell-surface therapeutics

Our systemic secreted and cell-surface therapeutics modality features programs directed to expression of secreted or cell-surface proteins including antibodies, circulating modulation factors, secreted enzymes and transmembrane proteins. Our mRNA-encoded antibody against Chikungunya virus reported positive interim Phase 1 results in clinical trials and utilizes the same LNP formulation being advanced for our MMA program and other rare disease programs. Patent protection for mRNA-encoded antibody against Chikungunya virus is being sought by way of a pending U.S. and European patent applications, in which we share joint ownership rights.

Our Relaxin development candidate is covered by several pending foreign patent applications outside the United States, for example, in several Asian, European, Middle Eastern, South American and other jurisdictions, and by a pending U.S. application and by issued U.S. Patent No. 10,730,924.

Our PD-L1 and IL-2 development candidates are each covered in pending PCT patent applications.

Inhaled pulmonary therapeutics

Our inhaled pulmonary therapeutics modality currently has one development candidate directed to expression of therapeutic protein in the lungs. This Cystic Fibrosis (CF) development candidate is covered by pending U.S., European and PCT patent applications.

Trademarks

Our trademark portfolio currently contains at least 200 trademark registrations, including at least 12 registrations in the United States and the remaining in Canada, the European Union, the United Kingdom, Israel, China, Japan, Australia, and elsewhere. In addition, we have at least 375 pending trademark applications in more than 75 jurisdictions, including in the aforementioned locations and additional countries throughout Africa, Asia, and South America.

In-licensed intellectual property

While we develop and manufacture our potential mRNA medicines using our internally created mRNA technology platform, we also seek out and evaluate third party technologies and IP that may be complementary to our platform.

Patent sublicense agreements with Cellscript and mRNA RiboTherapeutics

The Trustees of the University of Pennsylvania owns several issued U.S. patents, granted European patents and pending U.S. patent applications directed, in part, to nucleoside-modified mRNAs and their uses, or the Penn Modified mRNA Patents. mRNA

RiboTherapeutics, Inc. (MRT) obtained an exclusive license to the Penn Modified mRNA Patents and granted its affiliate, Cellscript, LLC (Cellscript), a sublicense to the Penn Modified mRNA Patents in certain fields of use.

In June 2017, we entered into two sublicense agreements, one with Cellscript, and one with MRT, which agreements we collectively refer to as the Cellscript-MRT Agreements. Together, the Cellscript-MRT Agreements grant us a worldwide, sublicensable sublicense to the Penn Modified mRNA Patents to research, develop, make, and commercialize products covered by the Penn Modified mRNA Patents, or licensed products, for all *in vivo* uses in humans and animals, including therapeutic, prophylactic, and diagnostic applications. The Cellscript-MRT Agreements are non-exclusive, although Cellscript and MRT are subject to certain time restrictions on granting additional sublicenses for *in vivo* uses in humans under the Penn Modified mRNA Patents.

We paid Cellscript and MRT aggregate sublicense grant fees of $28 million upon entering into the Cellscript-MRT Agreements, $25 million in early 2018, and $22 million in early 2019. Cellscript and MRT are collectively eligible to receive, on a licensed product-by-licensed product basis, milestone payments totaling up to $0.5 million upon the achievement of certain regulatory-based events for diagnostic products, and milestone payments totaling up to $1.5 million upon the achievement of certain development and regulatory-based events for either therapeutic or prophylactic products, and up to $24 million upon the achievement of certain commercial-based events for either therapeutic or prophylactic products. The Cellscript-MRT Agreements require us to pay royalties based on annual net sales of licensed products at rates in the low single digits for therapeutic, prophylactic, and diagnostic uses, and royalties based on annual net sales of licensed products sold for research uses at rates in the mid-single digits, subject to certain reductions, with an aggregate minimum floor. Following the first commercial sale of licensed products under a Cellscript-MRT Agreement, we are required to pay Cellscript or MRT, as applicable, minimum annual royalties ranging from $10,000 to $400,000 depending on the use of such licensed product, with all such payments creditable against earned royalties on net sales. In 2021, we paid $641 million in royalties and milestone payments to Cellscript in connection with sales of our COVID-19 vaccine.

The Cellscript-MRT Agreements will terminate upon the expiration or abandonment of the last to expire or become abandoned of the Penn Modified mRNA Patents. Cellscript or MRT, as applicable, may terminate its respective Cellscript-MRT Agreement if we fail to make required payments or otherwise materially breach the applicable agreement, subject to specified notice and cure provisions. Cellscript or MRT, as applicable, may also terminate the applicable Cellscript-MRT Agreement upon written notice in the event of our bankruptcy or insolvency or if we challenge the validity or enforceability of the Penn Modified mRNA Patents. We have the right to terminate each Cellscript-MRT Agreement at will upon 60 days' prior notice to Cellscript or MRT, as applicable, provided that we cease all development and commercialization of licensed products upon such termination. If rights to MRT or Cellscript under the Penn Modified mRNA Patents are terminated (e.g., due to bankruptcy of MRT or Cellscript), the terminated party will assign its interest in the respective Cellscript-MRT Agreement to the licensor from which it received rights under the Penn Modified mRNA Patents and our rights will continue under the new licensor.

Formulation technology in-licenses

Our development candidates use internally developed formulation technology that we own. We do, however, have rights to use and exploit multiple issued and pending patents covering formulation technologies under licenses from other entities. If in the future we elect to use or to grant our strategic collaborators sublicenses to use these in-licensed formulation technologies, we or our strategic collaborators may be liable for milestone and royalty payment obligations arising from such use. We consider the commercial terms of these licenses and their provisions regarding diligence, insurance, indemnification and other similar matters, to be reasonable and customary for our industry.

HUMAN CAPITAL

We had approximately 2,700 full-time employees as of December 31, 2021, representing a more than doubling of our workforce from 1,300 full-time employees as of the end of the prior year. We have undertaken significant hiring of employees to facilitate manufacturing of our COVID-19 vaccine, in addition to building out our commercial and regulatory organizations, as well as other functions, to support this continued roll-out. We also increased our hiring outside the United States during 2021, and at year-end we had employees in 12 countries around the world, with a presence in North America, Europe and the Asia-Pacific region. Much of this hiring has been of talent with experience at other pharmaceutical companies as we continue to build out our commercial and regulatory capabilities, particularly as we fill roles to facilitate our operations and commercial activities in markets around the globe. We have also continued to hire talent to support our research and clinical capabilities across the rest of our pipeline, unrelated to our COVID-19 vaccine.

We operate in a highly competitive environment for human capital, particularly as we seek to attract and retain talent with experience in the biotechnology and pharmaceutical sectors. Our workforce is highly educated, and as of December 31, 2021, 47% of our employees hold Ph.D., Doctorate, M.D., J.D., or Master's degrees. Among our employees, as of December 31, 2021, 47% are female. Among our leadership (which we define as employees at the vice president level and above), as of December 31, 2021, approximately 39% are female, an increase from 37% in the prior year. 40% of our U.S. employees identify as racially or ethnically diverse as of

December 31, 2021, an increase from 35% in the prior year. In 2021, we continued to act on our commitment to belonging, inclusion & diversity by, among other things:

- engaging all members of our Executive Committee, vice presidents and managers in our Conscious Inclusion education series;
- conducting diversity-related events, celebrations and learning opportunities for all employees throughout the year, including Pride Month, Hispanic Heritage Month and Asian & Pacific Islander Month;
- hosting a company-wide event on Neurodiversity in line with the CEO Action of Diversity & Inclusion's #DayofUnderstanding;
- increased our monitoring and reporting program regarding company-wide gender and ethnicity data;
- doubling the number of our Employee Resource Groups; and
- joining the Disability:IN Inclusion Works Program, an initiative that assists employers in all aspects of disability inclusion at work.

To help promote alignment between our employees and our shareholders, all employees participate in our equity programs through the receipt of equity grants, and the percentage of equity as a component of overall pay mix increases with seniority. We believe that in addition to incentivizing growth that leads to shareholder value, broad eligibility for our equity programs helps promote employee retention as these awards generally vest over a four-year period.

Throughout the COVID-19 pandemic, we have implemented various initiatives to promote the safety of our workforce and continuity of our operations. We created a Coronavirus Response Team that is responsible for implementing various safety measures at our global sites. Our protocols include regular COVID-19 testing and the provision personal protective equipment (PPE). Throughout the pandemic, much of our workforce has worked remotely, wherever possible and when local conditions recommend social distancing. We also implemented remote hiring and onboarding programs to facilitate significant hiring during 2021 in a remote work environment.

Since October 2021, we have required all of our employees in the United States to be vaccinated against COVID-19, including having received a booster dose, absent an approved medical or religious accommodation. In December 2020, following the receipt of an Emergency Use Authorization from the FDA for our COVID-19 vaccine, we made the vaccine available to our employees and adult members of their households to help ensure continuity of our operations due to the critical nature of our production of the vaccine. In December 2021 and early 2022, as the Omicron variant drove a surge in COVID-19 cases globally, we made booster doses of our vaccine available to our U.S.-based employees and adult members of their households, as well as to employees of our Swiss subsidiary.

None of our employees are represented by a labor union, and none of our employees have entered into a collective bargaining agreement with us, other than a small number of employees in France, Italy and Spain who are covered by collective bargaining agreements governing certain benefits and working conditions. We consider our employee relations to be good.

We believe that our employees are highly engaged, and we and our employees have been recognized by surveys conducted by external groups. *Science* magazine ranked us as a top employer for each of the last seven years. Additionally, in 2021, *Biospace* ranked us the number one employer in its 2022 Best Places to Work in Biopharma report and *Fast Company* named us the number one company on its 2021 Best Workplaces for Innovators list. We measure employee engagement through a vendor-supplied engagement software, using validated external benchmarks to track quarter-over-quarter employee engagement factors.

Our approach to attracting and retaining talent

We are committed to ensuring that our employees find that their careers at Moderna are filled with purpose, growth and fulfillment. We believe that a career at Moderna provides opportunity for:

- **Impact**: Our people will have the opportunity to do work that is unparalleled in terms of its innovation and scope of impact on people's lives.
- **Growth**: We provide incredible opportunities for growth and we obsess over learning (as demonstrated, in part, by our Mindsets (see below)). We invest in the development of our people as scientists and as leaders.
- **Well-being**: We are committed to the health and well-being of our employees and their families by providing family-friendly benefits and opportunities to be healthy, including annual allowances for personal enrichment and monthly allowances for fitness and nutrition.
- **Inclusive environment**: We believe in the benefits of bringing together a diverse set of perspectives and backgrounds, and creating an environment where differences are celebrated and leveraged.
- **Compelling rewards**: To attract and retain the best talent, we provide competitive rewards that help to drive groundbreaking work and allow employees to share in the value we will create together, including through our equity programs.

Our approach to training our employees

We have established a structured training curriculum for our employees called Moderna University and have a full-time team dedicated to developing the curriculum and conducting activities for Moderna University. The objective of Moderna University is for every employee to be deeply familiar with our core technology and able to learn about technologies that might further enable our science. In addition, Moderna University is also focused on creating strong leaders through management and leadership training. There are four core areas within Moderna University including:

- **Professional development**: Includes on-site training programs for our employees including those focused on leadership and project management, as well as tools to improve interpersonal communication.
- **Digital learning library**: We have built an online library of videos of a variety of scientific material that our employees can access flexibly. This content includes:
    - Presentations by external speakers to scientific seminars conducted in-house;
    - Scientific courses at external universities; and
    - Peer-to-peer video series in which in-house experts provide an introductory view of complex topics they tackle within their teams.
- **Learning management system**: We have deployed a digital system to track and administer training programs for each of our employees. Training content is developed digitally and offered to our employees.
- **New hire orientation**: This program is designed to onboard all new employees. During this training program, new employees meet with members of the management team and senior functional leaders to learn about the Company and functional activities.

In December 2021, we announced the launch of our Artificial Intelligence (AI) Academy in partnership with Carnegie Mellon University. The AI Academy is intended to educate and empower our workforce to identify and integrate AI and machine learning solutions into our systems and processes.

Additionally, with the continued rapid growth of our company, we articulated the Moderna Mindsets in late 2021. The Moderna Mindsets are a set of leadership behaviors we use to make decisions and lead the company. We consider the Mindsets to be key as our company continues to scale, and we are working to integrate them into all of our HR processes, including performance management. Our employees participate in the Mindsets Workshops, which is an interactive, full-immersion learning experience designed to provide the opportunity to engage with, better understand and learn how to apply the Mindsets in the workplace.

To further develop and retain our workforce, we conduct periodic talent reviews that identify key talent within the organization. We use that data to inform specific development opportunities for key current and potential future leaders, and to support our periodic succession planning activities for key roles. These steps together ensure we have a robust understanding of our workforce and a talent pipeline to grow future leaders.

CORPORATE SOCIAL RESPONSIBILITY

In pursuit of our mission to deliver on the promise of mRNA science to create a new generation of transformative medicines for patients, we have scaled our operations, invested in research and building out our manufacturing and commercial capabilities, and hired top-tier talent. As we continue to mature, we believe it is important to develop long-term programs that underscore our commitment to corporate social responsibility. Please refer to the “Responsibility” section of our website, which can be found at www.modernatx.com, as well as our proxy statement related to our 2022 Annual Meeting of Stockholders that we will file with the SEC, for a description of some of the measures we have taken to support our commitment to corporate social responsibility.

COMPETITION

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. There is also a strong emphasis on defense of intellectual property and proprietary products.

mRNA Medicines and Our COVID-19 Vaccine

We believe that mRNA as a medicine coupled with our capabilities across mRNA technology, drug discovery, development, and manufacturing provide us with a competitive advantage. However, we face competition from others developing mRNA vaccines and therapeutics, as well as other medicines that compete or could compete with our mRNA products, development candidates and investigational medicines. We face competition from various sources, including large pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and public and private research institutions. For any products that we eventually commercialize, we will not only compete with existing medicines but also compete with medicines that may become available in the future. We also face competition when entering into strategic alliances to advance and grow our pipeline.

We face significant competition in the market for our COVID-19 vaccine, particularly from established pharmaceutical companies with longer operating histories and significant experience in producing and marketing pharmaceutical products. In the United States, the U.S. FDA has granted a BLA to the Pfizer/BioNTech COVID-19 vaccine for the prevention of COVID-19 in individuals 16 years of age and older. The Pfizer/BioNTech COVID-19 vaccine has also been authorized under an EUA as a two-dose primary series for individuals five years of age and older, as a third primary series dose for individuals five years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 12 years of age and older at least five months after completing a primary series of the vaccine. The Pfizer/BioNTech COVID-19 vaccine has also been authorized for use as a single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine. The CDC has recommended that individuals starting their COVID-19 vaccine series or receiving a booster dose receive either our COVID-19 vaccine or the Pfizer/BioNTech COVID-19 vaccine. The Johnson & Johnson/Janssen viral vector COVID-19 vaccine is also authorized under an EUA. Outside the United States, our COVID-19 vaccine has been authorized for use or approved in more than 70 countries, in addition to receiving authorization from the World Health Organization. In many of these jurisdictions, our vaccine is authorized for use in adolescents (ages 12-17). Internationally, our COVID-19 vaccine competes against over two dozen vaccines that have been authorized in various jurisdictions, and many other vaccine candidates remain in development, including other mRNA vaccines.

Additionally, competitors have developed treatments for COVID-19, and additional treatments may be developed in the future. For example, Pfizer and Merck have developed antiviral pills for the treatment of mild-to-moderate COVID-19 disease for certain adults who have tested positive for COVID-19. To the extent that these or other treatments are viewed as an alternative to vaccination against COVID-19, our competitive position could be harmed.

Competition for the sale of our COVID-19 vaccine can be impacted by a number of factors, including: the efficacy of our vaccine in preventing COVID-19 (particularly in the prevention of severe cases of COVID-19); the ability of our vaccine, or future iterations of the vaccine, and boosters to protect effectively against variants of the SARS-CoV-2 virus; perceptions of the efficacy of our vaccine; concerns about potential side effects from the vaccine, its safety or tolerability; the novelty of mRNA-based technology; storage and handling conditions for our vaccine and the ease or difficulty with which it can be distributed; the timing and scope of regulatory approvals; reimbursement coverage; our costs to produce and distribute our vaccine; and our ability to scale our manufacturing and distribution effectively as we continue to expand shipments internationally. The competitiveness of our COVID-19 vaccine in the future may also depend upon whether we are successful in efforts to combine the vaccine with other vaccines, like seasonal flu and RSV, and whether our competitors are successful in similar efforts. Additionally, standalone vaccines we may develop for respiratory diseases, such as seasonal flu vaccines, will face competition from existing vaccines and treatments, as well as future medicines developed by competitors. Our competitive positioning may also be affected by the fact that we do not have as long a history of producing pharmaceutical products or existing commercial relationships compared to certain of our competitors.

There are additional companies that are working on mRNA medicines, some of which have reached commercialization. Companies with mRNA programs include BioNTech and Pfizer (alone and in partnership with BioNTech and others). Other competitors include Sanofi (through the acquisition of Translate Bio), CureVac and GlaxoSmithKline, Arcturus Therapeutics, eTheRNA Immunotherapies Ethris, Genevant Sciences, Stemirna Therapeutics and Abogen Biosciences, which is developing a COVID-19 mRNA vaccine in collaboration with Walvax Biotechnology and the PLA Academy of Military Science. We also compete against other pharmaceutical companies in the market for COVID-19 vaccines that do not utilize mRNA-based technologies, including AstraZeneca and Johnson & Johnson, among others.

Beyond mRNA

We and our strategic collaborators face competition from companies developing therapies in various areas, other than the development of mRNA medicines, related to our collaborations. For example, there are a growing number of pharmaceutical, biotechnology and academic institutions researching and developing autologous and allogeneic CAR-T therapies in both the solid and liquid tumor setting. These CAR-T cell therapies are at various stages of development and approval and could compete against any CAR-T therapeutics we discover, develop and commercialize in collaboration with Carisma Therapeutics.

Similarly, there are many companies and institutions researching and developing CRISPR and other gene editing systems, which could compete against any therapies for genetic diseases we develop and commercialize in collaboration with Metagenomi or other collaborators.

GOVERNMENT REGULATION

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacture and marketing of our products and product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained and submitted for review and approved by the regulatory authority.

U.S. drug and biological product development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations and biologics under the FDCA, the Public Health Service Act (PHSA), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. Failure to comply with applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Any of our investigational medicines must be approved by the FDA through a BLA or new drug application, NDA, process before they may be legally marketed in the United States. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our current or future investigational medicines will be granted on a timely basis, or at all.

Preclinical studies

Before any of our product candidates may be tested in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Unless the FDA raises concerns, an IND automatically becomes effective 30 days after receipt by the FDA. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators and in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to clinical trial subjects and monitors the clinical trial until completed. Further, progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and more frequently in other situations, including the occurrence of serious adverse events. Information about certain clinical trials must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

Under the U.S. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (the NIH Guidelines), supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee (IBC), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. While the NIH Guidelines are only mandatory for research being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of a BLA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data.

Clinical trials generally are conducted in three sequential phases, which may overlap:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients to assess the metabolism, pharmacologic action, side effect tolerability, and safety of the product candidate.
- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product, and provide an adequate basis for product labeling.

The FDA may also require post-approval Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of a drug.

The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, and purity of the final product.

FDA review process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA or NDA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. A BLA is a request for approval to market a biologic for one or more specified indications and must contain proof of the biologic's safety, purity, and potency. An NDA for a new drug must contain proof of the drug's safety and efficacy. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA or NDA must be obtained before a biologic or drug may be marketed in the United States.

Before approving a BLA or NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee of expert advisors for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The committee makes a recommendation to the FDA that is not binding but is generally followed.

After the FDA evaluates a BLA or NDA, it will grant marketing approval, request additional information or issue a complete response letter (CRL), outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data, for the FDA to reconsider the application. Even if such additional information and data are submitted, the FDA may decide that the BLA or NDA still does not meet the standards for approval. If the FDA grants approval, it issues an approval letter that authorizes commercial marketing of the product with specific prescribing information for specific indications.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in very limited circumstances, such if the latter product is shown to be clinically superior to the orphan product. Orphan drug exclusivity, however, also could block the approval of our products for seven years if a competitor first obtains approval of the same product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease.

Expedited development and review programs

The FDA may employ one of several tools to facilitate and expedite the development and review of a drug, including fast track designation, breakthrough therapy designation, accelerated approval and priority review designation. Fast track designation is designed to facilitate the development and review of a drug that treats a serious condition and fills an unmet medical need. Breakthrough therapy designation is designed to expedite the development and review of a drug that treats a serious condition and

preliminary clinical evidence demonstrates substantial improvement over available therapies. Priority review designation means the FDA's goal is to take action on an application within six months of filing. The FDA may grant priority review designation to a drug that would provide significant improvement in the safety or effectiveness of a treatment, diagnosis or prevention of a serious condition.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. If the FDA determines that the conditions of approval are not being met, the FDA can withdraw its accelerated approval for such drug or biologic.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval.

Emergency Use Authorization (EUA)

The Secretary of Health and Human Services (HHS) may authorize unapproved medical products to be marketed in the context of an actual or potential emergency that has been designated by the U.S. government. The COVID-19 pandemic has been designated as such an emergency. After an emergency has been announced, the Secretary of HHS may authorize the issuance of and the FDA Commissioner may issue EUAs for the use of specific products based on certain criteria, including that the product may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. From December 18, 2020, our COVID-19 vaccine was available under an EUA for active immunization to prevent COVID-19 in individuals 18 years of age and older. In January 2022, the FDA approved the BLA for our COVID-19 vaccine, Spikevax, to prevent COVID-19 in individuals 18 years of age and older in the United States. A booster dose of our COVID-19 vaccine at the 50 µg dose level is authorized for use under an EUA for adults 18 years and older. A third dose of our COVID-19 vaccine at the 100 µg dose level is authorized for use under an EUA in immunocompromised individuals 18 years of age or older in the United States who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. The FDA may revoke an EUA for a variety of reasons, including if the underlying health emergency no longer exists or warrants such authorization.

In the United States, the Public Readiness and Emergency Preparedness Act, the PREP Act, provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include "qualified pandemic or epidemic products," including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. On March 17, 2020, the Secretary of HHS issued a declaration under the PREP Act and has issued subsequent amendments thereto since then to provide liability immunity for activities related to certain countermeasures against the ongoing COVID-19 pandemic. While we believe our products would be covered under the provisions of the PREP Act, this cannot be assured.

Pediatric information

Under the Pediatric Research Equity Act of 2003, all marketing applications for new active ingredients, indications, dosage forms, dosing regimens or routes of administration must contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred or inapplicable.

Under the Best Pharmaceuticals for Children Act, a product may be eligible for pediatric exclusivity, which adds six months to existing exclusivity periods and patent terms. This exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued written request for such a study.

Post-approval requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications

to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or NDA or BLA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy (REMS) to assure the benefits of the product outweigh the risks. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. Product approvals may be withdrawn for non-compliance with regulatory standards, or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We and our third-party manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections for compliance with cGMP requirements and other laws. The discovery of violations could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA or NDA, including recall.

U.S. patent term restoration and marketing exclusivity

In certain circumstances, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND and the submission date of a BLA or NDA, plus the time between the submission date of a BLA or NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for such an extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

If the FDA approves a drug product that contains an active ingredient not previously approved, the product is typically entitled to five years of non-patent regulatory exclusivity. Other products may be entitled to three years of exclusivity if approval was based on the FDA's reliance on new clinical studies essential to approval submitted by the NDA applicant. If the NDA applicant studies the product for use by children, the FDA may grant pediatric exclusivity, which extends by 180 days each existing exclusivity (patent and regulatory) related to the product.

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (the BPCI Act). Biosimilarity requires a showing that the product is "highly similar" to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

European Union drug development

Medicinal products can be marketed in the EU only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. Effective January 2022, the European Commission adopted a new Clinical Trials Regulation to streamline and harmonize the procedures for assessment and governance of clinical trials throughout the EU and to require that information on the authorization, conduct and results of each clinical trial conducted in the EU be publicly available.

Pediatric investigation plan

An application for marketing authorization of a medicinal product for human use that is not yet authorized in the EU must include a Pediatric Investigational Plan (PIP), unless a waiver applies. A scientific committee assesses the content of any PIP, waivers, and

deferrals for a medicinal product submitted to it in accordance with the regulation on medicinal products for pediatric use and formulates an opinion thereon.

European drug review and approval

In the European Economic Area (EEA), which is comprised of the 27 Member States of the EU and Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization. A company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders, or diabetes, and optional for those medicines that are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU Member States. In addition to the centralized procedure, the EEA also has a nationalized procedure, which requires a separate application to and approval determination by each country; a decentralized procedure, whereby applicants submit identical applications to several countries and receive simultaneous approval; and a mutual recognition procedure, where applicants submit an application to one country for review and other countries may accept or reject the initial decision.

European exclusivity

In the EEA, new innovative products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon the grant of a marketing authorization. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. There is no guarantee that a product will be considered by the European Union's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity.

European orphan designation and exclusivity

Orphan drug designation is available in the EEA to promote the development of products that are intended for the diagnosis, prevention, or treatment of life threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU community, or where it is unlikely that the development of the medicine would generate sufficient return to justify the necessary investment in its development, and in each case for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected). Medicinal products that receive and maintain orphan drug designation are entitled to 10 years of market exclusivity following approval.

European data collection

The Data Protection Directive and the General Data Protection Regulation (GDPR) governs the collection and use of personal data in the EU. The GDPR imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20.0 million or 4.0% of the annual global revenues of the infringer, whichever is greater.

The UK has incorporated the GDPR (as it existed on December 31, 2020, but subject to certain UK specific amendments) into UK law (the UK GDPR). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

EU drug marketing

Like the Anti-Kickback Statute prohibition in the United States discussed below, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. Infringement of relevant EU laws could result in substantial fines and imprisonment. Payments may be made to physicians in limited circumstances, and in certain EU Member States such payments must be publicly disclosed. Moreover, agreements with physicians for the provision of services often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Rest of the world regulation

Outside of the United States and the EU, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. If we fail to comply with such requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, or criminal prosecution.

Other healthcare laws

Healthcare providers, physicians, and third-party payors, including governmental payors such as Medicare and Medicaid will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Any arrangements with these parties may expose us to certain fraud and abuse and other healthcare laws and regulations. In the United States, these laws include, among others:

- The Anti-Kickback Statute, which makes it illegal for any person to knowingly and willfully solicit, receive, offer, or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug or any other good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid.
- The federal False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government.
- Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, or falsifying, concealing, or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose, among other things, requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information.
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, the ACA, which requires certain pharmaceutical manufacturers with products reimbursed under certain government programs to disclose annually to the federal government (for re-disclosure to the public) certain payments and other transfers of value provided to physicians, teaching hospitals and certain non-physician practitioners.
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor.

Additionally, certain state and foreign laws also govern the privacy and security of health information. Such data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts. For example, the California Consumer Protection Act (CCPA) established a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Further, the California Privacy Rights Act (CPRA), which is scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022), will create additional obligations with respect to processing and storing personal information. While clinical trial data and information governed by HIPAA are currently exempt from the current versions of the CCPA and CPRA, other personal information may be applicable and possible changes to the CCPA and CPRA may broaden its scope.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. If our operations are found to be in violation of any of these laws or other related governmental regulations, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight, and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with

whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Current and future healthcare reform legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our investigational medicines, restrict or regulate post-approval activities, and affect our ability to profitably sell any approved products. The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and, annual fees based on pharmaceutical companies' share of sales to federal health care programs. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any strategic collaborators, may receive for any approved products.

In the United States, it is unclear whether the ACA will be overturned or further amended. We cannot predict what effect further changes to the ACA would have on our business. Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted, including the Budget Control Act of 2011, which includes provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare payments to providers, which began in April 2013 and will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Then, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the federal government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the federal government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs.

Environment

We are subject to state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in foreign countries that impose similar obligations.

CORPORATE INFORMATION

We were incorporated under the laws of the State of Delaware on July 22, 2016. We are the successor in interest to Moderna LLC, a limited liability company formed under the laws of the State of Delaware in 2013. Moderna LLC was the successor in interest to Moderna Therapeutics, Inc., a Delaware corporation incorporated in 2009 as Newco LS18, Inc. by Flagship Pioneering. In August 2018, we changed our name from Moderna Therapeutics, Inc. to Moderna, Inc. Our principal corporate office is located at 200 Technology Square, Cambridge, MA 02139, and our telephone number is (617) 714-6500.

Our website, www.modernatx.com including the Investor Relations section, www.investors.modernatx.com; and corporate blog www.modernatx.com/moderna-blog; as well as our social media channels: Facebook, www.facebook.com/modernatx; Twitter, www.twitter.com/modernatx; and LinkedIn, www.linkedin.com/company/modernatx; contain a significant amount of information about us, including financial and other information for investors. We encourage investors to visit these websites and social media channels as information is frequently updated and new information is shared. The information on our website and that we disclose through social media channels is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the Securities and Exchange Commission (the SEC).

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Exchange Act. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, and our

Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

The SEC also maintains a website that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC. The SEC's Internet website address is http://www.sec.gov.

Item 1A. Risk Factors

You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10-K. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations, and the market price of our common stock.

Risks related to COVID-19, mRNA-1273 and our other vaccine candidates against the SARS-CoV-2 virus

We may encounter difficulties producing, shipping or successfully commercializing our COVID-19 vaccine consistent with our existing or potential contractual obligations including due to delays or difficulties experienced by our commercial partners.

In response to the global COVID-19 pandemic, we are continuing to pursue the rapid manufacture, distribution and clinical testing of our COVID-19 vaccine (mRNA-1273), which is our only commercial product and source of product revenues. We may encounter difficulties producing the vaccine on the timelines and in the quantities set forth in our existing or future supply agreements. We may also be unsuccessful in entering into contracts for future sales of COVID-19 vaccines. Our ability to commercialize an effective vaccine depends on our manufacturing capability, both at our own manufacturing facility and those of our manufacturing partners, which we rapidly scaled in response to the pandemic. We are committing substantial financial resources and personnel to the development, manufacture and distribution of our COVID-19 vaccine, including to support the scale-up of manufacturing to enable our pandemic response, which may cause delays in or otherwise negatively impact our other development programs. We may need to, or the U.S. government may require us to, divert resources and capital from our other programs to the production of COVID-19 vaccines.

We do not have sufficient internal manufacturing infrastructure to support the global roll-out of our COVID-19 vaccine on our own. We have entered into strategic collaborations for the production, as well as for commercial fill-finish manufacturing, of our COVID-19 vaccine to supply markets both in and outside the United States. We may need to engage additional collaborators in the future, including contract manufacturing organizations (CMOs), government and non-government organizations, and other manufacturing partners, to assist in meeting our capacity needs. If we cannot enter into such arrangements on favorable terms, or at all, our ability to develop, manufacture and distribute our COVID-19 vaccine would be adversely affected.

Prior to 2020, we had not ramped up our organization for a commercial launch of any product, and doing so during a pandemic with an urgent, critical global need poses additional challenges, such as setting up distribution channels, building global teams with specialized skills, and managing potential intellectual property disputes or challenges. We may also face challenges sourcing a sufficient amount of raw materials to support the demand for our COVID-19 vaccine. We may be unable to effectively create a supply chain for the vaccine to adequately support demand as we rely on our third-party collaborators being able to fulfill demand. For example, we have in the past and may in the future experience international shipping delays as our supply chain expands and grows more complex. Any capacity or production issues or delays experienced by our collaborators may cause us to fail to meet certain product volume or delivery timing obligations under our COVID-19 supply agreements. Furthermore, we will require significant additional investment, whether from our own capital resources or other sources of funding, as we continue to expand our commercial launch efforts. We cannot guarantee that any of these challenges and requirements will be met in a timely manner or at all.

The pharmaceutical market is intensely competitive. We may be unsuccessful in competing effectively in the market for existing products, new treatment methods, and new technologies, including for COVID-19 vaccines.

The pharmaceutical market is intensely competitive and rapidly changing. Many pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research organizations are pursuing the development of products for the same diseases that we are targeting or expect to target, including COVID-19 vaccines, and these institutions and competitors may have:

- greater financial, technical, manufacturing, and human resources than we have at every stage of the discovery, development, manufacture, and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing, and selling products;
- multiple products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We face intense competition with respect to our COVID-19 vaccine from other vaccines and treatments, and our vaccine may not continue to compete favorably with existing or future products. Over two dozen COVID-19 vaccines have been authorized in various jurisdictions, including those produced by AstraZeneca, Johnson & Johnson, and Pfizer/BioNTech, and many more remain in development. These vaccines or other treatments, such as antiviral pills produced by Pfizer and Merck, may prove to be safer, more

effective, more convenient, have fewer side effects, be easier to ship or distribute, or able to be developed at a lower cost than our vaccine. These factors, or the perception of these factors, among others, could lead to a competitor's vaccine or other treatment to become the standard of care for COVID-19, have broader market acceptance, or be more successfully commercialized. The actual or perceived success or failure of other entities may adversely impact our ability to commercialize our COVID-19 vaccine.

We also will face competition from products that have already been approved and accepted by the medical community for the treatment of conditions we target. For example, we are developing a seasonal flu vaccine, for which there is a well-developed market, and we may be unsuccessful in developing a product or achieving market share. We also may compete with products that are under development for the treatment of conditions we target, which other products may be more effective, safer, less expensive, or marketed and sold more effectively.

If we successfully develop and obtain approval for investigational medicines, we will face competition based on many factors, including the safety and effectiveness of our products relative to any alternative therapies; the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration; the timing and scope of regulatory approvals; the availability and cost of manufacturing, marketing, and sales capabilities; the price of any approved medicine; reimbursement coverage; and patent position.

Our competitors may commercialize products with significant advantages over any products we develop, and may benefit from strategic alliances with or funding from larger pharmaceutical or biotechnology companies. If our competitors are more successful in commercializing their products than we are, our competitive position and business would be adversely affected. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

We may be delayed or prevented from receiving full regulatory approval of our COVID-19 vaccine in certain jurisdictions or for certain demographics.

Efficacy, effectiveness, safety, and immunogenicity data with respect to our COVID-19 vaccine, as well as real-world evidence, continue to accumulate. Further results from clinical trials, as well as the experience of vaccinated individuals, could show diminished protection compared to the results released to date, as efficacy and antibody persistence wane over time. Additionally, we may observe new, more frequent or adverse events of greater severity in subjects participating in ongoing clinical trials or among those individuals vaccinated with our COVID-19 vaccine. For example, some studies have suggested that our vaccine may be associated with higher rates of myocarditis and pericarditis in young males compared to other COVID-19 vaccines. Unexpected safety issues could significantly damage our reputation and that of our mRNA platform, and lead to other issues, including delays in our other programs, the need to re-design our clinical trials and the need for significant additional financial resources. In addition, the interpretation of the data from our clinical trials of our COVID-19 vaccine by the FDA and other regulators may differ from our interpretation and such agencies may require us to conduct additional studies or analyses, which may lead to delays in obtaining authorization for these medicines. For example, in October 2021, the FDA requested that we explore a lower dosage for our COVID-19 vaccine in adolescents, which extended the length of clinical trials in this population, delaying potential authorization in the U.S. These factors could delay or prevent us from receiving regulatory approval of our COVID-19 vaccine in certain jurisdictions or for certain demographics.

The assays used to estimate the effectiveness of COVID-19 vaccines have only recently been developed and continue to evolve. Validation reports for these assays have been submitted for review to regulatory agencies. Results obtained in clinical studies of mRNA-1273 with later versions of these assays may be less positive than the results we have obtained to date. Moreover, blood samples from people who have recovered from COVID-19, used to benchmark the level of antibodies produced by subjects receiving mRNA-1273 in clinical studies, have been taken from a small number of people and may not be representative of the antibody levels in a broader population of people who have recovered from COVID-19, particularly as variant strains continue to emerge. The future results in clinical studies of mRNA-1273 may not be as positive when compared to the antibody levels in other blood samples.

We may be unsuccessful in developing future versions of our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, or booster doses of our vaccine may not protect against such variants, and a market for vaccines and boosters against these variants may not develop.

Our original COVID-19 vaccine, mRNA-1273, was developed based upon the genetic sequence of the SARS-CoV-2 virus that was first detected in Wuhan, China. As the SARS-CoV-2 virus continues to evolve, new strains of the virus, or those that are already in circulation, may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains to date. For example, the Omicron and Delta variants have been observed to be more transmissible, or contagious, than previous variants. There is a risk that mRNA-1273 will not be as effective in protecting against these or other future variant strains. For example, a standard two-dose inoculation of mRNA-1273 appears to be less effective at neutralizing the Omicron variant, which emerged in November 2021, than against the ancestral strain of SARS-CoV-2. Additionally, administration of booster doses of our vaccine may prove to be

ineffective, or less effective than desired, against certain variants. We have several development candidates against variants of concern, and may develop others in the future. If these efforts are unsuccessful, we are slower to develop variant-specific vaccines than competitors, or these vaccine candidates prove less effective than competitors' vaccines, these shortcomings may lead to reputational harm, loss of market share, and adverse financial results. It is also possible that we may expend significant resources adapting our COVID-19 vaccine or conducting clinical trials to protect against variants of the SARS-CoV-2 virus, but that a market for this adapted vaccine does not develop or demand does not align with our projections or cost expenditures.

The regulatory pathway for COVID-19 vaccines is continually evolving, and may result in unexpected or unforeseen challenges.

Our COVID-19 vaccine has moved rapidly through the regulatory review and authorization and approval processes in the U.S. and other jurisdictions. The speed at which COVID-19 vaccines and therapeutics are being created and tested is atypical, and evolving or changing plans or priorities within the FDA or other regulatory authorities, including changes based on new knowledge of COVID-19 and how the disease, and new variants of the virus, affect the human body, may significantly affect the regulatory timeline for further authorizations or approvals for our COVID-19 vaccine, including variant-specific versions of the vaccine. We cannot anticipate or predict with certainty the timelines or regulatory processes that may be required for the authorization or approval of updated versions of our COVID-19 vaccine, or vaccines that may be developed to fight against variants of the SARS-CoV-2 virus.

Although we currently operate under an EUA provided by the FDA for mRNA-1273 for as a booster dose for adults 18 years and older at least five months after completing a primary series of the vaccine, and as a third dose in immunocompromised individuals 18 years of age or older who have undergone solid organ transplantation, the FDA may revoke such authorization if it determines that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long the EUA will remain in place. Such revocation could adversely impact our business in a variety of ways.

The EMA has made a positive recommendation for the administration of Spikevax for children ages 6 to 11, in addition to the existing conditional marketing authorization from the EMA for Spikevax in adults and adolescents ages 12 and older. Although a conditional marketing authorization is a formal marketing authorization and covers all batches produced for the EU, we are obliged to provide certain additional information and data by specified timelines as conditions of the authorization, and the EMA can take regulatory action if we fail to comply. Conditional marketing authorizations are valid for one year and can be renewed annually; however, the EMA may decide not to renew. If new data emerges that shows the benefits of our vaccine do not continue to outweigh its risks, the EMA can suspend or revoke our authorization. Similar temporary, emergency authorizations that we have received for mRNA-1273 could be revoked if the conditions for granting the authorization no longer apply. Any such revocation of the temporary authorization to distribute mRNA-1273, without receiving final approval to distribute the vaccine, could adversely impact our ability to realize the full financial benefit of our existing or future supply agreements.

Our ability to deliver our vaccine to customers may be curtailed by one or more government actions or interventions, which may be more likely during a global health crisis, such as the COVID-19 pandemic.

It is possible that one or more government entities may take actions that directly or indirectly diminish our rights or opportunities with respect to our COVID-19 vaccine, limiting our economic prospects. In the United States, the Defense Production Act of 1950, as amended (the Defense Production Act), gives the U.S. government rights and authorities that may directly or indirectly diminish such rights or economic opportunities. Our current and potential third-party service providers may be impacted by government entities potentially invoking the Defense Production Act or other potential restrictions to all or a portion of services they might otherwise offer.

Government entities imposing restrictions or limitations on our third-party service providers may require us to obtain alternative service sources for our COVID-19 vaccine or our vaccine candidates. If we are unable to timely enter into alternative arrangements on satisfactory terms, we will experience delays in the development or production of our COVID-19 vaccine and our vaccine candidates, increased expenses, and delays in distribution or commercialization of our COVID-19 vaccine, or, when and if approved, our vaccine candidates.

In addition, our supply contracts with the U.S. government for our COVID-19 vaccine restrict our ability to export vaccine that is produced from our U.S.-dedicated supply chain to markets outside the United States prior to satisfying our delivery obligations to the U.S. government. Furthermore, governments have threatened to block or limit the export of COVID-19 vaccines manufactured in their territories in instances where manufacturers have been delayed or have not fully satisfied their delivery obligations to those governments. Governments of the jurisdictions in which we or our contract manufacturing partners produce our COVID-19 vaccine may impose export restrictions, prohibiting us from delivering our COVID-19 vaccine to customers in other jurisdictions. The imposition of export controls could severely and adversely impact our manufacturing activities, commercial activities and financial results.

In addition, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated, national borders create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccines and vaccine candidates within self-contained national or international borders, at potentially much greater expense and with longer timeframes for public distribution.

Risks related to our pipeline, product development and regulatory review

Preclinical 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 the clinic, any of which may have a material adverse impact on our platform or our business.

Much of our pipeline is in preclinical development, and these programs could be delayed or not advance into the clinic. Before we can initiate clinical trials for a development candidate, we must complete extensive preclinical studies, including IND-enabling good laboratory practice (GLP) toxicology testing, to support our planned INDs in the United States, or similar applications in other jurisdictions. We must also complete extensive work on Chemistry, Manufacturing, and Controls (CMC) activities (including yield, purity and stability data) to be included in an IND submission. CMC activities for a new class of medicines such as mRNA require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures as we scale up our manufacturing have occurred and may continue to occur. In addition, we have in the past and may in the future have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our development candidates. If we must produce new batches, preclinical studies or clinical trials could be delayed. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, whether the FDA or other regulators will accept the results, or if the outcome of our preclinical testing, studies, and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulators allowing clinical trials to begin.

Clinical development is lengthy and uncertain, especially with a new class of medicines such as mRNA medicines. Clinical trials of our investigational medicines may be delayed and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which could have a material adverse impact on our platform or our business.

Clinical testing is expensive, complex and lengthy, and its outcome is inherently uncertain. There is a high rate of attrition for product candidates proceeding through clinical trials and most investigational medicines that commence clinical trials are never approved as products. We may not be able to initiate, may experience delays in, or may have to discontinue clinical trials for our investigational medicines. We and our strategic collaborators also may experience unforeseen events during, or as a result of, any clinical trials that we or they conduct that could delay or prevent us or them from successfully developing our investigational medicines and gaining approval from regulators. Delays or other events that might prevent us from proceeding with clinical trials include:

- regulators, Institutional Review Boards (IRBs), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective contract research organizations (CROs);
- changes to the scale and site of our manufacturing could lead to significant delays or changes in our clinical trial designs;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish or achieve clinically meaningful endpoints for our studies;
- if we make changes to our investigational medicines after clinical trials have commenced (which we have done in the past), we may be required to repeat earlier stages or delay later stages of clinical testing;
- clinical trials of any investigational medicines may fail to show safety or efficacy, or produce negative or inconclusive results, and we may decide, or regulators may require us to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and many investigational medicines believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- our investigational medicines, or other medicines in the same class as ours, may have undesirable side effects, such as the immunogenicity of the LNPs or their components, the immunogenicity of the protein made by the mRNA, or degradation products, any of which could lead to serious adverse events, or other effects;
- administration of our LNPs could lead to systemic side effects related to the components of the LNPs and could contribute, in whole or in part, to one or more of the following: immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions, or reactions to PEG;

- significant adverse events or other side effects could be observed in our trials, including those involving dosing of young, human subjects with an investigational medicine;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require that we add new clinical trial sites;
- regulators may impose a complete or partial clinical hold on a trial, or we or our investigators, IRBs, or ethics committees may elect to suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to an unacceptable benefit-risk ratio;
- regulators may impose a complete or partial clinical hold on clinical trials of other companies working on mRNA medicines;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any investigational medicines may be greater than we anticipate;
- the supply or quality of our investigational medicines or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety and efficacy concerns regarding one or more of our investigational medicines will be considered by us and by the FDA and other global regulators as we pursue clinical trials of new investigational medicines, develop effective informed consent documentation and work with IRBs and scientific review committees (SRCs);
- safety or efficacy concerns could arise from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours;
- adverse side effects could be observed in future clinical trials where our investigational medicines are administered in combination with other therapies (such as the co-administration of our PCV investigational medicine, mRNA-4157); and
- a lack of adequate funding to continue a particular clinical trial.

The FDA has indicated that, prior to commencing later-stage clinical trials for our programs, we will need to develop assays to measure and predict the potency of a given dose of our investigational medicines. Any delay in developing assays that are acceptable to the FDA or other regulators could delay the start of future clinical trials. Additionally, we have conducted and may conduct in the future clinical trials that utilize an "open-label" trial design, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an approved drug or placebo. The results from an open-label trial may not be predictive of future clinical trial results from a controlled environment with a placebo or active control. Further, the FDA or other regulators may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Significant preclinical or nonclinical testing and studies or clinical trial delays for our investigational medicines could allow our competitors to bring products to market before we do. Any delays in the development of our investigational medicines may harm our business, financial condition, and prospects significantly.

There are risks that are unique to each of our programs and modalities and risks that are applicable across programs and modalities. These risks may impair our ability to advance one or more of our programs in clinical development, obtain regulatory approval, or ultimately commercialize our products, or cause us to experience significant delays in doing so, any of which may materially harm our business.

We have a large pipeline of development candidates and investigational medicines, of which many are in clinical trials or have an open IND. Certain features in our development candidates and investigational medicines, including those related to mRNA, chemical modifications, surface chemistries, LNPs, and their components, may result in risks that apply to some or all of our programs and modalities. As our development candidates and investigational medicines progress, we or others may determine that: certain of our risk allocation decisions were incorrect or insufficient; we made platform-level technology mistakes; individual programs or our mRNA science in general has technology or biology risks that were unknown or under-appreciated; our choices on how to develop our infrastructure to support our scale will result in an inability to manufacture our investigational medicines for clinical trials or otherwise impair our manufacturing; or we have allocated resources in such a way that we cannot recover large investments or rapidly re-direct capital.

We utilize earlier programs in a modality to understand the technology risks within the modality, including manufacturing and pharmaceutical properties. Even if our earlier programs in a modality are successful in any phase of development, any program may fail at a later phase of development, and other programs within the same modality may fail at any phase of development, including at phases where earlier programs in that modality were successful. This may be a result of technical challenges unique to that program or due to biology risk, which is unique to every program. The biology risk across the majority of our pipeline represents targets and pathways not clinically validated by one or more approved drugs, and the risk that the targets or pathways that we have selected may not be effective will continue to apply across the majority of our current and future programs.

As we progress our programs through clinical development, new technical challenges may arise that cause an entire modality to fail. Additionally, any portfolio spanning risks, whether known or unknown, if realized in any one of our programs, would have a material and adverse effect on our other programs and on our business as a whole.

There are also specific additional risks to certain of our modalities and our programs as a whole. For example, prophylactic vaccines typically require clinical testing in up to tens of thousands of healthy volunteers to define an approvable benefit-risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Even if we observe positive safety, tolerability, and levels of immunogenicity in early clinical trials, there can be no assurance that we will observe acceptable safety or efficacy profiles in later-stage trials required for approval of these programs.

For neoantigen cancer vaccines, to date, no molecular (non-cell-based) therapeutic protein vaccine has been shown to be effective against cancer and there are many clinical and manufacturing challenges to personalized medicines, including cell-based therapies and vaccines. These risks include: a rapid production turn-around time that is measured in weeks in order to supply patients in our clinical trials before further progression and mutation of their tumors, the significant costs incurred in making individualized vaccines, and potential lack of immune responses due to the biology of the tumor or immune status of the patient. These risks apply to our personalized cancer vaccine (PCV) and other neoepitope investigational medicine programs. Additionally, there may be challenges in delivering an adequate quantity of active pharmaceutical ingredient (API) required to drive efficacy due to the limitation in volume of API that can be delivered to a specific location, like a tumor or injured tissue. Our investigational therapies for local injections often require specialized skills for conducting a clinical trial that could delay trials or slow or impair commercialization of an approved investigational medicine due to the poor adoption of injected local therapeutics or intratumoral therapies. In addition, the uncertain translatability of target selection from preclinical animal models, including mouse and non-human primate models, to successful clinical trial results may be impossible, particularly for immuno-oncology and systemic therapies, and cancer vaccines. In general, several biological steps are required for delivery of mRNA to translate into therapeutically active medicines. These processing steps may differ between individuals or tissues, potentially leading to variable levels of therapeutic protein, variable activity, immunogenicity, or variable distribution to tissues for a therapeutic effect. Gene therapies and mRNA-based medicines may activate one or more immune responses against any and all components of the drug product (e.g., the mRNA or the delivery vehicle, such as an LNP) as well as against the encoded protein, giving rise to potential immune reaction related adverse events. Eliciting an immune response against the encoded protein may impede our ability to achieve a pharmacologic effect upon repeat administration or a side effect. These risks apply to all of our programs, including our systemic secreted therapeutics and systemic intracellular therapeutics modalities.

We may experience delays in identifying and enrolling participants in our clinical trials, which would delay the progress of our investigational medicines and result in increased expenses.

Identifying and qualifying trial participants for our clinical trials of our investigational medicines is critical to our success. Difficulties or delays in enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our investigational medicines and obtain regulatory approval of potential products.

We may be unable to identify, recruit, and enroll a sufficient number of trial participants, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. As we did in our Phase 3 clinical study of mRNA-1273, we may slow enrollment in a trial to focus on achieving greater diversity in the subject population. Patient and subject enrollment is affected by factors including:

- severity of the disease under investigation;
- complexity and design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question, including age-based eligibility criteria limiting subject enrollment to adolescent or pediatric populations;
- proximity and availability of clinical study sites for prospective trial participants;
- availability of competing therapies and clinical trials, including by third parties or our own clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and trial participants' perceptions as to the potential advantages and side effects of the investigational medicine being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- adverse results or other adverse safety signals in our trials or related to other investigational medicines, and the resulting negative publicity, which could discourage potential trial participants and their doctors from participating in our trials;
- in the case of our PCV, the need to wait for the manufacture of the personalized drug product; and
- our ability to obtain and maintain participant informed consent.

We also have entered into strategic alliances under which our strategic collaborators control the development of certain of our investigational medicines, which may provide us limited or no ability to influence the enrollment rate of our clinical trials. Even if we or our strategic collaborators are able to enroll trial participants, there is no guarantee that they will ultimately be dosed as part of, or complete, a clinical trial.

mRNA drug development has substantial clinical development and regulatory risks due to the novel nature of this new class of medicines, and the negative perception of the efficacy, safety, or tolerability profile of any investigational medicines that we or others develop could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.

No mRNA medicine has been granted full or conditional approval by the FDA or other regulators, other than COVID-19 vaccines. Successful discovery and development of mRNA medicines by us or our strategic collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. We constantly make business decisions and take calculated risks to advance our development efforts and pipeline, including those related to mRNA technology, delivery technology, and manufacturing processes, which ultimately may be unsuccessful.

Our mRNA investigational medicines that appear promising in the early phases of development may fail to advance, experience delays in the clinic, experience clinical holds, or fail to reach the market for many reasons, including:

- nonclinical or preclinical study, or clinical trial, results may show potential mRNA medicines to be less effective than desired or to have harmful or problematic side effects or toxicities;
- adverse results in our clinical trials, or in those of others developing similar products, or adverse effects relating to mRNA, or our LNPs, may lead to negative publicity or delays in or termination of one or more of our programs;
- adverse events related to products that are perceived to be similar to mRNA medicines, such as those related to gene therapy or gene editing, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our investigational medicines, and less demand for any product that we may develop;
- the insufficient ability of our translational models to reduce risk or predict outcomes in humans, particularly given that each component of our investigational medicines and development candidates may have a dependent or independent effect on safety, tolerability, and efficacy, which may, among other things, be species-dependent;
- manufacturing failures or insufficient supply of cGMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make mRNA-based medicines commercially unattractive;
- changes that we make to optimize our manufacturing, testing or formulating of cGMP materials could impact the safety, tolerability, and efficacy profile of our investigational medicines and development candidates;
- pricing or reimbursement issues or other factors that delay clinical trials or make any mRNA medicine uneconomical or noncompetitive with other therapies;
- our large pipeline of development candidates and investigational medicines could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole;
- failure to timely advance our programs or a failure or delay in receiving necessary regulatory approvals due to, among other factors, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, preparation of a BLA, or the equivalent application, discussions with the FDA or EMA, a regulatory request for additional nonclinical or clinical data, or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding;
- new legislation or regulations passed by U.S., state, or foreign governments in response to negative public perception of mRNA medicines; and
- the proprietary rights of others and their competing products and technologies that may prevent our mRNA medicines from being commercialized.

Because we are developing some of our development candidates or investigational medicines for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There are no pharmacologic therapies approved to treat the underlying causes of many diseases that we currently attempt to address or may address in the future. For instance, for both MMA and PA, few clinical trials have been attempted, and there are no approved drugs to treat these diseases. As a result, the design and conduct of clinical trials of investigational medicines for the treatment of these disorders and other disorders may take longer, be more costly, or be less effective due to the novelty of development in these diseases.

Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our strategic collaborators conduct. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and may view the efficacy results in the context of safety as not being supportive of licensure. Regulators in other countries may make similar findings with respect to these endpoints.

Some of our investigational medicines are classified as gene therapies by the FDA and the EMA. The association of our medicines with gene therapies could result in increased regulatory burdens, impair the reputation of our investigational medicines, or negatively impact our platform or our business.

There have been few approved gene therapy products in the United States or foreign jurisdictions, and there have been well-reported significant adverse events associated with their testing and use. Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future, and the implications for mRNA-based therapies are unknown. For example, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research (CBER) to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the EU, mRNA has been characterized as a gene therapy medicinal product, which falls within a broader category known as Advanced Therapy Medicinal Products (ATMPs), which are subject to additional regulatory requirements. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us; for example, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. Notwithstanding the differences between mRNA medicines and gene therapies, the classification of some of our mRNA investigational medicines as gene therapies in the United States, the EU, and potentially other countries could adversely impact our ability to develop our investigational medicines, negatively impacting our platform and our business. For instance, a clinical hold on gene therapy products may apply to our mRNA investigational medicines irrespective of the differences between gene therapies and mRNA.

Adverse events reported with respect to gene therapies could adversely impact one or more of our programs. Although our mRNA development candidates and investigational medicines are generally designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapies caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our mRNA investigational therapies, and as a result may delay one or more of our trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory review agencies may negatively affect our business by lengthening the regulatory review process, requiring us to perform additional or larger studies, or increasing our development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of our investigational medicines, or lead to significant post-approval studies, limitations, or restrictions. As we advance our investigational medicines, we will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of some or all of our investigational medicines.

Additionally, we have established Moderna Genomics (MGX) with the vision of becoming a leader in large, complex genomic editing. In November 2021, we announced a multi-year research collaboration with Metagenomi to leverage Metagenomi's discovery platform and expertise to develop next-generation *in vivo* gene editing therapies. Our work in genomic editing is subject to all risks associated with gene therapies. Although there have been significant advances in recent years in fields of gene therapy and genome editing, *in vivo* CRISPR-based genome editing technologies are relatively new and their therapeutic utility is largely unproven. Public perception and related media coverage of potential therapy-related efficacy or safety issues, as well as ethical concerns related specifically to genome editing, may adversely influence the willingness of subjects to participate in clinical trials. In addition, any review conducted by an institutional biosafety committee may result in delay or prevent initiation of a gene therapy clinical trial.

Additionally, if any such therapeutic is approved, physicians and patients may be slow or fail to accept these novel and personalized treatments. Physicians, health care providers and third-party payors often are slow to adopt new products, technologies and treatment practices, particularly those that may also require additional upfront costs and training. Physicians may not be willing to undergo training to adopt these novel and potentially personalized therapies, may decide the particular therapy is too complex or potentially risky to adopt without appropriate training, and may choose not to administer the therapy. Further, due to health conditions, genetic profile or other reasons, certain patients may not be candidates for the therapies. In addition, responses by federal and state agencies, congressional committees and foreign governments to negative public perception, ethical concerns or financial considerations may result in new legislation, regulations, or medical standards that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. Based on these and other factors, health care providers and payors may decide that the benefits of these new therapies do not or will not outweigh their costs.

A breakthrough therapy designation or fast track designation, or accelerated approval, by the FDA or comparable pathways in other jurisdictions for a drug may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the drug will receive marketing approval.

We have received Fast Track Designation for some of our investigational medicines and may seek Fast Track Designation or breakthrough therapy designation for others. The FDA has broad discretion whether or not to grant either designation, and the receipt of either designation for a drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures. Even if one or more of our investigational medicines qualify for Fast Track Designation or as breakthrough therapies, the FDA may later decide that the investigational medicine no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened. Additionally, even if we obtain accelerated approval in the United States or under comparable pathways in other jurisdictions, we may face requirements and limitations that will adversely affect our prospects. For example, the FDA generally requires pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Further,
we may not receive ultimate approval or we may be approved only for a limited indication, we may not successfully complete required post-approval trials, such trials may not confirm the clinical benefit of our drug, or approval of the drug may be withdrawn.

We may fail to obtain and maintain orphan drug designations for our investigational medicines.

We may file for orphan drug designation where available for our investigational medicines. We may never receive such designation for any particular medicine. Although we have received orphan drug designation from both the FDA and the European Commission for PA (mRNA-3927) and GSD1a (mRNA-3745), orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication, or may be lost if the FDA later determines that the request for designation was materially defective. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care.

Our investigational medicines may face competition from biosimilars approved through an abbreviated regulatory pathway.

During the 12-year period of exclusivity provided by the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, another company may still market a competing version of a product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials demonstrate the safety, purity, and potency of the other company's product. The BPCI Act is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

There is also a risk that any exclusivity we receive for an investigational medicine could be shortened due to Congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCI Act, some of which may impact the BPCI Act's exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we cannot obtain, or are delayed in obtaining, required regulatory approvals, we will be unable to commercialize, or will be delayed in commercializing, investigational medicines we may develop.

Any mRNA medicine we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, record-keeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and comparable foreign regulators. To obtain required regulatory approvals to commercialize any of our investigational medicines, we and our strategic collaborators must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure, and potent in humans, including the target population. Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, a marketing authorization application (MAA) to the EMA, and similar marketing applications to comparable global regulatory authorities, for each investigational medicine and, consequently, the ultimate approval and commercial marketing of any investigational medicines.

We have not received approval to market any investigational medicine, other than our COVID-19 vaccine, in any jurisdiction, and our current or future development candidates or investigational medicines may never obtain regulatory approval. We have limited experience in filing and supporting the necessary applications for marketing approvals and may need to rely on third-party CROs or

regulatory consultants to assist us in this process. Although we expect to submit BLAs for our mRNA-based investigational medicines in the United States, other jurisdictions may consider our mRNA-based investigational medicines to be new drugs, not biologics, and require different marketing applications. Preclinical studies and clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and approval in one country does not guarantee regulatory approval in another. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any investigational medicines we develop may be ineffective, only moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

Additionally, the process of obtaining marketing approvals, both in the United States and abroad, is expensive, time-consuming, and uncertain, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the investigational medicines involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may delay the review of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of an investigational medicine. Additional delays or non-approval may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval.

The FDA and other regulators review the CMC section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may result in delays in clinical trials and commercialization. In addition, the regulatory agencies conduct pre-approval inspections at the time of a BLA. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential investigational medicine.

If we experience delays in obtaining approval or if we fail to obtain approval of any investigational medicines we may develop, the commercial prospects for those investigational medicines will be harmed, and our ability to generate revenues will be materially impaired.

Our products are, and any future products will be, subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction, the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our investigational medicines.

If we, our contract manufacturers or other strategic collaborators fail to comply with applicable regulatory requirements following approval of any of our investigational medicines, a regulatory agency may: issue a warning letter asserting that we are in violation of the law; seek an injunction or impose civil or criminal penalties or monetary fines; suspend or withdraw regulatory approval or revoke a license; suspend any ongoing clinical trials; refuse to approve a pending BLA or supplements to a BLA submitted by us; seize or recall investigational medicines or products; or refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

Additionally, the FDA or other regulators could require us to adopt a Risk Evaluation and Mitigation Strategy for any approved investigational medicine to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including the suspension or withdrawal of approvals and licenses; the addition of warning labels; changes to the way a product is administered; the requirement to conduct further clinical trials; lawsuits or increased liability for harm to patients and their children; and reputational harm. Any of these events could prevent us from achieving or maintaining market acceptance of any products we develop and could have a material adverse impact on our business, financial condition, results of operations, and prospects.

Even though the Moderna COVID-19 Vaccine/Spikevax has been approved by the FDA for individuals 18 years of age and older in the United States, it remains the subject of regulatory scrutiny. For example, we are required to conduct post-marketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Spikevax. Additionally, we have committed to conducting additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Spikevax during pregnancy. We or others could identify previously unknown side effects, or known side effects could be observed as being more frequent or severe than in clinical studies or earlier post-marketing periods, in which case:

- sales of mRNA-1273 may be more modest than originally anticipated;
- the FDA and other regulatory agencies may revoke authorizations for the vaccine;
- we may decide, or be required, to conduct recalls or send field alerts to physicians, pharmacists and hospitals;
- additional nonclinical or clinical studies, changes in labeling, or changes to manufacturing processes, specifications and/or facilities may be required; and
- government investigations or lawsuits, including class-action lawsuits, may be brought against us.

Any of the above occurrences could reduce or prevent sales of our COVID-19 vaccine, increase our expenses and impair our ability to successfully commercialize the vaccine.

Risks related to the manufacturing of our commercial products, development candidates, investigational medicines and our future pipeline

Our mRNA products, including our COVID-19 vaccine, development candidates and investigational medicines are based on novel technologies and are complex and difficult to manufacture. We or our third-party manufacturers may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management, or shipping for any of our medicines.

The manufacturing processes for our medicines, including our COVID-19 vaccine, are novel and complex. No mRNA medicine, other than COVID-19 vaccines, has been commercialized to date. Due to the novel nature of mRNA technology and our limited experience at larger scale production, we and our collaborators have experienced and may continue to encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management, or shipping. These issues could be due to many reasons, including complexities of producing batches at larger scale, equipment failure, human error, choice and quality of raw materials and excipients, analytical testing technology, and product instability. Further, mRNA medicines encapsulated in LNPs must be developed and manufactured under well-controlled conditions, or pharmacological activity can be adversely impacted.

In an effort to optimize product features, we have in the past and may in the future make changes to our development candidates or investigational medicines in their manufacturing and stability formulation and conditions. This has in the past and may in the future result in our having to resupply batches for preclinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our development candidates and investigational medicines could materially delay our or our strategic collaborators' ability to continue the clinical trial for that development candidate or investigational medicine or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply.

Our rate of innovation is high, which has resulted in and will continue to cause a high degree of technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships.

In many cases, we may need to utilize multiple batches of drug substance and drug product to meet the clinical supply requirement of a single clinical trial. Failure in our ability to scale up batch size or failure in any batch may lead to a substantial delay in our clinical trials or in the commercialization of any approved product. For example, the changes we make as we continue developing new manufacturing processes for our drug substance and drug product may impact specification and stability of the drug product, and may lead to failure of batches, resulting in a substantial delay in delivery of commercial product or conduct of our clinical trials. Our mRNA investigational medicines may prove to have a stability profile that leads to a lower than desired shelf life of the final approved mRNA medicine. This poses risk in supply requirements, wasted stock, and higher cost of goods.

We are dependent on a number of equipment providers who are also implementing novel technology. Further, we have developed our own custom manufacturing equipment for certain of our medicines. If we encounter unexpected performance issues with such equipment, we could encounter delays or interruptions to clinical and commercial supply. Due to the number of different programs, we may have cross contamination of investigational medicines inside of our factories, CROs, suppliers, or in the clinic that affect the integrity of our investigational medicines.

As we scale the manufacturing output for commercial production and particular programs, we plan to continuously improve yield, purity, and the pharmaceutical properties of our commercial products, development candidates and investigational medicines from

IND-enabling studies through commercial launch, including shelf life stability, and solubility properties of drug product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after a change in process, more time will be required for pharmaceutical property testing, such as 6 or 12 month stability testing. That may require resupplying clinical material or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

We are utilizing a number of raw materials and excipients that have a single source of supply, are new to the pharmaceutical industry, and are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our investigational medicines.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our mRNA investigational medicines. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy, or stability. This may lead to an inability to release mRNA investigational medicines until the manufacturing or testing process is rectified.

As our drug development pipeline increases and matures, the increased demand for clinical and commercial supplies from our facilities and third parties may impact our ability to operate. We rely on many service providers, all of whom have inherent risks in their operations that may adversely impact our operations.

Completion of our clinical trials and commercialization of our vaccine candidates require access to, or development of, facilities to manufacture our vaccine candidates at sufficient yields and at commercial-scale. We have limited experience manufacturing any of our vaccine candidates in the volumes that are necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality. If we are unable to institute necessary controls related to product development, manufacturing and quality, our operations may be adversely impacted. In addition, other companies, many with substantial resources, compete with us for access to the materials needed to manufacture our vaccines.

We currently utilize, and expect to continue to utilize, third parties to, among other things, manufacture raw materials, components, parts, and consumables, and to perform quality testing. If the field of mRNA and other nucleic acid medicines continues to expand, we may encounter increasing competition for these materials and services. Demand for third-party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of such raw materials, components, parts, and consumables required to manufacture our mRNA investigational medicines. The use of service providers and suppliers could expose us to risks, including, but not limited to:

- termination or non-renewal of supply and service agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruptions to the operations of these suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the supplier or service provider; and
- inspections of third-party facilities by regulatory authorities that could have a negative outcome and result in delays to or termination of their ability to supply our requirements.

Our reliance on third-party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk vaccines on a commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our vaccine. A third-party manufacturer may also encounter difficulties in production, including:

- difficulties with production costs, scale up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced regulations that vary in each country where products might be sold; and
- lack of capital funding.

Any delay or interruption could adversely affect our business, financial condition, or results of operations.

We are subject to operational risks associated with the physical and digital infrastructure at both our internal manufacturing facilities and at those of our external service providers.

Our MTC facility in Norwood, Massachusetts incorporates a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. Our high level of digitalization may pose risk of process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, but not limited to, design issues, system compatibility, or potential cybersecurity breaches.

Our facilities or those of our contract manufacturers may also be subject to intentional attacks or acts of sabotage by outside actors, contractors or employees. Any disruption in our or our contract manufacturers' manufacturing capabilities could cause delays in production capacity for our drug substances or products or a shutdown of facilities, could impose additional costs, or may require us to identify, qualify, and establish an alternative manufacturing site, the occurrence of which could adversely affect our business, financial condition, results of operations, and prospects.

As we expand our development and commercial capacities, we have and expect that we will continue to establish additional manufacturing capabilities inside the MTC footprint and that we will expand to other locations and geographies, such as Africa, Australia and Canada. This expansion may lead to regulatory delays or prove more costly than anticipated. If we fail to select a suitable location, complete construction in an efficient manner, engage effectively with local regulators, recruit the required personnel, and generally manage our growth effectively, the development and production of commercial products or our investigational medicines could be delayed or curtailed. We expect that we will continue to make additional investments in our manufacturing processes as we expand the MTC and our other manufacturing infrastructure.

Our products and investigational medicines are sensitive to shipping and storage conditions, which, in some cases, requires cold-chain logistics and subjects our investigational medicines to risk of loss or damage.

Our COVID-19 vaccine and our investigational medicines are sensitive to temperature, storage, and handling conditions, and we could lose medicines if the product or product intermediates are not stored or handled properly. Shelf life for our products and investigational medicines is expected to be variable, and our investigational medicines may expire prior to use. Cold-chain logistics are required for certain of our investigational medicines and our COVID-19 vaccine. If we or third-party distributors do not maintain effective cold-chain supply logistics, then we may experience an unusual number of returned or out of date products and critical batches of products may be rendered unusable. This has in the past and could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials, commercial sale, or otherwise. In addition, the cost associated with such transportation services and the limited pool of vendors could cause supply disruptions.

We are subject to significant regulatory oversight with respect to manufacturing our COVID-19 vaccine and our mRNA investigational medicines. Our manufacturing facilities or the manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by the FDA, EMA, and other global health authorities could result in significant delays in any approval of and costs of our products.

The manufacturing of medicines for clinical trials or commercial sale is subject to extensive regulation, and components of such products must be manufactured in accordance with cGMP requirements, which are enforced, in the case of the FDA, in part through its facilities inspection program. The regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of the cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive. Such production process issues include but are not limited to:

- critical deviations in the manufacturing process;
- facility and equipment failures;
- contamination of the product due to an ineffective quality control strategy;
- facility contamination as assessed by the facility and utility environmental monitoring program;
- raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers;
- ineffective product stability;
- ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and
- failed or defective components or consumables.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with cGMP and manufacturing controls. If we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, the product approval to commercialize may not be granted. Inspections by regulatory authorities may occur at any time during the

development or commercialization phase of products. The inspections may be product specific or facility specific for broader cGMP inspections, or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may negatively impact the ability of our third-party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs.

The manufacturing process for our COVID-19 vaccine, and for any other products that we may develop, is subject to the FDA and foreign regulatory authority approval process. If we or our third-party manufacturers are unable to reliably produce products or investigational medicines to specifications acceptable to the FDA or other regulatory authorities, we or our strategic collaborators may not obtain or maintain the approvals needed to commercialize such products. Even if regulatory approval is obtained for any of our mRNA medicines, there is no assurance that either we or our CMOs will be able to manufacture the approved medicine to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our investigational medicines, impair commercialization efforts, or increase our cost of goods, which, in turn, could have an adverse effect on our business, financial condition, results of operations, and prospects.

In addition, we may not have direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. Our contract manufacturers supply or manufacture materials or products for other companies, and their failure to meet applicable regulatory requirements may generally affect the regulatory status of their facilities. In addition, to the extent that we rely on foreign contract manufacturers, including for our COVID-19 vaccine, we are subject to additional risks, including the need to comply with import and export regulations. Additionally, our potential future dependence on others to manufacture our investigational medicines and raw materials may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, the EMA, and other foreign regulatory authorities may require us to submit product samples of any lot of any approved product, together with the protocols showing the results of applicable tests, at any time. In some cases, regulators may prohibit us from distributing a lot or lots until it authorizes release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may cause unacceptable changes in the product, resulting in lot failures or product recalls. Our third-party contract manufacturers have experienced lot failures and one has experienced a product recall related to our COVID-19 vaccine. Lot failures have in the past caused, and lot failures or product recalls in the future with respect to product produced by either our own or our third-party manufacturers' facilities could cause, us and our strategic collaborators to delay clinical trials or product launches, which could harm our business, financial condition, results of operations, and prospects.

We and our manufacturing partners also may encounter problems hiring and retaining the experienced scientific, quality control, and manufacturing personnel needed to operate our manufacturing processes and operations or those of our manufacturing partners, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Additionally, we may not be able to control for or ultimately detect intentional sabotage or negligence by any employee or contractor.

Our PCV investigational medicine is uniquely manufactured for each patient using a novel, complex manufacturing process and we may encounter difficulties in production.

We custom design and manufacture PCVs that are unique and tailored specifically for each patient. Manufacturing unique lots of PCVs is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient's tumor, blood, or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next generation sequencing of the tumor mRNA;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our investigational medicine, to assist with the design of the patient-specific mRNA, which software must be maintained and secured;
- effective design of the patient-specific mRNA that encodes for the required neoantigens;
- batch specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch;
- quality control testing failures;
- unexpected failures of batches placed on stability;
- shortages or quality control issues with single-use assemblies, consumables, or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the patient site of care; and

- the ability to define a consistent safety profile at a given dose when each participant receives a unique vaccine.

We have built and installed custom manufacturing equipment for PCVs that has been incorporated into a personalized vaccine unit in the MTC. This equipment may not function as designed, resulting in deviations in the drug product produced, which could lead to increased batch failure and the inability to supply patients enrolled in the clinical trial. If our clinical development plans are expanded, due to the custom nature of the equipment and single-use assemblies, we may require significant investments. In addition, it would take considerable time to scale up our facilities or build new facilities to meet any commercial demand if our PCV product is approved. This expansion or addition of new facilities could also lead to product comparability issues, which could further delay introduction of new capacity.

Because our PCVs are manufactured for each individual patient, we are required to maintain a chain of identity with respect to each patient's tissue sample, sequence data derived from such tissue sample, results of analysis of such patient's genomic analysis, and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so has in the past and may in the future result in product mix up, adverse patient outcomes, loss of product, or regulatory action including withdrawal of any approved products from the market. Further, as our PCV is developed through early-stage clinical trials to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture, and delivery process will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our PCVs to perform differently than we expect, potentially affecting the results of clinical trials.

Risks related to our reliance on third parties

We are dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our products, development candidates and investigational medicines.

We depend on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop and commercialize, our COVID-19 vaccine, development candidates and investigational medicines. We cannot ensure that these suppliers will remain in business, have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that will cease working with us. Our use of single-source suppliers exposes us to several risks, including disruptions in supply, price increases, or late deliveries. Any disruption in supply from any single-source supplier could lead to supply delays or interruptions that would damage our business, financial condition, results of operations, and prospects.

There are, in general, relatively few alternative sources of supply for substitute components. If we have to switch to a replacement supplier, the manufacture and delivery of our products, development candidates or investigational medicines could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our products or investigational medicines, if required, may not be accomplished quickly, if at all. Any replacement supplier would need to be qualified and may require additional regulatory authority approval, resulting in further delay. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our investigational medicines. Additionally, as part of the FDA's approval of our investigational medicines, the FDA will review the individual components of our process, which include the manufacturing processes and facilities of our single-source suppliers.

We have in the past entered into, and in the future may enter into, strategic alliances with third parties for the development and commercialization of our and their products, development candidates and investigational medicines. If these strategic alliances are not successful, our business could be adversely affected.

We have entered into strategic alliances under which our strategic collaborators have provided, and may in the future provide, funding and other resources for developing, manufacturing and commercializing our investigational medicines. Additionally, as we have begun to generate revenue, we have begun to enter into strategic alliances where we agree to provide funding and other resources to third parties. We expect to enter into additional strategic alliances in the future. Our existing strategic alliances, and any future strategic alliances we enter into, may pose a number of risks, including the following:

- strategic collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of such strategic alliance may not be successful;
- strategic collaborators may not pursue development and commercialization of any investigational medicines that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the strategic collaborators' focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- strategic collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon an investigational medicine, repeat or conduct new clinical trials, or require a new formulation of an investigational medicine for clinical testing;
- strategic collaborators could develop, independently or with third parties, products that compete directly or indirectly with our products or investigational medicines if such collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- products or investigational medicines developed in strategic alliances with us may be viewed by our strategic collaborators as competitive with their own investigational medicines or products, which may cause strategic collaborators to cease to devote resources to the development or commercialization of our investigational medicines;
- a strategic collaborator with marketing and distribution rights to one or more of our products or investigational medicines that achieve regulatory approval may commit insufficient resources to the marketing and distribution of any such product;
- disagreements with strategic collaborators, including over proprietary rights, contract interpretation, or the course of development of any investigational medicines, may cause delays or termination of the research, development, or commercialization of such investigational medicines, lead to additional responsibilities for us with respect to such investigational medicines, or result in litigation or arbitration, any of which would be time-consuming and expensive;
- strategic collaborators may not properly maintain or defend our IP rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our IP or proprietary information;
- disputes may arise with respect to the ownership of IP developed pursuant to our strategic alliances;
- strategic collaborators may infringe the IP rights of third parties, exposing us to potential litigation and liability;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate strategic collaborators and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions, or joint ventures may expose us to certain operating, legal, and other risks not encountered in the United States.

Our strategic collaborators generally may materially amend or terminate their agreements with us for convenience, which has happened in the past. If any collaboration agreement is terminated, we may not receive future research funding or milestone, earn-out royalty or other contingent payments, and the development of our investigational medicines may be delayed. It may also be difficult to attract new strategic collaborators to continue development or commercialization of the applicable investigational medicine, and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described in this Annual Report on Form 10-K apply to the activities of our strategic collaborators.

We may seek to establish additional strategic alliances and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our strategic alliance agreements may restrict our ability to develop certain products.

Our development programs and the potential commercialization of our development candidates and investigational medicines will require substantial additional cash to fund expenses. We may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of some of our investigational medicines, and we face significant competition in seeking appropriate strategic collaborators. Our ability to establish additional strategic alliances will depend, among other things, on our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed strategic alliance, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject investigational medicine, the costs and complexities of manufacturing and delivering such investigational medicine to trial participants, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. Any potential strategic collaborator may ultimately collaborate on alternative investigational medicines or technologies for similar indications rather than collaborate with us.

We are also restricted under our existing strategic alliance agreements from entering into agreements on certain terms with potential strategic collaborators to pursue other targets on our own. These restrictions on working with targets, polypeptides, routes of administration, and fields could limit our ability to enter into strategic collaborations with other collaborators or to pursue certain potentially valuable development candidates or investigational medicines.

Strategic alliances are complex and time-consuming to negotiate and document. If we cannot negotiate and enter into new strategic alliances on a timely basis, on favorable terms, or at all, we may need to curtail the development of the investigational medicine for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and

undertake development or commercialization activities at our own expense. We may need to obtain additional capital to fund these efforts, and the inability to obtain such funding on favorable terms may prevent us from further developing our investigational medicines or bringing them to market and generating product revenue.

We rely on and expect to continue to rely on third parties to conduct aspects of our research, preclinical studies, protocol development, and clinical trials for our development candidates and investigational medicines. If these third parties do not perform satisfactorily, comply with regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our investigational medicines and our business could be substantially harmed.

We rely on third parties such as CROs to help manage certain preclinical work and our clinical trials, and on medical institutions, clinical investigators and CROs to assist in the design and review of, and to conduct, our clinical trials, including enrolling qualified patients. In addition, we engage third-party contractors and collaborators to support numerous other research, commercial and administrative activities, which reduces our control over these activities but does not relieve us of our responsibilities, such as ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocols. Moreover, the FDA requires us to comply with GLPs and good clinical practices for conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that in the case of clinical trials the rights, integrity and confidentiality of trial participants are protected. Such standards will evolve and subject us and third parties to new or changing requirements.

If third parties do not successfully carry out their contractual duties or meet expected deadlines, we may need to replace them, which could cause a delay of the affected clinical trial, drug development program or applicable activity. If clinical trials are not conducted in accordance with our contractual expectations or regulatory requirements, action by regulatory authorities may significantly and adversely affect the conduct or progress of such trials or even require a clinical trial to be redone. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates could be delayed. In addition, failure of any third-party contractor to conduct activities in accordance with our expectations could adversely affect the relevant research, development, commercial or administrative activity.

Risks related to our intellectual property

If we are not able to obtain and enforce patent protection for our discoveries, or protect the confidentiality of our trade secrets, our ability to effectively compete using our development candidates will be harmed.

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other IP laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. Because certain U.S. patent applications are confidential until the patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions, including our COVID-19 vaccine. For this and other reasons, we may be unable to secure desired patent rights, thereby losing exclusivity. Further, we may be required to obtain licenses under third-party patents to market our proposed products or conduct our research and development or other activities. If licenses are not available to us on favorable terms, we may not be able to market the affected products or conduct the desired activities.

The process of obtaining patent protection is expensive and time-consuming and our pending patent applications may not result in issued patents. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent applications may fail to result in valid enforceable patents, or our patent protection could be reduced or eliminated, for non-compliance with these requirements. If we or our present or future strategic collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business may be adversely affected.

Despite our and our strategic collaborators' efforts to protect our proprietary rights, unauthorized parties may obtain and use information that we regard as proprietary. While issued patents are presumed valid, they may not survive a validity challenge and could be held unenforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, adjudged unenforceable, or circumvented by parties seeking to design around our IP. Also, third parties or the USPTO may commence interference proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation, or circumvention of, our patents or patent applications, would be costly, would require significant time and attention of our management, could reduce or eliminate royalty payments to us from third-party licensors, and could have a material adverse impact on our business.

The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and foreign countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts, and lawmakers. For example, the America Invents Act, which took effect in March 2013, included a number of changes to the patent laws of the United States. If any of the enacted changes prevent us from adequately protecting our discoveries, including our ability to pursue infringers of our patents to obtain injunctive relief or for substantial damages, our business could be adversely affected. One major provision of the America Invents Act changed U.S. patent practice from a first-to-invent to a first-to-file system. If we fail to file an invention before a competitor files on the same invention, we no longer have the ability to provide proof that we were in possession of the invention prior to the competitor's filing date, and thus would not be able to obtain patent protection for our invention. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable.

Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. We also rely on non-disclosure agreements and invention assignment agreements entered into with our employees, consultants, and third parties. If any trade secret, know-how, or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

Failure to obtain and maintain all available regulatory exclusivities and broad patent scope and to maximize patent term restoration or extension on patents covering our products may lead to loss of exclusivity and early biosimilar entry resulting in a loss of market share and/or revenue.

In addition, we may choose not to enforce our IP rights in certain circumstances or for certain periods of time. For example, in October 2020 we announced that while the COVID-19 pandemic continues, we will not enforce our COVID-19-related patents against those making vaccines intended to combat the pandemic. We also noted that to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our IP for COVID-19 vaccines to others for the post-pandemic period. However, we may never enter into such licenses of our IP for the post-pandemic period, and our business may be otherwise adversely impacted by our decision not to enforce this IP.

Uncertainty over IP in the pharmaceutical and biotechnology industry has been the source of litigation and other disputes, which is inherently costly and unpredictable, and can have adverse financial and freedom-to-operate consequences.

mRNA medicines are a relatively new scientific field and, as the field continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. It is likely that there will be significant litigation and other proceedings, such as patent infringement lawsuits, interference, reexamination, and opposition proceedings, as well as inter-partes and post-grant-review proceedings introduced by provisions of the America Invents Act, in various patent offices relating to patent rights in the mRNA field.

We have issued patents and pending patent applications in the United States and in key markets around the world that claim many different methods, compositions, and processes relating to the discovery, development, manufacture, and commercialization of mRNA medicines and our delivery technology, including LNPs. An opposition has been filed against one of our European platform patents covering uridine-modified mRNAs and we expect that further oppositions will be filed in the European Patent Office (EPO) and elsewhere relating to patents and patent applications in our portfolio. In many cases, the possibility of appeal exists for either us or our opponents, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. We cannot be certain that such patent will survive or that the claims will remain in the current form. Even if our rights are not directly challenged, disputes could lead to the weakening of our IP rights.

There are many issued and pending third-party patents that claim aspects of oligonucleotide and delivery technologies that we may need for our mRNA therapeutic and vaccine candidates or marketed products, including our COVID-19 vaccine. There are also many issued third-party patents that claim targeting genes or portions of genes that may be relevant for mRNA medicines we wish to develop. For example, there are issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party's belief that we may need such patents for our mRNA therapeutic candidates. Thus, it is possible that one or more organizations hold patent rights to which we may need a license or which could be asserted against us. If those organizations refuse to license such patent rights on reasonable terms or a court rules that we need such patent rights that have

been asserted against us and we are not able to obtain a license on reasonable terms, we may owe damages to such party, and further may be unable to market products, including our COVID-19 vaccine, covered by such patents.

In certain instances, we have instituted and may in the future institute inter partes review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties in the field of mRNA medicines. We have a number of these proceedings ongoing against third-party patents related to RNA vaccinations and mRNA delivery. If we are unsuccessful in invalidating such third-party patents, those third parties may attempt to assert those patents against investigational medicines that obtain regulatory approval, including our COVID-19 vaccine. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our development candidates may be subject to claims of infringement of the patent rights of third parties.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages, or be required to stop our product development and commercialization efforts.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our investigational medicines, and third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our investigational medicines, any molecules formed during the manufacturing process, or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to commercialize such investigational medicine unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture, or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable investigational medicine unless we obtained a license or until such patent expires.

Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and divert employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense.

In addition, any such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability, which could jeopardize our ability to sustain our operations. Moreover, we expect that a number of our collaborations will provide that royalties payable to us for licenses to our IP may be offset by amounts paid by our collaborators to third parties who have competing or superior IP positions in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

In addition, in connection with certain license and strategic alliance agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to IP rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to IP rights, even if resolved in our favor, could be substantial, and litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could delay our research, development and commercialization efforts and limit our ability to continue our operations.

If third-party owners of any patent rights that we license do not properly or successfully obtain, maintain, or enforce the patents underlying such licenses, our competitive position and business prospects may be harmed.

We may become a party to licenses that give us rights to third-party IP that is necessary or useful for our business. In such a case, our success may depend in part on the ability of our licensors to obtain, maintain, and enforce patent protection for our licensed IP. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the IP we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we sublicense our rights under various third-party licenses to our strategic collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our strategic alliance agreements or result in termination of an agreement by one or more of our strategic collaborators.

If we fail to comply with our obligations in the agreements under which we license IP rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We license IP, which involves complex legal, business, and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. We are a party to certain IP license agreements and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license and may be subject to additional liabilities.

In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our strategic collaborators. Disputes may arise regarding IP subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether our technology and processes that are not subject to the licensing agreement infringe on IP of the licensor;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of IP by our licensors and us and our strategic collaborators; and
- the priority of invention of patented technology.

If disputes over IP that we have licensed prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected development candidates or investigational medicines. We are generally also subject to all of the same risks with respect to protection of IP that we license as we are for IP that we own. If we or our licensors fail to adequately protect this IP, our ability to commercialize products could suffer.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. From time to time, we are subject to claims that we or our employees, consultants, or independent contractors, have inadvertently or otherwise used or disclosed IP, including trade secrets or other proprietary information, of third parties, including our employees' former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other IP.

We may be and have been subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other IP. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our development candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights, including exclusive ownership of, or right to use, valuable IP. Such an outcome could have a material adverse impact on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract management and other employees, and could impact or patenting strategy.

Changes in U.S. patent and regulatory law could impair our ability to protect our products.
Our success is heavily dependent on IP, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and the process is costly, time-consuming and inherently uncertain. In addition, the United States has enacted and is implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have increased uncertainty with regard to our ability to obtain patents in the future, as well as with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. See "—Risks related to the research, development, regulatory review, and

approval of our existing and future pipeline—Our investigational medicines may face competition from biosimilars approved through an abbreviated regulatory pathway."

We may not be able to protect our IP rights throughout the world.

Filing, prosecuting, and defending patents on development candidates and investigational medicines in every country would be prohibitively expensive, and our foreign IP rights can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect IP rights to the same extent as U.S. federal and state laws. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection or may export infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products.

Many companies have encountered significant problems in protecting and defending IP rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other IP protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our IP rights around the world may be inadequate to obtain a significant commercial advantage from the IP that we develop or license.

Additionally, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. As a result, in response to the COVID-19 pandemic, it is possible that certain countries may take steps to facilitate compulsory licenses that permit the distribution of a COVID-19 vaccine in those countries. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the relevant patent rights. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Our reliance on government funding and collaboration from governmental and quasi-governmental entities for certain of our programs adds uncertainty to our research and development efforts with respect to those programs and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.

The development of our Zika vaccine (mRNA-1893) is funded by BARDA and our COVID-19 vaccine was developed in collaboration with NIAID. BARDA has agreed to fund the advancement of our COVID-19 vaccine to FDA licensure. Contracts and grants funded by the U.S. government and its agencies, including our agreements funded by BARDA and DARPA and our collaboration with NIAID, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including IP rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act, and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the

U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination, and affirmative action programs, and environmental compliance requirements.

Further, under these agreements we are subject to the obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980 (Bayh-Dole Act). As a result, the U.S. government may have rights in certain inventions developed under these government-funded programs, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights." Any exercise of the march-in rights by the U.S. government could harm our competitive position, business, financial condition, results of operations, and prospects. If the U.S. government exercises such march-in rights, we may receive compensation that is deemed reasonable by the U.S. government in its sole discretion, which may be less than what we might be able to obtain in the open market. IP generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

In addition, the U.S. government requires that any products embodying any invention generated through the use of U.S. government-funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the IP can show that it made reasonable but unsuccessful efforts to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. manufacturers for products covered by such IP.

As an organization, we are relatively new to government contracting and the related regulatory compliance obligations. If we fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts.

As a U.S. government contractor, we are subject to financial audits and other reviews by the U.S. government of our costs and performance on their contracts, as well as our accounting and general business practices related to these contracts. Based on the results of its audits, the government may adjust our contract-related costs and fees, including allocated indirect costs. We cannot assure you that future audits and reviews will not have a material adverse impact on our financial condition or results of operations.

Risks related to the commercialization of our pipeline

We have limited sales, distribution, and marketing experience, and have only recently invested significant financial and management resources to establish these capabilities. If we cannot effectively establish such capabilities or enter into agreements with third parties to market and sell our products or to help ensure compliance with local regulatory requirements, our ability to generate revenues may be adversely affected.

Our COVID-19 vaccine is our only commercial product, and we are investing in the development of sales, marketing, distribution, managerial and other non-technical capabilities in and out of the United States, both on our own and with others. We may seek to enter into strategic alliances with other entities to utilize their marketing and distribution capabilities, but may be unable to enter into agreements on favorable terms, if at all. If we rely on third parties to commercialize any approved product, we will receive lower revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of such third parties. If our collaborators do not commit sufficient resources to commercialize our products, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product revenue to sustain our business.

The commercialization and distribution of our COVID-19 vaccine also subjects us to pharmacovigilance obligations under various regulatory regimes in the jurisdictions where our vaccine is distributed. These regulations generally require us to collect, process,

analyze and monitor safety data and to identify and evaluate adverse reactions to our vaccine as it is administered in those jurisdictions. We partner with third-party organizations to assist us in collecting and processing this safety data as it is reported from healthcare providers, vaccine recipients and others. If we or these third parties cannot comply with relevant regulations, including with respect to the timely processing of safety data, we may be subject to sanctions, increased costs, and reputational harm, or our authorizations to distribute our vaccine in the relevant jurisdiction may be revoked or curtailed. There are a limited number of third-party service providers who are qualified and capable of providing pharmacovigilance services on a global basis, and our inability to identify or contract with them may impede our commercial activities.

We compete with many companies that currently have extensive and well-funded marketing, sales and pharmacovigilance operations, and we must also compete with such companies to recruit, hire, train and retain marketing and sales personnel. We also incur expenses associated with hiring third-party contractors to assist in conducting local pharmacovigilance services. Without a significant internal team or the support of a third party to perform these functions, we may be unable to compete successfully against these more established companies.

The terms of certain of our supply agreements may require us to refund certain prepayments from customers of our COVID-19 vaccine if they reduce purchase commitments or if we fail to deliver the purchased volume.

Some customers for our COVID-19 vaccine prepay us for a portion of the product payment for the vaccine doses that they expect to receive from us. Such prepayments can be substantial. We are generally not required by our contracts to retain these prepayments in cash or otherwise and we generally use them to make capital expenditures and fund the manufacturing scale-up and commercialization of our vaccine. Under certain supply agreements, if we fail to deliver a portion or all of the committed number of doses by a certain date, or if we are unable to successfully obtain regulatory authorization or approval for the commercialization of the vaccine in the relevant jurisdiction, a customer may reduce the volume of vaccine doses that it commits to purchase or terminate the contract. Upon termination, we would generally be required to refund a portion of that customer's prepayment. We may not have the cash or other available resources to satisfy that repayment obligation. In this situation, our business, financial condition, results of operations, and reputation could be materially and adversely affected. Furthermore, if customers do not prepay us for our services in the future, we may have to find other sources of funding, which may not be available when needed or on acceptable terms.

The commercial success of any current or future investigational medicine, if approved, will depend on the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Ethical, social, and legal concerns about genetic research could result in additional regulations restricting or prohibiting the products and processes we may use, including new areas of research such as in gene editing. Additionally, the commercial success of our products will depend in part on the medical community, patients, and third-party or governmental payors accepting mRNA medicines, and our products in particular, as medically useful, cost-effective, and safe. The degree of market acceptance of our investigational medicines, if approved for commercial sale, will depend on numerous factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the ability to offer our products, if approved, at competitive prices;
- the prevalence and severity of any side effects, including any limitations, restrictions (including for use together with other medicines) or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from checkpoint inhibitors or other products or therapies with which our products are co-administered;
- relative convenience and ease of administration;
- the willingness of the target patient population to try, and physicians to prescribe, new therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will be unknown until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources, especially due to the complexity and uniqueness of our programs, and may never be successful.

We are subject to the risks of doing business outside of the United States.

Because we market our COVID-19 vaccine, and plan to market other products, if approved, and to conduct manufacturing activities outside of the United States, our business is subject to risks associated with doing business outside of the United States. We have limited experience as a company operating outside the United States. We are not permitted to market or promote any of our developmental candidates or investigational medicines before we receive regulatory approval or other authorization from an applicable authority, and we may never receive such approval for any of our developmental candidates or investigational medicines. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, manufacturing, commercial sales, pricing and distribution of our developmental candidates and investigational medicines, and we cannot predict success in these jurisdictions. We are rapidly expanding our global operations, establishing commercial subsidiaries, and entering into arrangements to support the worldwide manufacture and distribution of our COVID-19 vaccine and other medicines, including with third parties, which is a complex task that we are undertaking on an accelerated timeline. Accordingly, our business and financial results may be adversely affected due to a variety of factors associated with our expanding global business, including:

- efforts to develop an international commercial sales, marketing, and supply chain and distribution organization, including efforts to mitigate longer accounts receivable collection times, longer lead times for shipping, and potential language barriers; for example, in the second half of 2021, we felt the impact of longer delivery lead times for international shipments and exports, which shifted certain anticipated deliveries of our COVID-19 vaccine from 2021 to 2022;
- our customers' ability to obtain reimbursement for our products in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- changes in a specific country's or region's political and cultural climate or economic condition, including as a result of the COVID-19 pandemic;
- an increased legal and compliance burden to establish, maintain and operate legal entities in foreign countries;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, including the European General Data Protection Regulation 2016/679 (GDPR);
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute, and the difficulty of effective enforcement of contractual provisions in local jurisdictions, and the existence of potentially relevant third-party IP rights;
- inadequate IP protection in foreign countries, and the existence of potentially relevant third-party IP rights;
- trade-protection measures including trade restrictions, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties, or suspension or revocation of export privileges, the imposition of government controls, and changes in tariffs;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and
- significant adverse changes in foreign currency exchange rates.

We are also subject to extensive federal, state and foreign anti-bribery regulations, including the U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, and similar laws in other countries. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside the United States, we will need to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs.

We cannot guarantee that we, or our employees, consultants, or third-party contractors, are or will be in compliance with all federal, state, and foreign regulations regarding bribery and corruption. Moreover, our strategic collaborators and third-party contractors outside the United States may have inadequate compliance programs or fail to respect the laws and guidance of the territories in which they operate, which may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Even if we are not determined to have violated these laws, government investigations typically require the expenditure of significant resources and generate negative publicity, which could adversely affect our business, financial condition, and results of operations.

Sales of pharmaceutical products depends on the availability and extent of reimbursement from third-party payors, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Third-party payor coverage and reimbursement for our COVID-19 vaccine is not currently available and there is no guarantee payors will provide coverage and reimbursement for the vaccine in the future. Even if coverage is provided, we may not be able to establish or maintain pricing sufficient to realize a sufficient return on our investment. While coverage is expected to be provided under Medicare Part B, it is unclear to what extent other payors, including certain federal entitlement programs, such as the Vaccines for Children Program, will provide coverage for the product. Additionally, it is uncertain whether any combination respiratory vaccine we develop, if approved, would qualify for coverage under Medicare Part B.

In addition, sales of pharmaceutical products in general depends, to a significant extent, on adequate coverage, pricing and reimbursement from third-party payors. When a new product is approved, the availability and extent of government and private reimbursement, and the pricing, for that product may be uncertain. Pricing and reimbursement for any product we develop may be adversely affected by a number of factors, including:

- changes in, and implementation of, federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs; and
- consolidation and increasing assertiveness of payors seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value.

Our ability to set the price for any product we develop will vary significantly from country to country. Our inability to obtain and maintain adequate prices in a particular country may limit the revenues from our products within that country and adversely affect our ability to secure acceptable prices in existing and potential new markets, which may limit market growth. This may create the opportunity for third-party cross-border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

Drug prices are under significant scrutiny in many countries. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. Competition may negatively impact our ability to maintain pricing and our market share. New products marketed by competitors could cause our revenues to decrease due to potential price reductions and lower sales volumes. Additionally, the introduction of competing versions of our products or products approved under abbreviated regulatory pathways may reduce the price that we are able to charge for our products and lower our sales volume.

Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs. Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors would increase the negotiating leverage such entities have over us and other drug manufacturers. Additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

Additionally, target patient populations for some of our investigational medicines, including for rare genetic diseases, may be small, and some of our investigational medicines, like PCV, require individual customization. The pricing and reimbursement of our medicines, if approved, must be adequate to support commercial infrastructure. If we cannot obtain adequate levels of reimbursement, we may be unable to successfully market and sell our investigational medicines. The manner and level at which reimbursement is provided for services related to our investigational medicines (e.g., for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products.

Our failure to obtain or maintain adequate coverage, pricing or reimbursement for our products could have an adverse effect on our business, reputation, revenues and results of operations.

Recent federal legislation and actions by federal, state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the United States for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries with price controls on pharmaceutical products. For example, in October 2020, the FDA published a final rule that would allow for the importation of certain prescription drugs from Canada, where there are government price controls. Since the issuance of the final rule, several industry groups filed federal lawsuits requesting injunctive relief to prevent the rule from taking effect and challenging multiple aspects of the final rule. This litigation has not progressed and the market implications are currently unknown, but legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products we may develop and adversely affect our future revenues and potential profitability.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

In the United States, federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our products, if approved, are prescribed and purchased. For example, provisions of the ACA have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the PHSA. See the section titled "Business—Government Regulation—Current and future healthcare reform legislation."

We may face uncertainties as a result of efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. There is no assurance that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There is increasing public attention on the costs of prescription drugs and there have been, and are expected to continue to be, legislative proposals to address prescription drug pricing, which could have significant effects on our business. These actions and the uncertainty about the future of the ACA and healthcare laws may put downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs.

There is also significant economic pressure on state budgets, including as a result of the COVID-19 pandemic, that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. In recent years, some states have considered legislation and ballot initiatives that would control the prices of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the United States and laws intended to impose price controls on state drug purchases. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding limitation on prices and reimbursement for our products, if approved.

In the EU and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures, and may in the future implement new or additional measures, to reduce health care costs to limit the overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possible retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower-cost countries. These measures may adversely affect our revenues and results of operations.

If the market opportunities for our programs, development candidates or investigational medicines are smaller than we believe they are, or we are unable to successfully identify clinical trial participants, our revenue may be adversely affected and our business may suffer.

We focus certain of our research and product development activities on treatments for severe rare genetic diseases, where the patient populations are difficult to ascertain or small. Additionally, we expect to initially seek approval of our PCV and intratumoral immuno-oncology investigational medicines for use by patients with relapsed or refractory advanced disease, i.e., the populations the FDA often approves new therapies for initially. If any such medicines prove to be sufficiently beneficial, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy. There is no guarantee that our investigational medicines, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have these diseases, as well as the subset of those who have the potential to benefit from treatment with our investigational medicines, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants, both in and outside the United States, may be lower than expected and potential clinical trial participants or patients may not be otherwise amenable to treatment with our investigational medicines or products, or new clinical trial participants or patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Even if we obtain significant market share for our products, if approved, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

The illegal distribution and sale by third parties of counterfeit or stolen versions of mRNA products, or the unauthorized donation or re-sale of mRNA products, could have a negative impact on our financial performance or reputation.

Third parties could illegally distribute and sell, especially online, counterfeit versions of mRNA products that do not meet the rigorous cGMP manufacturing and testing standards. Counterfeit products are frequently unsafe or ineffective, and could be life-threatening. Counterfeit medicines may contain harmful substances or the wrong dose. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting, or unsafe mRNA products could materially affect patient confidence in our mRNA products. It is possible that adverse events caused by unsafe counterfeit or other non-mRNA products will mistakenly be attributed to our mRNA products. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation, and our business. Public loss of confidence in the integrity in mRNA products as a result of counterfeiting, theft, or improper manufacturing processes could have a material adverse effect on our business, results of operations, and financial condition.

Further, the unauthorized donation or resale of our product could adversely affect our ability to sell in a particular territory, and have other adverse effects on our business, results of operations, and financial condition.

Risks related to our finances

We have a limited history of recognizing revenue from product sales and may not be able to achieve or maintain long-term sustainable profitability.

Before the year ended December 31, 2021, we incurred net losses in each year since our inception. Other than for our COVID-19 vaccine, we have not completed pivotal clinical trials for any of our programs, and it may be years for most of our investigational medicines, if ever, before we or our strategic collaborators have a product ready for commercialization. Our ability to generate revenue and maintain profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of and obtain the regulatory approvals necessary to commercialize our products and investigational medicines, including commercializing our COVID-19 vaccine, which is subject to numerous risks.

We have incurred, and expect to continue to incur, significant costs associated with the commercialization of our COVID-19 vaccine and our clinical and preclinical development activities. We may not be able to achieve or maintain long-term sustainable profitability and may need to obtain additional funding to continue operations.

We anticipate that our expenses will increase substantially if and as we:

- continue or expand our research or development of our programs in preclinical development;
- initiate additional preclinical, clinical, or other studies for our development candidates and investigational medicines, including under our strategic alliance agreements;
- continue to invest in our platform to conduct research to identify novel mRNA technology improvements, including to identify methods of mRNA delivery, such as improvements to our LNPs;
- change or add to internal manufacturing capacity or capability, or additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our investigational medicines toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our product development and planned future commercialization efforts, including new sites in the United States and abroad;
- seek marketing approvals and reimbursement for our investigational medicines;
- establish a sales, marketing, and distribution infrastructure to commercialize any products;

- acquire or in-license other development candidates, investigational medicines, and technologies;
- make milestone or other payments under any in-license agreements; and
- experience any delays or encounter issues with any of the above.

Our quarterly and annual operating results may fluctuate. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. As such, a period-to-period comparison of our operating results may not be a good indication of our future performance. In any particular quarter, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described in these *Risk Factors* and elsewhere in this Annual Report on Form 10-K:

- our ability to manufacture and deliver supply of our COVID-19 vaccine;
- variations in our financial results, development timelines or recommendations by securities analysts, or those of companies that are perceived to be similar to us;
- delays or failures in advancement of existing or future development candidates into the clinic or investigational medicines in clinical trials;
- the feasibility of developing, manufacturing, and commercializing our programs;
- the outcomes of research programs, clinical trials (including any adverse safety events), or other product development or approval processes conducted by us and our strategic collaborators;
- the timing of disclosure of any milestones related to any of our programs that are managed by our strategic collaborators or competitors;
- our ability to consistently manufacture our development candidates and investigational medicines;
- our ability to accurately report our financial results in a timely manner; and
- our ability to obtain, protect, and enforce our IP rights, as well as our know-how and technologies.

The investment of our cash, cash equivalents, and investments is subject to risks which may cause losses and affect the liquidity of these investments.

As of December 31, 2021, we had approximately $17.6 billion in cash, cash equivalents, and investments, which are subject to general credit, liquidity, market, inflation and interest rate risks. We may realize losses in the fair value of these investments. In addition, if our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These and other market risks associated with our investment portfolio may adversely affect our results of operations, liquidity, and financial condition.

Risks related to our business and operations

We may encounter difficulties in managing the development and expansion of our company, which could disrupt our operations.

As of December 31, 2021, we had approximately 2,700 full-time employees and, in connection with the growth and advancement of our pipeline and commercialization of our company, we expect to increase the number of employees and the scope of our operations. To manage such development and expansion, including internationally, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and recruit and train qualified personnel. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

We are pursuing development candidates and investigational medicines in many therapeutic areas and across a wide range of diseases. Successfully developing products for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and diseases requires significant depth of talent, resources, and corporate processes in order to allow simultaneous execution across multiple areas. We may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. The physical expansion of our operations, including the construction of the Moderna Science Center in Cambridge, the expansion of our Norwood campus and the construction of manufacturing facilities overseas, may lead to significant costs and may divert financial resources from other projects, such as the development of our investigational medicines. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to

commercialize our COVID-19 vaccine, or our other investigational medicines, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Our failure to upgrade and maintain our enterprise resource planning system (ERP) could adversely impact our business and results of operations.

We are working to upgrade our global ERP system to support our anticipated future growth and expansion as a commercial operation. We expect to incur substantial costs in implementing our ERP system, and any disruptions or difficulties in implementing or using our ERP system could adversely affect our controls, resulting in harm to our business, including our ability to forecast or make sales and collect our receivables. Significant delays in documenting, reviewing and testing our internal control could cause us to fail to comply with our SEC reporting obligations related to our management's assessment of our internal control over financial reporting. Moreover, such disruptions or difficulties could result in unanticipated costs and diversion of management attention.

Our success depends on our ability to retain key employees, consultants, and advisors and to attract, retain, and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends on our ability to attract and retain highly qualified managerial, scientific, technical, quality-control, manufacturing, medical and commercial personnel. We are highly dependent on members of our management and scientific teams. Each of our executive officers and employees, including key scientists and clinicians, are employed "at will," meaning we or each officer or employee may terminate the employment relationship at any time. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing, and commercialization objectives. We do not have "key person" insurance on any of our employees. Several of our key employees, including members of our executive team, have been with us for a long period of time, and have valuable, fully vested stock options or other long-term equity incentives. We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in Cambridge, Massachusetts.

In addition, we rely on consultants, contractors, and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval, manufacturing and commercialization strategies. These individuals may be employed by other employers and may have commitments under contracts with others that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval, manufacturing and commercialization objectives. In addition, we have flexibly grown our workforce through the use of contractors and part time workers. If we cannot retain the services of such personnel, we could experience delays in the operation of our business.

Competition for skilled personnel, including in mRNA and LNP research, clinical operations, regulatory affairs, therapeutic area management, and manufacturing, is intense and the turnover rate is high. We may be unable to attract and retain personnel on favorable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In some instances, failure to attract and retain personnel could result in delays in production or difficulties in maintaining compliance with regulatory requirements. In addition, adverse publicity, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. We may also be unable to attract and retain highly qualified sales and marketing professionals to support our COVID-19 vaccine and any future products. The inability to recruit, or loss of services of certain executives, key employees, consultants, or advisors, may impede the progress of our research, development and global commercialization objectives and adversely impact our business, financial condition, results of operations, and prospects.

If we cannot maintain our corporate culture, we could lose the innovation, teamwork and passion that we believe contribute to our success, and our business may be harmed.

We invest substantial time and resources in building and maintaining our culture and developing our personnel; however, as we continue to expand, it may be increasingly difficult to maintain our culture. Throughout the COVID-19 pandemic, much of our workforce has worked remotely and we implemented remote hiring and onboarding programs to facilitate significant hiring during 2021 in a remote work environment. The dramatic growth of our workforce, coupled with shifts in workplace and workstyle, increase the risk of our ability to maintain culture. Any failure to preserve our culture could negatively affect our future success, including our ability to retain and recruit personnel and to effectively pursue our strategic plans.

Our internal computer systems and physical premises, or those of third parties with which we share sensitive data or information, may fail or suffer security breaches, which could materially disrupt our product development programs and manufacturing operations.

Our internal computer systems and those of our current and any future strategic collaborators, vendors, contractors, consultants or regulatory authorities with whom we share sensitive data or information are vulnerable to damage from computer viruses, unauthorized access, natural disasters (which may become more frequent in the future as a result of climate change), terrorism, cybersecurity threats, war, and telecommunication and electrical failures. We have experienced, and may experience in the future, cyber-attacks on our information technology systems by threat actors of all types (including nation states, criminal enterprises, individual actors and/or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by any of these threat actors. If any such cyber-attack or physical intrusion were to cause interruptions in our operations, such as a material disruption of our development programs or our manufacturing operations, or due to a loss of any of our proprietary information, it would have a material and adverse effect on us. For example, the loss of clinical trial data from one or more clinical trials could cause delays in our regulatory approval efforts and increase our costs to recover or reproduce the data. In addition, because we run multiple clinical trials in parallel, any breach of our computer systems or physical premises may result in a loss of data or compromised data integrity across many of our programs in many stages of development. Our cybersecurity liability insurance may not cover all damages we would sustain based on any breach of our computer security protocols or cybersecurity attack.

Any data breach, security incident loss, or compromise of personal information, including any clinical trial participant personal data may also subject us to civil fines and penalties, or claims for damages either under the GDPR and relevant member state law in the EU, other foreign laws, and the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and other relevant state and federal privacy laws in the United States including the California Consumer Privacy Act (the CCPA). We have from time to time received information that companies working on vaccine research and development may be a particular focus for those planning cyberattacks. For example, on May 13, 2020, the Federal Bureau of Investigation (FBI) and Cybersecurity and Infrastructure Security Agency (CISA), announced that the FBI was investigating the targeting and compromise of U.S. organizations conducting COVID-19-related research by People's Republic of China, or PRC-affiliated cyber actors. Furthermore, on July 16, 2020, the National Security Agency and other U.S. and foreign agencies released a joint cybersecurity advisory regarding the Russian Intelligence Services' targeting of COVID-19 research and vaccine development. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including but not limited to information related to the research and manufacturing of our COVID-19 vaccine and/or other vaccines, we could incur liability, our competitive and reputational position could be harmed, and the further development and commercialization of our investigational medicines could be delayed. With respect to potential liability for breaches involving personal information, the CCPA is of particular concern since it provides for a private right of actions for certain personal information breaches.

We may use our financial and human resources to pursue a particular research program or investigational medicine and fail to capitalize on programs or investigational medicines that may be more profitable or for which there is a greater likelihood of success.

We pursue and fund the development of selected research programs or investigational medicines and may choose to forego or delay pursuit of opportunities with other programs or investigational medicines that could later prove to have greater commercial potential. For example, we have focused a significant amount of resources on our COVID-19 vaccine since the commencement of the COVID-19 pandemic. Our resource allocation decisions, or our contractual commitments to provide resources to our strategic collaborators, may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for investigational medicines may not yield commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular investigational medicine, we may relinquish valuable rights to that investigational medicine through a strategic alliance, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such investigational medicine, or we may allocate internal resources to an investigational medicine in a therapeutic area in which it would have been more advantageous to enter into a strategic alliance.

If we are not successful in discovering, developing, and commercializing additional products beyond our current portfolio, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to discover, develop, and potentially commercialize additional products beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our own drug discovery efforts, exploring potential strategic alliances for the development of new products, and in-licensing technologies. Identifying new investigational medicines requires substantial technical, financial, and human resources. We may fail to identify promising investigational medicines and, even if we do identify such medicines, we may fail to successfully develop and commercialize products for many reasons, including:

- competitors may develop alternatives that render our investigational medicines obsolete;
- investigational medicines we develop may be covered by third parties' patents or other exclusive rights;
- an investigational medicine may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

- we may be incapable of producing an investigational medicine in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional products, our potential for growth may be impaired.

Our business could be harmed if we suffer damage to our reputation, including as a result of a product recall.

The FDA and similar foreign governmental authorities have the authority to require the recall of certain commercialized products. In the case of the FDA, the authority to require a recall of a biologic product must be based on an FDA finding that a batch, lot of other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, foreign governmental bodies have the authority to require the recall of any investigational medicine in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or our strategic collaborators could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues, as occurred with the recall of certain batches of our COVID-19 vaccine shipped to Japan that were found to contain foreign particulate. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales. Our reputation could be further impacted by public discourse regarding our business and the perception of our business strategy.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any product or investigational medicine that we may develop, such as our COVID-19 vaccine.

We are exposed to product liability risk related to the development, testing, manufacturing and marketing of our COVID-19 vaccine and our investigational medicines in clinical trials. Product liability claims and related cross-claims and claims for indemnification may be brought against us by patients, healthcare providers or others using, prescribing, selling or otherwise coming into contact with our COVID-19 vaccine or investigational medicines. For example, we may be sued if the COVID-19 vaccine or any investigational medicine allegedly causes injury or is found to be otherwise unsuitable during clinical trials, manufacturing, or, if approved, marketing, sale or commercial use. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities.

We could also face product liability claims relating to the worsening of a patient's condition, injury or death alleged to have been caused by one of our COVID-19 vaccine or investigational medicines. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, knowledge of risks, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. Such claims might not be fully covered by product liability insurance. If we succeed in marketing products, including our COVID-19 vaccine, product liability claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs, and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, suspension or withdrawal of approvals or license revocation. Regardless of the merits or eventual outcome, liability claims may result in decreased demand for our products, injury to our reputation and significant negative media attention, costs to defend the related litigation, withdrawal of clinical trial participants, loss of revenue, a diversion of management's time and our resources, substantial monetary awards to trial participants, patients or their family members, payments to indemnify clinical trial sites and other clinical trial partners, and a decline in our stock price.

We are also exposed to liabilities that are unique to developing and commercializing an mRNA vaccine during an ongoing global pandemic. Although the U.S. and certain foreign governments have contractually agreed to indemnify us or make statutory immunity available to us, such indemnification or statutory immunity may not be available to cover potential claims or liabilities resulting from the research, development, manufacture, distribution or commercialization of our COVID-19 vaccine. Additionally, other foreign government that we contract with in the future may not provide us with similar contractual indemnity or statutory immunity. Substantial claims arising from the vaccine outside the scope of or in excess of U.S. or foreign government indemnity or statutory immunity could harm our financial condition and operating results. Moreover, any adverse event or injury for which we are liable, even if fully covered under an indemnity or immunity, could negatively affect our reputation.

We may not be able to maintain our product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. While our current insurance program includes coverage for the sale of commercial products for when we obtain marketing approval for our medicines, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in individual, mass tort and class-action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and could adversely affect our results of operations and business.

If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Additionally, even if we maintain insurance coverage for a type of liability, a particular claim may not be covered if it is subject to a coverage exclusion or we do not otherwise meet the conditions for coverage. If we operate our business with inadequate insurance, we could be responsible for paying claims or judgments against us, which could adversely affect our results of operations or financial condition.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and false claims laws. If we cannot comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. See the section entitled "Business—Government Regulation—Other healthcare laws."

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, is time- and resource-consuming and can divert a company's attention from the business. If our operations are found to violate any of these laws or any other regulations that apply to us, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance. Furthermore, if any physician or other healthcare provider or entity with whom we do business is found to be not in compliance with applicable laws, they may be subject to similar penalties. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of the business. In addition, the approval and commercialization of any product candidate we develop outside the United States will subject us to foreign healthcare laws.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU and the U.K. The provision of benefits or advantages to induce or reward improper performance generally is also governed by the national anti-bribery laws of EU Member States, and the U.K. Bribery Act 2010 in the U.K. Infringement of these laws could result in substantial fines and imprisonment. The EU Directive (2001/83/EC, as amended) governing medicinal products for human use provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the U.K. despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often are the subject of prior notification and approval by the physician's employer, his or her competent professional organization, or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

We are subject to various and evolving laws and regulations governing the privacy and security of personal data, and our failure to comply could adversely affect our business, result in fines and/or criminal penalties, and damage our reputation.

Privacy and data security have become significant issues in the United States, Europe and in many other jurisdictions in which we operate and/or collect personal information. We are subject to data privacy and security laws and regulations in various jurisdictions that apply to the collection, storage, use, sharing and security of personal data, including health information, and impose significant compliance obligations. In addition, numerous other federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and security of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues.

For example, the GDPR has imposed stringent obligations on us with respect to our processing personal data and the cross-border transfer of such data, including higher standards of obtaining consent, more robust transparency requirements, data breach notification requirements, requirements for contractual language with our data processors, and stronger individual data rights. Different EEA Member States have interpreted the GDPR differently and many have imposed additional requirements, adding to the complexity of processing personal data in the EEA. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA that are not considered to provide "adequate" protection to personal data, including the United States, and permits data protection authorities to impose large penalties for violations. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices. Despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any activities falling within the scope of the GDPR.

In the United States, California has passed the California Consumer Privacy Act and several other states and the federal government are actively considering proposed legislation governing the protection of personal data. Additionally, Brazil passed the General Data Protection Law, which went into effect in August 2020. Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges. Each law is also subject to various interpretations by courts and regulatory agencies, creating additional uncertainty, and our efforts to comply with the evolving data protection rules may be unsuccessful.

We must devote significant resources to understanding and complying with the changing landscape in this area. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by authorities, private rights of action in some jurisdictions, and potential significant penalties if we are found to be non-compliant. Failure to comply with the GDPR and applicable national data protection laws of EEA member states could lead to substantial fines. Some of these laws and regulations also carry the possibility of criminal sanctions. For example, we could be subject to penalties, including criminal penalties, if we knowingly obtain or disclose individually identifiable health information from a HIPAA-covered health care provider or research institution that has not complied with HIPAA's requirements for disclosing such information. Furthermore, the number of government investigations related to data security incidents and privacy violations continues to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and our reputation.

The COVID-19 pandemic has added further complexity to the processing of personal data. For example, safety measures intended to protect our employees, contractors, and other visitors to our sites may require the collection of certain personal data. Our efforts to protect personal data may be unsuccessful and we could unintentionally be subject to unauthorized access or disclosure of such personal data.

The Clinical Trials Regulation (EU) No. 536/2014 (the Clinical Trial Regulation) and the EMA policy on publication of clinical data for medicinal products for human use both permit the EMA to publish clinical information submitted in MAAs. The ability of third parties to review and/or analyze data from our clinical trials may increase the risk of commercial confidentiality breaches and result in enhanced scrutiny of our clinical trial results. Such scrutiny could result in public misconceptions regarding our drugs and drug candidates. These publications could also result in the disclosure of information to our competitors that we might otherwise deem confidential, which could harm our business.

Certain aspects of our business may be adversely affected by the ongoing COVID-19 pandemic.

Certain of our clinical trials have been adversely affected by the ongoing COVID-19 pandemic, resulting in paused enrollment or delayed site initiations. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed (or continue to be paused or delayed) due to changes in hospital or university policies, federal, state or local regulations or restrictions, prioritization of hospital resources toward pandemic efforts, travel restrictions, concerns for patient safety in a pandemic environment, or other pandemic-related reasons. As the pandemic persists, some participants and clinical investigators may be unable to comply with clinical trial protocols. For example, many countries have implemented quarantines or travel limitations (whether voluntary or required), which may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials.

The COVID-19 pandemic has disrupted and may continue to disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay the review and/or approval by the FDA and other regulatory agencies with respect to, our clinical trials or product approvals, which could materially delay our clinical trials for development candidates or our commercial efforts.

We utilize third parties to, among other things, manufacture raw materials, components, parts, and consumables, perform quality testing and ship our products. We also manufacture our development candidates and investigational medicines and perform various services at our manufacturing facility. Certain of our third-party manufacturers and suppliers may encounter delays in providing their services in response to the COVID-19 pandemic. If either we or any third-party manufacturers or third parties in the supply chain for materials used in the production of our COVID-19 vaccine, development candidates or investigational medicines are adversely

impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture our COVID-19 vaccine, as well as investigational medicines for our clinical trials, research and development operations and commercialization. In addition, delays and disruptions experienced by our strategic collaborators due to the COVID-19 pandemic could adversely impact the ability of such parties to fulfill their obligations, which could affect the clinical development or regulatory approvals of development candidates and investigational medicines under joint control.

If we engage in acquisitions, joint ventures, or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may complete acquisitions and collaborations, including licensing or acquiring complementary products, IP rights, technologies, or businesses. Any such acquisition, joint venture, or collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- assimilation of operations, IP, and products, including difficulties associated with integrating new personnel;
- the diversion of management's attention from our existing product programs and initiatives;
- the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or investigational medicines and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

If we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense. Moreover, if we cannot locate suitable acquisition or strategic collaboration opportunities, our ability to grow or obtain access to technology or products that may be important to the development of our business may be impaired.

Risks related to ownership of our common stock

The price of our common stock has been volatile and fluctuates substantially, which could result in substantial losses for stockholders.

Our stock price has been, and is expected to continue to be, subject to substantial volatility. From December 7, 2018, our first day of trading on the Nasdaq Global Select Market, through December 31, 2021, our stock has traded within a range of a high price of $497.49 and a low price of $11.54 per share. Since we began our development efforts with respect to our COVID-19 vaccine in early 2020, our stock has experienced pronounced and extended periods of volatility. As a result of the volatility in our stock price, our stockholders could incur substantial losses.

Public statements by us, government agencies, the media, competitors, financial analysts, or others relating to the COVID-19 pandemic and efforts to combat it have in the past resulted, and may in the future result, in significant fluctuations in our stock price. Given the global focus on the COVID-19 pandemic, information in the public arena on this topic, whether or not accurate, has had and will likely continue to have an outsized impact (positive or negative) on our stock price. Information related to our clinical trials, manufacturing, regulatory and commercialization efforts with respect to our COVID-19 vaccine, or information regarding such efforts by competitors, or the evolution of the pandemic, may meaningfully impact our stock price.

The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your initial purchase price. The market price for our common stock may be influenced by many factors, including:

- the success of our COVID-19 vaccine sales and anticipated product revenue;
- results of clinical trials of our investigational medicines or those of our competitors;
- the success of competitive products or technologies, particularly vaccines or treatments for COVID-19;
- the emergence or decline of new or existing variants of the SARS-CoV-2 virus;
- commencement or termination of strategic alliances;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- expenses related to any of our products, investigational medicines or clinical development programs;
- the results of our efforts to discover, develop, acquire, or in-license additional investigational medicines;

- actual or anticipated changes in estimates of financial results, development timelines, or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions;
- the numerous programs in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts;
- announcement by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments; and
- public announcements by us or our strategic collaborators regarding the progress of our development candidates or investigational medicines or similar public announcements by our competitors.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, and results of operations, and prospects.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of February 18, 2022, our executive officers, directors, and affiliated stockholders beneficially owned approximately 14% of our outstanding common stock. In addition, non-affiliated five percent or greater stockholders beneficially owned approximately 25% of our outstanding common stock. These stockholders will have the ability to influence us through their ownership positions. For example, if these stockholders were to act together, they could exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Provisions in our amended and restated certificate of incorporation and by-laws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation, by-laws, and Delaware law contain provisions that may have the effect of delaying or preventing a hostile takeover or change in control of us or changes in our management. Our amended and restated certificate of incorporation and amended and restated by-laws include provisions that:

- authorize "blank check" preferred stock, which could be authorized for issuance by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter, or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Any provision of our amended and restated certificate of incorporation or amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We do not currently intend to declare or pay cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business or to return cash to shareholders through share repurchases. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our amended and restated by-laws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated by-laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (3) any action asserting a claim against us or any of our current or former directors, officers, employees, or stockholders arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated by-laws, or (4) any action asserting a claim governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated by-laws further provide that the United States District Court for the District of Massachusetts is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the Federal Forum Provision). Our amended and restated by-laws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated by-laws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees, which may discourage the filing of lawsuits against us and our directors, officers, and employees, even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is unenforceable or invalid, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs in resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General risk factors

Our employees, principal investigators, and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators leading our clinical trials, and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions; provide accurate information to the FDA, the EMA, and other regulatory authorities; comply with healthcare fraud and abuse laws and regulations in the United States and abroad; or report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and serious harm to our reputation. Sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. It is not always possible to identify and deter employee misconduct, and the precautions we take may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition, or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets, including by the COVID-19 pandemic, or any other health epidemic. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our investigational medicines and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment, or other employment issues. In recent years, there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their business. Any employment-related claim could negatively affect our business.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous and flammable materials and wastes, including chemicals and biological materials. We generally contract with third parties for the disposal of these hazardous materials and waste products, and we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs to comply with current or future environmental, health, and safety laws and regulations. These laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Changes in tax law could adversely affect our business and financial condition.

We are subject to evolving and complex tax laws in the jurisdictions in which we operate. The rules dealing with U.S. federal, state, and local and non-U.S. income taxation are constantly under review by legislative and tax authorities. Changes to tax laws (which changes may have retroactive application) could adversely affect us and our stockholders. In recent years, such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our research, development candidates, investigational medicines, and the diseases our development candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This uncertainty creates risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, subjects may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our development candidates and investigational medicines. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Item 1B - Unresolved Staff Comments

None.

Item 2. Properties

We have two campuses in Massachusetts. We occupy a multi-building campus in Cambridge, Massachusetts (Cambridge campus), consisting of a mix of offices and research laboratory space totaling approximately 261,000 square feet. The Cambridge campus is the location of our corporate headquarters, platform, drug discovery and clinical development. The Cambridge campus is leased with the majority of the space being leased through 2029.

The Moderna Technology Center (MTC campus) is located in Norwood, Massachusetts and is comprised of three buildings (MTC South, MTC North and MTC East). MTC South is approximately 200,000 square feet. MTC North is approximately 200,000 square feet and provides lab and office space, directly supporting improvement in our manufacturing capabilities. MTC East is approximately 240,000 square feet for expansion of our commercial and clinical activities. The MTC campus is leased through 2042 and we have the option to extend it for three five-year terms.

We also lease other office and lab spaces globally for our business operations.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Our Common Stock

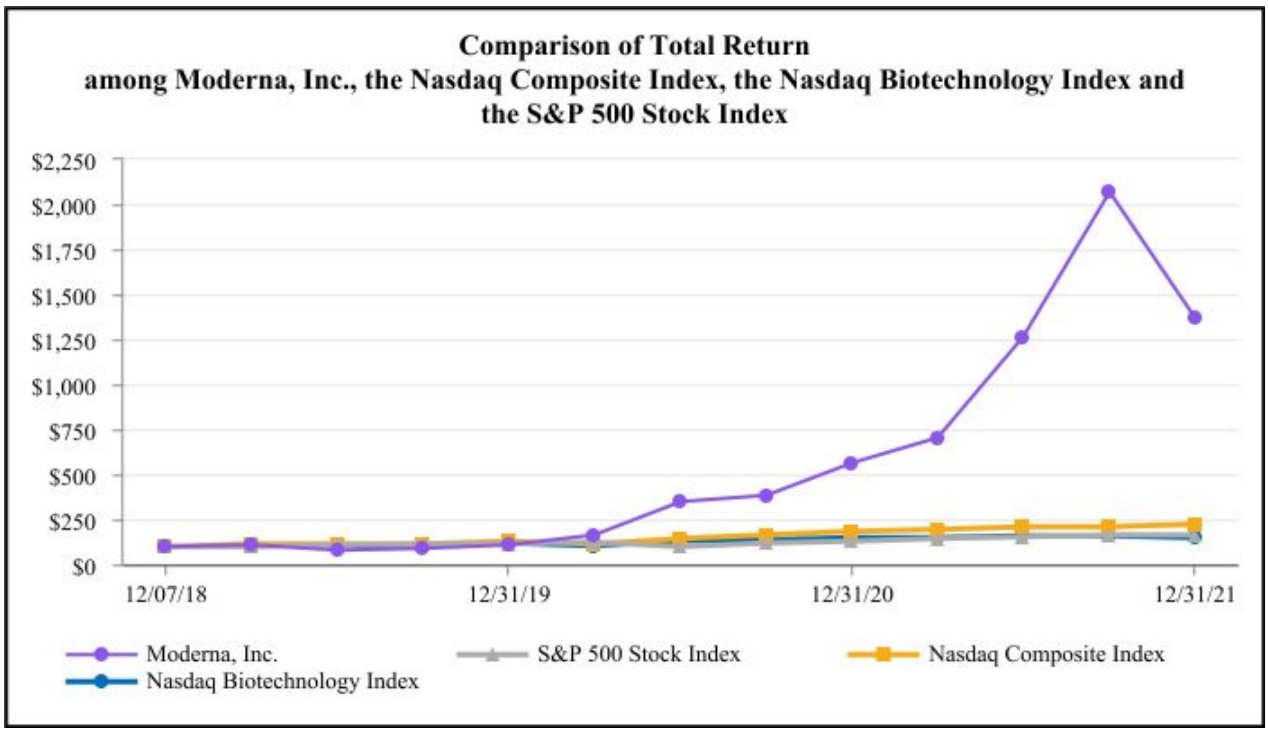
Our common stock began trading on the Nasdaq Global Select Market under the symbol “MRNA” on December 7, 2018. Prior to that time, there was no public market for our common stock.

Stock Performance Graph

The following performance graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of the Exchange Act or otherwise subject to the liabilities under that section, and shall not be deemed to be incorporated by reference into any filing of Moderna, Inc. under the Securities Act or the Exchange Act.

The following graph shows a comparison from December 7, 2018, the date on which our common stock first began trading on the Nasdaq Global Select Market, through December 31, 2021 of the cumulative total return for our common stock, the Nasdaq Composite Total Return Index and the Nasdaq Biotechnology Index, each of which assumes an initial investment of $100 and reinvestment of all dividends. Such returns are based on historical results and are not intended to suggest future performance. In 2021, we became part of the Standard & Poor’s 500 Stock Index (the “S&P 500”). As a result, this year we are including the cumulative total return of that index in addition to the broad equity market indices that we included in our Annual Report on Form-10-K for the year ended December 31, 2020.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.



Stockholders

We had approximately 85 stockholders of record as of February 18, 2022. Because many of our outstanding shares are held in accounts with brokers and other institutions, the number of beneficial owners is significantly greater than the number of record holders. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock and do not expect to pay dividends on our common stock for the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans in Item 12 of Part III of this Annual Report on Form 10-K is incorporated herein by reference. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The following table provides information with respect to the shares of common stock repurchased by us during the three months ended December 31, 2021:

Period	Total Number of Shares Purchased	Average Price Paid per Share [1]	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
October 1 - October 31, 2021	189,212	$ 317.10	189,212	$ 940,000,261
November 1 - November 30, 2021	2,249,198	$ 240.08	2,438,410	$ 400,003,774
December 1 - December 31, 2021	1,049,732	$ 245.06	3,488,142	$ 142,751,231
Total	3,488,142			

[1] Average price paid per share includes related expenses.

On August 2, 2021, our Board of Directors authorized a Share Repurchase Program (2021 Repurchase Program) of our common stock, with an expiration date no later than August 2, 2023. Pursuant to the 2021 Repurchase Program, we may repurchase up to $1.0 billion of our outstanding common stock. Since inception of the 2021 Repurchase Program through December 31, 2021, we repurchased a total of 3.5 million shares of our common stock for an aggregate purchase price of $857 million. Subsequent to December 31, 2021, the remaining amounts authorized under the 2021 Repurchase Program have been fully utilized.

Item 6. [Reserved]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in "Part I, Item 1A - Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines to improve the lives of patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane, or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, autoimmune diseases and cardiovascular diseases, independently and with our strategic collaborators. In January 2022, the U.S. Food and Drug Administration (FDA) approved the Biologics License Application (BLA) for our COVID-19 vaccine, Spikevax, for individuals 18 years of age and older in the United States. Spikevax is our first product to achieve licensure in the United States, and it has been authorized for use or approved by regulators in more than 70 countries.

Within our platform, we develop technologies that enable the development of mRNA medicines for diverse applications. When we identify technologies that we believe could enable a new group of potential mRNA medicines with shared product features, we call that group a "modality." While the programs within a modality may target diverse diseases, they share similar mRNA technologies, delivery technologies, and manufacturing processes to achieve shared product features. The programs within a modality will also generally share similar pharmacology profiles, including the desired dose response, the expected dosing regimen, the target tissue for protein expression, safety and tolerability goals, and pharmaceutical properties. Programs within a modality often have correlated technology risk, but because they pursue diverse diseases they often have uncorrelated biology risk. We have created seven modalities to date:

- prophylactic vaccines;
- systemic secreted and cell surface therapeutics;
- cancer vaccines;
- intratumoral immuno-oncology;
- localized regenerative therapeutics;
- systemic intracellular therapeutics; and
- inhaled pulmonary therapeutics.

We have designated our prophylactic vaccines and systemic secreted and cell surface therapeutics modalities as our "core modalities." In these core modalities, our strategy is to invest in additional development candidates using our accumulated innovations in technology, our process insights and our preclinical and clinical experience. Our exploratory modalities continue to be a critical part of advancing our strategy to maximize the application of our potential mRNA medicines.

Since our founding in 2010, we have transformed from a research-stage company advancing programs in the field of mRNA to a commercial enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. We have established relationships with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of our manufacturing capabilities. Most recently, our capabilities have come together to allow the authorization and approval of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

2021 Business Highlights

Moderna COVID-19 Vaccine

On December 18, 2020, we received an Emergency Use Authorization (EUA) from the FDA for the emergency use of the Moderna COVID-19 Vaccine (also referred to as mRNA-1273 and marketed under the brand name Spikevax) in individuals 18 years of age or

older. Subsequently, we have also received authorization for our COVID-19 vaccine from health agencies in more than 70 countries and from the World Health Organization (WHO). Additional authorizations are currently under review in other countries. In addition, we have received authorization for our COVID-19 vaccine for use in adolescents in the European Union, the United Kingdom, Australia, Canada, Switzerland and other countries, and have pending applications for authorization to administer the vaccine to adolescents with regulatory agencies in the United States and other countries. In January 2022, we received full FDA approval for Spikevax to prevent COVID-19 in individuals 18 years of age and older in the United States.

A booster dose of our COVID-19 vaccine at the 50 µg dose level is authorized for use under an EUA for adults 18 years and older. A third dose of our COVID-19 vaccine at the 100 µg dose level is authorized for use under an EUA in immunocompromised individuals 18 years of age or older in the United States who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. The European Medicines Agency (EMA) has also authorized a third dose of the Moderna COVID-19 vaccine given at least 28 days after the second dose to severely immunocompromised individuals 12 years of age or older, as well as the administration of 50 µg booster doses for individuals 18 years of age and older.

Manufacturing Scaling

In 2021, we rapidly scaled our manufacturing capabilities for our COVID-19 vaccine. By June, we had delivered 200 million doses of the Moderna COVID-19 Vaccine to the U.S. government. By end of September, we and our partners ramped up our capacity worldwide and supplied more than 500 million doses of our COVID-19 vaccine globally. We took measures to scale capacity at a significant pace, including the expansion of our Moderna Technology Center (MTC) in Norwood, Massachusetts. By the end of 2021, we had shipped approximately 800 million doses of our COVID-19 vaccine worldwide.

In April 2021, we announced new funding commitments to increase supply at our owned and partnered manufacturing facilities. We expect these investments will allow for a doubling of drug substance manufacturing at Lonza's Switzerland-based facility, a more than doubling of formulation, fill and finish and drug substance manufacturing at Rovi's Spain-based facility, as well as a 50 percent increase of drug substance at Moderna's facilities in the U.S. When completed, the investments are also expected to result in an increase in safety stock of raw materials and finished product used to deliver committed volumes.

Access Expansion

We recognize that vaccine availability continues to be a challenge in many parts of the world, and we remain focused on ensuring that low-income countries have access to our vaccine. In April, we announced additional investments to increase global supply of our COVID-19 vaccine and in May we announced an agreement with Gavi, the Vaccine Alliance to supply up to 500 million doses of our vaccine at our lowest tiered price, in line with our global access commitments. This agreement has subsequently been revised to provide up to 650 million doses to be delivered across 2021 and 2022.

Additionally, in October, we announced that Moderna will build a state-of-the-art mRNA facility in Africa with the goal of producing up to 500 million doses of vaccines each year at the 50 µg dose level. We also announced the first step in our long-term partnership with the African Union with a Memorandum of Understanding to supply up to 110 million doses of our COVID-19 vaccine to address the needs of low-income countries in Africa. In January 2022, African Union informed us that it will not exercise its option for 60 million doses in the second quarter of 2022, due to its expectation that existing supplies will be sufficient to meet its vaccination targets.

Program Development

Throughout the year, we continued to build a diverse clinical portfolio of vaccines and therapeutics across our seven modalities. Our longstanding approach to portfolio development, pursuing programs that have shared technology or biology, has helped us reduce risk as our pipeline has grown to 40 programs in development, including 23 in clinical studies as of December 31, 2021.

Beyond our COVID-19 vaccine, in 2021 we launched the second pivotal trial in our company's history with CMVictory, a Phase 3 study of our vaccine to prevent congenital cytomegalovirus (CMV), which is the number one cause of birth defects in the U.S. This milestone takes us one step closer to potentially bringing another important vaccine to millions of people.

We are making other significant advances across our programs. Our seasonal influenza vaccine showed positive interim Phase 1 data, and our respiratory syncytial virus (RSV) vaccine moved to a Phase 2/3 trial of 34,000 participants in the fourth quarter of 2022. In oncology, our Personalized Cancer Vaccine Phase 2 trial is now fully enrolled, and we expect a readout as early as the fourth quarter of 2022. We also saw early positive data from the Phase 2 study of our mRNA VEGF-A therapeutic with AstraZeneca moving it to the next stage of clinical development.

Financial Highlights

We have entered into supply agreements with the U.S. Government, other international governments, Gavi (on behalf of the COVAX Facility), and the African Union for the supply of our COVID-19 vaccine. The agreements are generally subject to receipt of authorization or approval for the use and distribution of the vaccine from the relevant regulatory authority in each jurisdiction. Under these agreements, we are entitled to upfront deposits for our COVID-19 vaccine supply, which is initially recorded as deferred revenue. As of December 31, 2021, we had approximately $6.7 billion in deferred revenue in connection with the supply agreements with the U.S. Government and other customers, which will be recognized as revenue when revenue recognition criteria have been met. For the year ended December 31, 2021, we delivered approximately 332 million doses of our COVID-19 vaccine to the U.S. Government and approximately 475 million doses to other governments, and we recognized $17.7 billion in product sales.

As of December 31, 2021, we had cash, cash equivalents and investments of approximately $17.6 billion. We are using this capital to fund operations and investing activities for technology creation, drug discovery and clinical development programs, infrastructure and capabilities to enable our research and early development activities (which includes our MTC), our digital infrastructure, creation of our portfolio of intellectual property, acquisition of key raw materials and supplies to support our commercial production quantities, development of a commercial team, expansion into global markets, funding our strategic collaborations and administrative support. We also use this capital to fund our Share Repurchase Program, designed to return value to our stockholders and minimize dilution from stock issuances.

Other Business Updates

In May 2021, we announced an expansion of our MTC. The MTC has been core to our long-term strategy and has enabled us to provide the scale and flexibility to support the development of our mRNA medicines and vaccines, including our COVID-19 vaccine. This investment will more than double the space at the MTC to approximately 650,000 square feet and allow us to continue to optimize our mRNA products as we explore new pharmaceutical delivery forms such as prefilled syringes and lyophilized products.

We are also investing in a new Moderna Science Center (MSC) in Cambridge, Massachusetts, to create a purpose-built space to support our next chapter of discovery and serve as our principal executive offices. The MSC will integrate digital-first scientific research and development labs along with space for innovation and co-creation with our people and our partners around the world. As part of our ongoing commitment to sustainability, the high-performance building is designed to be the most sustainable commercial lab building in Cambridge.

In addition to our owned facilities in the U.S., we have expanded our footprint across the globe, with active subsidiaries in more than 12 countries, including the U.S., Canada, many European countries and the Asia Pacific region. As Moderna expands internationally, we also announced in 2021 preliminary agreements with the governments of Canada and Australia to bring state-of-the-art mRNA manufacturing facilities to those countries to provide direct access to rapid pandemic response capabilities as well as domestically manufactured mRNA vaccines against other diseases.

Financial Operations Overview

Revenue

The following table summarizes revenue for the periods presented (in millions):

	Years Ended December 31,		
	2021	2020	2019
Revenue:			
Product sales	$ 17,675	$ 200	$ —
Grant revenue	735	529	12
Collaboration revenue	61	74	48
Total revenue	$ 18,471	$ 803	$ 60

We began to record product sales for our COVID-19 vaccine subsequent to its authorization for emergency use by the FDA and Health Canada in December 2020. For the years ended December 31, 2021 and 2020, we recognized $17.7 billion and $200 million, respectively, of product sales from sales of our COVID-19 vaccine.

Other than product sales, our revenue in 2021 and 2020 was derived from government-sponsored and private organizations including BARDA, DARPA and the Bill & Melinda Gates Foundation and from strategic alliances with AstraZeneca, Merck and Vertex to discover, develop, and commercialize potential mRNA medicines.

The following table summarizes grant revenue for the periods presented (in millions):

	Years Ended December 31,		
	2021	2020	2019
BARDA	$ 713	$ 522	$ 8
Other grant revenue	22	7	4
Total grant revenue	$ 735	$ 529	$ 12

The following table summarizes collaboration revenue for the periods presented (in millions):

	Years Ended December 31,		
	2021	2020	2019
Collaboration revenue:			
AstraZeneca	$ 7	$ 33	$ 5
Merck	23	26	37
Vertex	26	15	6
Other	5	—	—
Total collaboration revenue	$ 61	$ 74	$ 48

As of December 31, 2021, we had signed supply agreements of approximately $20.6 billion for the future supply of our COVID-19 vaccine to be delivered in 2022 and 2023 and had deferred revenue of $6.7 billion associated with customer deposits received or billable under these agreements. Additional supply agreements have been agreed upon since December 31, 2021, and others are under discussion for 2022 and 2023 deliveries. We believe that the SARS-CoV-2 virus will evolve to an endemic phase in 2022 and as a result, we expect our product sales to be larger in the second half of 2022 than in the first half.

In addition, we expect to continue to receive funding from our contract with BARDA. As of December 31, 2021, the remaining available funding, net of revenue earned was $189 million under the BARDA contract. To the extent that existing or potential future products generate revenue, our revenue may vary due to many uncertainties in future product demand, the development of our mRNA medicines and other factors.

Cost of sales

Cost of sales includes raw materials, personnel and facility and other costs associated with manufacturing our commercial product. These costs include production materials, production costs at our manufacturing facilities, third-party manufacturing costs, and final formulation and packaging costs. Cost of sales also includes shipping costs, royalties payable to third parties based on sales of our products, and charges for inventory valuation reserves.

Research and development expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development costs.

Research and development expenses represent costs incurred by us for the following:

- cost to develop our platform;
- discovery efforts leading to development candidates;
- preclinical, nonclinical, and clinical development costs for our programs;
- cost to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs related to our drug discovery efforts and clinical trials.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, and stock-based compensation expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations, or CROs, that conduct our preclinical studies and clinical trials, and in-licensing arrangements;

- expenses associated with developing manufacturing capabilities and acquiring materials for preclinical studies, clinical trials and pre-launch inventory, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs;
- expenses incurred for the procurement of materials, laboratory supplies, and non-capital equipment used in the research and development process; and
- facilities, depreciation, and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

We use our employee and infrastructure resources for the advancement of our platform, and for discovering and developing programs. Due to the number of ongoing programs and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development programs are generally not recorded or maintained on a program- or modality-specific basis.

The following table reflects our research and development expenses, including direct program specific expenses summarized by modality and indirect or shared operating costs summarized under other research and development expenses during the years ended December 31, 2021, 2020, and 2019 (in millions):

	Years Ended December 31,		
	2021	2020	2019
Program expenses by modality:			
Prophylactic vaccines	$ 1,099	$ 707	$ 48
Systemic secreted and cell surface therapeutics	3	2	11
Cancer vaccines	47	29	44
Intratumoral immuno-oncology	20	9	18
Localized regenerative therapeutics	—	—	3
Systemic intracellular therapeutics	26	21	33
Inhaled pulmonary therapeutics	1	—	—
Total program-specific expenses by modality [(1)]	$ 1,196	$ 768	$ 157
Other research and development expenses:			
Discovery programs	$ 85	$ 56	$ 56
Platform research	125	93	91
Technical development and unallocated manufacturing expenses	275	279	85
Shared discovery and development expenses	242	118	59
Stock-based compensation	68	56	48
Total research and development expenses	$ 1,991	$ 1,370	$ 496

(1) Includes a total of 37 development candidates at December 31, 2021 and 21 development candidates at each of December 31, 2020 and 2019. Program-specific expenses include external costs and allocated manufacturing costs of pre-launch inventory, mRNA supply and consumables, and are reflected as of the beginning of the period in which the program was internally advanced to development or removed if development was ceased.

A *"modality"* refers to a group of programs with common product features and the associated combination of enabling mRNA technologies, delivery technologies, and manufacturing processes. The program-specific expenses by modality summarized in the table above include expenses we directly attribute to our programs, which consist primarily of external costs, such as fees paid to outside consultants, central laboratories, investigative sites, and CROs in connection with our preclinical studies and clinical trials, CMOs, and allocated manufacturing costs of pre-launch inventory, mRNA supply and consumables. Costs to acquire and manufacture pre-launch inventory, mRNA supply for preclinical studies and clinical trials are recognized and included in unallocated manufacturing expenses when incurred, and subsequently allocated to program-specific manufacturing costs after completion of the program-specific production. The timing of allocating manufacturing costs to the specific program varies depending on the program development and production schedule. We generally do not allocate personnel-related costs, including stock-based compensation, costs associated with our general platform research, technical development, and other shared costs on a program-specific basis. These costs were therefore excluded from the summary of program-specific expenses by modality.

Discovery program expenses are costs associated with research activities for our programs in the preclinical discovery stage, and primarily consist of external costs for CROs and lab services, and allocated manufacturing cost of preclinical mRNA supply and consumables.

Platform research expenses are mainly costs to develop technical advances in mRNA science, delivery science, and manufacturing process design. These costs include personnel-related costs, computer equipment, facilities, preclinical mRNA supply and consumables, and other administrative costs to support our platform research. Technology development and unallocated manufacturing expenses are primarily related to non-program-specific manufacturing process development and manufacturing costs.

Shared discovery and development expenses are research and development costs such as personnel-related costs and other costs, which are not otherwise included in development programs, discovery programs, platform research, technical development and unallocated manufacturing expenses, stock-based compensation, and other expenses.

The largest component of our total operating expenses has historically been our investment in research and development activities, including development of our platform, mRNA technologies, and manufacturing technologies. We expense research and development costs as incurred and cannot reasonably estimate the nature, timing, and estimated costs required to complete the development of the development candidates and investigational medicines we are currently developing or may develop in the future. There are numerous risks and uncertainties associated with the research and development of such development candidates and investigational medicines, including, but not limited to:

- scope, progress, and expense of developing ongoing and future development candidates and investigational medicines;
- entry in and completion of related preclinical studies;
- enrollment in and completion of subsequent clinical trials;
- safety and efficacy of investigational medicines resulting from these clinical trials;
- changes in laws or regulations relevant to the investigational medicines in development;
- receipt of the required regulatory approvals; and
- commercialization, including establishing manufacturing and marketing capabilities.

As we continue to pursue our indication expansion of mRNA-1273 during the current pandemic, and continue to develop variant-specific COVID-19 vaccine candidates and our next-generation COVID-19 vaccine candidate (mRNA-1283), we expect to continue to incur significant additional expenses. At this time, the magnitude of these potential expenditures is not known. In connection with the BARDA agreement to accelerate development of mRNA-1273, grant revenue and expenses within the committed funding scope are expected to continue in 2022. BARDA's funding is expected to offset those expenses that are covered under the BARDA agreement, subject to our obtaining reimbursement from BARDA. As of December 31, 2021, the remaining available funding from BARDA, net of revenue earned was $189 million. Please refer to Note 4 to our consolidated financial statements.

Changes in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures. Continued research and development is central to the ongoing activities of our business. Investigational medicines in later stages of clinical development, such as our CMV vaccine (mRNA-1647) and our COVID-19 vaccine, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development costs to continue to increase for the foreseeable future as our investigational medicines progress through the development phases and as we identify and develop additional programs. There are numerous factors associated with the successful commercialization of any of our investigational medicines, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time due to the early stage of development of our investigational medicines. Moreover, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Selling, general and administrative expenses

We started to incur sales and marketing expenses in the fourth quarter of 2020 to prepare for commercial operations in connection with the sale of our COVID-19 vaccine, and these expenses increased throughout the course of 2021. Selling, general and administrative expenses consist primarily of personnel-related costs, including stock-based compensation, for executives, finance, legal, human resources, business development and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs, and expenses associated with obtaining and maintaining intellectual property, or IP. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

We anticipate selling, general and administrative expenses will increase as we continue to expand the number of programs in development and prepare for the establishment of commercial activities both within and outside the United States. We have already incurred additional expenses related to building out a regulatory, sales and marketing team to support the sale, marketing and distribution of our COVID-19 vaccine and the expansion of our footprint across the globe, with active subsidiaries in more than 12 countries. If we obtain regulatory approval for additional investigational medicines, and do not enter into one or more third-party

commercialization collaboration and manufacturing arrangements, we will incur significant additional expenses related to building out these functions.

We have a broad IP portfolio covering our development and commercialization of mRNA vaccine and therapeutic programs, including those related to mRNA design, formulation, and manufacturing platform technologies. We regularly file patent applications to protect innovations arising from our research and development. We also hold trademarks and trademark applications in the United States and foreign jurisdictions. Costs to secure and defend our IP are expensed as incurred, and are classified as selling, general and administrative expenses.

Interest income

Interest income consists of interest generated from our investments in cash and cash equivalents, money market funds, and high-quality fixed income securities.

Other expense, net

Other expense, net consists of interest expense, gains (losses) from the sale of investments in marketable securities, and other income and expense unrelated to our core operations. Interest expense is primarily derived from our finance leases related to our Moderna Technology Center and certain contract manufacturing service agreements.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, are reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Income taxes

We account for income taxes based on an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. We determine our deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance. If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made. As of December 31, 2021, we maintained a valuation allowance against a portion of the state deferred tax assets based on management's evaluation of all available evidence.

We are subject to income tax audits and adjustments by tax authorities. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. We develop our assessment of uncertain tax positions and as additional information becomes available, estimates are revised and refined. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions. These reserves are based on a determination of whether and how much of a tax benefit taken by us in our tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Differences between estimates and final settlement may occur resulting in additional tax expense.

Recently issued accounting pronouncements

We have reviewed all recently issued standards and have determined that such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Results of operations

A discussion regarding our results of operations for the year ended December 31, 2021 compared to 2020 is presented below. A discussion regarding our results of operations for the year ended December 31, 2020 compared to 2019 can be found under Part II -Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission (SEC) on February 26, 2021.

The following tables summarize our consolidated statements of operations for the periods presented (in millions):

	Years Ended December 31,		Change 2021 vs. 2020	
	2021	2020	Change	%
Revenue:				
Product sales	$ 17,675	$ 200	$ 17,475	8,738 %
Grant revenue	735	529	206	39 %
Collaboration revenue	61	74	(13)	(18)%
Total revenue	18,471	803	17,668	2,200 %
Operating Expenses:				
Cost of sales	2,617	8	2,609	32,613 %
Research and development	1,991	1,370	621	45 %
Selling, general and administrative	567	188	379	202 %
Total operating expenses	5,175	1,566	3,609	230 %
Income (loss) from operations	13,296	(763)	14,059	1,843 %
Interest income	18	25	(7)	(28)%
Other expense, net	(29)	(6)	(23)	383 %
Income (loss) before income taxes	13,285	(744)	14,029	1,886 %
Provision for income taxes	1,083	3	1,080	36,000 %
Net income (loss)	$ 12,202	$ (747)	$ 12,949	1,733 %

	Years Ended December 31,		Change 2020 vs. 2019	
	2020	2019	Change	%
Revenue:				
Product sales	$ 200	$ —	$ 200	100 %
Grant revenue	$ 529	$ 12	$ 517	4,308 %
Collaboration revenue	74	48	26	54 %
Total revenue	803	60	743	1,238 %
Operating Expenses:				
Cost of sales	8	—	8	100 %
Research and development	1,370	496	874	176 %
Selling, general and administrative	188	110	78	71 %
Total operating expenses	1,566	606	960	158 %
Loss from operations	(763)	(546)	(217)	40 %
Interest income	25	39	(14)	(36)%
Other expense, net	(6)	(8)	2	(25)%
Loss before income taxes	(744)	(515)	(229)	44 %
Provision for (benefit from) income taxes	3	(1)	4	(400)%
Net loss	$ (747)	$ (514)	$ (233)	45 %

Revenue

Total revenue increased by $17.7 billion in 2021, primarily due to increases in product sales. Product sales increased by $17.5 billion in 2021 from sales of our COVID-19 vaccine to domestic and international government customers and international purchasing organizations, such as Gavi (on behalf of the COVAX Facility) and the African Union, subsequent to the authorization by the FDA and Health Canada for emergency use in December 2020. Grant revenue increased by $206 million, or 39%, in 2021, mainly due to an increase in grant revenue from BARDA related to our COVID-19 vaccine development in 2021.

Operating expenses

Cost of sales

We began capitalizing our COVID-19 vaccine inventory costs in December 2020, in connection with an Emergency Use Authorization from the FDA and an Interim Order from Health Canada for use of our COVID-19 vaccine, and based upon our expectation that these costs would be recoverable through commercialization of mRNA-1273. Prior to the capitalization of our COVID-19 vaccine inventory costs, costs related to our pre-launch inventory were recorded as research and development expenses in the period incurred. We expensed $242 million of pre-launch inventory costs in 2020.

Our cost of sales was $2.6 billion, or 15% of our product sales, in 2021, including third-party royalties of $641 million. A portion of the inventory costs associated with our product sales for the year ended 2021 was expensed previously. If inventory sold for the year ended 2021 was valued at cost, including what was expensed as pre-launch inventory, our cost of sales for the period would have been $2.8 billion, or 16% of our product sales. We utilized all of our pre-launch inventory during 2021. We expect that our cost of sales as a percentage of product sales will increase in 2022 due to higher manufacturing costs and lower average selling price per dose, driven by the expected increase in deliveries to low income countries.

Research and development expenses

Research and development expenses increased by $621 million, or 45%, in 2021. The increase was primarily attributable to an increase in clinical trial expenses of $721 million, an increase in personnel-related costs of $79 million, and an increase in consulting and outside services of $59 million, partially offset by a decrease in manufacturing expenses of $251 million, attributable to pre-launch inventory expensed in 2020 prior to FDA authorization. The increase in 2021 was largely attributable to the continued clinical development of mRNA-1273. The increase in personnel-related costs was primarily driven by an increase in the number of employees supporting our mRNA-1273 development activities as well as other research and development programs.

We expect that research and development expenses will increase in 2022 as we continue to progress our indication expansion of mRNA-1273, and continue to develop our pipeline and advance our product candidates into later-stage development. In addition, we also expect to incur significant costs related to the development of variant-specific COVID-19 candidates and our next-generation COVID-19 vaccine candidate (mRNA-1283).

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $379 million, or 202%, in 2021. The increase was mainly due to an increase in consulting and outside services of $97 million, an increase in personnel-related costs of $73 million, an increase in marketing expense of $67 million, an increase in distributor fees of $64 million, and an increase in legal, licensing and insurance expenses of $42 million. The increases in personnel-related costs and consulting and outside services were primarily attributable to mRNA-1273 commercialization-related activities and increased headcount.

We expect that selling, general and administrative expenses will increase in 2022, as we continue to build out our global commercial, regulatory, sales and marketing infrastructure to support the commercialization of our COVID-19 vaccine, and continue to expand the number of programs and our business operations.

Interest income

Interest income generated from our investments in marketable securities decreased by $7 million, or 28%, in 2021, mainly attributable to an overall lower interest rate.

Other expense, net

The following table summarizes other expense, net for the periods presented (in millions):

	Years Ended December 31,		Change 2021 vs. 2020	
	2021	2020	Change	%
Gain on investments	$ 1	$ 1	$ —	— %
Interest expense	(18)	(10)	(8)	80 %
Other (expense) income, net	(12)	3	(15)	(500)%
Total other expense, net	$ (29)	$ (6)	$ (23)	383 %

Total other expense, net increased by $23 million, or 383%, in 2021. The increase was primarily due to losses related to remeasurements and our balance sheet hedging activities, partially offset by gains on foreign currency transactions. Our interest expense is primarily related to our finance leases. The increase in interest expense was driven by new finance leases that commenced in 2021. Please refer to Note 11 to our consolidated financial statements.

Provision for income taxes

Provision for income taxes increased by $1.1 billion in 2021, primarily due to an increase in pre-tax income. Our effective tax rate for the year ended December 31, 2021 was 8.1%, which included tax benefits related to the release of the valuation allowance on most of our deferred tax assets, foreign-derived intangible income deduction, and stock-based compensation. Provision for income taxes was immaterial for the year ended December 31, 2020. We expect that our effective tax rate will increase in 2022 as the valuation allowance against our deferred tax assets was mostly released in 2021.

Liquidity and capital resources

Prior to the commercialization of our COVID-19 vaccine, we have historically funded our operations primarily from the sale of equity instruments and from proceeds from certain strategic alliance arrangements and grant agreements. Starting in August 2020, we entered into supply agreements with the U.S. Government, other international governments, Gavi, and the African Union for the supply of our COVID-19 vaccine. Under these agreements, we are entitled to upfront deposits for our COVID-19 vaccine supply, which are initially recorded as deferred revenue and will be recognized as revenue when revenue recognition criteria have been met. As of December 31, 2021, we had $6.7 billion in deferred revenue related to customer deposits received or billable. In addition, we expect to continue to receive funding from our contract with BARDA related to our mRNA-1273 program. As of December 31, 2021, the remaining available funding, net of revenue earned was $189 million.

As of December 31, 2021, we had cash, cash equivalents and investments of $17.6 billion. Cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting primarily of government and corporate debt securities are stated at fair value. As of December 31, 2021, we had current and non-current investments of approximately $3.9 billion and $6.8 billion, respectively.

Effective January 1, 2022, research and development expenses are required to be capitalized and amortized for U.S. tax purposes. Unless modified or repealed, and based on current assumptions, the mandatory capitalization would increase our cash tax liabilities.

We continue to work toward the large-scale technical development, manufacturing scale-up in several countries and larger scale deployment of our COVID-19 vaccine. To support the scale-up, we have expended and will need to continue to expend significant resources and capital.

Cash flow

The following table summarizes the primary sources and uses of cash for the periods presented (in millions):

	Years Ended December 31,		
	2021	2020	2019
Net cash provided by (used in):			
Operating activities	$ 13,620	$ 2,027	$ (459)
Investing activities	(8,523)	(1,672)	(15)
Financing activities	(873)	2,033	52
Net increase (decrease) in cash and cash equivalents	$ 4,224	$ 2,388	$ (422)

Operating activities

We derive cash flows from operations primarily from cash collected from customer deposits related to our COVID-19 vaccine supply agreements as well as certain government-sponsored and private organizations and strategic alliances. Our cash flows from operating activities are significantly affected by our use of cash for operating expenses and working capital to support the business. Prior to 2020, we experienced negative cash flows from operating activities as we invested in our mRNA technologies, development pipeline, digital infrastructure, manufacturing technology, and infrastructure.

Net cash provided by operating activities in 2021 was $13.6 billion and consisted of net income of $12.2 billion and non-cash adjustments of $110 million, plus a net change in assets and liabilities of $1.3 billion. Non-cash items primarily included depreciation and amortization of $232 million, stock-based compensation of $142 million, deferred income taxes of $318 million, and amortization of investment premiums and discounts of $54 million. The net change in assets and liabilities was primarily due to an increase in deferred revenue of $2.8 billion, an increase in accrued liabilities of $989 million, an increase in income taxes payable of $876 million, and an increase in accounts payable of $204 million, partially offset by an increase in accounts receivable of $1.8 billion, an increase in inventory of $1.4 billion, and an increase in prepaid expenses and other assets of $489 million.

Net cash provided by operating activities in 2020 was $2.0 billion and consisted of net loss of $747 million less non-cash adjustments of $196 million, plus a net change in assets and liabilities of $2.6 billion. Non-cash items primarily included stock-based compensation of $93 million, leased assets expensed of $62 million, depreciation and amortization of $31 million, and amortization of investment premiums and discounts of $10 million. The net change in assets and liabilities was primarily due to an increase in deferred revenue of $3.8 billion, an increase in accrued liabilities of $388 million, an increase in accounts payable of $12 million, and an increase in operating lease liabilities of $12 million, partially offset by an increase in accounts receivable of $1.4 billion, an increase in prepaid expenses and other assets of $241 million, an increase of inventory of $47 million, and an increase in operating lease right-of-use assets of $11 million.

Net cash used in operating activities in 2019 was $459 million and consisted of net loss of $514 million less non-cash adjustments of $108 million, plus a net change in assets and liabilities of $53 million. Non-cash items primarily included stock-based compensation of $81 million, and depreciation and amortization of $31 million. The net change in assets and liabilities was primarily due to a decrease in deferred revenue of $44 million, and a decrease in accounts payable of $24 million, partially offset by an increase in operating lease liabilities, non-current of $13 million, and a decrease in prepaid expenses and other assets of $10 million.

Investing activities

Our primary investing activities consist of purchases, sales, and maturities of our investments and capital expenditures for manufacturing, laboratory, computer equipment, and software.

Net cash used in investing activities in 2021 was $8.5 billion, which included purchases of marketable securities of $12.7 billion, purchases of property and equipment of $284 million, and investment in convertible notes of $30 million, partially offset by proceeds from sales of marketable securities of $3.1 billion and proceeds from maturities of marketable securities of $1.3 billion.

Net cash used in investing activities in 2020 was $1.7 billion, which included purchases of marketable securities of $3.0 billion and purchases of property and equipment of $68 million, partially offset by proceeds from maturities of marketable securities of $1.1 billion and proceeds from sales of marketable securities of $215 million.

Net cash used in investing activities in 2019 was $15 million, which included purchases of marketable securities of $1.1 billion and purchases of property and equipment of $32 million, partially offset by proceeds from maturities of marketable securities of $993 million and proceeds from sales of marketable securities of $169 million.

Financing activities

Net cash used in financing activities in 2021 was $873 million, primarily from repurchases of common stock of $857 million and changes in financing lease liabilities of $140 million, partially offset by net proceeds from the issuance of common stock in connection with the exercise of stock options and employee stock purchases under our equity plans of $124 million.

Net cash provided by financing activities in 2020 was $2.0 billion, primarily from net proceeds from equity offerings of $1.9 billion and net proceeds from the issuance of common stock in connection with the exercise of stock options and employee stock purchases under our equity plans of $186 million.

Net cash provided by financing activities in 2019 was $52 million, primarily from net proceeds from the issuance of common stock in connection with the exercise of stock options and employee stock purchases under our equity plans of $51 million.

Operation and funding requirements

From our inception to the end of 2020, we incurred significant losses from operations due to our significant research and development expenses. We generated net income for the year ended 2021 in connection with product sales following the authorization of our first commercial product. We have retained earnings of $10.0 billion as of December 31, 2021. We have significant future capital requirements including expected operating expenses to conduct research and development activities, operate our organization, meet capital expenditure needs, and fund our share repurchase program. We expect our expenses to increase in connection with our ongoing activities as we continue research and development of our development candidates and clinical activities for our investigational medicines. We also expect our expenses to increase associated with manufacturing costs, including our arrangements with our international supply and manufacturing partners. Our ongoing work on mRNA-1273, including development of any new generations of boosters and vaccines against variants of SARS-CoV-2, and buildout of global commercial, regulatory, sales and marketing infrastructure to support the commercialization of our COVID-19 vaccine will require significant cash outflows during 2022, most of which may not be reimbursed or otherwise paid for by our partners or collaborators. In addition, we have substantial facility, lease and purchase obligations. We have entered into certain collaboration agreements with third parties that include the funding of certain research and development activities and potential future milestone and royalty payments by us.

We believe that our cash, cash equivalents, and investments as of December 31, 2021, will be sufficient to enable us to fund our projected operations, capital expenditures and share repurchases through at least the next 12 months from the issuance of the financial statements included in this Annual Report on Form 10-K. We are subject to all the risks related to the development and commercialization of novel medicines, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors including expenses related to the ongoing COVID-19 pandemic, which may adversely affect our business. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

If we fail to sustain profitability on a continuing basis, we may be required to finance future cash needs through a combination of public or private equity offerings, structured financings and debt financings, government funding arrangements, potential future strategic alliances from which we receive upfront fees, milestone payments, and other forms of consideration, and marketing, manufacturing, distribution and licensing arrangements. If we are required to finance future cash needs, additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the development or commercialization of one or more of our investigational medicines, or slow down or cease work on one or more of our programs. If we raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise funds through strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or investigational medicines or grant licenses on terms that may not be favorable to us. Any of these events could significantly harm our business, financial condition, and prospects.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2021 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating leases	$ 191	$ 54	$ 54	$ 32	$ 51
Financing leases [1]	1,323	184	40	41	1,058
MSC lease [2]	1,051	—	65	117	869
Purchase obligations [3]	2,587	2,004	541	42	—
Total contractual cash obligations	$ 5,152	$ 2,242	$ 700	$ 232	$ 1,978

(1) The amounts in the table include a total payment of $637 million associated with our MTC leases for the optional lease extension periods. For accounting purpose, a lease term is the non-cancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised. Please refer to Note 11 to our consolidated financial statements.

(2) We entered into a lease agreement for approximately 462,000 square feet in Cambridge, Massachusetts (Moderna Science Center) and will undergo an approximately two-year building project. Following the building project, the lease term is 15 years, subject to our right to extend the lease for up to two additional seven-year terms. The rent will commence on the Initial Phase Commencement date defined in the lease agreement that is currently estimated to be in July 2023.

(3) The amounts represent non-cancelable fixed payment obligations related to purchases of raw materials, contract manufacturing services, clinical services and other goods or services in the normal course of business.

We have agreements with certain vendors for various services, including services related to clinical operations, and support and contract manufacturing, which we are not contractually able to terminate for convenience. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly to reimburse them for their unrecoverable outlays incurred prior to cancellation. The exact amounts of such obligations are dependent on the timing of termination, and the exact terms of the relevant agreement and cannot be reasonably estimated. At December 31, 2021, we had cancelable open purchase orders of $2.4 billion in total under such agreements for our clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at December 31, 2021, assuming we would not cancel these agreements. The actual amounts we pay in the future to the vendors under such agreements may differ from the cancelable open purchase order amounts of $2.4 billion.

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. It is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

As of December 31, 2021 and 2020, we had cash, cash equivalents, restricted cash, and investments in marketable securities of $17.6 billion and $5.2 billion, respectively. Our investment portfolio comprises money market funds and marketable debt securities (including U.S. Treasury securities, debt securities of U.S. government agencies and corporate entities, and commercial paper), which are classified as available-for-sale securities. Our primary investment objectives are the preservation of capital and the maintenance of liquidity, and our investment policy defines allowable investments based on quality of the institutions and financial instruments designed to minimize risk exposure. Our exposure to interest rate sensitivity is affected by changes in the general level of U.S. interest rates.

Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term maturities and low risk profiles of our investments, we do not anticipate a significant exposure to interest rate risk. If market interest rates were to increase immediately and uniformly by one percentage point from levels at December 31, 2021, the net fair value of our marketable securities would decrease by approximately $146 million.

Foreign Currency Risk

Our revenue generating activities and operations have been primarily denominated in U.S. dollars. Our significant foreign currency revenue exposure for the year ended December 31, 2021 was the equivalent of $5.9 billion in Euros. As we expand internationally our results of operations and cash flows become increasingly subject to fluctuations due to changes in foreign currency exchange rates. To help manage the exposure to foreign currency exchange rate fluctuations, we have implemented cash flow hedging and balance sheet hedging programs.

Cash Flow Hedging Activities

We hedge foreign currency product sales denominated in Euros, including the use of foreign exchange forward contracts or purchased options. We hedge our cash flow exposures to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. These transactions are designated and qualify as cash flow hedges. Our foreign exchange contracts as of December 31, 2021, carried at fair value, had maturities of up to 9 months.

Balance Sheet Hedging Activities

We use foreign currency forward contracts to mitigate foreign currency exchange risk associated with foreign currency-denominated monetary assets and liabilities. These contracts reduce the impact of currency exchange rate movements on our assets and liabilities. As of December 31, 2021, our outstanding balance sheet hedging derivatives, carried at fair value, had maturities of less than three months.

We enter into these foreign exchange contracts to hedge our forecasted revenue and monetary assets and liabilities denominated in foreign currency in the normal course of business and accordingly, they are not speculative in nature. We believe the counterparties to our foreign currency forward contracts are creditworthy multinational commercial banks. While we believe the risk of counterparty nonperformance is not material, a sustained decline in the financial stability of financial institutions as a result of disruption in the financial markets could affect our ability to secure creditworthy counterparties for our foreign currency hedging programs.

Notwithstanding our efforts to mitigate some foreign currency exchange risks, there can be no assurance that our hedging activities will adequately protect us against the risks associated with foreign currency fluctuations. As of December 31, 2021, a hypothetical adverse movement of 10 percent in foreign currency exchange rates compared to the U.S. dollars across all maturities would have resulted in potential declines in the fair value on our foreign currency forward contracts used in cash flow hedging of approximately $54 million. As of December 31, 2021, a hypothetical adverse movement of 10 percent in foreign currency exchange rates compared to the U.S. dollars across all maturities would have resulted in potential declines in the fair value on our foreign currency forward contracts used in balance sheet hedging of approximately $115 million. We expect that any increase or decrease in the fair value of the portfolio would be substantially offset by increases or decreases in the underlying exposures being hedged.

Item 8. Financial Statements and Supplementary Data

MODERNA, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Moderna, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Moderna, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 25, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Product Sales Revenue Recognition

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, the Company has entered into supply agreements with the U.S. Government, other international governments, Gavi (on behalf of the COVAX facility), and the African Union. Under the supply agreements, the Company is entitled to upfront deposits for COVID-19 vaccine supply, which are initially recorded as deferred revenue. Revenue is recognized pursuant to Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, based on the fixed price per dose when control of the product has transferred and customer acceptance has occurred, unless such acceptance provisions are deemed perfunctory. The Company must evaluate the contractual terms and conditions in its supply agreements to determine the timing of revenue recognition. For the year ended December 31, 2021, product sales revenue totaled $17.7 billion and related deferred revenue totaled $6.7 billion.

Auditing the Company's revenue recognition was especially challenging due to the volume of executed supply agreements, the varying contractual terms within the agreements, and because the amounts are material to the consolidated financial statements and related disclosures.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of the Company's internal controls over the recognition of revenue related to product sales. This included testing controls over the Company's process to evaluate the contractual terms of the supply agreements and determine the appropriate revenue recognition. We also tested the Company’s controls over evaluating transfer of control and customer acceptance, as applicable, and controls over the Company’s IT systems that are important to the initiation, processing and recording of revenue transactions.

To test the recognition of revenue associated with supply agreements, our audit procedures included, among others, evaluating the contractual terms of supply agreements, testing the transfer of control, and assessing the timing of revenue recognition. For example, we performed procedures to test the completeness and accuracy of the underlying data in the Company’s revenue and deferred revenue calculations, including testing the mathematical accuracy of the Company’s calculations, and testing the accuracy of revenue recognized by tracing key terms to the supply agreements and agreeing a sample of revenue transactions to supporting documentation, including evidence of control transfer. We also assessed the appropriateness of the related disclosures in the consolidated financial statements.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2014.

Boston, Massachusetts

February 25, 2022

MODERNA, INC.
CONSOLIDATED BALANCE SHEETS
(In millions, except per share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 6,848	$ 2,624
Investments	3,879	1,984
Accounts receivable	3,175	1,391
Inventory	1,441	47
Prepaid expenses and other current assets	728	252
Total current assets	16,071	6,298
Investments, non-current	6,843	639
Property and equipment, net	1,241	297
Right-of-use assets, operating leases	142	90
Restricted cash, non-current	12	11
Deferred tax assets	326	—
Other non-current assets	34	2
Total assets	$ 24,669	$ 7,337
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 302	$ 18
Accrued liabilities	1,472	470
Deferred revenue	6,253	3,867
Income taxes payable	876	—
Other current liabilities	225	34
Total current liabilities	9,128	4,389
Deferred revenue, non-current	615	177
Operating lease liabilities, non-current	106	97
Financing lease liabilities, non-current	599	110
Other non-current liabilities	76	3
Total liabilities	10,524	4,776
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001; 162 shares authorized as of December 31, 2021 and 2020; no shares issued or outstanding at December 31, 2021 and 2020	—	—
Common stock, par value $0.0001; 1,600 shares authorized as of December 31, 2021 and 2020; 403 and 399 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Additional paid-in capital	4,211	4,802
Accumulated other comprehensive (loss) income	(24)	3
Retained earnings (accumulated deficit)	9,958	(2,244)
Total stockholders' equity	14,145	2,561
Total liabilities and stockholders' equity	$ 24,669	$ 7,337

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In millions, except per share data)

	Years Ended December 31,		
	2021	**2020**	**2019**
Revenue:			
Product sales	$ 17,675	$ 200	$ —
Grant revenue	735	529	12
Collaboration revenue	61	74	48
Total revenue	18,471	803	60
Operating expenses:			
Cost of sales	2,617	8	—
Research and development	1,991	1,370	496
Selling, general and administrative	567	188	110
Total operating expenses	5,175	1,566	606
Income (loss) from operations	13,296	(763)	(546)
Interest income	18	25	39
Other expense, net	(29)	(6)	(8)
Income (loss) before income taxes	13,285	(744)	(515)
Provision for (benefit from) income taxes	1,083	3	(1)
Net income (loss)	$ 12,202	$ (747)	$ (514)
Earnings (loss) per share:			
Basic	$ 30.31	$ (1.96)	$ (1.55)
Diluted	$ 28.29	$ (1.96)	$ (1.55)
Weighted average common shares used in calculation of earnings (loss) per share:			
Basic	403	381	331
Diluted	431	381	331

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In millions)

	Years Ended December 31,		
	2021	**2020**	**2019**
Net income (loss)	$ 12,202	$ (747)	$ (514)
Other comprehensive (loss) income, net of tax			
Available-for-sales securities:			
Unrealized (losses) gains on available-for-sale debt securities	(42)	2	3
Less: net realized (gains) on available-for-sale securities reclassified to net income (loss)	(1)	(1)	—
Net (decrease) increase from available-for-sale debt securities	(43)	1	3
Cash flow hedges:			
Unrealized gains on derivative instruments	74	—	—
Less: net realized (gains) on derivative instruments reclassified to net income (loss)	(58)	—	—
Net increase from derivatives designated as hedging instruments	16	—	—
Total other comprehensive (loss) income	(27)	1	3
Comprehensive income (loss)	$ 12,175	$ (746)	$ (511)

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In millions)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	329	$ —	$ 2,538	$ (1)	$ (1,007)	$ 1,530
Vesting of restricted common stock and restricted stock units	1	—	—	—	—	—
Exercise of options to purchase common stock	7	—	48	—	—	48
Purchase of common stock under employee stock purchase plan	—	—	3	—	—	3
Transition adjustment from adoption of ASC 606	—	—	—	—	28	28
Transition adjustment from adoption of ASC 842	—	—	—	—	(4)	(4)
Stock-based compensation	—	—	81	—	—	81
Other comprehensive income, net of tax	—	—	—	3	—	3
Net loss	—	—	—	—	(514)	(514)
Balance at December 31, 2019	337	$ —	$ 2,670	$ 2	$ (1,497)	$ 1,175

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	337	$ —	$ 2,670	$ 2	$ (1,497)	$ 1,175
Proceeds from public offering of common stock, net of issuance costs of $2	48	—	1,853	—	—	1,853
Exercise of options to purchase common stock	14	—	179	—	—	179
Purchase of common stock under employee stock purchase plan	—	—	7	—	—	7
Stock-based compensation	—	—	93	—	—	93
Other comprehensive income, net of tax	—	—	—	1	—	1
Net loss	—	—	—	—	(747)	(747)
Balance at December 31, 2020	399	$ —	$ 4,802	$ 3	$ (2,244)	$ 2,561

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	399	$ —	$ 4,802	$ 3	$ (2,244)	$ 2,561
Exercise of options to purchase common stock	7	—	112	—	—	112
Purchase of common stock under employee stock purchase plan	—	—	12	—	—	12
Stock-based compensation	—	—	142	—	—	142
Other comprehensive loss, net of tax	—	—	—	(27)	—	(27)
Repurchase of common stock	(3)	—	(857)	—	—	(857)
Net income	—	—	—	—	12,202	12,202
Balance at December 31, 2021	403	$ —	$ 4,211	$ (24)	$ 9,958	$ 14,145

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In millions)

	Years Ended December 31,		
	2021	2020	2019
Operating activities			
Net income (loss)	$ 12,202	$ (747)	$ (514)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Stock-based compensation	142	93	81
Depreciation and amortization	232	31	31
Leased assets expensed	—	62	—
Amortization/accretion of investments	54	10	(4)
Deferred income taxes	(318)	—	—
Changes in assets and liabilities:			
Accounts receivable	(1,784)	(1,385)	7
Prepaid expenses and other assets	(489)	(241)	10
Inventory	(1,394)	(47)	—
Right-of-use assets, operating leases	(58)	(11)	(6)
Accounts payable	204	12	(24)
Accrued liabilities	989	388	(3)
Deferred revenue	2,824	3,842	(44)
Income taxes payable	876	—	—
Operating lease liabilities	17	12	13
Other liabilities	123	8	(6)
Net cash provided by (used in) operating activities	13,620	2,027	(459)
Investing activities			
Purchases of marketable securities	(12,652)	(2,956)	(1,145)
Proceeds from maturities of marketable securities	1,338	1,137	993
Proceeds from sales of marketable securities	3,105	215	169
Purchases of property and equipment	(284)	(68)	(32)
Investment in convertible notes	(30)	—	—
Net cash used in investing activities	(8,523)	(1,672)	(15)
Financing activities			
Proceeds from offerings of common stock, net of issuance costs	—	1,853	—
Proceeds from issuance of common stock through equity plans, net	124	186	51
Repurchase of common stock	(857)	—	—
Changes in financing lease liabilities	(140)	(6)	1
Net cash (used in) provided by financing activities	(873)	2,033	52
Net increase (decrease) in cash, cash equivalents and restricted cash	4,224	2,388	(422)
Cash, cash equivalents and restricted cash, beginning of year	2,636	248	670
Cash, cash equivalents and restricted cash, end of year	$ 6,860	$ 2,636	$ 248
Supplemental cash flow information			
Cash paid for income taxes	$ 480	$ 1	$ —
Cash paid for interest	$ 14	$ 9	$ 6
Non-cash investing and financing activities			
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 111	$ 18	$ 5

The accompanying notes are an integral part of these consolidated financial statements.

MODERNA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Moderna, Inc. (collectively, with its consolidated subsidiaries, any of Moderna, we, us, our or the Company) was incorporated in Delaware on July 22, 2016. We are the successor in interest to Moderna LLC, a limited liability company formed under the laws of the State of Delaware in 2013. Our principal executive office is located at 200 Technology Square, Cambridge, MA.

We are a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines to improve the lives of patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane, or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology, and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, autoimmune diseases and cardiovascular diseases, independently and with our strategic collaborators.

On December 18, 2020, we received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the emergency use of the Moderna COVID-19 Vaccine (also referred to as mRNA-1273 and marketed under the brand name Spikevax) in individuals 18 years of age or older. We have also received authorization for our COVID-19 vaccine from health agencies in more than 70 countries and from the World Health Organization (WHO). Additional authorizations are currently under review in other countries. In addition, we have received authorization for our COVID-19 vaccine for use in adolescents in the United Kingdom, European Union, Japan, Canada, Switzerland, Taiwan, Saudi Arabia, Australia, and the Philippines, and have pending applications for authorization to administer the vaccine to adolescents with regulatory agencies in the United States and other countries. In January 2022, we received full FDA approval for Spikevax to prevent COVID-19 in individuals 18 years of age and older in the United States. In February 2022, we received approval for the administration of Spikevax to children ages 6-11 in Australia and a positive recommendation from the European Medicines Agency's Committee for Medicinal Products for Human Use for the administration of Spikevax in children ages 6-11 years.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

The consolidated financial statements include the Company and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

We have made estimates and judgments affecting the amounts reported in our consolidated financial statements and the accompanying notes. We base our estimates on historical experience and various relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods that are not readily apparent from other sources. Significant estimates relied upon in preparing these financial statements include, but are not limited to, revenue recognition, research and development expense, leases, fair value of financial instruments, derivative financial instruments, inventory, useful lives of property and equipment, stock-based compensation, income taxes, and our valuation allowance on our deferred tax assets. The actual results that we experience may differ materially from our estimates.

Segment Information

We have determined that our chief executive officer is the chief operating decision maker (CODM). The CODM reviews financial information presented on a consolidated basis. Resource allocation decisions are made by the CODM based on consolidated results. There are no segment managers who are held accountable by the CODM for operations, operating results, and planning for levels or components below the consolidated unit level. As such, we have concluded that we operate as one segment.

Revenue Recognition

On January 1, 2019, we adopted ASC 606 *(Revenue from Contracts with Customers*) using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2019. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. To determine the appropriate amount of revenue to be recognized for arrangements that we determine are within the scope of ASC 606, we perform the following five steps (the five-step model): (i) identify the contract(s) with our customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as each performance obligation is satisfied.

Our revenue is primarily generated through product sales. We also generate grant revenue from government-sponsored and private organizations, and collaboration revenue through collaboration arrangements.

Product Sales

Product sales are associated with our COVID-19 vaccine supply agreements with the U.S. Government, other international governments, Gavi (on behalf of the COVAX Facility), and the African Union. These agreements generally do not include variable consideration, such as discounts, rebates or returns. Under these agreements, we are entitled to upfront deposits for our COVID-19 vaccine supply, initially recorded as deferred revenue. We recognize revenue from product sales, using the five-step model under ASC 606, based on the fixed price per dose according to the contracts when control of the product transfers to the customer and customer acceptance has occurred, unless such acceptance provisions are deemed perfunctory.

We pay distribution fees to certain customers in connection with the sales of our product. We record distribution fees paid to our customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and we can reasonably estimate the fair value of the goods or services received. If both conditions are met, we record the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale. Such distribution fees were immaterial for the year ended December 31, 2021. We did not have any distribution fees for the years ended December 31, 2020 and 2019.

Grant Revenue

We have contracts with 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); the U.S. government's Defense Advanced Research Projects Agency (DARPA); the Bill & Melinda Gates Foundation (Gates Foundation) and other government-sponsored and private organizations for research and development related activities that provide for payments for reimbursed costs, which may include overhead and general and administrative costs as well as a related profit margin. We recognize revenue from these contracts as we perform services under these arrangements when the funding is committed. Associated expenses are recognized when incurred as research and development expense. Revenues and related expenses are presented gross in the consolidated statements of operations as we have determined we are the primary obligor under the arrangements relative to the research and development services we perform as lead technical expert.

Collaboration Revenue

We have entered into several strategic collaborations and other similar arrangements with third parties for research and other licenses, development and commercialization of certain products and product candidates. Such arrangements provide for various types of payments to us, including upfront fees, funding of research and development services and preclinical and clinical material, technical, development, regulatory, and commercial milestone payments, licensing fees, option exercise fees, and royalty and earnout payments on product sales. Such payments are often not commensurate with the timing of revenue recognition and therefore result in deferral of revenue recognition. We recognize revenue based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good or service to the customer.

Cash and Cash Equivalents

We consider all highly liquid investments with an original maturity of 90 days or less from the date of purchase to be cash equivalents.

Restricted Cash

Restricted cash is composed of amounts held on deposit related to our lease arrangements. The funds are maintained in money market accounts and are recorded at fair value. We classify our restricted cash as either current or non-current based on the terms of the underlying lease arrangement.

Cash, Cash Equivalents and Restricted Cash shown in the Consolidated Statements of Cash Flows

The following table provides a reconciliation of cash, cash equivalents and restricted cash in the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows (in millions):

	December 31,		
	2021	2020	2019
Cash and cash equivalents	$ 6,848	$ 2,624	$ 236
Restricted cash [(1)]	—	1	1
Restricted cash, non-current	12	11	11
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 6,860	$ 2,636	$ 248

[(1)] Included in prepaid expenses and other current assets in the consolidated balance sheets.

Investments

We invest our excess cash balances in marketable debt securities. We classify our investments in marketable debt securities as available-for-sale. We report available-for-sale investments at fair value at each balance sheet date, and include any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive (loss) income, a component of stockholders' equity. Realized gains and losses are determined using the specific-identification method, and are included in other expense, net in our consolidated statements of operations. We classify our available-for-sale marketable securities as current or non-current based on each instrument's underlying effective maturity date and for which we have the intent and ability to hold the investment for a period of greater than 12 months. Marketable securities with maturities of less than 12 months are classified as current and are included in investments in the consolidated balance sheets. Marketable securities with maturities greater than 12 months for which we have the intent and ability to hold the investment for greater than 12 months are classified as non-current and are included in investments, non-current in the consolidated balance sheets.

We evaluate securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Any impairment that is not credit- related is recognized in other comprehensive (loss) income, net of applicable taxes.

Accounts Receivable and Allowance for Doubtful Accounts

We have accounts receivable amounts due from our product sales and related vaccine supply agreements and our grant agreements. We also have accounts receivable amounts due from strategic collaborators as a result of manufacturing and research and development services provided under collaboration arrangements, or milestones achieved, but not yet paid. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional. To estimate the allowance for doubtful accounts, we make judgments about the creditworthiness of our customers based on ongoing credit evaluation and historical experience. There was no allowance for doubtful accounts at December 31, 2021 or 2020. There was no bad debt expense for the years ended December 31, 2021, 2020 or 2019.

Concentrations of Credit Risk

Financial instruments that subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash, marketable securities, and accounts receivable. Our investment portfolio comprises money market funds and marketable debt securities, including U.S. Treasury securities, debt securities of U.S. government agencies and corporate entities and commercial paper. Our cash management and investment policy limits investment instruments to investment-grade securities with the objective to preserve capital and to maintain liquidity until the funds can be used in business operations. Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. Our primary operating accounts significantly exceed the FDIC limits.

Significant Customers

Our accounts receivable are generally unsecured and are from customers in different countries. We generated revenue from product sales to the U.S. Government, other international governments, Gavi (on behalf of the COVAX Facility), the African Union. grants made by government-sponsored and private organizations, and to a lesser extent, strategic alliances in 2021 and 2020. Historically, we generated revenue primarily from strategic alliances.

A significant portion of our revenue to date has been generated from the following entities that accounted for more than 10% of total revenue and accounts receivable for the periods presented:

	Percentage of Revenue Years Ended December 31,			Percentage of Accounts Receivable December 31,	
	2021	2020	2019	2021	2020
European Commission	32 %	*	*	46 %	28 %
U.S. Government (excluding BARDA)	29 %	24 %	*	*	*
BARDA	*	65 %	13 %	16 %	22 %
Merck	*	*	61 %	*	*
Vertex	*	*	10 %	*	*
United Kingdom Government	*	*	*	*	11 %
South Korea Government	*	*	*	*	24 %

* - *Represents an amount of less than 10%*

Derivative Instruments and Hedging Activities

We record all derivatives on our consolidated balance sheets at fair value. The accounting for changes in the fair value of a derivative depends on whether the derivative has been designated and qualifies for hedge accounting. Derivatives designated and qualifying as a hedge of the exposure to variability in expected future cash flows, or other types of forecasted transactions, are considered cash flow hedges. Hedge accounting generally provides for the matching of the timing of gain or loss recognition on the hedging instrument with the recognition of the changes in the fair value of the hedged asset or liability that are attributable to the hedged risk in a fair value hedge or the earnings effect of the hedged forecasted transactions in a cash flow hedge.

The gains or losses resulting from changes in the fair value of cash flow hedges are initially recorded as a component of accumulated other comprehensive (loss) income (AOCI) in stockholders' equity and subsequently reclassified to product sales in the period during which the hedged transaction affects earnings. In the event the underlying forecasted transaction does not occur, or it becomes probable that it will not occur, within the defined hedge period, we reclassify the gains or losses on the related cash flow hedge from AOCI to other expense, net, in our consolidated statements of operations. We may enter into derivative contracts that are intended to economically hedge certain risk, even though hedge accounting does not apply or we elect not to apply hedge accounting. Gains or losses associated with foreign currency derivatives that are not designated as hedging instruments for accounting purposes are recorded within other expense, net, in our consolidated statements of operations.

Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities, which are required to be recorded at fair value, we consider the principal or most advantageous market in which we would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risk. ASC 820 *(Fair Value Measurement*) establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and our assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from our independent sources. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used to value the assets and liabilities:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

- Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; or
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Our cash equivalents and marketable securities are reported at fair value determined using Level 1 and Level 2 inputs (Note 6). The fair value of our foreign currency forward contracts is calculated using Level 2 inputs, which include currency spot rates, forward rates, interest rate curve and credit or non-performance risk (Note 7). We do not have any non-financial assets or liabilities that should be recognized or disclosed at fair value on a recurring basis at December 31, 2021, 2020, and 2019.

We maintained letters of credit of $12 million as of December 31, 2021 and 2020, related to our lease arrangements, which are secured by money market accounts in accordance with certain of our lease agreements. The amounts are recorded at fair value using Level 1 inputs and included as restricted cash in our consolidated balance sheets.

Inventory

Inventory is recorded at the lower of cost or net realizable value, with cost determined using first-in, first-out and average cost methods for different components of inventory. We periodically review the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the decline in value is first recognized through a charge to cost of sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. The determination of net realizable value requires judgment including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions and potential product obsolescence, among others.

Prior to an initial regulatory approval for our investigational medicines, we expense costs relating to raw materials and production of inventory as research and development expense in our consolidated statements of operations, in the period incurred. Upon the authorization of distribution and use of our COVID-19 vaccine under an EUA in December 2020, we began to capitalize inventory costs associated with our COVID-19 vaccine, as it was determined that inventory costs incurred subsequent to the EUA had a probable future economic benefit.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of property and equipment are described below:

	Estimated Useful Life
Laboratory equipment	5 years
Leasehold improvements	Lesser of estimated useful life of improvement or remaining life of related lease
Computer equipment and software	3 years
Internally developed software	3 years
Furniture, fixtures and other	5 years
Right of use asset, financing	Lease term

Construction in progress includes direct costs related to the construction of various property and equipment, including leasehold improvements, and is stated at original cost. Construction in progress includes costs incurred under construction contracts including project management services, engineering services, design services and development, construction services and other construction-related fees and services. Such costs are not depreciated until the asset is completed and placed into service. Once the asset is placed into service, these capitalized costs will be allocated to certain property and equipment categories and will be depreciated over the estimated useful life of the underlying assets.

Expenditures for maintenance and repairs are charged to expense as incurred. Upon retirement or sale, the cost of the assets disposed of, and the related accumulated depreciation, are removed from the accounts, and any resulting gain or loss is recorded to other expense, net in our consolidated statements of operations.

Impairment of Long-Lived Assets

We evaluate our long-lived assets, which consist of property and equipment, to determine if facts and circumstances indicate that the carrying amount of assets may not be recoverable. If such facts and circumstances exist, we assess the recoverability of the long-lived assets by comparing the projected future undiscounted net cash flows associated with the related asset or group of assets over their remaining lives against their respective carrying amounts. If such review indicates that such cash flows are not expected to be sufficient to recover the recorded value of the assets, the assets are written down to their estimated fair values based on the expected discounted future cash flows attributable to the assets or based on appraisals. Impairment expenses for the years ended December 31, 2021, 2020 and 2019 were immaterial.

Leases

Leases are classified at their commencement date, which is defined as the date on which the lessor makes the underlying asset available for use by the lessee, as either operating or finance leases based on the economic substance of the agreement. We recognize lease right-of-use assets and related liabilities in our consolidated balance sheets for both operating and finance leases. Lease liabilities are measured at the lease commencement date as the present value of the future lease payments using the interest rate implicit in the lease. If the rate implicit is not readily determinable, we will utilize our incremental borrowing rate as of the lease commencement date. Lease right-of-use assets are measured as the lease liability plus initial direct costs and prepaid lease payments less lease incentives. The lease term is the non-cancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised.

We recognize operating lease cost in operating expenses in our consolidated statements of operations, inclusive of rent escalation provisions and rent holidays, on a straight-line basis over the respective lease term. For our finance leases, we recognize depreciation expense associated with the leased asset acquired and recognize interest expense related to the portion of the financing in our consolidated statements of operations.

We do not separate non-lease components from lease components for all classes of underlying assets. We do not recognize right-of-use assets and lease liabilities for leases with a lease term of 12 months or less. Instead, these lease payments are recognized in profit or loss on a straight-line basis over the lease term.

Cost of Sales

Cost of sales includes cost of raw materials, production, transportation, freight and indirect overhead costs associated with our product sales during the period and third-party royalties on net sales of our product. Cost of sales also includes adjustments for excess and obsolete inventory to the extent management determines that the cost cannot be recovered based on estimates about future demand.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, overhead costs, contract services, and other outside costs. The value of goods and services received from contract research organizations and contract manufacturing organizations in the reporting period are estimated based on the level of services performed, and progress in the period in cases when we have not received an invoice from the supplier.

Equipment or facilities that are acquired or constructed for research and development activities and that have alternative future uses, in research and development projects or otherwise, should be capitalized and depreciated as tangible assets. However, the costs of equipment or facilities that are acquired or constructed and intangibles that are purchased from others for a particular research and development project and that have no alternative future uses and therefore no separate economic values are considered research and development costs and are expensed when incurred.

Stock-Based Compensation

We issue stock-based awards to employees and non-employees, generally in the form of stock options, restricted stock units (RSUs), and performance stock units (PSUs). We account for our stock-based compensation awards in accordance with ASC 718 *(Compensation—Stock Compensation)*. Most of our stock-based awards have been made to employees. We measure compensation cost for equity awards at their grant-date fair value and recognize compensation expense over the requisite service period, which is generally the vesting period, on a straight-line basis. The grant date fair value of stock options is estimated using the Black-Scholes option pricing model, which requires management to make assumptions with respect to the fair value of our common stock on the grant date, including the expected term of the award, the expected volatility of our stock, calculated based on a period of time generally commensurate with the expected term of the award, risk-free interest rates and expected dividend yields of our stock. The grant date fair value of RSUs is estimated based on the fair value of our underlying common stock. For performance-based stock awards, we recognize stock-based compensation expense over the requisite service period using the accelerated attribution method when achievement is probable. We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified. We made an accounting policy election to recognize forfeitures of stock-based awards as they occur.

Income Taxes

We account for income taxes based on an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided when the expected realization of deferred tax assets does not meet a "more likely than not" criterion. We make estimates and judgments about our future taxable income that are based on assumptions that are consistent with our plans and estimates. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted. Changes in these estimates may result in significant increases or decreases to our tax provision in a period in which such estimates are changed, which in turn would affect net income or loss. We recognize tax benefits from uncertain tax positions if we believe the position is more likely than not to be sustained on examination by the taxing authorities based on the technical merits of the position. We make adjustments to these tax reserves when facts and circumstances change, such as the closing of a tax audit or the refinement of an estimate. The provision for income taxes includes the effects of any reserves for uncertain tax positions, as well as the related net interest and penalties.

Earnings (Loss) per Share

We calculate diluted net earnings (loss) per share attributable to common stockholders by dividing net earnings (loss) by the weighted average number of common shares outstanding after giving consideration to the dilutive effect of restricted common stock and stock options that are outstanding during the period. For periods in which we have generated a net loss, the basic and diluted net loss per share attributable to common stockholders are the same, as the inclusion of the potentially dilutive securities would be anti-dilutive.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net income (loss) and other comprehensive income (loss) for the period. Other comprehensive income (loss) consists of unrealized gains and losses on our investments and derivatives designated as hedging instruments. Total comprehensive income (loss) for all periods presented has been disclosed in the consolidated statements of comprehensive income (loss).

The components of accumulated other comprehensive (loss) income for the years ended December 31, 2021 and 2020 were as follows (in millions):

	Unrealized Gain (Loss) on Available-for-Sale Debt Securities	Net Unrealized Gains on Derivatives Designated As Hedging Instruments	Total
Accumulated other comprehensive income, balance at December 31, 2019	$ 2	$ —	$ 2
Other comprehensive income	1	—	1
Accumulated other comprehensive income, balance at December 31, 2020	3	—	3
Other comprehensive loss	(43)	16	(27)
Accumulated other comprehensive loss, balance at December 31, 2021	$ (40)	$ 16	$ (24)

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial statements and disclosures.

3. Product Sales

Product sales are primarily associated with our COVID-19 vaccine supply agreements with the U.S. Government, other international governments, Gavi (on behalf of the COVAX Facility), and the African Union.

Product sales by customer geographic location was as follows (in millions):

	Year Ended December 31,	
	2021	2020
United States	$ 5,393	$ 194
Europe	6,834	—
Rest of world [1]	5,448	6
Total	$ 17,675	$ 200

[1] Includes product sales recognized under the agreement with Gavi as Gavi facilitates a fair allocation and distribution of our COVID-19 vaccine around the world.

There were no product sales in 2019. As of December 31, 2021 and 2020, our COVID-19 vaccine was our only commercial product authorized for use.

As of December 31, 2021 and 2020, we had deferred revenue of $6.7 billion and $3.8 billion, respectively, related to customer deposits. We expect $6.2 billion of our deferred revenue related to customer deposits as of December 31, 2021 to be realized in less than one year. Timing of product manufacturing, delivery and receipt of marketing approval will determine the period in which revenue is recognized.

4. Grant Revenue

In September 2020, we entered into an agreement with the DARPA for an award of up to $56 million to fund development of a mobile manufacturing prototype leveraging our existing manufacturing technology that is capable of rapidly producing vaccines and therapeutics. As of December 31, 2021, the committed funding, net of revenue earned was $2 million. An additional $42 million of funding will be available if DARPA exercises additional contract options.

In April 2020, we entered into an agreement with BARDA for an award of up to $483 million to accelerate development of mRNA-1273, our vaccine candidate against COVID-19. In July 2020, we amended our agreement with BARDA to provide for an additional commitment of up to $472 million to support late-stage clinical development of mRNA-1273, including the execution of a 30,000 participant Phase 3 study in the U.S. We further amended the agreement in March 2021 to provide for an additional commitment of $63 million to further support late-stage clinical development, including Phase 2/3 mRNA-1273 pediatric studies. In April 2021, we entered into a further amendment to the BARDA agreement, increasing the amount of potential reimbursements by $236 million in connection with costs associated with the Phase 3 clinical trials for mRNA-1273 and pharmacovigilance efforts. In June 2021, the agreement with BARDA was further amended to award additional funding of $144 million to support pediatric clinical trials for mRNA-1273. The maximum award from BARDA, inclusive of the 2020 and 2021 amendments, was $1.4 billion. Under the terms of the agreement, BARDA will fund the advancement of mRNA-1273 to FDA licensure. All contract options have been exercised. As of December 31, 2021, the remaining available funding, net of revenue earned was $189 million.

In September 2016, we received from BARDA an award of up to $126 million, subsequently adjusted to $117 million in 2021, to help fund our Zika vaccine program. Three of the four contract options have been exercised. As of December 31, 2021, the remaining available funding, net of revenue earned was $48 million, with an additional $8 million available if the final contract option is exercised.

In January 2016, we entered a global health project framework agreement with the Gates Foundation to advance mRNA-based development projects for various infectious diseases, including human immunodeficiency virus (HIV). As of December 31, 2021, the

available funding, net of revenue earned was $7 million, with up to an additional $80 million available if additional follow-on projects are approved.

The following table summarizes grant revenue for the periods presented (in millions):

	Years Ended		
	2021	2020	2019
BARDA	$ 713	$ 522	$ 8
Other grant revenue	22	7	4
Total grant revenue	$ 735	$ 529	$ 12

5. Collaboration Agreements

AstraZeneca – Strategic Alliances in Cardiovascular and Oncology

2013 Option Agreement and Services and Collaboration Agreement, amended and restated in 2018

In March 2013, we entered into an Option Agreement, the AZ Option Agreement, and a related Services and Collaboration Agreement (2013 AZ Agreements), the AZ Services Agreement, with AstraZeneca, which were amended and restated in June 2018 (2018 A&R Agreements). Under the 2018 A&R Agreements, we granted AstraZeneca certain exclusive rights and licenses, and options to obtain exclusive rights to develop and commercialize potential therapeutic mRNA medicines directed at certain targets for the treatment of cardiovascular and cardiometabolic diseases and cancer, and agreed to provide related services to AstraZeneca. The activities to be performed by the parties under the 2018 A&R Agreements are limited to defined biological targets in the cardiovascular and cardiometabolic fields and one defined target in the cancer field.

As of the effective date of the 2013 AZ Agreements, AstraZeneca made upfront cash payments to us totaling $240 million in exchange for the acquired options and our performance of certain research-related services, each as described above. Under the 2018 A&R Agreements, we are entitled to receive, on a product-by-product basis, payments for achievement of certain development, regulatory and commercial milestones, as well as earn-out payments on worldwide net sales of products ranging from a high-single digit percentage to 12%, subject to certain reductions, with an aggregate minimum floor.

In 2016, AstraZeneca exercised a product option under the 2013 AZ Agreements to obtain exclusive rights to develop and commercialize with respect to AstraZeneca's VEGF-A product (AZD8601). It is currently being developed in a Phase 2 clinical trial.

2016 Strategic Alliance with AstraZeneca – IL-12

In January 2016, we entered into a Strategic Drug Development Collaboration and License Agreement (2016 AZ Agreement) with AstraZeneca to discover, develop and commercialize potential mRNA medicines for the treatment of a range of cancers. Under the terms of the 2016 AZ Agreement, we and AstraZeneca have agreed to work together on an immuno-oncology program focused on the intratumoral delivery of a potential mRNA medicine to make the IL-12 protein. During a limited period of time, each party had an opportunity to propose additional discovery programs to be conducted under the 2016 AZ Agreement. We are responsible for conducting and funding all discovery and preclinical development activities under the 2016 AZ Agreement in accordance with an agreed upon discovery program plan for the IL-12 program and any other discovery program the parties agree to conduct under the 2016 AZ Agreement.

Merck – Strategic Alliances in Infectious Diseases and Cancer Vaccines

2016 Cancer Vaccine Strategic Alliance-Personalized mRNA Cancer Vaccines

In June 2016, we entered into a personalized mRNA cancer vaccines (PCV) Collaboration and License Agreement with Merck (PCV Agreement), to develop and commercialize PCVs for individual patients using our mRNA vaccine and formulation technology. Under the strategic alliance, we identify genetic mutations present in a particular patient’s tumor cells, synthesize mRNA for these mutations, encapsulate the mRNA in one of our proprietary LNPs and administer to each patient a unique mRNA cancer vaccine designed to specifically activate the patient’s immune system against her or his own cancer cells.

Pursuant to the PCV Agreement, we are responsible for designing and researching PCVs, providing manufacturing capacity and manufacturing PCVs, and conducting Phase 1 and Phase 2 clinical trials for PCVs, alone and in combination with KEYTRUDA (pembrolizumab), Merck’s anti-PD-1 therapy, all in accordance with an agreed upon development plan and budget and under the

oversight of a committee comprised of equal representatives of each party. The parties have entered into a clinical quality agreement with respect to Moderna's manufacture and supply activities. We received an upfront payment of $200 million from Merck.

2018 Expansion of the Cancer Vaccine Strategic Alliance-Shared Neoepitope Cancer Vaccines

In April 2018, we and Merck agreed to expand our cancer vaccine strategic alliance to include the development and commercialization of our KRAS vaccine development candidate, mRNA-5671 or V941, and potentially other shared neoantigen mRNA cancer vaccines (SAVs). We preclinically developed mRNA-5671 prior to its inclusion in the cancer vaccine strategic alliance and it is comprised of a novel mRNA construct designed by us and encapsulated in one of our proprietary LNPs. The PCV Agreement was amended and restated to include the new SAV strategic alliance (PCV/SAV Agreement).

We have granted Merck certain licenses and we and Merck have agreed to certain exclusivity obligations with respect to SAVs and particular SAV programs, which obligations are subject to termination or expiration upon certain triggering events. Under the PCV/SAV Agreement, Merck will be responsible for conducting Phase 1 and Phase 2 clinical trials for mRNA-5671 and for all costs associated with such activities, in accordance with a jointly agreed development plan and budget, and we will be responsible for manufacturing and supplying all mRNA-5671 required to conduct such trials and for all costs and expenses associated with such manufacture and supply. Under the PCV/SAV Agreement, our budgeted commitment for PCV increased to $243 million. Until the expiration of a defined period of time following the completion of Phase 1 and Phase 2 clinical trials for mRNA-5671 under the PCV/SAV Agreement and our delivery of an associated data package to Merck, Merck has the right to elect to participate in future development and commercialization of mRNA-5671 by making a participation payment to us. In connection with the amendment of the PCV Agreement to include the development and commercialization of mRNA-5671 and potentially other SAVs, Merck made a contemporaneous equity investment in our Series H redeemable convertible preferred stock, resulting in gross proceeds of $125 million, of which $13 million was determined to be a premium and recorded to deferred revenue. In December 2021, Merck elected to terminate the Merck participation election with respect to the joint SAV program.

Vertex – Strategic Alliance in Cystic Fibrosis

2016 Strategic Alliance in Cystic Fibrosis

In July 2016, we entered into a Strategic Collaboration and License Agreement (Vertex Agreement), with Vertex Pharmaceuticals Incorporated, and Vertex Pharmaceuticals (Europe) Limited, together, Vertex. The Vertex Agreement, which was amended in July 2019 (2019 Vertex Amendment), is aimed at the discovery and development of potential mRNA medicines for the treatment of cystic fibrosis (CF) by enabling cells in the lungs of people with CF to produce functional cystic fibrosis transmembrane conductance regulator (CFTR) proteins. Pursuant to the Vertex Agreement, we lead discovery efforts during an initial research period that currently extends until August 2022, leveraging our Platform technology and mRNA delivery expertise along with Vertex's scientific experience in CF biology and the functional understanding of CFTR. Vertex is responsible for conducting development and commercialization activities for candidates and products that arise from the strategic alliance, including the costs associated with such activities. Subject to customary "back-up" supply rights granted to Vertex, we exclusively manufacture (or have manufactured) mRNA for preclinical, clinical and commercialization purposes.

2020 Strategic Alliance in Cystic Fibrosis

In September 2020, we entered into a new Strategic Collaboration and License Agreement with Vertex (Vertex 2020 Agreement). The Vertex 2020 Agreement is aimed at the discovery and development of potential medicines to treat CF by delivering gene-editing therapies to lung cells to facilitate production of functional CFTR proteins. The three-year research period of the Vertex 2020 Agreement will initially focus on the identification and optimization of novel LNPs and mRNAs that can deliver gene-editing therapies to cells in the lungs. Following the initial three-year period, Vertex is responsible for conducting development and commercialization activities for candidates and products that arise from the strategic alliance, including the costs associated with such activities. Vertex is also obligated to pay us for research services in connection with our performance of certain activities in accordance with a jointly agreed research plan. Subject to customary "back-up" supply rights granted to Vertex, under the agreement, we are the exclusive manufacturer of related mRNA and LNPs for preclinical, clinical, and commercialization purposes.

The following table summarizes our total consolidated net revenue from our strategic collaborators for the periods presented (in millions):

	Years Ended December 31,		
Collaboration Revenue by Strategic Collaborator:	**2021**	**2020**	**2019**
AstraZeneca	$ 7	$ 33	$ 5
Merck	23	26	37
Vertex	26	15	6
Other	5	—	—
Total collaboration revenue	$ 61	$ 74	$ 48

The following table presents changes in the balances of our receivables and contract liabilities related to our strategic collaboration agreements during the year ended December 31, 2021 (in millions):

	December 31, 2020	**Additions**	**Deductions**	**December 31, 2021**
Contract Assets:				
Accounts receivable	$ 6	$ 26	$ (23)	$ 9
Contract Liabilities:				
Deferred revenue	$ 240	$ 27	$ (63)	$ 204

As of December 31, 2021, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was $286 million.

In addition to the collaborative arrangements mentioned above, we have other collaborative and licensing arrangements that we do not consider to be individually significant to our business at this time. Pursuant to these agreements, we may be required to make upfront payments and payments upon achievement of various development, regulatory and commercial milestones, which in the aggregate could be significant. Future milestone payments, if any, will be reflected in our consolidated financial statements when the corresponding events become probable. In addition, we may be required to pay significant royalties on future sales if products related to these arrangements are commercialized.

6. Financial Instruments and Fair Value Measurements

Cash and Cash Equivalents and Investments

The following tables summarize our cash and available-for-sale securities by significant investment category at December 31, 2021 and 2020 (in millions):

	December 31, 2021						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 6,848	$ —	$ —	$ 6,848	$ 6,848	$ —	$ —
Available-for-sale:							
Certificates of deposit	80	—	—	80	—	80	—
U.S. treasury bills	479	—	—	479	—	479	—
U.S. treasury notes	6,595	—	(31)	6,564	—	1,984	4,580
Corporate debt securities	3,508	—	(20)	3,488	—	1,323	2,165
Government debt securities	112	—	(1)	111	—	13	98
Total	$ 17,622	$ —	$ (52)	$ 17,570	$ 6,848	$ 3,879	$ 6,843

	December 31, 2020						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 2,624	$ —	$ —	$ 2,624	$ 2,624	$ —	$ —
Available-for-sale:							
Certificates of deposit	239	—	—	239	—	215	24
U.S. treasury bills	492	—	—	492	—	492	—
U.S. treasury notes	87	—	—	87	—	38	49
Corporate debt securities	1,788	4	—	1,792	—	1,239	553
Government debt securities	13	—	—	13	—	—	13
Total	$ 5,243	$ 4	$ —	$ 5,247	$ 2,624	$ 1,984	$ 639

The amortized cost and estimated fair value of marketable securities, by contractual maturity at December 31, 2021 and 2020 were as follows (in millions):

	December 31, 2021	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 3,882	$ 3,879
Due after one year through five years	6,892	6,843
Total	$ 10,774	$ 10,722

	December 31, 2020	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 1,981	$ 1,984
Due after one year through five years	638	639
Total	$ 2,619	$ 2,623

In accordance with our investment policy, we place investments in investment grade securities with high credit quality issuers, and generally limit the amount of credit exposure to any one issuer. We evaluate securities for impairment at the end of each reporting period. We did not record any impairment charges related to our available-for-sale securities during the years ended December 31, 2021, 2020, and 2019. We did not recognize any credit-related allowance to available-for-sale securities as of the years ended December 31, 2021 and 2020.

The following table summarizes the amount of gross unrealized losses and the estimated fair value for our available-for-sale securities in an unrealized loss position by length of time the securities have been in an unrealized loss position at December 31, 2021 (in millions):

	Less than 12 Months		12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2021:						
U.S. treasury bills	$ —	$ 329	$ —	$ —	$ —	$ 329
U.S. treasury notes	(31)	6,332	—	—	(31)	6,332
Corporate debt securities	(20)	2,573	—	1	(20)	2,574
Government debt securities	(1)	112	—	—	(1)	112
Total	$ (52)	$ 9,346	$ —	$ 1	$ (52)	$ 9,347

As of December 31, 2020, we did not have material gross unrealized losses. We neither intend to sell these investments nor conclude that we are more-likely-than-not that we will have to sell them before recovery of their carrying values. We also believe that we will be able to collect both principal and interest amounts due to us at maturity.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following tables summarize our financial assets measured at fair value on a recurring basis as of December 31, 2021 and 2020 (in millions):

	Fair value at December 31, 2021	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 2,329	$ 2,329	$ —
Certificates of deposit	80	—	80
U.S. treasury bills	479	—	479
U.S. treasury notes	6,564	—	6,564
Corporate debt securities	3,488	—	3,488
Government debt securities	111	—	111
Derivative instruments (Note 7)	21	—	21
Total	$ 13,072	$ 2,329	$ 10,743
Liabilities:			
Derivative instruments (Note 7)	$ 7	$ —	$ 7

	Fair value at December 31, 2020	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 660	$ 660	$ —
Certificates of deposit	239	—	239
U.S. treasury bills	492	—	492
U.S. treasury notes	87	—	87
Corporate debt securities	1,792	—	1,792
Government debt securities	13	—	13
Total	$ 3,283	$ 660	$ 2,623

During the years ended December 31, 2021 and 2020, we did not have non-financial assets or liabilities measured at fair value on a recurring basis.

7. Derivative Financial Instruments

We transact business in various foreign currencies and have international sales and expenses denominated in foreign currencies. Therefore, we are exposed to certain risks arising from both our business operations and economic conditions. Our risk management strategy includes the use of derivative financial instruments to hedge foreign currency exchange rate fluctuations on monetary assets or liabilities denominated in foreign currencies. We do not enter into derivative financial contracts for speculative or trading purposes. We do not believe that we are exposed to more than a nominal amount of credit risk in our foreign currency hedges, as counterparties are large, global and well-capitalized financial institutions. We classify cash flows from our derivative transactions as cash flows from operating activities in our consolidated statements of cash flows.

Cash Flow Hedges

We mitigate the foreign exchange risk arising from the fluctuations in foreign currency denominated product sales in Euro through a foreign currency cash flow hedging program, using forward contracts and foreign currency options that do not exceed 15 months in duration. We hedge these cash flow exposures to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. To receive hedge accounting treatment, all hedging relationships are formally documented at the inception of the hedge, and the hedges must be highly effective in offsetting changes to future cash flows on hedged transactions. The derivative assets or liabilities associated with our hedging activities are recorded at fair value in other current assets or other current liabilities, respectively, in our consolidated balance sheets. The gains or losses resulting from changes in the fair value of these hedges are initially recorded as a component of AOCI in stockholders' equity and subsequently reclassified to product sales in the period during which the hedged transaction affects earnings. In the event the underlying forecasted transaction does not occur, or it becomes

probable that it will not occur, within the defined hedge period, we reclassify the gains or losses on the related cash flow hedge from AOCI to other expense, net, in our consolidated statements of operations. We evaluate hedge effectiveness at the inception of the hedge prospectively, and on an on-going basis both retrospectively and prospectively. If we do not elect hedge accounting, or the contract does not qualify for hedge accounting treatment, the changes in fair value from period to period are recorded as a component of other expense, net, in our consolidated statements of operations. As of December 31, 2021, we had net deferred gains of $21 million on our foreign currency forward contracts included in AOCI that are expected to be recognized into product sales within the next 12 months.

Balance Sheet Hedges

We enter into foreign currency forward contracts to hedge fluctuations associated with foreign currency denominated monetary assets and liabilities, primarily accounts receivable, accounts payable, and lease liabilities in Euro and Swiss Franc, that are not designated for hedge accounting treatment. Therefore, these forward contracts are accounted for as derivatives whereby the fair value of the contracts are reported as other current assets or other current liabilities on our consolidated balance sheets, and gains and losses resulting from changes in the fair value are recorded as a component of other expense, net, in our consolidated statements of operations. The gains and losses on these foreign currency forward contracts generally offset the gains and losses in the underlying foreign currency denominated assets and liabilities, which are also recorded to other expense, net, in our consolidated statements of operations.

Total gross notional amount and fair value for foreign currency derivatives were as follows (in millions):

	December 31, 2021		
		Fair Value	
	Notional Amount	Asset [1]	Liability [2]
Derivatives designated as cash flow hedging instruments:			
Foreign currency forward contracts	$ 565	$ 20	$ —
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	1,370	1	7
Total derivatives	$ 1,935	$ 21	$ 7

	December 31, 2020		
		Fair Value	
	Notional Amount	Asset [1]	Liability [2]
Derivatives not designated as hedging instruments			
Foreign currency forward contracts	$ 368	$ —	$ —
Total	$ 368	$ —	$ —

[1] As presented in the consolidated balance sheet within prepaid expenses and other current assets.
[2] As presented in the consolidated balance sheets within other current liabilities.

Gains on our foreign currency derivatives, net of tax, recognized in our consolidated statements of comprehensive income (loss) for the year ended December 31, 2021 was as follows (in millions):

	Year Ended December 31, 2021
Derivatives in cash flow hedging relationships:	
Foreign currency forward contracts	$ 74

The effect of derivative instruments in our consolidated statements of operations for the year ended December 31, 2021 was as follows (in millions):

	Statement of Operations Classification	Year Ended December 31, 2021
Derivatives in cash flow hedging relationships:		
Foreign currency forward contracts		
Net gains reclassified from AOCI into income	Product sales	$ 58
Derivatives not designated as hedging instruments:		
Foreign currency forward contracts		
Net realized and unrealized (losses)	Other expense, net	$ (8)

There were immaterial hedging gains and losses for the year ended December 31, 2020 and no hedging gains or losses for the year ended December 31, 2019.

8. Inventory

Inventory as of December 31, 2021 and 2020 consisted of the following (in millions):

	December 31, 2021	December 31, 2020
Raw materials	$ 870	$ 37
Work in progress	338	9
Finished goods	233	1
Total inventory	$ 1,441	$ 47

9. Property and Equipment

Property and equipment, net as of December 31, 2021 and 2020 consisted of the following (in millions):

	December 31,	
	2021	2020
Laboratory equipment	$ 175	$ 121
Leasehold improvements	313	180
Furniture, fixtures and other	11	5
Computer equipment and software	16	13
Internally developed software	9	7
Right-of-use asset, financing	857	56
Construction in progress	212	35
	1,593	417
Less: Accumulated depreciation	(352)	(120)
Property and equipment, net	$ 1,241	$ 297

Depreciation and amortization expense for the years ended December 31, 2021, 2020, and 2019 was $232 million, $31 million, and $31 million, respectively.

10. Other Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of December 31, 2021 and 2020 consisted of the following (in millions):

	December 31,	
	2021	2020
Down payments to manufacturing vendors	$ 405	$ 217
Other prepaid expenses	126	7
Value added tax receivable	70	7
Derivative assets	21	—
Tenant improvement allowance receivable	51	10
Other current assets	55	11
Prepaid expenses and other current assets	$ 728	$ 252

Accrued Liabilities

Accrued liabilities, as of December 31, 2021 and 2020 consisted of the following (in millions):

	December 31,	
	2021	2020
Clinical trials	$ 283	$ 98
Raw materials	260	78
Royalties	241	—
Development operations	137	29
Manufacturing	227	53
Other external goods and services	79	92
Compensation-related	126	95
Other	119	25
Accrued liabilities	$ 1,472	$ 470

Other Current Liabilities

Other current liabilities, as of December 31, 2021 and 2020 consisted of the following (in millions):

	December 31,	
	2021	2020
Lease liabilities - financing (Note 11)	$ 165	$ 24
Lease liabilities - operating (Note 11)	46	6
Other	14	4
Other current liabilities	$ 225	$ 34

Deferred Revenue

The following table summarizes the activities in deferred revenue during the year ended December 31, 2021 (in millions):

	December 31, 2020	Additions	Deductions	December 31, 2021
Product sales	$ 3,799	$ 11,657	$ (8,798)	$ 6,658
Grant revenue	5	12	(11)	6
Collaboration revenue	240	27	(63)	204
Total deferred liabilities	$ 4,044	$ 11,696	$ (8,872)	$ 6,868

11. Leases

We have entered into various long-term non-cancelable lease arrangements for our facilities and equipment expiring at various times through 2042. Certain of these arrangements have free rent periods or escalating rent payment provisions, which we recognize lease cost under such arrangements on a straight-line basis over the life of the leases. We have two campuses in Massachusetts, our Cambridge campus and our Moderna Technology Center (MTC), located in Norwood. We also lease other office and lab spaces globally for our business operations.

Operating Leases

Cambridge Campus

We occupy a multi-building campus at Technology Square in Cambridge, Massachusetts with a mix of offices and research laboratory space totaling approximately 261,000 square feet. Our Cambridge campus leases have expiry ranges from 2024 to 2029.

In August 2019, we entered into an amendment to our lease agreements to consolidate our Technology Square space in Cambridge, Massachusetts. This included entering into a forward-starting lease agreement starting in January 2020 to acquire approximately 50,000 square feet of additional space at 200 Technology Square. In addition, our existing 200 Technology Square lease was extended for two years to 2029. As part of the lease amendment, we completely exited our leased space of approximately 60,000 square feet at 500 Technology Square by May 2020. We are also investing in a new Moderna Science Center (MSC) in Cambridge, to create a purpose-built space to support our next chapter of discovery (see Note 12). In connection with our MSC investment, in September 2021, we entered into an amendment to our lease agreements to allow for an option for early termination of the leases, either in part or full. Notification of the intent to exercise the option must be provided by August 2023. We have not elected to exercise this option.

We record operating lease cost for each of our operating leases on a straight-line basis from lease commencement date through the end of the lease term. Operating lease cost is recorded in operating expenses in our consolidated statements of operations.

Finance Leases

Moderna Technology Center

We have an industrial technology center in Norwood, Massachusetts, our Moderna Technology Center (MTC), which comprises three buildings, MTC South, MTC North, and MTC East.

In August 2016, we entered into a lease agreement for approximately 200,000 square feet of office, laboratory, and light manufacturing space (MTC South). The lease had an initial expiration of September 2032 with the option to extend the term for two extension periods of ten years each at market-based rents.

In February 2019, we entered into a lease agreement for office and laboratory space of approximately 200,000 square feet (MTC North). The lease commenced in the second quarter of 2019 and had an initial expiration date of 2031 with the option to extend the lease for up to four additional five-year terms. In May 2020, we entered into an amendment to the lease whereby we exercised an option available in the original lease to receive a tenant improvement allowance in the amount of $22 million to be paid back over the term of the lease with interest and extend the term of the lease to 2035.

In April 2021, we entered into a lease agreement for a 240,000 square foot building for expansion of our commercial and clinical activities (MTC East). The lease had an initial expiration date of February 2034 with the option to extend the term for two extension periods of five years each at market-based rents.

In December 2021, we entered into an omnibus amendment to extend the lease terms of our three MTC leases to 2042. We have the option to extend the term for three extension periods of five years. The base rent is subject to increases over the term of the lease.

Embedded Leases

We have entered into multiple contract manufacturing service agreements with third parties which contain embedded leases within the scope of ASC 842. As of December 31, 2021 and 2020, we had lease liabilities of $166 million and $24 million, respectively, related to the embedded leases. Certain embedded leases dedicated to our COVID-19 vaccine program prior to the EUA from the FDA were deemed to have no alternative use. The related right-of-use assets of $62 million were charged to research and development expense for the year ended December 31, 2020.

Operating and financing lease right-of-use assets and lease liabilities as of December 31, 2021 and 2020 were as follows (in millions):

	December 31,	
	2021	2020
Assets:		
Right-of-use assets, operating, net [1] [2]	$ 142	$ 90
Right-of-use assets, financing, net [3] [4]	665	55
Total	$ 807	$ 145
Liabilities:		
Current:		
Operating lease liabilities [5]	$ 46	$ 6
Financing lease liabilities [5]	165	24
Total current lease liabilities	211	30
Non-current:		
Operating lease liabilities, non-current	106	97
Financing lease liabilities, non-current	599	110
Total non-current lease liabilities	705	207
Total	$ 916	$ 237

[1] These assets are real estate related assets, which include land, office and laboratory spaces.
[2] Net of accumulated amortization.
[3] These assets are real estate assets related to the MTC leases as well as assets related to contract manufacturing service agreements.
[4] Included in property and equipment in the consolidated balance sheets, net of accumulated depreciation.
[5] Included in other current liabilities in the consolidated balance sheets.

The components of the lease costs for the years ended December 31, 2021 and 2020 were as follows (in millions):

	December 31,	
	2021	2020
Operating lease costs	$ 24	$ 17
Financing lease costs:		
Amortization of right-of-use assets, financing leases	189	1
Interest expense for financing lease liabilities	17	10
Total financing lease costs	$ 206	$ 11
Short term lease costs	$ 49	$ 13
Variable lease costs	$ 100	$ 5

Supplemental cash flow information relating to our leases for the years ended December 31, 2021 and 2020 was as follows (in millions):

	December 31,	
	2021	2020
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows used in operating leases	$ (19)	$ (15)
Operating cash flows used in financing leases	(14)	(9)
Financing cash flows used in financing leases	(140)	(8)
Operating lease non-cash items:		
Changes in right-of-use assets related to lease modifications and reassessments	$ (7)	$ 7
Right-of-use assets obtained in exchange for operating lease liabilities	72	17
Finance lease non-cash items:		
Changes in right-of-use assets related to lease modifications and reassessments	$ 674	$ 46
Right-of-use assets obtained in exchange for financing lease liabilities	126	—
Changes in financing lease liabilities	3	1

Weighted average remaining lease terms and discount rates as of December 31, 2021 were as follows:

	December 31,
	2021
Remaining lease term:	
Operating leases	5 years
Finance leases	28 years
Discount rate:	
Operating leases	6.8 %
Finance leases	3.1 %

Future minimum lease payments under non-cancelable lease agreements as of December 31, 2021, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases [1]
2022	$ 54	$ 184
2023	39	20
2024	15	20
2025	16	20
2026	16	21
Thereafter	51	1,058
Total minimum lease payments	191	1,323
Less amounts representing interest	(39)	(559)
Present value of lease liabilities	$ 152	$ 764

[1] Include the optional extensions in the MTC lease terms which represent a total of $637 million undiscounted future lease payments.

12. Commitments and Contingencies

Legal Proceedings

We are not currently a party to any material legal proceedings.

Indemnification Obligations

As permitted under Delaware law, we indemnify our officers, directors, and employees for certain events, occurrences while the officer, or director is, or was, serving at our request in such capacity. The term of the indemnification is for the officer's or director's lifetime.

We have standard indemnification arrangements in our leases for laboratory and office space that require us to indemnify the landlord against any liability for injury, loss, accident, or damage from any claims, actions, proceedings, or costs resulting from certain acts, breaches, violations, or non-performance under our leases.

We enter into indemnification provisions under our agreements with counterparties in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited.

Through December 31, 2021 and 2020, we had not experienced any losses related to these indemnification obligations, and no material claims were outstanding. We do not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Purchase Commitments and Purchase Orders

We enter into agreements in the normal course of business with vendors and contract manufacturing organizations (CMOs) for raw materials and manufacturing services and with vendors for preclinical research studies, clinical trials and other goods or services. As of December 31, 2021, we had $2.5 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2025. As of December 31, 2021, we had $89 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2026. These amounts represent our minimum contractual obligations, including termination fees.

In addition to purchase commitments, we have agreements with third parties for various services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At December 31, 2021, we had cancelable open purchase orders of $2.4 billion in total under such agreements for our significant clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at December 31, 2021, assuming we would not cancel these agreements. The actual amounts we pay in the future to the vendors under such agreements may differ from the purchase order amounts.

Licenses to Patented Technology

On June 26, 2017, we entered into sublicense agreements with Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc. to sublicense certain patent rights. Pursuant to each agreement, we are required to pay certain license fees, annual maintenance fees, minimum royalties on future net sales and milestone payments contingent on achievement of certain development, regulatory and commercial milestones for specified products, on a product-by-product basis. Commercial milestone payments, up to $24 million, and royalties based on annual net sales of licensed products for therapeutic and prophylactic products are accounted for as additional expense of the related product sales in the period in which the corresponding sales occur. In 2021 and 2020, we recognized $641 million and $7 million, respectively, of royalties and commercial milestone payments associated with our product sales, which was recorded to cost of sales in our consolidated statements of operations. We did not recognize any such royalties and payments in 2019.

Additionally, we have other in-license agreements with third parties which require us to make future development, regulatory and commercial milestone payments for specified products associated with the agreements. The achievement of these milestones was not deemed probable as of December 31, 2021.

Moderna Science Center

In September 2021, we announced an investment in the development of the MSC in Cambridge, Massachusetts. The MSC is expected to integrate scientific and non-scientific spaces, including our principal executive offices, and will be built to support our growth as we continue to advance our pipeline of mRNA medicines. In relation to the investment, we entered into a lease agreement for approximately 462,000 square feet and will undergo an approximately two-year building project. Following completion of the building project, the lease term is 15 years, subject to our right to extend the lease for up to two additional seven-year terms. Pursuant to this lease agreement, we are committed to approximately $1.1 billion non-cancellable rent payments for the initial lease term. We expect to begin a phased move-in process in 2023.

13. Stockholders' Equity

On February 14, 2020, we sold 26,315,790 shares of common stock at a price of $19.00 per share through a public equity offering. The aggregate net proceeds from the offering were $478 million, net of underwriting discounts, commissions and offering expenses. In addition, the underwriters exercised their options to purchase an additional 3,947,368 shares of common stock at the public offering price less underwriting discounts, resulting in additional net proceeds of $72 million.

On May 21, 2020, we sold 17,600,000 shares of common stock at a price of $76.00 per share through a public equity offering. The aggregate net proceeds from the offering were $1.3 billion, net of underwriting discounts, commissions and offering expenses.

14. Stock-Based Compensation

Equity Plans

In August 2016, we adopted the 2016 Stock Option and Grant Plan (the 2016 Equity Plan), which replaced the 2013 Option Plan and the 2013 Incentive Plan. The 2016 Equity Plan and provided for the grant of incentive stock options, non-qualified stock options, restricted stock, unrestricted stock, and restricted stock units to our employees, officers, directors, consultants, and other key persons.

In connection with our initial public offering (IPO), we adopted the 2018 Stock Option and Incentive Plan (the 2018 Equity Plan) in November 2018. The 2018 Equity Plan became effective on the date immediately prior to the effective date of the IPO and replaced our 2016 Plan. The 2018 Equity Plan provides flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce. The 2018 Equity Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Compensation and Talent Committee of our Board of Directors. The Compensation and Talent Committee chose not to increase the number of shares available under the 2018 Plan on January 1, 2021 or January 1, 2022. The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Equity Plan and the 2016 Plan will be added back to the shares of common stock available for issuance under the 2018 Equity Plan.

The terms and conditions of stock-based awards are defined at the sole discretion of our Board of Directors. We issue service-based awards, vesting over a defined period of service, and performance-based awards, vesting upon achievement of defined conditions. Service based awards generally vest over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service. The remaining awards vests in twelve quarterly installments over the following twelve quarters. Stock options granted under the 2018 Equity Plan and the 2016 Equity Plan expire ten years from the date of grant and the exercise price must be at least equal to the fair market value of common stock on the grant date.

As of December 31, 2021, we had a total of 57 million shares reserved for future issuance under our Equity Plans, of which 30 million shares were reserved for equity awards previously granted, and 27 million shares were available for future grants under the 2018 Equity Plan. No additional awards will be granted under the 2016 Equity Plan as it was replaced by the 2018 Equity Plan.

Options

We have granted options generally through the 2018 Equity Plan and 2016 Equity Plan. The following table summarizes our option activity as of December 31, 2021 and 2020:

	Number of Options (in millions)	Weighted Average Exercise Price per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value [1] (in millions)
Outstanding at December 31, 2020	34.06	$ 17.14	6.7 years	$ 2,976
Granted	1.48	209.41		
Exercised	(7.07)	15.84		
Canceled/forfeited	(1.06)	37.46		
Outstanding at December 31, 2021	27.41	27.08	5.8 years	6,247
Exercisable at December 31, 2021	17.33	13.23	4.9 years	4,173
Expected to vest at December 31, 2021	10.08	50.94	7.5 years	2,074

[1] Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of common stock for those options in the money as of December 31, 2021.

The total intrinsic value of options exercised was $1.6 billion, $786 million, and $76 million for the years ended December 31, 2021, 2020, and 2019, respectively. The aggregate intrinsic value represents the difference between the exercise price and the selling price received by option holders upon the exercise of stock options during the period. The excess tax benefits realized from tax deductions from option exercises were $325 million during the year ended December 31, 2021. For the years ended December 31, 2020 and 2019, there were no excess tax benefits realized from tax deductions from option exercises due to cumulative losses and valuation allowances. The total consideration recorded as a result of stock option exercises was approximately $112 million, $179 million, and $48 million for the years ended December 31, 2021, 2020, and 2019.

Restricted Common Stock Units (RSUs) and Performance Stock Units (PSUs)

We have granted RSUs and PSUs generally through the 2018 Equity Plan. The following table summarizes our RSU and PSU activity during the year ended December 31, 2021:

	Number of Units (in millions)	Weighted Average Grant Date Fair Value per Unit
Outstanding, non-vested at December 31, 2020	2.19	$ 30.85
Issued	0.71	210.33
Vested	(0.60)	29.29
Canceled/forfeited	(0.16)	63.72
Outstanding, non-vested at December 31, 2021	2.14	88.55

The total fair value of RSUs and PSUs vested during the years ended December 31, 2021, 2020, and 2019, was $18 million, $5 million, and $5 million, respectively. The total intrinsic value of RSUs and PSUs vested during the years ended December 31, 2021, 2020, and 2019, was $141 million, $14 million and $12 million, respectively.

During the first quarter of 2021, we granted an immaterial amount of PSUs to certain senior executives with vesting that is contingent upon the achievement of specified preestablished goals over the performance period, generally three years. The actual number of common shares ultimately issued is calculated by multiplying the number of PSUs by a payout percentage ranging from 0% to 200%. The estimated fair value of PSUs is based on the grant date fair value.

2018 Employee Stock Purchase Plan

In November 2018, we adopted the 2018 Employee Stock Purchase Plan (ESPP), which became effective on December 5, 2018. We will make one or more offerings, consisting of one or more purchase periods, each year to our eligible employees to purchase shares under the ESPP. Offerings will usually begin every six months and will continue for six-month periods, referred to as offering periods.

The purchase price at which shares are sold under the ESPP will be equal to 85% of the lower of the fair market value of the shares on the first business day of the offering period or the last business day of the purchase period. Employees are generally eligible to participate through payroll deductions of between 1% to 50% of their compensation and may not purchase more than 3,000 shares of common stock during each purchase period or $25,000 worth of shares of common stock in any calendar year. We began our first ESPP offering on June 1, 2019. There were 81,423, 251,752, and 171,343 shares of common stock sold at a weighted average price of $145.90, $27.97, and $16.87 per share under the ESPP during the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, 4 million shares were available for future issuance under the ESPP.

Valuation and Stock-Based Compensation Expense

Stock-based compensation for options granted under our Equity Plans and share purchases under our ESPP is determined using the Black-Scholes option pricing model. The weighted-average assumptions used to estimate the fair value of options granted and ESPP for the years ended December 31, 2021, 2020, and 2019 were as follows:

	Weighted Average Years Ended December 31,		
	2021	2020	2019
Options:			
Risk-free interest rate	0.84 %	0.83 %	2.29 %
Expected term	6.10 years	6.11 years	6.07 years
Expected volatility	46 %	58 %	61 %
Expected dividends	— %	— %	— %
Weighted average fair value per share	$ 91.84	$ 19.30	$ 11.35
ESPP:			
Risk-free interest rate	0.08 %	0.14 %	1.95 %
Expected term	0.50 years	0.50 years	0.50 years
Expected volatility	34 %	54 %	53 %
Expected dividends	— %	— %	— %
Weighted average fair value per share	$ 64.25	$ 32.18	$ 5.98

Stock-Based Compensation Expense

The following table presents the components and classification of stock-based compensation expense for the years ended December 31, 2021, 2020, and 2019 (in millions):

	Years Ended December 31,		
	2021	2020	2019
Options	$ 96	$ 78	$ 75
RSUs and PSUs	42	12	5
ESPP	4	3	1
Total	$ 142	$ 93	$ 81
Cost of sales	$ 22	$ —	$ —
Research and development	68	56	48
Selling, general and administrative	52	37	33
Total	$ 142	$ 93	$ 81

For the years ended December 31, 2021, 2020, and 2019, we recognized stock-based compensation expense of $16 million, $10 million, and $10 million, respectively, related to performance-based awards, including awards with vesting or commencement contingent upon our IPO. Stock-based compensation expenses related to non-employee awards were immaterial for the years ended December 31, 2021, 2020, and 2019.

As of December 31, 2021, there were $349 million of total unrecognized compensation cost related to non-vested stock-based compensation with respect to options, RSUs and PSUs granted. That cost is expected to be recognized over a weighted-average period of 2.9 years at December 31, 2021.

Share Repurchase Program

On August 2, 2021, our Board of Directors authorized a Share Repurchase Program (2021 Repurchase Program) of our common stock, with an expiration date no later than August 2, 2023. Pursuant to the 2021 Repurchase Program, we may repurchase up to $1.0 billion of our outstanding common stock. The timing and actual number of shares repurchased depend on a variety of factors, including price, general business and market conditions, and other investment opportunities, and shares may be repurchased through open market purchases through the use of trading plans intended to qualify under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the Exchange Act).

In the fourth quarter of 2021, we repurchased 3.5 million shares of our common stock under the 2021 Repurchase Program for an aggregate of $857 million, including commissions and fees. As of December 31, 2021, there was a total of $143 million remaining for repurchases of our common stock under the 2021 Repurchase Program.

15. Employee Benefit Plans

We provide a retirement savings option to our eligible U.S. employees through the Moderna, Inc. 401(k) Plan (the 401(k) Plan), subject to certain limitations. As allowed under Section 401(k) of the Internal Revenue Code, the 401(k) Plan allows tax deferred salary deductions for eligible employees. We match 50% up to the first 6% contributed by a participant. All matching contributions are immediately vested. Total matching contributions to the 401(k) Plan were $18 million, $5 million, and $4 million for the years ended December 31, 2021, 2020, and 2019, respectively.

We maintain various defined benefit plans to provide termination and postretirement benefits to certain eligible employees outside of the U.S. The unfunded benefit plan obligations were $9 million as of December 31, 2021, which is recognized in other long-term liabilities in our consolidated balance sheets.

16. Income Taxes

Income (loss) before income taxes for the years ended December 31, 2021, 2020, and 2019 consisted of the following (in millions):

	Years Ended December 31,		
	2021	2020	2019
United States	$ 13,108	$ (745)	$ (509)
Foreign	177	1	(6)
Income (loss) before income taxes	$ 13,285	$ (744)	$ (515)

The provision for (benefit from) income taxes for the years ended December 31, 2021, 2020, and 2019 consisted of the following components (in millions):

	Years Ended December 31,		
	2021	2020	2019
Current:			
Federal	$ 1,304	$ —	$ —
State	35	—	—
Foreign	40	3	—
Total current	$ 1,379	$ 3	$ —
Deferred:			
Federal	$ (288)	$ —	$ (1)
State	(6)	—	—
Foreign	(2)	—	—
Total deferred	(296)	—	(1)
Total provision for (benefit from) income taxes	$ 1,083	$ 3	$ (1)

The reconciliation of the federal statutory income tax rate to our effective tax rate for the years ended December 31, 2021, 2020, and 2019 was as follows:

	Years Ended December 31,		
	2021	2020	2019
Federal statutory tax rate	21.0 %	21.0 %	21.0 %
Change in valuation allowance	(5.4)%	(47.4)%	(33.0)%
Foreign-derived intangible income	(4.8)%	— %	(0.2)%
Stock-based compensation	(2.6)%	19.8 %	— %
Federal research and development credits	(0.7)%	3.8 %	2.5 %
State taxes, net of federal benefits	0.5 %	3.6 %	7.9 %
Non-deductible items	— %	(0.8)%	1.6 %
Other	0.1 %	(0.3)%	0.2 %
Effective tax rate	8.1 %	(0.3)%	— %

We are subject to U.S. federal, state, and foreign income taxes. Our effective tax rate for the year ended December 31, 2021 was 8.1% and was lower than the federal statutory tax rate primarily due to the tax benefits related to the release of the valuation allowance on most of our deferred tax assets, foreign-derived intangible income deduction and stock-based compensation. Our effective tax rate for the years ended December 31, 2020 and December 31, 2019 was lower than the federal statutory tax rate primarily due to the valuation allowance on our deferred tax assets.

Deferred income taxes reflect the tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes, tax credit carryforwards and the tax effect of net operating loss carryforwards. Significant components of our deferred tax assets and tax liabilities as of December 31, 2021 and 2020 were as follows (in millions):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 69	$ 587
Stock-based compensation	44	33
Capitalized licenses, research and development and start-up costs	204	14
Tax credit carryforwards	80	99
Deferred revenue	43	30
Operating lease liabilities	32	22
Financing lease liabilities	136	24
Other	67	65
Total deferred tax assets	675	874
Less: valuation allowance	(149)	(823)
Net deferred tax assets	$ 526	$ 51
Deferred tax liabilities:		
Right-of-use assets, financing	$ (119)	$ (12)
Right-of-use assets, operating	(31)	(20)
Property and equipment	(49)	(18)
Other	(1)	(1)
Total deferred tax liabilities	(200)	(51)
Net deferred tax assets	$ 326	$ —

On a quarterly basis, we reassess the valuation allowance on our deferred tax assets, weighing positive and negative evidence to assess the realizability of the deferred tax assets. In the first quarter of 2021, we reassessed the valuation allowance noting the increase in positive evidence, including significant revenue growth, expectations regarding future profitability, and successful supply chain and

manufacturing capabilities to meet global product demand. After assessing both the positive evidence and negative evidence, we determined it was more likely than not that we will realize the majority of our deferred tax assets, and we released the valuation allowance on the majority of our deferred tax assets, accordingly. We continue to maintain a valuation allowance on certain state deferred tax assets.

Changes in the valuation allowance for deferred tax assets during the year ended December 31, 2021 primarily related to the release of the valuation allowance on deferred tax assets. The changes during the years ended December 31, 2020 and 2019 primarily related to the increase in valuation allowance on net operating loss carryforwards and research and development tax credit carryforwards. The changes were as follows (in millions):

	Years Ended December 31,		
	2021	2020	2019
Valuation allowance at beginning of the period	$ 823	$ 471	$ 308
Decreases recorded as benefit to income tax provision	(722)	—	—
Increases to valuation allowance	48	352	163
Valuation allowance at December 31	$ 149	$ 823	$ 471

At December 31, 2021, we had $1.0 billion of state net operating loss carryforwards, which begin to expire in 2032. At December 31, 2021, we also had state tax credit carryforwards of $102 million, the majority of which will begin to expire in 2030.

We file U.S. federal income tax returns and income tax returns in various state, local and foreign jurisdictions. All tax years since date of incorporation remain open to examination by the major taxing jurisdictions (federal and state) to which we are subject, as carryforward attributes generated in past years may still be adjusted upon examination by the Internal Revenue Service or the state authorities if they have or will be used in a future period. There are no open tax examinations at this time.

We recognize, in our financial statements, the effect of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. A reconciliation of the beginning and ending amounts of unrecognized tax benefits during the years ended December 31, 2021, 2020, and 2019 were as follows (in millions):

	Years Ended December 31,		
	2021	2020	2019
Unrecognized tax benefits at beginning of the period	$ —	$ —	$ —
Additions based on tax positions for current year	54	—	—
Additions based on tax positions for prior years	14	—	—
Unrecognized tax benefits at end of the period	$ 68	$ —	$ —

As of December 31, 2021, we had $43 million of net unrecognized tax benefits, which would affect our tax rate if recognized. Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business. We do not anticipate a material change to our unrecognized tax benefits over the next twelve months that would have an adverse effect on our consolidated operating results. We recognize interest and penalties, if applicable, related to uncertain tax positions as a component of income tax expense; however, there has been no interest or penalties accrued to date.

17. Earnings (Loss) per Share

The computation of basic earnings (loss) per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and potential dilutive common shares outstanding during the period as determined by using the treasury stock method.

Basic and diluted EPS for the years ended December 31, 2021, 2020 and 2019 were calculated as follows (in millions, except per share data):

	Years Ended December 31,		
	2021	2020	2019
Numerator:			
Net income (loss)	$ 12,202	$ (747)	$ (514)
Denominator:			
Basic weighted-average common shares outstanding	403	381	331
Effect of dilutive securities	28	—	—
Diluted weighted-average common shares outstanding	431	381	331
Basic EPS	$ 30.31	$ (1.96)	$ (1.55)
Diluted EPS	$ 28.29	$ (1.96)	$ (1.55)

The following common stock equivalents, presented based on amounts outstanding as of December 31, 2021, 2020 and 2019, were excluded from the calculation of diluted net income (loss) per share attributable to common stockholders for the periods indicated because their inclusion would have been anti-dilutive (in millions):

	December 31,		
	2021	2020	2019
Stock options	1	34	46
Restricted common stock units	—	2	1
Total	1	36	47

18. Geographic Information

Geographic Revenue

We operate in one reporting segment that primarily focuses on the discovery, development and commercialization of mRNA medicines. Our chief executive officer manages our operations and evaluates our financial performance on a consolidated basis. Most of our principal operations, other than manufacturing, and our decision-making functions are located at our corporate headquarters in the United States.

Total revenue by geographic area of our customers and collaboration partners was as follows (in millions):

	Years Ended December 31,		
	2021	2020	2019
United States	$ 6,177	$ 764	$ 55
Europe	6,846	33	5
Rest of world [(1)]	5,448	6	—
Total	$ 18,471	$ 803	$ 60

[(1)] Includes product sales recognized under the agreement with Gavi (on behalf of the COVAX Facility) as Gavi facilitates a fair allocation and distribution of our COVID-19 vaccine around the world.

Our property and equipment, including financing right-of-use assets, by geographic area was as follows (in millions):

	December 31, 2021
United States	$ 1,050
Europe	181
Rest of world	10
Total	$ 1,241

Our property and equipment, including financing right-of-use assets, was principally located within the United States as of December 31, 2020.

19. Subsequent Events

In January 2022, we repurchased an additional 0.6 million shares of our common stock under the 2021 Repurchase Program for an aggregate of $143 million including commissions and fees. We have repurchased the entire $1.0 billion of common stock that was authorized under the 2021 Repurchase Program.

On February 22, 2022, our Board of Directors authorized a new Share Repurchase Program (2022 Repurchase Program) of our common stock, with no expiration date. Pursuant to the 2022 Repurchase Program, we may repurchase up to $3.0 billion of our outstanding common stock. The timing and actual number of shares repurchased will depend on a variety of factors, including price, general business and market conditions, and other investment opportunities, and shares may be repurchased through open market purchases through the use of trading plans intended to qualify under Rule 10b5-1 under the Exchange Act.

Subsequent to December 31, 2021, we have entered into several supply agreements with customers to provide our COVID-19 vaccine, up to 66 million doses, and have received upfront deposits of $210 million, based on the initial confirmed volume, subject to modifications.

Subsequent to December 31, 2021, we have entered binding purchase commitments with third-party contractual manufacturing organizations for dedicated facilities and fill & finish services for our COVID-19 vaccine. We are currently committed to minimum non-cancelable purchase obligations of $1.9 billion related to these agreements, of which $213 million is expected to be paid within 2022 and the remaining is expected to be paid through 2029.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Exchange Act Rule 13a-15(f)) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Management assessed our internal control over financial reporting as of December 31, 2021. Management based its assessment on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report on Form 10-K.

Changes in Internal Controls over Financial Reporting

During the three months ended December 31, 2021, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believe that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by the collusion of two or more people or by a management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Moderna, Inc.

Opinion on the Internal Control Over Financial Reporting

We have audited Moderna, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Moderna, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and December 31, 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 25, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 25, 2022

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2022 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2022 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2022 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2022 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accounting Fees and Services

Our independent public accounting firm is Ernst & Young LLP, Boston, Massachusetts, PCAOB Auditor ID 00042.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2022 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

(1) Financial statements.

For a list of the consolidated financial statements included herein, see "Index to Consolidated Financial Statements" under Part I, Item 8 of this Annual Report on Form 10-K.

(2) Schedules.

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the consolidated financial statements or the notes thereto.

(3) Exhibits.

Exhibit No.	Exhibit Index
3.1	Amended and Restated Certificate of Incorporation of the Registrant. (2)
3.2	Amended and Restated By-laws of the Registrant. (2)
4.1	Specimen Common Stock Certificate. (1)
4.2	Second Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated May 7, 2018. (1)
4.3	Description of Capital Stock. (10)
10.1#	2016 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder. (1)
10.2#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder. (1)
10.3#	Form of Indemnification Agreement between the Registrant and each of its directors. (1)
10.4†	Master Collaboration and License Agreement, by and between Moderna Therapeutics, Inc. and Merck Sharp & Dohme Corp., dated as of January 12, 2015, as amended by Amendment No. 1 dated as of January 8, 2016, Amendment No. 2 dated as of June 28, 2016, Amendment No. 3 dated as of June 28, 2016 and Amendment No. 4 dated as of June 28, 2016. (1)
10.5†	Amended and Restated mRNA Cancer Vaccine Collaboration and License Agreement, by and between ModernaTX, Inc. and Merck Sharp & Dohme Corp., dated as of April 17, 2018. (1)
10.6†	Amended and Restated Option Agreement by and between ModernaTX, Inc. and AstraZeneca AB, dated as of June 15, 2018. (1)
10.7†	Amended and Restated Services and Collaboration Agreement by and between ModernaTX, Inc. and AstraZeneca AB, dated as of June 15, 2018. (1)
10.8†	Patent Sublicense Agreement, by and among ModernaTX, Inc. and Cellscript, LLC and mRNA RiboTherapeutics, Inc. (solely with respect to certain provisions), dated as of June 26, 2017. (1)
10.9	Lease Agreement, by and between Moderna Therapeutics, Inc. and ARE-Tech Square, LLC, dated as of May 26, 2016, as amended by Amendment No. 1 dated as of August 31, 2016, Amendment No. 2 dated as of December 31, 2016, Amendment No. 3 dated as of April 24, 2017, Amendment No. 4 dated as of April 13, 2018. (1)
10.10	Fifth Amendment to Lease Agreement, by and between ModernaTX, Inc. and ARE-Tech Square, LLC, dated as of August 28, 2019. (3)
10.11	Net Lease by and between Moderna Therapeutics, Inc. and Campanelli-TriGate Norwood Upland, LLC, dated as of August 29, 2016, as amended by Amendment No. 1 dated as of April 10, 2017 and Amendment No. 2 dated as of March 16, 2018. (1)
10.12*	Third Amendment, dated September 11, 2018, Fourth Amendment, dated March 28, 2019, and Omnibus Amendment, dated December 30, 2021, to Net Lease, dated as of August 29, 2016, as amended.
10.13#	Amended and Restated Executive Severance Plan and Form of Participation Letter, as amended on November 4, 2018. (1)
10.14#	Letter Agreement by and between the Company and Stéphane Bancel, dated as of June 13, 2018, as amended by Amendment No. 1 dated as of November 4, 2018. (1)
10.15#	Letter Agreement by and between the Company and Stephen Hoge, dated as of October 17, 2017. (1)
10.16#*	Offer Letter by and between ModernaTX, Inc. and Corinne Le Goff, dated as of December 28, 2020.

10.17#*	Executive Separation and Transitional Services Agreement by and between ModernaTX, Inc. and Corinne Le Goff, dated as of November 11, 2021.
10.18#*	Consulting Agreement by and between ModernaTX, Inc. and Corinne Le Goff, effective as of December 17, 2021.
10.19#*	Employment Letter Agreement between ModernaTX, Inc. and Shannon Klinger, dated as of March 4, 2021.
10.20#	Senior Executive Cash Incentive Bonus Plan. (1)
10.21#	Amended and Restated Non-Employee Director Compensation Policy. (4)
10.22#	Form of Indemnification Agreement between the Registrant and each of its officers. (1)
10.23#	2018 Employee Stock Purchase Plan. (1)
10.24#*	Form of Employee Restricted Stock Unit Award Agreement.
10.25#*	Form of Employee Non-Qualified Stock Option Agreement.
10.26#*	Form of Non-Employee Director Restricted Stock Unit Award Agreement.
10.27#*	Form of Non-Employee Director Non-Qualified Stock Option Agreement.
10.28#	Form of Performance-Based Restricted Stock Unit Award Agreement under the 2018 Stock Option and Incentive Plan. (4)
10.29†	Agreement No. HHSO100201600029C, by and between the Company and the Biomedical Advanced Research and Development Authority, dated as of April 16, 2020, as amended on May 24, 2020, June 16, 2020, July 25, 2020, August 31, 2020 and September 15, 2020. (5)
10.30†	Amendment No. 6, dated February 16, 2021, to Agreement No. HHSO100201600029C, by and between ModernaTX, Inc. and the Biomedical Advanced Research and Development Authority, dated as of April 16, 2020. (4)
10.31†	Amendment No. 7, dated March 12, 2021, to Agreement No. HHSO100201600029C, by and between ModernaTX, Inc. and the Biomedical Advanced Research and Development Authority, dated as of April 16, 2020. (4)
10.32†	Amendment Nos. 8 and 9 to Agreement No. HHSO100201600029C, by and between ModernaTX, Inc. and the Biomedical Advanced Research and Development Authority, dated as of April 16, 2020. (8)
10.33†	Amendment No. 10 to Agreement No. HHSO100201600029C, by and between ModernaTX, Inc. and the Biomedical Advanced Research and Development Authority, dated as of April 16, 2020. (9)
10.34†*	Amendment No. 11 to Agreement No. HHSO100201600029C, by and between ModernaTX, Inc. and the Biomedical Advanced Research and Development Authority, dated as of November 4, 2021.
10.35†	Global Long Term Agreement, by and among ModernaTX Inc., Lonza Sales Ltd., and Lonza Ltd., dated September 4, 2020. (6)
10.36†	Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated August 9, 2020, as amended September 8, 2020, and September 11, 2020. (6)
10.37†	Amendment No. P00003 to Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated December 11, 2020. (7)
10.38†	Amendment Nos. P00004, P00005, P00006, P00007, P00008, P00009, P00010, P00011 and P00012 to Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated August 9, 2020. (8)
10.39†	Amendment Nos. P00012, P00013, P00014, P00015, P00016 and P00017 to Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated August 9, 2020. (9)
10.40†*	Amendment Nos. P00018, P00019, P00020, and P00021 to Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated August 9, 2020.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document

101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Link Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

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* Filed herewith.

† Pursuant to 17 C.F.R. §§230.406 and 230.83, the confidential portions of this exhibit have been omitted and are marked accordingly.

# Indicates a management contract or any compensatory plan, contract or arrangement.

\+ The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

(1) Incorporated by reference to the Registration Statement on Form S-1 (File No. 333-228300) filed with the Securities and Exchange Commission on November 9, 2018.

(2) Incorporated by reference to the Current Report on Form 8-K (File No. 001-38753) filed with the Securities and Exchange Commission on December 14, 2018.

(3) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on November 6, 2019.

(4) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on May 6, 2021.

(5) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on August 6, 2020.

(6) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on October 30, 2020.

(7) Incorporated by reference to the Annual Report on Form 10-K (File No. 001-38753) filed with the Securities and Exchange Commission on February 26, 2021.

(8) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on August 5, 2021.

(9) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on November 4, 2021.

(10) Incorporated by reference to the Annual Report on Form 10-K (File No. 001-38752) filed with the Securities and Exchange Commission on February 27, 2020.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MODERNA, INC.

Date:
February 25, 2022

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer and Director

POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints each of Stéphane Bancel and David Meline and as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stéphane Bancel Stéphane Bancel	Chief Executive Officer and Director *(Principal Executive Officer)*	February 25, 2022
/s/ David Meline David Meline	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 25, 2022
/s/ Noubar B. Afeyan, Ph.D. Noubar B. Afeyan, Ph.D.	Chairman and Director	February 25, 2022
/s/ Stephen Berenson Stephen Berenson	Director	February 25, 2022
/s/ Sandra Horning, M.D. Sandra Horning M.D.	Director	February 25, 2022
/s/ Robert Langer, Sc.D. Robert Langer, Sc.D.	Director	February 25, 2022
/s/ Francois Nader, M.D. Francois Nader M.D.	Director	February 25, 2022
/s/ Elizabeth Nabel, M.D. Elizabeth Nabel, M.D.	Director	February 25, 2022
/s/ Paul Sagan Paul Sagan	Director	February 25, 2022
/s/ Elizabeth Tallett Elizabeth Tallett	Director	February 25, 2022

Exhibit 10.12

THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (this **"Third Amendment")** is made as of September 11, 2018, by and between **ARE-MA REGION NO. 64, LLC,** a Delaware limited liability company **("Landlord"),** and **MODERNA, INC.,** a Delaware corporation **("Tenant").**

RECITALS

A. Tenant and Landlord are now parties to that certain Net Lease dated as of August 29, 2016 **("Original Lease"),** as amended by that certain First Amendment to Lease dated as of April 10, 2017, and as further amended by that certain Second Amendment to Lease dated as March 16, 2018 (as amended, the **"Lease").** Pursuant to the Lease, Tenant leases certain premises known as 100 Tech Drive, Norwood, Massachusetts (the **"Premises"**). The Premises are more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B. At Tenant's request, Landlord and Tenant have agreed to amend the Lease as more particularly set forth in this Third Amendment.

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Use of Initial Tenant Work Allowance.** Section 3.1(f) of the Original Lease is hereby amended to provide that the Initial Tenant Work Allowance shall not be available for any work completed (or reimbursement requested) after March 31, 2019.

2. **Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, **"Broker")** in connection with the transaction reflected in this Third Amendment and that no Broker brought about this transaction. Landlord shall only pay commissions to Broker pursuant to a separate written agreement between Landlord and Broker. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this Third Amendment.

3. **OFAC.** Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List or the Sectoral Sanctions Identifications List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

4. **Miscellaneous.**

a. This Third Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Third Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Third Amendment is binding upon and shall inure to the benefit of the parties hereto, and their respective successors and assigns.

c. This Third Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Third Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this Third Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Third Amendment. In the event of any conflict between the provisions of this Third Amendment and the provisions of the Lease, the provisions of this Third Amendment shall prevail. Whether or not specifically amended by this Third Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Third Amendment.

[Signatures are on the next page.]

IN WITNESS WHEREOF, the parties hereto have executed this Third Amendment as of the day and year first above written.

LANDLORD:

ARE-MA REGION NO. 64, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

/s/ Jackie Clem
By: Jackie Clem
Senior Vice President, RE Legal Affairs

TENANT:

MODERNATX, INC.,
a Delaware corporation

By: /s/ Steve Harbin
Its: Norwood Site Head

FOURTH AMENDMENT TO LEASE

THIS FOURTH AMENDMENT TO LEASE (this "**Fourth Amendment")** is made as of March 28, 2019, by and between **ARE-MA REGION NO. 64, LLC,** a Delaware limited liability company **("Landlord"),** and **MODERNA, INC.,** a Delaware corporation **("Tenant").**

RECITALS

A. Tenant and Landlord are now parties to that certain Net Lease dated as of August 29, 2016 **("Original Lease"),** as amended by that certain First Amendment to Lease dated as of April 10, 2017, as further amended by that certain Second Amendment to Lease dated as of March 16, 2018, and as further amended by that certain Third Amendment to Lease dated as of September 11, 2018 (as amended, the "**Lease")**. Pursuant to the Lease, Tenant leases certain premises known as 100 Tech Drive, Norwood, Massachusetts (the **"Premises"**). The Premises are more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B. At Tenant's request, Landlord and Tenant have agreed to amend the Lease as more particularly set forth in this Fourth Amendment.

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Use of Initial Tenant Work Allowance.** Section 3.1(f) of the Original Lease is hereby amended to provide that the Initial Tenant Work Allowance shall not be available for any work completed (or reimbursement requested) after September 30, 2019.

2. **Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker")** in connection with the transaction reflected in this Fourth Amendment and that no Broker brought about this transaction. Landlord shall only pay commissions to Broker pursuant to a separate written agreement between Landlord and Broker. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this Fourth Amendment.

3. **OFAC.** Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List or the Sectoral Sanctions Identifications List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

4. **Miscellaneous.**

a. This Fourth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written

agreements and discussions. This Fourth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Fourth Amendment is binding upon and shall inure to the benefit of the parties hereto, and their respective successors and assigns.

c. This Fourth Amendment may be executed in 2 or more counterparts, each of which-shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Fourth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this Fourth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Fourth Amendment. In the event of any conflict between the provisions of this Fourth Amendment and the provisions of the Lease, the provisions of this Fourth Amendment shall prevail. Whether or not specifically amended by this Fourth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Fourth Amendment.

[Signatures are on the next page.]

IN WITNESS WHEREOF, the parties hereto have executed this Fourth Amendment as of the day and year first above written.

LANDLORD:

ARE-MA REGION NO. 64, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

/s/ Jackie Clem
By: Jackie Clem
Senior Vice President, RE Legal Affairs

TENANT:

MODERNATX, INC.,
a Delaware corporation

/s/ Juan Andres
By: Juan Andres
Its: Chief Tecnical Operations and Quality Officer

OMNIBUS AMENDMENT TO THREE MODERNA LEASE AGREEMENTS

THIS OMNIBUS AMENDMENT TO THREE MODERNA LEASE AGREEMENTS (this "Amendment") is made as of December 30, 2021, by and between **ARE-MA REGION NO. 92, LLC**, a Delaware limited liability company and owner of the property commonly known as One Investors Way, Norwood, Massachusetts ("One Investors Landlord"), **ARE-MA REGION NO. 64, LLC**, a Delaware limited liability company and owner of the property commonly known as 100 Tech Drive, Norwood, Massachusetts ("100 Tech Landlord"), and **ARE-MA REGION NO. 83, LLC**, a Delaware limited liability company and owner of the property commonly known as One Upland Road, Norwood, Massachusetts ("One Upland Landlord") (collectively, "Landlords"), and **MODERNATX, INC.**, a Delaware corporation ("Tenant").

RECITALS

A. One Investors Landlord and Tenant are parties to that certain Lease Agreement dated as of April 16, 2021 (the "One Investors Lease"), with respect to the real property and improvements thereon located at 1 Investors Way, Norwood, Massachusetts, as more particularly described in the One Investors Lease.

B. 100 Tech Landlord (as successor-in-interest to Campanelli-TriGate Norwood Upland, LLC) and Tenant are parties to that certain Net Lease dated as of August 29, 2016, as amended by that certain First Amendment to Lease dated as of April 10, 2017, as further amended by that certain Second Amendment to Lease dated as of March 16, 2018, as further amended by that certain Third Amendment to Lease dated as of September 11, 2018, as further amended by that certain Fourth Amendment to Lease dated as of March 28, 2019 (as amended, the "100 Tech Lease"), with respect to the real property and improvements thereon located at 100 Tech Drive, Norwood, Massachusetts, as more particularly described in the 100 Tech Lease.

C. One Upland Landlord (as successor-in-interest to BR Norwood Owner, LLC) and Tenant are parties to that certain Lease Agreement dated as of October 10, 2007, as amended by that certain First Amendment to Lease dated as of February 15, 2019, as further amended by that certain Second Amendment to Lease dated as of February 15, 2019, as further amended by that certain First Amendment to Lease Guaranty dated April 30, 2019, and as further amended by that certain Third Amendment to Lease Agreement dated as of May 21, 2020 (as amended, the "One Upland Lease"). Collectively, the One Investors Landlord, 100 Tech Landlord, and One Upland Landlord shall be referred to herein as the "Landlords", and the One Investors Lease, 100 Tech Lease, and One Upland Lease shall be referred to herein as the "Leases".

D. Landlords and Tenant desire to extend the terms of the Leases and otherwise amend the Leases upon the terms and conditions contained herein. All capitalized terms not defined herein shall have the same meaning ascribed to such terms in the Leases.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual promises and agreements hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlords and Tenant hereby agree as follows:

1. Term. The terms of the Leases are extended to and including September 30, 2042.

2. Base Rent. The base rent schedules for each of the Leases is hereby modified as follows:

a. One Investors Lease: The definition of "Base Rent" set forth on page 1 of the One Investors Lease is hereby deleted in its entirety and replaced with the following:

"Beginning on the Rent Commencement Date, annual Base Rent shall be $6,466,500.00, subject to annual increases on the Adjustment Date as set forth herein.

Year	Annual Base Rent	Monthly Base Rent	Base Rent/RSF
February 17, 2022 – February 28, 2023	$6,466,500.00	$538,875.00	$26.94
March 1, 2023 – February 29, 2024	$6,660,495.00	$555,041.25	$27.75
March 1, 2024 – February 28, 2025	$6,860,310.00	$571,692.50	$28.58
March 1, 2025 – February 28, 2026	$7,066,119.00	$588,843.25	$29.44
March 1, 2026 – February 28, 2027	$7,278,103.00	$606,508.58	$30.33
March 1, 2027 – February 29, 2028	$7,496,446.00	$624,703.83	$31.24
March 1, 2028 – February 28, 2029	$7,721,339.00	$643,444.92	$32.17
March 1, 2029 – February 28, 2030	$7,952,979.00	$662,748.25	$33.14
March 1, 2030 – February 28, 2031	$8,191,569.00	$682,630.75	$34.13
March 1, 2031 – February 29, 2032	$8,437,316.00	$703,109.67	$35.16
March 1, 2032 – February 28, 2033	$8,690,435.00	$724,202.92	$36.21

March 1, 2033 – February 28, 2034	$8,951,148.00	$745,929.00	$37.30
March 1, 2034 – February 28, 2035	$9,847,200.00	$820,600.00	$41.03
March 1, 2035 – February 29, 2036	$10,142,400.00	$845,200.00	$42.26
March 1, 2036 – February 28, 2037	$10,447,200.00	$870,600.00	$43.53
March 1, 2037 – February 28, 2038	$10,761,600.00	$896,800.00	$44.84
March 1, 2038 – February 28, 2039	$11,085,600.00	$923,800.00	$46.19
March 1, 2039 – February 29, 2040	$11,419,200.00	$951,600.00	$47.58
March 1, 2040 – February 28, 2041	$11,762,400.00	$980,200.00	$49.01
March 1, 2041 – September 30, 2042	$12,115,272.00	$1,009,606.00	$50.48

b. 100 Tech Lease: Schedule I of the 100 Tech Lease is hereby deleted in its entirety and replaced with the Fixed Rent set forth below.

Lease Year	Annual Fixed Rent	Monthly Fixed Rent
October 1, 2017 – September 30, 2018	$6,193,317.90	$516,109.83
October 1, 2018 – September 30, 2019	$6,348,150.85	$529,012.57
October 1, 2019 – September 30, 2020	$6,506,854.62	$542,237.89
October 1, 2020 – September 30, 2021	$6,669,525.98	$555,793.83
October 1, 2021 – September 30, 2022	$6,836,264.13	$569,688.68

October 1, 2022 – September 30, 2023	$7,007,170.74	$583,930.90
October 1, 2023 – September 30, 2024	$7,182,350.01	$598,529.17
October 1, 2024 – September 30, 2025	$7,361,908.76	$613,492.40
October 1, 2025 – September 30, 2026	$7,545,956.48	$628,829.71
October 1, 2026 – September 30, 2027	$7,734,605.39	$644,550.45
October 1, 2027 – September 30, 2028	$7,927,970.53	$660,664.21
October 1, 2028 – September 30, 2029	$8,126,169.79	$677,180.82
October 1, 2029 – September 30, 2030	$8,329,324.03	$694,110.34
October 1, 2030 – September 30, 2031	$8,537,557.13	$711,463.09
October 1, 2031 – September 30, 2032	$8,750,996.06	$729,249.67
October 1, 2032 – September 30, 2033	$9,626,095.68	$802,174.64
October 1, 2033 – September 30, 2034	$9,914,878.56	$826,239.88
October 1, 2034 – September 30, 2035	$10,212,324.96	$851,027.08
October 1, 2035 – September 30, 2036	$10,518,694.68	$876,557.89
October 1, 2036 – September 30, 2037	$10,834,255.56	$902,854.63
October 1, 2037 – September 30, 2038	$11,159,283.24	$929,940.27
October 1, 2038 – September 30, 2039	$11,494,061.76	$957,838.48
October 1, 2039 – September 30, 2040	$11,838,883.56	$986,573.63

October 1, 2040 – September 30, 2041	$12,194,050.08	$1,016,170.84
October 1, 2041 – September 30, 2042	$12,559,871.64	$1,046,655.97

c. One Upland Lease: Article I of the One Upland Lease is hereby amended by modifying the following subsections as follows:

1.04 Term and Possession: The Initial Term of the Lease is hereby extended for a period expiring on September 30, 2042 (the "Expiration Date"). The Lease is hereby amended so that all references to the "Lease Term" and the "Initial Term" in the Lease shall refer to the Initial Term as extended hereunder, and the new Expiration Date as modified herein.

(a) From August 1, 2020, Base Rent for the Premises shall be paid as follows and all references to the "Base Rent" in the Lease shall be deemed to refer to the Base Rent set forth in the table below:

Period	Annual Base Rent	Monthly Base Rent
8/1/2020-7/31/2021	$5,700,024.47	$475,002.04
8/l/2021-7/31/2022	$5,794,593.41	$482,882.78
8/l /2022-7/31/2023	$5,794,593.41	$482,882.78
8/l/2023-7/31/2024	$5,891,999.42	$490,999.95
8/l/2024-7/31/2025	$5,891,999.42	$490,999.95
8/l/2025-7/31/2026	$5,992,327.61	$499,360.63
8/1/2026-7/31/2027	$5,992,327.61	$499,360.63
8/l/2027-7/31/2028	$6,095,665.65	$507,972.14
8/1/2028-7/31/2029	$6,095,665.65	$507,972.14
8/1/2029-7/31/2030	$6,202,103.82	$516,841.99
8/l/2030-7/31/2031	$6,202,103.82	$516,841.99
8/l/2031-7/31/2032	$6,311,735.15	$525,977.93
8/l/2032-7/31/2033	$6,311,735.15	$525,977.93
8/l /2033-7/31/2034	$6,424,655.41	$535,387.95
8/1/2034-7/31/2035	$6,424,655.41	$535,387.95
8/1/2035-9/30/2035	2 month period	$545,080.27
10/1/2035-9/30/2036	$7,195,227.20	$599,602.27
10/1/2036-9/30/2037	$7,411,084.02	$617,590.34
10/1/2037-9/30/2038	$7,633,416.54	$636,118.05
10/1/2038-9/30/2039	$7,862,419.04	$655,201.59
10/1/2039-9/30/2040	$8,098,291.61	$674,857.63
10/1/2040-9/30/2041	$8,341,240.36	$695,103.36
10/1/2041-9/30/2042	$8,591,477.57	$715,956.46

3. Extension Rights. In lieu of any existing extension rights in the Leases, Tenant is hereby granted three (3) consecutive extension rights for each of the three Leases. Accordingly, the Leases are hereby amended as follows:

a. One Investors Lease: Section 41(a) of the One Investors Lease is hereby amended by deleting “two (2) consecutive rights” and replacing it with “three (3) consecutive rights”.

b. 100 Tech Lease: Section 10.2 of the 100 Tech Lease is hereby amended by deleting the first sentence in its entirety and replacing it with the following:

“Tenant shall have three (3) consecutive rights to extend the term of this Lease for five (5) years each (each, an “Extension Term”), provided that Tenant shall give Landlord notice of Tenant's exercise of such option no sooner than twenty-four

(24) months and no later than eighteen (18) months prior to the expiration of the then current Term, and provided further that Tenant shall not be in default at the time of giving such notice under this Lease beyond applicable notice and cure periods."

c. One Upland Lease: Section 1.04 of the One Upland Lease is hereby amended by deleting "four options to extend" and replacing it with "three options to extend".

4. Alterations and Restoration. For ease of administration and consistency, Landlords and Tenant agree that the process for approval by Landlords of Tenant's proposed Tenant Improvements (as defined below), and the restoration obligations associated therewith, shall be governed by the One Investors Lease, notwithstanding any contrary provisions of the 100 Tech Lease or One Upland Road Lease. The Landlords acknowledge and agree that the Tenant Improvements will be designed and performed in furtherance of a master planning effort undertaken by Tenant and reviewed by the Landlords, the effect of which will be to treat the three Premises as a unified whole, without regard to property line and Premises boundaries. Each Landlord agrees to be reasonable in reviewing and approving applicable Tenant Improvements on its Premises, regardless of the location of such Tenant Improvements within the overall project. Notwithstanding anything to the contrary contained in the One Investors Lease regarding restoration of Installations (as defined in the One Investors Lease), Tenant shall have no obligation to remove and restore at the end of the Term any new buildings or expansions of existing buildings, landscaping, planted areas, walks, roadways, parking, and other new installations and improvements on the Premises outside of the existing buildings.

5. Tenant Improvement Allowance. Each of the three Landlords agrees to provide an additional tenant improvement allowance of $60.00 per rentable square foot of the applicable Premises, for an aggregate total of $41,010,780.00 (the "2021 Tenant Improvement Allowance" or "2021 TIA"), broken down as follows: $14,400,000.00 under the One Investors Lease, $12,025,860.00 under the 100 Tech Lease, and $14,584,920.00 under the One Upland Lease. Notwithstanding that the 2021 TIA has been allocated to each of the separate Landlords, Tenant is not bound by such allocation, and the Landlords acknowledge and agree that Tenant may apply any amount of the 2021 TIA to Tenant Improvements across the three Premises as Tenant sees fit, without regard to each Landlord's portion of the total. Notwithstanding contrary provisions of the Leases governing disbursement of tenant allowance funds, the 2021 Tenant Improvement Allowance shall be disbursed and used as follows:

a. Tenant shall have no right to any portion of the 2021 TIA that is not disbursed before the second anniversary of the date hereof.

b. Costs. The 2021 TIA shall be used solely for the payment of design (including A&E drawings), permits and construction, and construction management costs in connection with the construction of tenant improvements, site work, new structures and other hard construction costs (the "Tenant Improvements") at the properties covered by the three Leases (collectively, the "TI Costs"). The 2021 TIA shall not be used to purchase any furniture, personal property or other non-building system materials or equipment, including, but not be limited to, non-ducted biological safety cabinets and other scientific equipment not incorporated into the Tenant Improvements; provided,

however, the 2021 TIA may be used for Tenant's voice and data cabling, special electrical power distribution, telephone and security systems.

Landlord shall have no obligation to bear any portion of the cost of any of the Tenant Improvements except to the extent of the 2021 TIA and except to the extent that any remaining contributions or allowances remain under each of the existing Leases as of the date hereof.

c. Procedure. During the course of construction of the Tenant Improvements, Landlord shall reimburse Tenant for TI Costs once a month (such reimbursement not to exceed, in the aggregate, the amount of the 2021 TIA) against a draw request in Landlord's standard form, containing evidence of payment of such TI Costs by Tenant and such certifications, lien waivers (including a conditional lien release for each progress payment and unconditional lien releases for the prior month's progress payments), inspection reports and other matters as Landlord customarily obtains, to the extent of Landlord's approval thereof for payment, no later than the last day of the calendar month immediately following the calendar month in which the draw request was made. Upon completion of the Tenant Improvements (and prior to any final disbursement of the 2021 TIA), Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and first tier subcontractors who did the work and final, unconditional lien waivers from all such contractors and first tier subcontractors; (ii) as-built plans (one copy in print format and two copies in electronic CAD format) for such Tenant Improvements; (iii) a certification of substantial completion in Form AIA G704, (iv) a certificate of occupancy for the premises covered by each Lease, to the extent not already delivered; and (v) copies of all operation and maintenance manuals and warranties affecting the premises covered by each Lease.

d. Nonpayment; Offset Right; Disputes. If any Landlord fails timely to pay any portion of the 2021 TIA when such portion is properly due to Tenant and as to which Tenant has satisfied each of the foregoing requisition conditions, and such failure shall continue for 30 days after written notice from Tenant to such Landlord (which such notice shall describe in detail the basis on which Tenant asserts that such Landlord has wrongfully failed to disburse such amount), then Tenant, provided no Default has occurred and is continuing, may deliver a second notice to such Landlord that includes in at least 14 point-type and all capitals (with the rest of the notice in standard font and type-size) the phrase "FAILURE TO IMMEDIATELY RESPOND COULD RESULT IN THE FORFEITURE OF RIGHTS" (an "Offset Notice"), which notice shall specify the portion of the TI Allowance that has not been timely paid and the date upon which request for payment was first sent to such Landlord, and, if such Landlord fails to disburse the amount expressly referenced in the Offset Notice within 10 business days, then Tenant shall have the right to have such unpaid amount credited against the next installment(s) of Base Rent thereafter due under the applicable Lease, until such sums due Tenant have been fully paid by such Landlord or fully credited and accounted for; provided however, that the amount so offset by Tenant in any calendar month shall not exceed 20% of the amount of the monthly installment of Base Rent payable by Tenant to Landlord under the applicable Lease with respect to such calendar month. If, however, Landlord notifies Tenant prior to the expiration of such 10 business day period that Landlord disputes that Landlord has wrongfully

failed to disburse the amount claimed by Tenant, and if Landlord and Tenant are not able to reach agreement with respect to such dispute (with Landlord disbursing any undisputed amounts which Landlord is required to disburse under this Work Letter) within 10 business days after Tenant's receipt of a such notice from Landlord, then the parties shall submit such dispute to arbitration conducted by the American Arbitration Association in Boston, Massachusetts in accordance with the "Expedited Procedures" of its Commercial Arbitration Rules, in which case Base Rent shall not be offset by such disputed amount unless and until Tenant prevails in such arbitration and the arbitrator concludes that Tenant has the right to such offset right and determines the amount owed to Tenant by Landlord, if any, that is to be offset against Base Rent. All costs associated with arbitration shall be awarded to the prevailing party as determined by the arbitrator.

e. Tenant Improvement Progress Reports. On or before the 10th day of each calendar month during the course of design and construction of the Tenant Improvements, Tenant shall deliver to Landlords a Tenant Improvement progress report in a form provided by Landlords completed to provide all of the most up-to-date information regarding Tenant's progress with respect the design and construction of the Tenant Improvements.

6. Cross-Default. Tenant agrees that a "Default" under the One Investors Lease or "Event of Default" under the 100 Tech Lease and One Upland Lease shall automatically constitute a Default or Event of Default, as applicable, under all three Leases.

7. Authority. Landlords represent and warrant to Tenant that they have the right, power and authority to execute and deliver this Amendment and to perform their obligations hereunder, and this Amendment is a valid and binding obligation of Landlords enforceable against Landlords in accordance with the terms hereof. Tenant represents and warrants to Landlords that it has the right, power and authority to execute and deliver this Amendment and to perform its obligations hereunder, and this Amendment is a valid and binding obligation of Tenant enforceable against Tenant in accordance with the terms hereof. Tenant acknowledges and agrees that Landlords are in full compliance with the terms of the Leases and no event exists or has occurred that constitutes or could ripen into a Landlord default under the Leases.

8. Brokerage. Landlords and Tenant each hereby represents that, other than Newmark Grubb Knight Frank and Jones Lang LaSalle (collectively, the "Brokers"), it has not dealt with any broker, agent or other person entitled to a commission, compensation, or fee with respect to the transactions contemplated by this Amendment. Landlords and Tenant each hereby agree to defend, indemnify, and hold harmless the other, and its successors and assigns, against and from all claims, losses, liabilities, and expenses, including, without limitation, reasonable attorneys' fees, arising out of any claim by any broker, agent, or other person or entity, other than the Brokers, claiming a commission or other form of compensation based upon alleged dealings with the indemnifying party with respect to this Amendment. Landlords shall be responsible to pay the commission due to the Brokers pursuant to a separate agreement.

9. Ratification; Conflict; Amendment. Except as amended herein, the Leases shall remain in full force and effect and the parties hereto ratify and reconfirm the Leases. On and after the date hereof, each reference in the Leases to "this Lease," "the Lease," "hereunder," "hereof," or words of like import, and each reference to the Lease in any other agreements, documents, or instruments executed and delivered pursuant to, or in connection with, the Leases, will mean and be a reference to the Leases as amended by this Amendment. In the

event of any conflict between this Amendment and the Leases, the provisions of this Amendment shall control. No amendment or modification of this Amendment, and no further amendment or modification of the Leases, will be effective unless it is in writing and signed by Landlords and Tenant.

10. Governing Law. This Amendment shall be governed by the laws of the Commonwealth of Massachusetts without regard to its conflict of law provisions.

11. Counterparts. This Amendment may be executed in as many counterparts as the parties hereto may deem necessary or convenient, and each such counterpart shall be deemed an original but all of which, together, shall constitute but one and the same document. Counterparts may be delivered via electronic mail (including PDF or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method, and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

12. Successors and Assigns. The provisions hereof shall inure to the benefit of, and be binding upon, the parties hereto and their successors and permitted assigns.

13. Attorneys' Fees. In the event of a dispute between the parties, the prevailing party shall be entitled to have its reasonable attorneys' fees and costs paid by the other party.

14. Acknowledgment. Tenant and Landlords each acknowledge that it has read the provisions of this Amendment, understands them, and is bound by them. Time is of the essence in this Amendment.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have duly executed and delivered this Amendment under seal as of the day and year first above written.

LANDLORDS:

ARE-MA REGION NO. 92, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

/s/ Mark Hikin
By: Mark Hikin
Its: Vice President, RE Legal Affairs

ARE-MA REGION NO. 64, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

/s/ Mark Hikin
By: Mark Hikin
Its: Vice President, RE Legal Affairs

ARE-MA REGION NO. 83, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

/s/ Mark Hikin
By: Mark Hikin
Its: Vice President, RE Legal Affairs

TENANT:

MODERNATX, INC.,
a Delaware corporation

/s/ David Meline
By: David Meline
Its: Chief Financial Officer

Exhibit 10.16

December 28, 2020

Corinne Le Goff, Pharm. D., MBA
[***]
[***]

Re: Offer of Employment by ModernaTX, Inc.

Dear Corinne,

ModernaTX, Inc. (together with its affiliates, the "Company") is pleased to confirm, contingent on receiving appropriate references and the successful completion of a background check/drug screen, its offer to employ you as Chief Commercial Officer, reporting to the Chief Executive Officer. Your effective date of hire will be on or before January 19, 2021 (the "Start Date"), and you will perform services for the Company as a regular, full-time employee. The initial terms of your employment, should you accept this offer, are set forth below.

This a full-time, exempt level position. Your base salary will be at the rate of $625,000.00 (USD) per year. All wages will be paid in accordance with the Company's normal biweekly pay schedule for salaried employees, and is subject to change by the Company. Your base salary will be subject to periodic review and adjustment at the Company's discretion.

In addition to the foregoing, upon your commencement of employment with the Company, you will be paid a one-time signing bonus of $300,000.00 less applicable taxes (the "Signing Bonus"). You acknowledge and agree that you will repay the Signing Bonus to the Company within 10 days of your last day of employment if you voluntarily terminate your employment with the Company or your employment is terminated for cause (as determined by the Company) during the first 24 months of your employment. That amount may be collected by the Company, either directly or indirectly, from any (i) payment of any kind due to you from the Company or any affiliate thereof including, without limitation, accrued wages, vacation, final wages, and expense reimbursements to the fullest extent permitted by applicable law; and/or (ii) the forfeiture or cancellation of any equity interest owned by you in the Company or any subsidiary or affiliate thereof, whether now existing or hereafter formed, and regardless of the form such equity interest (e.g., common units, incentive units (also referred to as profits interests), options to acquire common units or otherwise).

You will be eligible to earn an annual performance bonus. The Company will initially target the bonus at up to 75% of your annual salary rate (pro-rated based on your Start Date, provided that your Start Date is on or before the first Monday of October of the applicable calendar year). If your Start Date is after the first Monday of October, you will not be eligible for a bonus for the calendar year in which you were hired. The actual bonus percentage is discretionary and will be subject to the Company's assessment of your performance, as well as business conditions at the Company. The bonus also will be subject to approval by and adjustment at the discretion of the Company and the terms of any applicable bonus plan. The bonus, if any, will be paid no later than March 15 of the calendar year following the calendar year to which such bonus relates. You must be employed on the date a bonus is paid to receive that bonus.

Subject to the commencement of your employment with the Company, the Company will recommend to the Board of Directors (the "Board") of the Company's parent entity ("Parent"), that you be eligible to participate in Moderna's equity incentive program and be granted, at such time as the Board so determines, an equity award equivalent to a total value of $8,000,000.00 as of the grant date (such equity award is referred to as the "New Hire Equity Award"). Subject to the Board's approval of the New Hire

Equity Award, the New Hire Equity Award will vest according to the following schedule: 25% of the New Hire Equity Award will vest on the first anniversary of the date of grant, and the remaining 75% of the New Hire Equity Award will vest in equal calendar quarterly installments over the next three (3) years, provided that, in each case, you continue to provide continuous services to the Company as of each such vesting date. The New Hire Equity Award is subject to our "Your Equity Selection" (YES) program. You may choose to have your award delivered to you in one of the following mixes of Non-Qualified Stock Options and/or Restricted Stock Units:

- 100% of the value delivered in the form of Non-Qualified Stock Options.
- 75% of the value delivered in the form of Non-Qualified Stock Options and 25% in value delivered in the form of Restricted Stock Units. This is the default choice if no selection is made.
- 50% of the value delivered in the form of Non-Qualified Stock Options and 50% in value delivered in the form of Restricted Stock Units.

You will receive an email from the Compensation Team at the Company to register your selection prior to your grant date. In the event of a stock split, stock consolidation or similar event prior to the grant of the New Hire Equity Award, the number of shares subject thereto shall be adjusted proportionately. The grant price of the New Hire Equity Award will be equal to the closing price on the day of grant. The grant of the New Hire Equity Award will be conditioned upon, among other things, your execution of all necessary documentation relating to the New Hire Equity Award as determined by the Company (all such documentation is collectively referred to as the "New Hire Equity Award Documentation"). The New Hire Equity Award will be subject to the terms and conditions set forth in the New Hire Equity Award Documentation.

Further, subject to the Board's approval, and provided your start date is on or before the first Monday of October of the applicable calendar year, you will be eligible to receive an annual equity award related to your performance for the eligible performance period (the "Annual Equity Award"). Annual Equity Awards typically will be issued in the first quarter of the year following the performance period. Your annual grants will be based on a combination of market data and performance. You will receive an annual grant that will be a mix of stock options, RSU's, and potentially PSU's subject to the current executive pay policies in place. The current range is between $2M-$4M. Your first Annual Equity Award, if any, will be pro-rated based upon your start date. Targets may be modified up or down based on your individual performance. Annual equity guidelines are subject to change and may be updated based on market conditions.

You may be required to relocate to the Greater Boston area, as applicable, by December 31, 2021, or as mutually agreed upon by both parties. The Company will pay reasonable costs associated with your relocation (the "Relocation Expenses") in accordance with the Employee Relocation Guidelines that are in effect at the time of the initiation of your relocation case. The Company will determine in its reasonable judgment what portion, if any, of your Relocation Expenses are for nondeductible expenses in accordance with applicable law and will comply with associated withholding and tax reporting obligations. You acknowledge and agree that you will repay the Relocation Expenses to the Company within 10 days of your last day of employment if you voluntarily terminate your employment with the Company or your employment is terminated for cause (as determined by the Company) within 24 months of the initiation of your relocation case. That amount may be collected by the Company, either directly or indirectly, from any (i) payment of any kind due to you from the Company or any affiliate thereof including, without limitation, accrued wages, vacation, final wages, and expense reimbursements to the fullest extent permitted by applicable law; and/or (ii) the forfeiture or cancellation of any equity interest owned by you in the Company or any subsidiary or affiliate thereof, whether now existing or hereafter formed, and regardless of the form such equity interest (e.g., common units, incentive units (also referred to as profits interests), options to acquire common units or otherwise).

In addition to your compensation, you may take advantage of various benefits offered by the Company from time to time, subject to any eligibility requirements. Currently the Company provides group medical and dental insurance, short term disability coverage, group life insurance and a 401(k)

plan. These benefits, of course, may be modified, changed or eliminated from time to time at the sole discretion of the Company, and the provision of such benefits to you in no way changes or impacts your status as an at-will employee. Where a particular benefit is subject to a formal plan (for example, medical insurance or life insurance), eligibility to participate in and receive any particular benefit is governed solely by the applicable plan document. Should you ever have any questions about Company benefits, you should ask for a copy of the applicable plan document. You will also be eligible for vacation pursuant to the Company's policies in effect from time to time.

All forms of compensation referred to in this offer letter are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law.

You acknowledge and agree that employment with the Company is "at will." You are not being offered employment for a definite period of time, and either you or the Company may terminate the employment relationship at any time and for any reason without prior notice and without additional compensation to you. Similarly, this offer letter sets forth the initial terms and conditions of your employment, which are subject to change at any time at the Company's discretion. Although your job duties, title, reporting structure, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer, which expressly states the intention to modify the at-will nature of your employment.

You are being hired as a Massachusetts employee and you must live and work in Massachusetts as a material condition of your employment. However, due to factors that affect your ability to relocate immediately, including the COVID-19 pandemic, you will be permitted to commence employment by working remotely from your home in California until your full relocation to Cambridge, Massachusetts by August 1, 2021. You will be taxed in your home state until you relocate. It is understood that the Company may change your normal place of work according to the Company's future needs.

As a condition of the commencement of your employment, you are required to enter into an Employee Confidentiality, Assignment, Nonsolicitation and Noncompetition Agreement (the "Restrictive Covenants Agreement", a copy of which is enclosed with this offer letter. This offer is conditioned on your representation that you are not subject to any confidentiality, non-competition agreement or any other similar type of restriction that may affect your ability to devote full time and attention to your work at the Company. If you have entered into any agreement that may restrict your activities on behalf of the Company, please provide me with a copy of the agreement as soon as possible. You further represent that you have not used and will not use or disclose any trade secret or other proprietary right of any previous employer or any other party.

The Immigration Reform and Control Act requires employers to verify the employment eligibility and identity of new employees. You will receive a Form 1-9 that you will be required to complete. Please bring the appropriate documents listed on that form with you when you report for work. We will not be able to employ you if you fail to comply with this requirement.

This offer letter and the enclosed Restrictive Covenants Agreement constitute the complete agreement between you and the Company, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company.

Please indicate your acceptance of this offer by signing and dating this offer letter and the enclosed Restrictive Covenants Agreement (PDF by email) and returning it by January 1, 2021.

Corinne, we look forward to your joining the Company and are pleased that you will be working with us to build a transformative company for patients.

Very truly yours,

ModernaTX, Inc.

By: April Eldred

Title: Vice President, Talent Acquisition

/s/ April Eldred

Accepted and Agreed:

Corinne Le Goff, Pharm. D, MBA

/s/ Corinne Le Goff

12/29/2020
Date

moderna

200 Technology Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

Personal and Confidential

November 11, 2021

Corinne Le Goff
[***]
[***]

Re: Executive Separation and Transitional Services Agreement

Dear Corinne:

In accordance with the Amended and Restated Executive Severance Plan (the "Severance Plan") of Moderna Inc. (individually, and together with any direct and indirect parents, subsidiaries, and affiliates, the "Company"), this executive separation and transitional services agreement (the "Agreement") sets forth the terms of your continued employment with the Company through the earliest of (i) the close of business on December 17, 2021 (the "Anticipated Separation Date") or (ii) such earlier date when your employment is terminated (a) by the Company with Cause, (b) due to your death or Disability, or (c) by you (such actual last day of employment, the "Separation Date")[1]. For purposes of this Agreement, the time period between the date first set forth above and the Separation Date shall be referred to as the "Transition Period." During the Transition Period you will continue to receive your salary and benefits (subject to eligibility under any applicable benefits plans) and continue to vest in your outstanding equity, but you will not be expected to come into the office or work remotely unless otherwise directed by the Company's Chief Executive Officer ("CEO"). For the avoidance of doubt, as of the date of this Agreement, the Company characterizes your termination as a termination without Cause. In the event that the Company should seek to terminate your employment for Cause following the date of this Agreement, it will promptly notify you in writing. Any such termination for Cause shall become effective within three (3) business days of delivery of the notice, unless the circumstances giving rise to the for Cause termination are cured within such three (3) business days.

Regardless of whether you enter into the Agreement, the following bulleted terms and obligations (the "Accrued Benefits") shall apply:

- You will continue to participate in the Company's Severance Plan and will be entitled to any benefits and payments thereunder in the event of a Qualified Termination Event (as defined in the Severance Plan), subject to the terms and conditions of the Severance Plan.
- On the Separation Date, the Company shall pay you for all salary plus any accrued but unused vacation to which you are entitled through the Separation Date.

[1] "Cause" is defined by the Company's Amended and Restated Executive Severance Plan effective as of November 4, 2018 (the "Severance Plan"). "Disability" is defined as your inability to perform the essential functions of your employment with the Company, with or without a reasonable accommodation, for more than 120 consecutive days, unless a longer period is required by federal or applicable state law, in which case that longer period would apply.

- Your eligibility to participate in the Company's health, dental and vision plans will cease on the last day of the month in which the Separation Date occurs. You may elect to continue your health, dental and vision benefits in accordance with and subject to the law known as COBRA. You will be notified by separate memoranda of your rights under COBRA including payment obligations. You will participate under COBRA in accordance with the provisions of Section 3(e) below.
- Your eligibility to participate in the Company's other employee benefit plans and programs will cease on the Separation Date in accordance with the terms and conditions of each of those benefit plans and programs. Your rights to benefits, if any, are governed by the terms and conditions of those benefit plans and programs. If you are currently participating in the Company's 401(k) plan, deductions for the 401(k) Plan will end with your December 17, 2021 paycheck, *provided* this date is the Separation Date. You will receive information by mail concerning 401(k) plan rollover procedures should you be a participant in this program. Without limiting the generality of the foregoing and for the avoidance of doubt, you are not eligible to receive any bonus or other forms of incentive compensation with respect to you working for the Company during fiscal year 2021 or thereafter, except as set forth in Section 3(b) below and *provided* you meet the conditions set forth in Section 2.
- If applicable, you shall also have the right to retain any and all vested restricted stock units and to exercise any and all vested options that you hold to purchase equity of the Company, and any such exercise shall be made in accordance with, and shall be subject to, the terms of any and all applicable unit option and grant plans, equity incentive plans and all other equity award plans and all agreements relating to any of the foregoing (all of the foregoing are collectively referred to as the "Equity Documents"), including without limitation the time limits on exercise. Pursuant to the terms of the Equity Documents, all unvested restricted stock units and stock options you may hold will expire and be null and void as of the Separation Date. If you have any questions about your equity interests, please contact the Company's Chief Legal Officer.
- You are obligated, to the maximum extent permitted by applicable law, to comply with each of the obligations set forth in your Employee Confidentiality, Assignment, Noncompetition and Nonsolicitation Agreement dated as of December 29, 2020 (the "Restrictive Covenants Agreement"), a copy of which is being provided to you with this Agreement as Exhibit A.

Except as noted above, the payments and other terms set forth above will not be affected by whether or not you agree to the terms set forth below.

In addition to the above-described non-contingent terms, you will be entitled to the Severance Benefits (described in Section 3 below) if you meet the Conditions (as defined in Section 2 below). If you enter into this Agreement, you acknowledge that you are doing so voluntarily.

With those understandings, you and the Company agree as follows:

1. Matters Relating to the Transition Period. If you enter into, do not revoke, and comply with this Agreement (including, without limitation the Conditions set forth in Section 2 below), your employment with the Company will end on the Anticipated Separation Date, unless your employment is terminated on an earlier date in accordance with this Agreement (a) by the Company, with or without Cause, (b) due to your death or Disability, or (c) by you. During the Transition Period, you will not report to the Company's offices or perform any duties for or on behalf of the Company unless specifically requested by the Company's CEO. Notwithstanding the foregoing, you will make yourself available to answer any questions from the CEO or any other Company executive related to the Company or to transitioning

matters to other employees. Any change to your duties as set forth herein shall not (a) constitute Good Reason as defined in and for purposes of the Severance Plan, and you hereby waive the application of Good Reason to your employment from the date of this Agreement to the Separation Date, or (b) alter any of your obligations under the Restrictive Covenants Agreement. On the earliest of (i) the Separation Date or (ii) a request by the Company, you will be deemed to have resigned from all officer positions that you hold with the Company or any of its respective subsidiaries and affiliates. You shall execute any documents in reasonable form as may be requested by the Company to confirm or effectuate any such resignations. With respect to compensation, you will continue to receive your current annual base salary and you will be eligible for employee benefits throughout the Transition Period (subject to your continued eligibility under the Company's benefits plans); *provided, however*, you will not be entitled to any other compensation, incentive compensation, or bonuses during the Transition Period or with respect to any period prior to the Transition Period, except as set forth in Section 3 below and *provided* you meet the conditions set forth in Section 2. In addition, you will continue to vest in your restricted stock units and stock options pursuant to the Equity Documents during the Transition Period. You may exercise any vested options consistent with the terms of the Equity Documents. All unvested restricted stock units and stock options will expire on the Separation Date and be of no further effect, except as otherwise set forth in Section 3(c) below and provided you meet the conditions set forth in Section 2.

2. Conditions. Subject to the terms of this Agreement, you will be entitled to continue to be employed at the Company during the Transition Period and receive the Severance Benefits (as defined below) *provided* you satisfy each of the following (collectively, the "Conditions"): (i) you enter into this Agreement during the Consideration Period (defined in Section 22 below), do not revoke it, and comply with it; (ii) your employment is not terminated by the Company for Cause, due to death or Disability or as a result of your voluntary resignation prior to the Anticipated Separation Date; (iii) you work cooperatively and in good faith with the Company during the Transition Period and perform the duties described in Section 1 above to the Company's satisfaction; and (iv) you comply with the Restrictive Covenants Agreement. For the avoidance of doubt, if you resign your employment or the Company terminates your employment for Cause before the Anticipated Separation Date, you will be paid only through the Separation Date, even if that date occurs prior to the Anticipated Separation Date, and you shall not be entitled to any payments from the Company from and after the Separation Date.

3. Severance Benefits. If you satisfy each of the Conditions, the Company will provide you with the following post-employment benefits (collectively, the "Severance Benefits"):

(a) Separation Pay. In accordance with the Severance Plan, the Company shall pay you $625,000, which amount equals twelve (12) months of your current annual base salary, less applicable deductions and withholdings (the "Separation Pay"). The Company shall pay you the Separation Pay in biweekly payments, beginning on the first regular payroll date following the later of the Separation Date and the Agreement Effective Date (as defined in Section 22).

(b) Bonus Payment. In accordance with the Severance Plan, you will receive a prorated portion, based on your Anticipated Separation Date, of your 2021 annual bonus at 100% of the target amount, which the parties agree to be a total of $450,721.15 before applicable deductions and withholdings (the "Bonus Payment"). The Company shall pay you the Bonus Payment in biweekly payments, beginning on the first regular payroll date following the later of the Separation Date and the Agreement Effective Date (as defined in Section 22).

(c) Post-Employment Consulting Period. Provided that you satisfy the Conditions, then upon the Separation Date, and with no break in your service relationship for purposes of vesting in your

unvested stock options and restricted stock units, the consulting agreement attached hereto as Exhibit B (the "Consulting Agreement") will become effective and shall, together with this Agreement, govern the post-employment relationship between you and the Company, pursuant to which you will provide consulting services to the Company related to Commercial operational and strategic matters on an as-needed basis through February 3, 2022 (the "Consulting Period"). For the avoidance of doubt, if this Agreement does not become effective, or if you fail to comply with the Agreement or satisfy all of the Conditions, the Consulting Agreement will be deemed void ab initio and be of no force or effect. As described in greater detail in the Consulting Agreement, during the Consulting Period, you will no longer be an employee of the Company, but instead will be retained as a consultant. For the avoidance of doubt, if the Consulting Agreement does not become effective, then your unvested stock options and restricted stock units will cease vesting on the Separation Date. You will not receive any new equity awards during the Consulting Period.

(d) COBRA Premium Assistance. Regardless of whether you enter into the Agreement, if you elect and remain eligible for COBRA, you may continue to participate in the medical, dental and/or vision care plans which you currently participate in by electing COBRA continuation coverage. If you remain covered under COBRA through at least twelve (12) months following the Separation Date, and in accordance with the Severance Plan, the Company will pay through that date the same portion of the COBRA premium that the Company would pay as its share of the cost of coverage if you were an active employee. However, you will not be entitled to this employer subsidy if, prior to the twelve (12) month anniversary of the Separation date, you become eligible to be covered under other group health care coverage, through a new employer or otherwise. During this Company subsidy period, you will be required to continue paying the employee share of premium payments to secure continued coverage. Thereafter, medical insurance coverage shall be continued only to the extent required by COBRA and only to the extent you timely pay the full premium payments yourself.

(e) Non-Competition and Non-Solicitation.

i. The non-competition obligation as set forth in Section 9(c) of the Restrictive Covenants Agreement is hereby modified as follows:

1)The defined term "Nucleic Acid-Based Technology" is replaced with the defined term "mRNA-Based Technology", which shall mean "*technology regarding the research, development, manufacture, use or commercialization of mRNA-based constructs for therapeutic, prophylactic, or diagnostic purposes, including sequence and chemical moieties, sequence engineering, biology, manufacturing, and characterization of any mRNA-based constructs or component thereof*."

2)The defined term "Delivery Technology" is amended and restated as follows: "*Delivery Technology shall mean technology regarding the research, development, manufacture, use or commercialization of delivery vehicles for mRNA-based cargo.*"

ii. The non-solicitation obligation set forth in Section 9(a) of the Restrictive Covenants Agreement is hereby amended and restated in its entirety, as follows:

"I shall not, directly or indirectly, in any manner, contact, solicit or transact any business with any of the customers of the Company or with any of its vendors in any way that interferes with the Company's relationship with such customers or vendors. For

purposes of this Agreement, (i) customers shall include then current customers to which the Company provided products or services during the twelve (12) months prior to the Last Day of Employment (the "One Year Lookback") that I had significant contact with or learned confidential information about in the course of employment and customer prospects that the Company solicited during the One Year Lookback and that I had significant contact with or learned confidential information about in the course of employment, and (ii) vendors shall include then current vendors and vendors that provided services to or in connection with the Company during the One Year Lookback that I had significant contact with or learned confidential information about in the course of employment.

Except with respect to the amendments as set forth above in this Section 3(e), the terms and conditions of the Restrictive Covenants Agreement remain unchanged and in effect. You acknowledge and reaffirm your post-employment restrictive covenants in the Restrictive Covenants Agreement and that, in exchange for the Severance Benefits (including the narrowing of the non-competition and non-solicitation obligations as set forth in this Section 3(e)), you shall not, directly or indirectly, whether as principal, owner, partner, shareholder, member, director, manager, officer, consultant, agent, employee, co-venturer or otherwise, anywhere in the world, (i) provide any of the types of services that you provided to the Company since December 28, 2020 in connection with any Competitive Business (as defined in the Restrictive Covenants Agreement) or (ii) engage or otherwise participate in any Competitive Business. You expressly agree that your receipt of the Severance Benefits constitutes adequate consideration for the foregoing restrictions and you further acknowledge and agree that if you violate any of the provisions of this section (including but not limited to the covenants set forth in your Restrictive Covenants Agreement, which are expressly reaffirmed and incorporated by reference), the running of the restricted periods will be extended by the time during which you engage in such violation(s), and the Company will not be obligated to provide any further Separation Benefits to you.

4. Early Separation. If your employment ends prior to the Anticipated Separation Date in accordance with this Agreement, the following terms shall apply: if the Company terminates your employment for Cause, you resign or your employment ends due to death or Disability, you will receive the Accrued Benefits, cease vesting in your stock options and restricted stock units as of the Separation Date and will not be eligible for any severance pay or benefits, other than as is stated in this Agreement. For purposes of clarity, termination for Cause, resignation, death or Disability are the only reasons your employment can end before the Anticipated Separation Date.

5. General Release of Claims. In consideration for, among other terms, the opportunity to remain employed through the Transition Period and the Severance Benefits, to which you acknowledge and agree that you would otherwise not be entitled, you voluntarily release and forever discharge the Company, its affiliated and related entities (including, without limitation, direct and indirect parent companies (including, without limitation, Moderna, Inc.), and direct and indirect subsidiaries and direct and indirect affiliates), its and their respective predecessors, successors and assigns, its and their respective employee benefit plans and fiduciaries of such plans, and the past, present and future officers, directors, stockholders, members, managers, employees, attorneys, accountants, agents and representatives of each of the foregoing in their official and personal capacities (collectively referred to as the "Releasees") generally from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown ("Claims") that, as of the date when you sign this Agreement, you have, ever had, now claim to have or ever claimed to have had against any or all of the Releasees, to the maximum extent permitted by applicable law. This release includes, without limitation, all Claims: relating to your employment by and termination of employment with the Company; of wrongful discharge; of breach of

contract; of discrimination or retaliation under federal, state or local law (including, without limitation, Claims of discrimination or retaliation under the Americans with Disabilities Act, the Age Discrimination in Employment Act, Title VII of the Civil Rights Act of 1964 or Massachusetts General Laws ch. 151B); under the California Fair Employment and Housing Act (FEHA), the California Labor Code, the California Constitution, and the California Family Rights Act (CFRA); under any other federal or state statute; of defamation or other torts; of violation of public policy; for wages, bonuses, incentive compensation, including without limitation Claims pursuant to the Massachusetts Wage Act, the Massachusetts Overtime Law, and the Massachusetts Payment of Wages Law, vacation pay or any other compensation or benefits; for stock, stock options, unit options, units, profit interests, incentive units, restricted stock units or any other equity interests or rights to acquire equity interests in the Company or any other Releasee; and for damages or other remedies of any sort, including, without limitation, compensatory damages, punitive damages, injunctive relief and attorney's fees. You further represent that you have not filed any Claim against the Releasees in any forum, and you agree not to accept damages of any nature, other equitable or legal remedies for your own benefit or attorney's fees or costs from any of the Releasees with respect to any Claim released by this Agreement. Notwithstanding the foregoing, this general release does not release any Claim: (a) that arises after the Agreement Revocation period has expired, including any rights that may arise under the Equity Documents; (b) for unemployment or workers' compensation benefits; (c) for vested rights under ERISA-covered employee benefit plans as applicable on the date you sign this Agreement; (d) to be covered under the Officer Indemnification Agreement between the Executive and the Company dated December 29, 2020 (the "Indemnification Agreement") and under applicable directors and officers liability insurance for acts or omissions while serving as an officer of the Company; (e) under this Agreement or the Consulting Agreement or (f) that by law cannot be waived. You agree not to accept damages of any nature, other equitable or legal remedies for your own benefit or attorney's fees or costs from any of the Releasees with respect to any Claim released by this Agreement. As a material inducement to the Company to enter into the Agreement, you represent that you have not assigned any Claim to any third party, and that you have not filed any complaints, charges, applications, lawsuits, or arbitrations against the Company or any of the Releasees. To the extent that you have knowledge concerning a potential violation of any federal, state or local law, you represent that you have fully disclosed such information to the Company.

6. Continuing Obligations; Cooperation. You understand and agree that you have been employed in a position of confidence and trust and have had access to information concerning the Company that the Company treats as confidential and the disclosure of which could negatively affect the Company's interests (collectively, the "Confidential Information"). You further agree that you will continue to be bound and will abide by the Restrictive Covenants Agreement, which is hereby incorporated by reference. You hereby agree that to the maximum extent permitted by applicable law, you have not and shall not in any way voluntarily assist, aid or participate in the pursuit of any claims or actions brought by another against the Company or Releasees. In the event that your assistance is requested or required in the pursuit of any claims brought against the Company or Releasees, you must provide written notice to the Company within five (5) business days of such request, unless requested by a governmental authority to the contrary.

Without additional compensation, you agree to cooperate reasonably with the Company and Releasees (including its and their outside counsel) in investigating, defending, prosecuting, litigating, filing, initiating, or asserting any actual or potential claims or other matters involving the Company and Releasees to the extent that the Company believes you may have relevant knowledge or information. You agree to make yourself available during and outside of regular business hours for such cooperation; *provided* that the Company shall not utilize this Section to require you to make yourself available to an

extent that would unreasonably interfere with your search for employment or any subsequent professional responsibilities that you may have. You agree to appear without the necessity of a subpoena to testify truthfully in any legal proceedings in which the Company calls you as a witness. In connection with fulfilling your obligations under this Section, your pre-approved, out of pocket and reasonable expenses will be reimbursed by the Company, which shall not include any attorneys' fees except as provided by the Company's by-laws and/or any applicable liability insurance policies.

7. Return of Company Property. You shall not dispose of any property of the Company including, without limitation, information or documents (including, without limitation, computerized data and any copies made of any computerized data or software) (all of the foregoing are collectively referred to as the "Documents") without the prior written authorization of the Company. On or before the Separation Date, as requested by the Company, you shall return to the Company all property of the Company, including, without limitation, computer equipment, electronic devices, iPads, iPhones, cellular phones and other mobile devices, software, keys and access cards, credit cards, files and any Documents containing information concerning the Company, its business or business relationships (in the latter two cases, actual or prospective). After returning all Documents and property of the Company, you shall delete and purge any duplicates of files or documents that may contain Company information from any non-Company computer or other device that remains your property. In the event that you discover that you continue to retain any such property, you shall return it to the Company or destroy it (in the case of computerized data and software already in the possession of the Company) immediately. For the avoidance of doubt, you may maintain copies of your own personnel records, to the extent applicable.

8. Non-disparagement.

(a) Subject to Section 9, you agree not to make any disparaging, critical or detrimental statements concerning the Company or any of its affiliates; its or their products or services provided or to be provided; its or their current or former officers, directors, stockholders, members, employees, managers or agents; and its or their business affairs or financial condition. You further agree not to take any actions or conduct yourself in any way that would reasonably be expected to affect adversely the reputation or goodwill of the Company or its affiliates; or its or their products or services provided or to be provided; or its or their current or former officers, directors, stockholders, members, employees, managers or agents. This non-disparagement obligation shall not in any way affect your obligation to testify truthfully in any legal proceeding.

(b) The Company will instruct each of the members of the Company's Executive Committee not to make any disparaging or detrimental statements concerning your employment with the Company or take any actions or conduct themselves in any way that would reasonably be expected to affect adversely your professional or personal reputation. This non-disparagement obligation shall not in any way affect any executive officer's obligation to testify truthfully in any legal proceeding.

9. Protected Disclosures. Nothing contained in this Agreement or the Other Agreements (including, without limitation, the Restrictive Covenants Agreement) limits your ability to file a charge or complaint with any federal, state or local governmental agency or commission (a "Government Agency"). In addition, nothing contained in this Agreement limits your ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, nor does anything contained in this Agreement apply to truthful testimony in litigation. If you file any charge or complaint with any Government Agency and if the Government Agency pursues any claim on your behalf, or if any other third party pursues any claim on your behalf, you waive any right to monetary or other individualized relief (either individually or as part of any

collective or class action); *provided however* that nothing in this Agreement limits any right you may have to receive a whistleblower award or bounty for information provided to the Securities and Exchange Commission. Nothing in this Agreement or the Other Agreements (including, without limitation, the Restrictive Covenants Agreement) is intended to conflict with 18 U.S.C. § 1833(b), which provides that: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal."

10. Communications Regarding Separation. You agree that you will not (without the prior written approval of the Company) communicate about your transition or separation with anyone until after the Company has made a formal written announcement about your transition and separation (the "Company Announcement"); provided that you may communicate with your tax advisors, attorneys, and family members about your transition and separation before the Company Announcement; provided further that you first advise such persons not to reveal information about your transition and separation and each such person agrees. Once the Company has announced your transition and separation, you agree to limit any communications regarding your transition and separation departure to statements that are consistent with the Company Announcement.

11. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you become entitled to under this Agreement on account of your separation from service would be considered deferred compensation otherwise subject to the twenty percent (20%) additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a

separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with, or are exempt from, Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with, or be exempt from, Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

12. Tax Treatment. The Company shall undertake to make deductions, withholdings and tax reports with respect to payments and benefits under this Agreement to the extent that it reasonably and in good faith determines that it is required to make such deductions, withholdings and tax reports. Payments under this Agreement are stated in gross amounts and shall be paid in amounts net of any such deductions or withholdings. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate you for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

13. Effect of Breach. In the event that you fail to comply with any of your obligations under this Agreement (including the obligations under the Other Agreements and the Restrictive Covenants Agreement), in addition to any other legal or equitable remedies it may have for such breach, including for damages and equitable relief, the Company shall have the right to (i) if you are still employed, end your employment for Cause, (ii) terminate its payments to you under the Agreement; and/or (iii) seek recovery of any payments made to you or for your benefit pursuant to this Agreement. Any such consequences of a breach by you will not affect the release or your continuing obligations under this Agreement, under the Other Agreements, under the Consulting Agreement or under the Restrictive Covenants Agreement.

14. Non-admission. This Agreement shall not be construed as an admission of any liability by the Company or you of any act of wrongdoing. Each of the Company and you specifically disclaims that the Company or any of its representatives has engaged in any wrongdoing or has taken any action that would be the basis for any finding of liability.

15. Legally Binding. You are advised to consult with an attorney before executing this Agreement. Once effective, this Agreement is a legally binding document and your signature will commit you to its terms. You acknowledge that you have been advised to discuss all aspects of this Agreement with your attorney, that you have carefully read and fully understand all of the provisions of this Agreement, and that you are voluntarily entering into this Agreement.

16. Absence of Reliance. In signing this Agreement, you are not relying upon any promises or representations made by anyone at or on behalf of the Company.

17. Enforceability. Except for the General Release of Claims in Section 5, if any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement, or of the Restrictive Covenants Agreement or the Consulting Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law. If the General Release of Claims in Section 5 is found to be invalid or unenforceable in whole or in part, the Company will have the option in its sole discretion either to sever the invalid or unenforceable portion and enforce the rest of the Agreement, or to cancel the entire Agreement. In the event the Company exercises such option to cancel the entire Agreement, the Agreement shall be null and void and none of the benefits set forth in Section 3 shall be owing, paid, or provided, and if such amounts or benefits have been paid or provided, you shall repay to the Company the total gross amount or value of any such benefits already paid or provided, and the total gross amount of the amounts otherwise being waived in Section 3.

18. Waiver; Amendment. No waiver of any provision of this Agreement shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company.

19. Forum; Equitable Relief.

(a) You and the Company hereby agree that the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts shall have the exclusive jurisdiction to consider any matters related to this Agreement, including without limitation any claim for violation of this Agreement. With respect to any such court action, you (i) submit to the jurisdiction of such courts, (ii) consent to service of process, and (iii) waive any other requirement (whether imposed by statute, rule of court or otherwise) with respect to personal jurisdiction or venue.

(b) You agree that it would be difficult to measure any harm caused to the Company that might result from any breach by you of your promises set forth in this Agreement and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, you agree that if you breach, or propose to breach, any portion of your obligations under this Agreement, the Company shall be entitled, in addition to all other remedies it may have, to an injunction or other appropriate equitable relief to restrain any such breach, without showing or proving any actual damage to the Company and without the necessity of posting a bond.

20. Governing Law; Construction of Agreement. This Agreement shall be construed and governed in accordance with the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision or rule (whether of the Commonwealth of Massachusetts or any other jurisdiction) that would cause the application of laws of any jurisdictions other than those of the Commonwealth of Massachusetts. The parties acknowledge and agree that this Agreement shall not be construed more strictly against one party than another party merely by virtue of the fact that it, or any part of it, may have been prepared by counsel for one of the parties, it being recognized that it is the result of arms-length negotiations between the parties and all parties have contributed substantially and materially to the preparation of this Agreement. The headings contained in this Agreement are for

reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. References to agreements and other documents shall be deemed to include all subsequent amendments and other modifications thereto. References to statutes shall include all regulations promulgated thereunder and references to statutes or regulations shall be construed as including all statutory and regulatory provisions consolidating, amending or replacing the statute or regulation.

21. Entire Agreement. This Agreement constitutes the entire agreement between you and the Company and supersedes any previous agreements or understandings between you and the Company, including that certain offer letter by and between the Company and you dated as of December 28, 2020, *provided however* that the Severance Plan, Indemnification Agreement, Restrictive Covenants Agreement, Other Agreements and Equity Documents shall remain in full force and effect and further provided that, if you meet the Conditions set forth in Section 2 of this Agreement and the parties enter into the Consulting Agreement, then this Agreement and the Consulting Agreement together will supersede any previous agreements or understandings between you and the Company.

22. Time for Consideration; Agreement Effective Date. You understand and acknowledge that you have been given the opportunity to consider this Agreement for 21 calendar days from your receipt of this Agreement before signing it (the "Agreement Consideration Period"). Any changes to this Agreement, material or otherwise, will not restart the running of the Agreement Consideration Period. In signing this Agreement, you acknowledge that you have knowingly and voluntarily entered into this Agreement without any duress or undue influence on the part or behalf of the parties hereto or any affiliate thereof. You acknowledge that your release of Claims is knowing and voluntary, including without implication of limitation your release of claims of age discrimination under the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq. To accept this Agreement, you must return a signed, unmodified original or PDF copy of this Agreement so that it is received by the undersigned at or before the expiration of the Agreement Consideration Period. If you sign this Agreement before the end of the Agreement Consideration Period, you acknowledge by signing this Agreement that such decision was entirely voluntary and that you had the opportunity to consider this Agreement for the entire Agreement Consideration Period. You have seven (7) business days following your execution of this Agreement to revoke the Agreement by written notice to the undersigned (such seven (7) business day period, the "Agreement Revocation Period"). For such a revocation to be effective, it must be delivered so that it is received by the Company at or before the expiration of the Agreement Revocation Period. This Agreement shall not become effective or enforceable during the Agreement Revocation Period. This Agreement shall become effective as of the first (1st) day after the expiration of the Agreement Revocation Period, *provided* that the Company has also executed this Agreement by that date (the "Agreement Effective Date.") For the avoidance of doubt, if you do not enter into this Agreement, your employment will end but you will not be entitled to any of the Severance Benefits set forth in this Agreement.

23. Counterparts. This Agreement may be executed in counterparts, each of which shall be considered an original and all of which shall constitute one agreement. The signature of each party may be delivered by facsimile or by scanned image (e.g., .pdf or .tiff file extension name) as an attachment to electronic mail (e-mail), and such facsimile or scanned signature shall be treated in all respects as having the same effect as an original inked signature.

[Remainder of Page Intentionally Left Blank]

Please indicate your agreement to the terms of this Agreement by signing and returning this letter to me within the time period set forth above.

Very truly yours,

/s/ Tracey Franklin
Tracey Franklin
Chief Human Resources Officer

The foregoing is agreed to and accepted by:

/s/ Corinne Le Goff
Signature

Corinne Le Goff
Employee Name

11/11/2021
Date

Exhibit A
Restrictive Covenants Agreement

Exhibit B
Consulting Agreement

Exhibit 10.18

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (together with the attached Appendix A, B and C, the "Agreement"), is made by and between ModernaTX, Inc., a Delaware corporation having a place of business at 200 Technology Square, Cambridge, MA 02139, USA ("Moderna"), and Corinne Le Goff, an individual residing at [***] ("Consultant"). This Agreement shall become effective on the last day of Consultant's employment with the Company (such actual last day of employment, the "Effective Date"), and as agreed to in the Executive Separation and Transitional Services Agreement (the "Executive Separation Agreement") to which this Agreement is attached as Exhibit A; provided that this Agreement shall be *void ab initio* if Consultant does not enter into the Executive Separation Agreement or satisfy each of the Conditions (as defined in the Executive Separation Agreement). Moderna desires to have the benefit of Consultant's knowledge and experience, and Consultant desires to provide services to Moderna, all as provided in this Agreement. Moderna and Consultant may be referred to herein individually as a "Party" and collectively as the "Parties."

1. **Services.** During the Term (as defined below), Moderna or its Affiliates (as defined below) may from time to time request, and Consultant agrees to provide, consulting and advisory services related to Commercial operations and strategy (the "Services") and certain deliverables ("Deliverables") to Moderna and its Affiliates in accordance with the terms attached hereto as Appendix A, which Appendix A is hereby incorporated herein by reference. Consultant will deliver all Deliverables to Moderna in the form specified, and on the schedule set forth, in Appendix A. Any changes to the Services or Deliverables must be agreed to in writing between Consultant and Moderna prior to implementation of the changes. Subject to compliance with Consultant's obligations in this Agreement, Consultant shall retain the sole control and discretion to determine the methods by which Consultant performs the Services. As used herein, "Affiliate" means, with respect to an entity, any other entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first entity, with "control" meaning the power to direct the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise.

2. **Performance.** Consultant agrees to provide the Services in accordance with all applicable laws and regulations, prevailing high-level professional standards and the additional applicable terms and policies set forth in Appendix B. Consultant will provide Services not to exceed twenty percent (20%) of the average level of services provided by Consultant as an employee of the Company prior to the Separation Date (as defined in the Executive Separation Agreement).

3. **Independent Contractor Relationship.** The Parties understand and agree that Consultant is an independent contractor and not an agent or employee of Moderna or its Affiliates. Consultant has no authority to obligate Moderna or its Affiliates by contract or otherwise. Consultant will not be eligible for any employee benefits of Moderna or its Affiliates and expressly waives any rights to any employee benefits. Consultant will bear sole responsibility for paying and reporting Consultant's own applicable federal and state income taxes, social security taxes, unemployment insurance, workers' compensation, health or disability insurance, retirement benefits, and other welfare or pension benefits, if any, and Consultant indemnifies and holds Moderna harmless from and against any liability with respect to such taxes, benefits and other matters.

4. **Compensation.** As full consideration for the performance of the Services and delivery of the Deliverables, Consultant shall continue to vest during the Term (as defined in Section 8 hereof) in (a) the non-qualified stock option to purchase 58,563 shares of the Company's common stock that he was granted on February 1, 2021 (the "2021 Option"); and (b) the award of 25,400 restricted units granted on February 1, 2021 (the "2021 RSUs"), and subject in each case ((a) through (b)) to

the terms of (i) the Moderna, Inc. 2018 Stock Option and Incentive Plan (the "Plan"); (ii) the applicable Non-Qualified Stock Option Grant Notice; (iii) the applicable Non-Qualified Stock Option Agreement; and (iv) the applicable Restricted Stock Unit Award Agreement ((i) through (iv) collectively, the "Equity Documents"). Consultant shall cease vesting in the 2021 Option and the 2021 RSUs on the last day of the Term and may exercise any vested portion of the 2021 Option in accordance with the terms of the Equity Documents and subject to the time limits on exercisability. Moderna also agrees to reimburse Consultant the expenses as expressly set forth in Appendix A.

5. **Restrictive Covenants.** Consultant acknowledges and agrees that the terms of the Employee Confidentiality, Assignment, Nonsolicitation and Noncompetition Agreement by and between Consultant and the Company, dated as of December 29, 2020, a copy of which is attached hereto as Appendix C (as amended by the Executive Separation Agreement, the "Restrictive Covenants Agreement"), shall apply during the Term and thereafter in accordance with its terms. The non-competition and non-solicitation restrictions contained in the Restrictive Covenants Agreement apply "[d]uring the period in which you perform services for or at the request of the Company [ModernaTX, Inc., or any present or future direct or indirect parent, subsidiary or affiliate thereof] and for one (1) year following the termination of your provision of services to the Company for any reason or for no reason." Accordingly, for the avoidance of doubt, the non-competition and non-solicitation restrictions shall apply during the Term and for the one (1) year period following the last day of the Term. The other obligations in the Restrictive Covenants Agreement shall apply during the Term and thereafter, in accordance with their terms.

6. **Compliance with Obligations to Third Parties.** Consultant represents and warrants to Moderna that the terms of this Agreement, Consultant's performance of the Services under the Agreement and Consultant's acceptance of related compensation do not and will not conflict with any of Consultant's obligations to any third parties. Consultant agrees not to use any trade secrets or other confidential information of any other person, firm, corporation, institution or other third party in connection with any of the Services. If Consultant is an employee of or consultant or advisor to another company or institution or an affiliate of any foreign, federal or state government, facility, university or institution, Consultant represents and warrants that Consultant is not prohibited by any applicable laws, regulations, policies (including policies concerning professional consulting, non-competition, and additional workload), procedures, or ethical guidelines from fulfilling any of Consultant's obligations or responsibilities pursuant to this Agreement or from accepting compensation under this Agreement. Consultant agrees not to make any use of any funds, space, personnel, facilities, equipment or other resources of a third party in performing the Services and agrees not to take any other action that would result in a third party asserting ownership of, or other rights in, any Inventions (as defined in the Restrictive Covenants Agreement), unless agreed upon in writing in advance by Moderna.

7. **Publicity.** Consultant shall not use the name or any trademark (or adaptation thereof) of Moderna or any of its Affiliates for any marketing purposes or other uses without Moderna's prior written consent.

8. **Expiration/Termination.** The term of this Agreement (the "Term") will commence on the Effective Date and expire on February 3, 2022, unless sooner terminated pursuant to the provisions of this Section 8. Moderna may terminate this Agreement at any time for Cause (as defined below) upon at least three (3) days' written notice to Consultant. Any such termination for Cause shall become effective within three (3) business days of delivery of the notice, unless the circumstances giving rise to the for Cause termination are cured within such three (3) business days. For purposes of this Agreement, "Cause" shall mean (i) Consultant's refusal to perform requested Services under this Agreement, or (ii) a material breach by Consultant of this

Agreement, the Restrictive Covenants Agreement or the Executive Separation Agreement. Consultant may terminate this Agreement for any reason upon not less than fourteen (14) days' prior written notice to Moderna. Any expiration or termination of this Agreement shall be without prejudice to any obligation of either Party that has accrued prior to the effective date of expiration or termination. Upon expiration or termination of this Agreement, neither Consultant nor Moderna will have any further obligations under this Agreement, except that (a) Consultant will terminate all Services in progress in an orderly manner as soon as practicable and in accordance with a schedule agreed to by Moderna, unless Moderna specifies in the notice of termination that Services in progress should not be completed; (b) Consultant will deliver to Moderna all Deliverables made through expiration or termination; (c) Consultant will immediately return to Moderna all Moderna property and other Confidential Information (as defined in the Restrictive Covenants Agreement) and copies thereof provided to Consultant under this Agreement; and (d) the terms, conditions and obligations under Sections 3, 5 through 8, 10, and relevant portions of Section 12 will survive expiration or termination of this Agreement.

9. **Warranties and Additional Covenants.** Consultant represents, warrants and covenants that: (a) Consultant has the full power and authority to enter into and perform the Services pursuant to this Agreement, without the need for any consents or approvals not yet obtained; (b) Consultant has the right to grant the rights and assignments granted herein, without the need for any assignments, releases, consents, approvals or other rights not yet obtained; (c) the Services, including any Deliverables required hereunder, shall be free from material errors or other defects; (d) the execution of this Agreement by Consultant and Consultant's performance hereunder will not violate or be a breach of any agreement or obligation with any other person or entity.

10. **Indemnification**. Moderna shall indemnify and hold harmless, and at Consultant's request, defend, Consultant from and against any and all third party claims, losses, liabilities, damages, settlements, expenses and costs (including attorneys' fees and costs) which arise out of or relate to (a) any breach (or claim or threat thereof that, if true, would be a breach) of this Agreement by Moderna, and (b) Moderna's products, including for claims arising out of the negligence or intentional wrongdoing of Moderna.

11. **Miscellaneous.**

(a) **Use of Name.** Consultant consents to the use by Moderna of Consultant's name on its website, in press releases, company brochures, offering documents, presentations, reports or other documents in printed or electronic form, and in any documents filed with or submitted to any governmental or regulatory agency or any securities exchange or listing entity.

(b) **Defend Trade Secrets Act.** 18 U.S.C. § 1833(b) provides: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal." Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly permitted by 18 U.S.C. § 1833(b).

(c) **Protected Disclosures.** Nothing contained in this Agreement limits Consultant's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

(d) **Entire Agreement; Counterparts.** This Agreement, together with Appendix A, Appendix B, and Appendix C, contains the entire agreement of the Parties with regard to its subject matter, and supersedes all prior or contemporaneous written or oral representations, agreements and understandings between the Parties relating to that subject matter; provided however, that the Executive Separation Agreement, the Indemnification Agreement as defined in the Executive Separation Agreement, the Equity Documents and the Restrictive Covenants Agreement shall remain in full force and effect. For the avoidance of doubt, the Indemnification Agreement between Consultant and the Company dated December 29, 2020, shall remain in full force and effect in accordance with its terms. This Agreement may be changed only by a writing signed by Consultant and an authorized representative of Moderna. This Agreement may be executed in any number of counterparts, each of which will be deemed an original.

(e) **Assignment and Binding Effect.** The Services to be provided by Consultant are personal in nature. Consultant may not assign or transfer this Agreement or any of Consultant's rights or obligations hereunder without Moderna's prior written consent. In no event will Consultant assign or delegate responsibility for actual performance of the Services to any third party. Moderna may transfer or assign this Agreement without the prior written consent of Consultant. Any purported assignment or transfer in violation of this Section is void. This Agreement will be binding upon and inure to the benefit of the Parties and their respective legal representatives, heirs, successors and permitted assigns.

(f) **Notices.** All notices required or permitted under this Agreement must be in writing and must be given by directing the notice to the address for the receiving Party set forth in this Agreement or at such other address as the receiving Party may specify in writing under this procedure. Notices to Moderna will be marked "Attention: Chief Legal Officer ("CLO")." All notices must be given (i) by personal delivery, with receipt acknowledged, (ii) by prepaid certified or registered mail, return receipt requested, (iii) by prepaid recognized next business day delivery service or 2-day international delivery service; or (iv) by email to Consultant's Moderna email address or, in the case of Moderna, to the CLO's email address. Notices will be effective upon receipt or at a later date stated in the notice.

(g) **Governing Law.** This Agreement and any disputes relating to or arising out of this Agreement will be governed by, construed, and interpreted in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to any choice of law principle that would require the application of the law of another jurisdiction. The Parties agree to submit to the exclusive jurisdiction of the state and federal courts located in Massachusetts and waive any defense of inconvenient forum to the maintenance of any action or proceeding in such courts.

(h) **Severability; Reformation; Waiver.** Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision shall be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the Parties, within the limits of applicable law. Any delay in enforcing a Party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by Consultant and an authorized representative of the waiving Party, as applicable

(i) **Remedies.** Consultant agrees that (i) Moderna may be irreparably injured by a breach of this Agreement by Consultant; (ii) money damages would not be an adequate remedy for any such breach; (iii) as a remedy for any such breach Moderna will be entitled to seek equitable relief, including injunctive relief and specific performance, without being required by Consultant to prove actual damages or post bond; and (iv) such remedy will not be the exclusive remedy for any breach of this Agreement.

(j) **Further Assurances.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

(k) **Extension to Affiliates**. Moderna shall have the right to extend the rights, licenses, immunities and obligations granted or imposed in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Moderna. Moderna shall remain fully liable for any acts or omissions, including financial liabilities, of such Affiliates. To the extent that this Agreement imposes obligations on any Affiliates of Moderna, Moderna agrees to cause its Affiliates to perform such obligations.

(l) **Electronic Transmissions.** This Agreement may be transmitted in electronic format and shall not be denied legal effect solely because it was formed or transmitted, in whole or in part, by electronic record; however, this Agreement must then remain capable of being retained and accurately reproduced, from time to time, by electronic record by the Parties to this Agreement and all other persons or entities required by law. An electronically transmitted signature to this Agreement will be deemed an acceptable original for purposes of consummating this Agreement and binding the Party providing such electronic signature.

(m) **Construction.** Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" (or "includes without limitations"). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. Except where the context otherwise requires, whenever used, the singular will include the plural and the plural the singular.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Consulting Agreement as of the Effective Date.

ModernaTX, Inc.	**CONSULTANT**
By: /s/ Tracey Franklin	/s/ Corinne Le Goff
Name: Tracey Franklin	Name: Corinne Le Goff
Title: Chief Human Resources Officer	Title: Consultant

Appendix A

To the Consulting Agreement between
ModernaTX, Inc. and Corinne Le Goff

1. **Services:**

Consultant will provide Services with respect to commercial operations and strategy, on a schedule and at a location or locations indicated above or as otherwise mutually agreed between Consultant and Moderna (or its Affiliate, if applicable). In addition, Consultant will be available for a reasonable number of telephone and/or written consultations.

2. **Deliverables:**

The Deliverables will relate to commercial operations and strategy and will be determined by the Company.

3. **Compensation:**

Equity Vesting: As explained in Section 4 above, Consultant shall continue to vest in the 2021 Option and the 2021 RSUs during the Term.

Expenses: Moderna will reimburse Consultant for any pre-approved expenses actually incurred by Consultant in connection with the provision of Services. Requests for reimbursement will be in a form reasonably acceptable to Moderna, will include supporting documentation and will accompany Consultant's invoices.

Appendix B

Additional Applicable Terms and Policies

A. Code of Business Ethics and Conduct of Moderna, Inc. (available at www.modernatx.com)

B. Insider Trading Policy of Moderna, Inc., a copy of which has been provided to Consultant.

Appendix C

Restrictive Covenants Agreement

Exhibit 10.19

March 4, 2021

Shannon Thyme Klinger [***]
[***]
[***]

Re: Employment Letter Agreement Between ModernaTX, Inc. and Shannon Klinger

Dear Shannon,

ModernaTX, Inc. (together with its affiliates, the "Company") is pleased to enter into this Employment Letter Agreement ("Agreement") regarding your employment as Chief Legal Officer, reporting to the Chief Executive Officer. You shall have all duties and authorities customary for such position. Your effective date of hire will be on or before June 1, 2021 (the "Start Date"), or another Start Date mutually agreed upon by you and the Company, and you will perform services for the Company as a regular, full- time employee. The initial terms of your employment are set forth below.

You agree to devote your full business time to the performance of your duties, and not engage in any other business activity without the approval of the CEO. Notwithstanding the foregoing, you will be permitted to manage your personal investments, engage in civic and charitable activities, and serve on boards and engage in other activities as are approved by the CEO from time to time, which approval shall not be unreasonably withheld or delayed, provided that such activities do not interfere with the performance of your duties, create a conflict of interest or violate any agreement with the Company.

Your initial base salary will be at the rate of $650,000.00 (USD) per year. All wages will be paid in accordance with the Company's normal biweekly pay schedule for salaried employees. Your base salary will be subject to periodic review for potential adjustment at the Company's discretion, and any such adjustments shall thereafter constitute your Base Salary for all purposes under this Agreement and related agreements or plans. Downward adjustments in your Base Salary, if any, will only be made in a manner that is consistent with the rest of the executive team and at the direction of the Board of Directors (and shall otherwise be subject to your rights under the Amended and Restated Executive Severance Plan ("ESP").

In addition to the foregoing, upon your commencement of employment with the Company, you will be paid a one-time signing bonus of $250,000.00 less applicable taxes (the "Signing Bonus"). You acknowledge and agree that you will repay a pro-rated portion of the Signing Bonus to the Company within 10 days of your last day of employment if you voluntarily terminate your employment with the Company not following the occurrence of Good Reason or your employment is terminated for Cause by the Company (as such terms are defined and otherwise pursuant to the terms of, the ESP in effect as of the date of this Agreement) during the first 24 months of your employment. That amount may be collected by the Company, unless prohibited by applicable law, either directly or indirectly, from any (i) payment of any kind due to you from the Company or any affiliate thereof including, without limitation, accrued wages, vacation, final wages, and expense reimbursements to the fullest extent permitted by applicable law; and/or (ii) the forfeiture or cancellation of any equity interest owned by you in the Company or any subsidiary or affiliate thereof, whether now existing or hereafter formed, and regardless of the form such equity interest (e.g., common units, incentive units (also referred to as profits interests), options to acquire common units or otherwise).

You will be eligible to earn an annual performance bonus. The Company will initially target the bonus at 60% of your Base Salary (pro-rated based on your Start Date, provided that your Start Date is on or before the first Monday of October of the applicable calendar year). If your Start Date is after the first Monday of October, you will not be eligible for a bonus for the calendar year in which you were hired. The actual bonus percentage earned will be subject to the Company's assessment of individual and Company performance based upon established criteria, and otherwise pursuant to the Senior Executive Cash Incentive Bonus Plan. The bonus, if any, will be paid no later than March 15 of the calendar year following the calendar year to which such bonus relates. Except as otherwise provided herein, including under the terms of the ESP, you must be employed on the date a bonus is paid to receive that bonus.

Within thirty (30) days of your Start Date , you shall be granted, pursuant to Moderna's equity incentive program an equity award equivalent to a total value of $8,000,000.00 as of the grant date (such equity award is referred to as the "New Hire Equity Award"). The New Hire Equity Award will vest according to the following schedule: 25% of the New Hire Equity Award will vest on the first anniversary of the date that the equity is granted to you which is set as the first Monday of each month on a consistent basis for all new employees at Moderna (the Grant Date), and the remaining 75% of the New Hire Equity Award will vest in equal calendar quarterly installments over the next three (3) years, provided that, in each case, except as otherwise provided herein, you continue to provide continuous services to the Company as of each such vesting date. The New Hire Equity Award is subject to our "Your Equity Selection" (YES) program. You may choose to have your award delivered to you in one of the following mixes of Non- Qualified Stock Options and/or Restricted Stock Units:

- 100% of the value delivered in the form of Non-Qualified Stock Options.
- 75% of the value delivered in the form of Non-Qualified Stock Options and 25% in value delivered in the form of Restricted Stock Units. This is the default choice if no selection is made.
- 50% of the value delivered in the form of Non-Qualified Stock Options and 50% in value delivered in the form of Restricted Stock Units.

You will receive an email from the Compensation Team at the Company to register your selection prior to your grant date. In the event of a stock split, stock consolidation or similar event prior to the grant of the New Hire Equity Award, the number of shares subject thereto shall be adjusted proportionately. The grant price of the New Hire Equity Award will be equal to the closing price on the Grant Date. The grant of the New Hire Equity Award will be conditioned upon your execution of all necessary documentation relating to the New Hire Equity Award as determined by the Company (all such documentation is collectively referred to as the "New Hire Equity Award Documentation"). The New Hire Equity Award will be subject to the terms and conditions set forth in the New Hire Equity Award Documentation.

In addition to the New Hire Equity Award within thirty (30) days of your Start Date, you shall also be granted an equity award equivalent to a total value of $2,000,000.00 as of the Grant Date (such equity award is referred to as the "Special Equity Award"), which shall be delivered in the form of Restricted Stock Units. The Special Equity Award will vest on the following schedule: 100% of the Special Equity Award will vest on the third anniversary of the Grant Date, provided that, except as otherwise provided herein, you continue to provide continuous services to the Company as of such vesting date.

In the event of a stock split, stock consolidation or similar event prior to the grant of the New Hire Equity Award or the Special Equity Award (collectively, the "Initial Awards"), the number of shares subject thereto shall be adjusted proportionately. The grant price of the Initial Awards will be equal to the closing price on the day of grant. The grant of these awards will be conditioned upon, your execution of all necessary documentation relating to the awards as determined by the Company (all such documentation is collectively referred to as the "New Hire Equity Award Documentation"). The Initial Awards will be subject to the terms and conditions set forth in the New Hire Equity Award Documentation. The forms of your New Hire Equity Award Documentation are attached hereto.

For avoidance of doubt, all accelerated/continued equity vesting and/or payment provisions provided to executives generally regarding equity awards, whether pursuant to the ESP, the Moderna, Inc. 2018 Stock Option and Incentive Plan ("Incentive Plan"), or otherwise, shall apply to your Initial Awards.

Further, subject to the Incentive Plan and provided your Start Date is on or before the first Monday of October of the applicable calendar year, you will be eligible to receive an additional annual equity award related to your performance for the eligible performance period (the "Annual Equity Award"). Annual Equity Awards typically will be issued in the first quarter of the year following the performance period. Your annual grants will be based on a combination of market data and performance. You will receive an annual grant that will be a mix of stock options, RSU's, and potentially PSU's subject to the current executive pay policies in place. The target value of your Annual Equity Award is $3,500,000.00. Your first Annual Equity Award will be pro-rated based upon your Start Date. Annual equity guidelines are subject to change and may be updated based on market conditions. Your Annual Equity Awards shall contain such terms and conditions (other than amounts), including but not limited to vesting schedule and treatment incident to a Sale Event and/or Termination, substantially similar to those generally provided to other members of the executive committee other than the CEO.

You may be required to relocate to the Greater Boston area, as applicable, by June 1, 2021, or as mutually agreed upon by both parties. Your principal place of employment shall be Cambridge, MA, except to the extent that remote work arrangements are necessitated by the Covid-19 pandemic. The Company will pay reasonable costs associated with your relocation (the "Relocation Expenses") in accordance with the Employee Relocation Guidelines ("Guidelines") that are in effect at the time of the initiation of your relocation case. Notwithstanding the foregoing and any terms or limitations in such Guidelines, however, the Company agrees to provide and pay (i) without regard to volume/weight, the costs of shipping and storage (for up to six (6) months) of your household goods and personal effects; (ii) the costs of temporary housing for you and your family for up to three (3) months; (iii) the costs of any amounts you are required to pay incident to early termination of your current residential lease; (iv) business class airfare for any travel incident to such relocation. In addition to the foregoing, you shall also receive a one-time Relocation Allowance of $25,000. The Company will determine in its reasonable judgment what portion, if any, of your Relocation Expenses are for nondeductible expenses in accordance with applicable law and will comply with associated withholding and tax reporting obligations. You acknowledge and agree that you will repay a pro-rated portion of the Relocation Expenses to the Company within 10 days of your last day of employment if you voluntarily terminate your employment with the Company not following an occurrence of Good Reason or your employment is terminated for Cause within 24 months of the initiation of your relocation case. That amount may be collected by the Company, unless prohibited by applicable law, either directly or indirectly, from any (i) payment of any kind due to you from the Company or any affiliate thereof including, without limitation, accrued wages, vacation, final wages, and expense reimbursements to the fullest extent permitted by applicable law; and/or (ii) the forfeiture or cancellation of any equity interest owned by you in the Company or any subsidiary or affiliate thereof, whether now existing or hereafter formed, and regardless of the form such equity interest (e.g., common units, incentive units (also referred to as profits interests), options to acquire common units or otherwise).

In addition to your compensation, you may take advantage of various benefits offered by the Company from time to time, subject to any eligibility requirements. Currently the Company provides group medical and dental insurance, short term disability coverage, group life insurance and a 401(k) plan. These benefits, of course, may be modified, changed or eliminated from time to time at the sole discretion of the Company, and the provision of such benefits to you in no way changes or impacts your status as an at-will employee. Where a particular benefit is subject to a formal plan (for example, medical insurance or life insurance), eligibility to participate in and receive any particular benefit is governed solely by the applicable plan document. Notwithstanding the foregoing, the Company agrees that you shall be entitled to a minimum of four (4) weeks annual paid vacation one of which will be the Company's annual shutdown if the Company determines in any year to have a shutdown. Should you ever have any questions about Company benefits, you should ask for a copy of the applicable plan document. You will also be eligible for any additional vacation pursuant to the Company's policies in effect from time to time.

You shall also be provided a Moderna, Inc. Officer's Indemnification Agreement, which shall be in addition to any rights of indemnification and to receive advancement to which you may be entitled under applicable law, Moderna's organizing documents, any agreement, a vote of stockholders or a resolution of directors, or otherwise.

All forms of compensation referred to in this Agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law.

You acknowledge and agree that employment with the Company is "at will." You are not being offered employment for a definite period of time, and either you or the Company may terminate the employment relationship at any time and for any reason without prior notice, subject to and in accordance with the terms and conditions of the ESP and other executive plans that may be applicable to you from time to time. Although your job duties, title, reporting structure, compensation and benefits, as well as the Company's personnel policies and procedures, may change prospectively from time to time, subject to your severance and termination rights in the ESP or any successor severance agreement or plan, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer, which expressly states the intention to modify the at-will term of your employment.

The Company acknowledges and agrees that you shall be a Participant in the current ESP upon your Start Date. A copy of the Participation Letter to the ESP is attached.

Further, for the avoidance of doubt, if the Company fails to employ you on the Start Date, you shall be entitled to: (i) all of the termination payments, treatment and benefits set forth in the ESP as if you were already a Participant on the day before you were notified of such failure; (ii) payment of the Hiring Bonus and Relocation Expenses as set forth above.

As a condition of the commencement of your employment, you are required to enter into an Employee Confidentiality, Assignment, Nonsolicitation and Noncompetition Agreement (the "Restrictive Covenants Agreement", a copy of which is enclosed with this Agreement**.** You also, represent that, based on your reasonable and good faith belief, you are not subject to any confidentiality, non-competition agreement or any other similar type of restriction that may affect your ability to devote full time and attention to your work at the Company, and have disclosed any applicable agreements to the Company. You further represent that you have not used and will not use or disclose any trade secret or other proprietary right of any previous employer or any other party.

The Immigration Reform and Control Act requires employers to verify the employment eligibility and identity of new employees. You will receive a Form I-9 that you will be required to complete. Please bring the appropriate documents listed on that form with you when you report for work. We will not be able to employ you if you fail to comply with this requirement.

This Agreement (including the documents references herein, e.g. the ESP, the New Hire Equity Award Documentation, the Incentive Plan, the Senior Executive Cash Incentive Bonus Plan, the Guidelines the Participation Agreement, the Indemnification Agreement and the enclosed Restrictive Covenants Agreement constitute the complete agreement between you and the Company, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company.

Shannon, we look forward to your joining the Company and are pleased that you will be working with us to build a transformative company for patients.

Very truly yours, MODERNATX, INC.

/s/ Tracey Franklin

By: Tracey Franklin

Title: Chief Human Resources Officer

Accepted and Agreed:

Shannon Thyme Klinger

/s/ Shannon Thyme Klinger

3/5/2021

Date

RESTRICTED STOCK UNIT AWARD AGREEMENT
FOR COMPANY EMPLOYEES
UNDER THE MODERNA, INC.
2018 STOCK OPTION AND INCENTIVE PLAN

Name of Grantee: **[Participant Name]**

No. of Restricted Stock Units: **[Number of Shares Granted]**

Grant Date: **[Grant date]**

Pursuant to the Moderna, Inc. 2018 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Moderna, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.0001 per share (the "Stock") of the Company.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the vesting schedule attached as Appendix A to this Agreement so long as the Grantee continues to have a Service Relationship with the Company or a Subsidiary on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 2.

3. Termination of Service Relationship. If the Grantee's Service Relationship with the Company or a Subsidiary terminates for any reason (other than death or permanent disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

(a) Termination Due to Death. If the Grantee's Service Relationship with the Company or a Subsidiary terminates by reason of the Grantee's death, then any Restricted Stock Units that have not vested as of the Grantee's death shall immediately vest in full as of the date of death.

(b) Termination Due to Permanent Disability. If the Grantee's Service Relationship with the Company or a Subsidiary terminates by reason of the Grantee's permanent disability (as defined below), then any Restricted Stock Units under this Award that have not vested as of the last date of the Grantee's Service Relationship shall immediately vest in full as of such date. For purposes of this Award, "permanent disability" shall mean the inability of the

Grantee to continue in his or her position for the Company (or an Affiliate) by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as determined by the Company in its sole discretion.

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Tax Withholding. In connection with the settlement of vested Restricted Stock Units, the Company shall issue the shares of Stock referred to in Paragraph 4 to a broker designated by the Company and acting on behalf and for the account of the Grantee with instructions to (i) sell a number of shares of such Stock sufficient to satisfy the applicable withholding taxes which arise in connection with such settlement; provided, that the amount sold does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment, along with any applicable third-party commission, and (ii) remit the proceeds of such sale to the Company. In the event the sale proceeds are insufficient to fully satisfy the applicable withholding taxes, the Grantee authorizes withholding from payroll and any other amounts payable to the Grantee, in the same calendar year, and otherwise agrees to make adequate provision through the submission of cash, a check or its equivalent for any sums required to satisfy the applicable withholding taxes. It is the intent of the parties that this Paragraph 6 comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act, and the Agreement will be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act. Unless the withholding tax obligations of the Company and/or any Affiliate thereof are satisfied, the Company shall have no obligation to issue any shares of Stock on the Grantee's behalf pursuant to the vesting of the Restricted Stock Units.

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

8. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee's Service Relationship with the Company or a Subsidiary and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Grantee's Service Relationship with the Company or a Subsidiary at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or

desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

Moderna, Inc.

By:

Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

[Signed Electronically]
Acceptance Date: **[Acceptance Date]**

Appendix A: Vesting Schedule

[Vesting Schedule]

Exhibit 10.25

NON-QUALIFIED STOCK OPTION AGREEMENT FOR COMPANY EMPLOYEES UNDER THE MODERNA, INC. 2018 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee: **[Participant Name]**

No. of Option Shares: **[Number of Shares Granted]**

Option Exercise Price per Share: $**[Grant Price]**

Grant Date: **[Grant date]**

Expiration Date: **[Expiration Date]**

Pursuant to the Moderna, Inc. 2018 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Moderna, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.0001 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below in Appendix A, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated on Appendix A to this Agreement so long as the Optionee continues to have a Service Relationship with the Company or a Subsidiary on such dates.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) if permitted by the Administrator, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the

Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) if permitted by the Administrator, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Service Relationship. If the Optionee's Service Relationship with the Company or a Subsidiary (as defined in the Plan) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Service Relationship with the Company or a Subsidiary terminates by reason of the Optionee's death, then any portion of this Stock Option that has not vested as of the Optionee's death shall immediately vest in full as of the date of death. Following any termination due to death, this Stock Option may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier.

(b) Termination Due to Permanent Disability. If the Optionee's Service Relationship with the Company or a Subsidiary terminates by reason of the Optionee's permanent disability (as defined below), then any portion of this Stock Option that has not vested as of the last date of the Optionee's Service Relationship (the "Accelerated Vesting Date") shall immediately vest in full as of the Accelerated Vesting Date. Following any termination due to disability, this Stock Option may thereafter be exercised by the Optionee for a period of 12 months from the Accelerated Vesting Date or until the Expiration Date, if earlier. For purposes of this Stock Option, "permanent disability" shall mean the inability of the Optionee to continue in his or her position for the Company (or an Affiliate) by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as determined by the Company in its sole discretion.

(c) Termination for Cause. If the Optionee's Service Relationship with the Company or a Subsidiary terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect. For purposes hereof, "Cause" shall mean, unless otherwise provided in an employment or other service agreement between the Company and the Optionee, a determination by the Administrator that the Optionee shall be dismissed as a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the conviction of, indictment for or plea of nolo contendere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliberate non-performance (other than by reason of disability) by the Optionee of the Optionee's duties to the Company.

(d) Other Termination. If the Optionee's Service Relationship with the Company or a Subsidiary terminates for any reason other than the Optionee's death, the Optionee's permanent disability or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's Service Relationship with the Company or a Subsidiary shall be conclusive and binding on the Optionee and his or her representatives or legatees.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the minimum required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the

Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the minimum withholding amount due.

7. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee in a Service Relationship with the Company or a Subsidiary and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Optionee's Service Relationship with the Company or a Subsidiary at any time.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

Moderna, Inc.

By:

Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Acceptance Date: **[Acceptance Date]**

Appendix A: Vesting Schedule

[Vesting Schedule]

Exhibit 10.26

RESTRICTED STOCK UNIT AWARD AGREEMENT FOR NON-EMPLOYEE DIRECTORS UNDER THE MODERNA, INC. 2018 STOCK OPTION AND INCENTIVE PLAN

Name of Grantee: **[Participant Name]**

No. of Restricted Stock Units: **[Number of Shares Granted]**

Grant Date: **[Grant date]**

Pursuant to the Moderna, Inc. 2018 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Moderna, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.0001 per share (the "Stock") of the Company.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains in service as a member of the Board on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

Notwithstanding the foregoing, in the event of a Sale Event, 100% of the then-outstanding and unvested Restricted Stock Units shall immediately be deemed vested on the date of such Sale Event; provided, that the Grantee remains in service as a member of the Board until the date of such Sale Event. The Administrator may at any time accelerate the vesting schedule specified in Appendix A.

3. Termination of Service. If the Grantee's service as a member of the Board terminates for any reason (other than death or permanent disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

(a) Termination Due to Death. If the Grantee's Service Relationship with the Company or a Subsidiary terminates by reason of the Grantee's death, then any Restricted Stock Units that have not vested as of the Grantee's death shall immediately vest in full as of the date of death.

(b) Termination Due to Permanent Disability. If the Grantee's service as a member of the Board terminates by reason of the Grantee's permanent disability (as defined below), then any Restricted Stock Units under this Award that have not vested as of the last date of the Grantee's service as a member of the Board of Directors shall immediately vest in full as

of such date. For purposes of this Award, "permanent disability" shall mean the inability of the Optionee to continue to perform service as a member of the Board of Directors by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as determined by the Company in its sole discretion.

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

7. No Obligation to Continue as a Director. Neither the Plan nor this Award confers upon the Grantee any rights with respect to continuance as a Director.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

Moderna, Inc.

By:

Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Acceptance Date: **[Acceptance Date]**

Appendix A: Vesting Schedule

[Vesting Schedule]

Exhibit 10.27

NON-QUALIFIED STOCK OPTION AGREEMENT FOR NON-EMPLOYEE DIRECTORS UNDER THE MODERNA, INC. 2018 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee: **[Participant Name]**

No. of Option Shares: **[Number of Shares Granted]**

Option Exercise Price per Share: **[Grant Price]**

Grant Date: **[Grant date]**

Expiration Date: **[Expiration Date]**

Pursuant to the Moderna, Inc. 2018 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Moderna, Inc. (the "Company") hereby grants to the Optionee named above, who is a Director of the Company but is not an employee of the Company, an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.0001 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains in service as a member of the Board on such dates:

[Vesting Date and Quantity]

Notwithstanding the foregoing, in the event of a Sale Event, 100% of the then-outstanding and unvested Option Shares shall immediately be deemed vested and exercisable on the date of such Sale Event; provided, that the Optionee remains in service as a member of the Board until the date of such Sale Event. Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) if permitted by the Administrator, through the delivery (or attestation to the

ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) if permitted by the Administrator, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination as Director. If the Optionee's service as a member of the Board ceases, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death or Permanent Disability. If the Optionee's service as a member of the Board terminates by reason of the Optionee's death or permanent disability, then any portion of this Stock Option that has not vested as of the date of such death or

permanent disability shall immediately vest in full as of the date of death or the last day of the Optionee's service as a member of the Board of Directors, as applicable (the "Accelerated Vesting Date"). Following any termination due to death or permanent disability, this Stock Option may thereafter be exercised by the Optionee or the Optionee's legal representative or legatee for a period of 12 months from the Accelerated Vesting Date or until the Expiration Date, if earlier. For purposes of this Stock Option, "permanent disability" shall mean the inability of the Optionee to continue to perform service as a member of the Board of Directors by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as determined by the Company in its sole discretion.

(b) Other Termination. If the Optionee's service as a member of the Board ceases for any reason other than the Optionee's death or permanent disability, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date the Optionee ceased to be a Director, for a period of six months from the date the Optionee ceased to be a Director or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee ceases to be a Director shall terminate immediately and be of no further force or effect.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. No Obligation to Continue as a Director. Neither the Plan nor this Stock Option confers upon the Optionee any rights with respect to continuance as a Director.

7. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

8. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

9. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

Moderna, Inc.

By:

Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Acceptance Date: **[Acceptance Date]**

Exhibit 10.34

Certain confidential portions of this exhibit have been omitted and replaced with "[***]." Such identified information has been excluded from this exhibit because it (i) is not material and (ii) is the type of information that the registrant treats as private or confidential.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES 1 3

2. AMENDMENT/MODIFICATION NO. P00011

3. EFFECTIVE DATE See Block 16C

4. REQUISITION/PURCHASE REQ. NO. See Schedule

5. PROJECT NO.(If applicable)

6. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W. Room 640-G
Washington DC 20201

7. ADMINISTERED BY (If other than item 6) CODE ASPR-BARDA02

US DEPT OF HEALTH & HUMAN SERVICES
ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING
Washington DC 20515

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)

MODERNATX, INC 1492235
Attn: [***]
MODERNATX, INC. 200 TECHNOLOGY
200 TECHNOLOGY SQ
CAMBRIDGE MA 021393578

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. 75A50120C00034

X 10B. DATED (SEE ITEM 13)

CODE 8PTM0 FACILITY CODE

04/03/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended, is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT /ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
FAR 43.103(a)

E. IMPORTANT: Contractor is not, is required to sign this document and return __1___ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT /MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: 27-0226313
DUNS Number: 069723520
The purpose of this "no cost" bilateral modification is to:
- Incorporate Executive Order 14042 - FAR Deviation Clause 52.223-99, Ensuring Adequate COVID Safety Protocols for Federal Contractors into Section I of the contract.
- Update Section G.8 Negotiated Indirect Rates and Ceiling
1. The following is hereby incorporated by full text, at no additional cost to the Government, into Section I:
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)
Shaun Ryan, SVP & Deputy General Counsel

16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
[***]

15B. CONTRACT OR/OFFEROR
/s/ Shaun Ryan
(Signature of person authorized to sign)

15C. DATE SIGNED
1/20/2022

16B. UNITED STATES OF AMERICA
BY [***]
(Signature of Contracting Officer)

16C. DATE SIGNED
2021.1.05

Previous edition unusable

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)

52.223-99 Ensuring Adequate COVID-19 Safety Protocols for Federal Contractors.

ENSURING ADEQUATE COVID-19 SAFETY PROTOCOLS FOR FEDERAL CONTRACTORS(OCT 2021) (DEVIATION)

(a) Definition. As used in this clause - United States or its outlying areas means

(1) The fifty States;

(2) The District of Columbia;

(3) The commonwealths of Puerto Rico and the Northern Mariana Islands;

(4) The territories of American Samoa, Guam, and the and United States Virgin Islands; and

(5) The minor outlying islands of Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Islands, Navassa Island, Palmyra Atoll, and Wake Atoll.

(b) Authority. This clause implements Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors, dated September 9, 2021 (published in the Federal Register on September 14, 2021, 86 FR 50985).

(c) Compliance. The Contractor shall comply with all guidance, including guidance conveyed through Frequently Asked Questions, as amended during the performance of this contract, for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force (Task Force Guidance) at https:/www.saferfederalworkforce.gov/contractors/.

(d) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (d), in subcontracts at any tier that exceed the simplified acquisition threshold, as defined in Federal Acquisition Regulation 2.101 on the date of subcontract award, and are for services, including construction, performed in whole or in part within the United States or its outlying areas.

(End of clause)

2. The total amount, scope, period of performance and all other terms and conditions of the contract remain unchanged.

3. By signing this modification, MODERNATX, INC, hereby releases the Government from any and all liability under this contract for further equitable adjustments attributable to such fact or circumstance giving rise to this modification. Period of Performance: 04/03/2020 to 08/31/2023

CONTINUATION PAGE

Section G.8 – Negotiated Indirect Rates and Ceiling

Below are the FY21 Provisional Indirect Rates that will be added to the contract with this modification.

Indirect Cost	Approved FY21 Provisional Rates %	Allocation Base
Fringe	[***]%	Total Labor Dollars
TechDev Overhead	[***]%	TechDev Department Direct Labor Dollars + Fringe
Research Overhead	[***]%	Research Department Direct Labor Dollars + Fringe
DevOps Overhead	[***]%	DevOps Department Direct Labor Dollars + Fringe
G&A Overhead		[redacted]
G&A	[***]%	Total Cost Input

The total amount, scope, period of performance and all other terms and conditions of the contract remain unchanged

Exhibit 10.40

Certain confidential portions of this exhibit have been omitted and replaced with "[***]." Such identified information has been excluded from this exhibit because it (i) is not material and (ii) is the type of information that the registrant treats as private or confidential.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 12

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00018	5-Nov-2021	See Schedule	

6. ISSUED BY CODE	7. ADMINISTERED BY (If other than item 6) CODE
W58P05	S2206A
ACC-APG - COVID RESPONSE - W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MD 21005-3013	DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
MODERNA US, INC. [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578		9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100
	X	10B. DATED (SEE ITEM 13)
CODE 8PTM0	FACILITY CODE	09-Aug-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended, is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:
(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

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B. THE ABOVE NUMBERED CONTRACT /ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return __1___ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT /MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: [***]
See Block 14 Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
Shaun Ryan, SVP & Deputy General Counsel	[***] TEL: [***] EMAIL: [***]

15B. CONTRACT OR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Shaun Ryan (Signature of person authorized to sign)	11/4/2021	BY [***] (Signature of Contracting Officer)	5-Nov-2021

EXCEPTION TO SF 30 APPROVED BY OIRM 11-84	30-105-04	STANDARD FORM 30 (Rev. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00018

OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00018) is to:

- Update H.19 to reflect revised term agreed on by USG and Moderna (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount remain unchanged.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

H.1 Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Name	Title
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

H.2 Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

a. Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

b. Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

c. The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

d. The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

H.5 Confidentiality of Information

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.6 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within [***] of award.

b. [***].

H.7 Performance Based Payment Liquidated under Termination

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

H.8 Public Readiness and Emergency Preparedness (PREP) Act:

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and

(iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act

Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

H.9 [***].

H.10 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government [***], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.11 [***].

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. [***].

H.13 Validation of IP/Data

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

H.14 Novation

Upon Moderna, US, Inc.'s registration in the System for Award Management, the Government will, at the Contractor's request, complete a novation of this Contract to recognize Moderna US, Inc. as a counterparty instead of Moderna TX, Inc. This novation will be completed through a modification executed by the Government that identifies Moderna US, Inc. as the contracting party for all purposes as if it had originally executed the Contract.

H.15 Base & Option 1 Delivery Acceleration

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract. If these manufacturing slots are

successfully utilized, [***] above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by $[***] for each successfully accelerated drug product fill under the Base Period ([***]) and $[***] for each successfully accelerated drug product fill under Option 1 ([***]).

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government $[***] for [***] and $[***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,
ii.) The basis of the cancellation, and
iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 Delivery Schedule, as revised 11Feb2021 via modification P00004

[***].

H.17 Post-Termination Disposition of Undelivered Product

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

H.18 [***]

In order to facilitate projections and invoicing, the Government shall provide or direct a third party ([***]) to provide to Moderna (1) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; (2) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; and (3) the number of [***] remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with a [***].

Both parties acknowledge that the delivery schedule is based on an [***] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, [***]. Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

H.19 Product [***] (as added via P00018)

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government [***]:

A) Adult Primary Series (mRNA1273 or other, as determined by EUA/BLA and any related supplement or amendment thereto accepted and authorized/licensed by FDA and mutually agreed upon; [***]

B) [***]

C) [***]

For avoidance of doubt, all doses delivered to the Government must be suitable for use in the United States pursuant to an active EUA or approved BLA at the time of product delivery. [***].

If US regulatory authorities determine there is a need for an updated vaccine containing one or more variant mRNA sequences for any reason, including improved efficacy against new or emerging virus strains, the Parties agree to work together in good faith to discuss any such situation and any potential impact on this contract. [***].

Both parties acknowledge that the EUA for mRNA1273 may be expanded such that doses procured under this contract may have utility beyond the currently authorized indications/populations, and in the event of any such expansion, the Government will not be restricted hereunder from use of mRNA1273 in accordance with the full scope of any FDA authorization and CDC recommendation to the extent consistent with the Government's obligations under Section H.8 and the terms of Section H.20.

The Government and Moderna agree that the total monthly delivery quantities for CLIN 3001 and 4001 will follow the following Delivery Schedule:

[***]

The Government and Moderna agree as follows:

- [***].
- *Sale of doses to the African Union.* The Government is agreeing to defer delivery of 33,000,000 doses previously scheduled for delivery in December and February to facilitate Moderna's supply of 50,000,000 doses of mRNA1273 to the African Union (AU) at a notforprofit price.

- [***].

EUA Wind Down. It is anticipated that all mRNA1273 under this contract will be delivered in accordance with an active EUA. If a BLA is issued during the term of this Contract for the mRNA1273 vaccine, the Government and Moderna shall discuss an appropriate transition of mRNA1273 to BLA which will include that any doses subsequently provided to the Government under this Contract are appropriately labeled and are otherwise suitable for use in the United States under the terms of the EUA (before expiration) or the BLA.

H.20 Donation of Excess Product

a. If the Government determines that a quantity of doses of mRNA-1273 supplied to the Government under this contract is no longer needed by the Government, the Government may donate such doses to a foreign nation or non- governmental organization (NGO) facilitating donation to a foreign nation, subject to the remainder of this Clause H.20. The Government shall notify Contractor in writing prior to any proposed donation to a foreign nation or NGO, which notice will include [***].

b. Contractor must verify in writing that all of the required conditions below are met before any such donation is made, [***]:

(i) [***];

(ii) [***];

(iii) [***]; and

(iv) [***].

c. The Government's donations will be from supplies of vaccine delivered to and accepted by the Government. To the extent the Government commits to deliver doses that have not yet been physically delivered to the Government, such donation will not occur until such doses have been delivered to the Government. The Government will be responsible for delivery of the donated doses to, and coordination of delivery with, the receiving foreign nation or NGO, as applicable. The Government or the receiving foreign nation or NGO, as applicable, will (i) satisfy all customs shipping requirements for import and export of the product; and (ii) as the exporter, file any required FDA export notifications. To the extent not already provided to the Government, the Contractor will provide all information necessary to complete any requirements identified in this paragraph in advance of shipment.

d. When the conditions above are met for any donation, the Parties will [***].

e. [***].

f. Shipment of any donated doses under this Article does not constitute a violation of the Defense Production Act.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES 1 14

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00019	15-NOV-2021	See Schedule	

6. ISSUED BY CODE W58P05

ACC-APG - COVID RESPONSE - W58P05
6472 INTEGRITY COURT (BUILDING 4401)
ABERDEEN PROVING GROUND MD 21005-3013

7. ADMINISTERED BY (If other than item 6) CODE S2206A

DCMA BOSTON
495 SUMMER STREET
BOSTON MA 02210-2138

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)

MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE 8PTM0 FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100

X 10B. DATED (SEE ITEM 13) 09-Aug-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended, is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT /ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return __1___ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT /MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: [***]
See Block 14 Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)
Shaun Ryan, SVP & Deputy General Counsel

16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
[***]
TEL: [***] EMAIL: [***]

15B. CONTRACT OR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Shaun Ryan	11/10/21	BY [***]	15-NOV-2021
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00019

OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00019) is to:

- Modify the H.20 Donation of Excess Product clause to capture clinical study donations (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).

- Add H.21 Healthcare Provider List clause (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).

- Update Exhibit B as outlined in clause H.20 with donation information for multiple recipients (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount remain unchanged.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

H.1 Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Name	Title
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

H.2 Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

a. Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

b. Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

c. The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

d. The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

H.5 Confidentiality of Information

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.6 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within [***] of award.

b. [***].

H.7 Performance Based Payment Liquidated under Termination

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

H.8 Public Readiness and Emergency Preparedness (PREP) Act:

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and

(iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act

Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

H.9 [***].

H.10 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government [***], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.11 [***].

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. [***].

H.13 Validation of IP/Data

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

H.14 Novation

Upon Moderna, US, Inc.'s registration in the System for Award Management, the Government will, at the Contractor's request, complete a novation of this Contract to recognize Moderna US, Inc. as a counterparty instead

of Moderna TX, Inc. This novation will be completed through a modification executed by the Government that identifies Moderna US, Inc. as the contracting party for all purposes as if it had originally executed the Contract.

H.15 Base & Option 1 Delivery Acceleration

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, [***] above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by $[***] for each successfully accelerated drug product fill under the Base Period ([***]) and $[***] for each successfully accelerated drug product fill under Option 1 ([***]).

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government $[***] for [***] and $[***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,
ii.) The basis of the cancellation, and
iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 Delivery Schedule, as revised 11Feb2021 via modification P00004

[***].

H.17 Post-Termination Disposition of Undelivered Product

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

H.18 [***]

In order to facilitate projections and invoicing, the Government shall provide or direct a third party ([***]) to provide to Moderna (1) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; (2) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; and (3) the number of [***] remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with a [***].

Both parties acknowledge that the delivery schedule is based on an [***] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, [***]. Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

H.19 Product [***] (as added via P00018)

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government [***]:

a. Adult Primary Series (mRNA-1273 or other, as determined by EUA/BLA and any related supplement or amendment thereto accepted and authorized/licensed by FDA and mutually agreed upon; [***]

b. [***]

c. [***]

For avoidance of doubt, all doses delivered to the Government must be suitable for use in the United States pursuant to an active EUA or approved BLA at the time of product delivery. [***].

If US regulatory authorities determine there is a need for an updated vaccine containing one or more variant mRNA sequences for any reason, including improved efficacy against new or emerging virus strains, the Parties agree to work together in good faith to discuss any such situation and any potential impact on this contract. [***].

Both parties acknowledge that the EUA for mRNA-1273 may be expanded such that doses procured under this contract may have utility beyond the currently authorized indications/populations, and in the event of any such expansion, the Government will not be restricted hereunder from use of mRNA-1273 in accordance with the full scope of any FDA authorization and CDC recommendation to the extent consistent with the Government's obligations under Section H.8 and the terms of Section H.20.

The Government and Moderna agree that the total monthly delivery quantities for CLIN 3001 and 4001 will follow the following Delivery Schedule:

[***]

The Government and Moderna agree as follows:

- [***].
- *Sale of doses to the African Union.* The Government is agreeing to defer delivery of 33,000,000 doses previously scheduled for delivery in December and February to facilitate Moderna's supply of 50,000,000 doses of mRNA-1273 to the African Union (AU) at a not-for-profit price.
- [***].

EUA Wind Down. It is anticipated that all mRNA-1273 under this contract will be delivered in accordance with an active EUA. If a BLA is issued during the term of this Contract for the mRNA-1273 vaccine, the Government and Moderna shall discuss an appropriate transition of mRNA-1273 to BLA which will include that any doses subsequently provided to the Government under this Contract are appropriately labeled and are otherwise suitable for use in the United States under the terms of the EUA (before expiration) or the BLA.

H.20 Donation of Excess Product

a. If the Government determines that a quantity of doses of mRNA-1273 supplied to the Government under this contract is no longer needed by the Government, the Government may donate such doses to a foreign nation or nongovernmental organization (NGO) facilitating donation to a foreign nation, subject to the remainder of this Clause H.20. The Government shall notify Contractor in writing prior to any proposed donation to a foreign nation or NGO, which notice will include [***].

b. Contractor must verify in writing that all of the required conditions below are met before any such donation is made, [***]:

(i) [***];

(ii) [***];

(iii) [***]; and

(iv) [***].

c. Additionally, the Government may donate product for use in the clinical study to be conducted pursuant to the Clinical Trial Agreement (as amended on October 28, 2021) between The National Institute of Allergy and Infectious Disease ("NIAID") and the South African Medical Research Counsel ("SAMRC") under Protocol CoVPN 3008 (the "CoVPN 3008 Study"), subject to the Government's having a binding written agreement(s) in place with the sponsor that satisfies the conditions set forth below in this clause (c):

(i) [***],

(ii) [***];

(iii) [***].

(iv) [***];

(v) [***];

(vi) [***];

(vii) [***];

(viii) [***];

(ix) [***]; and

(x) [***].

d. The Government's donations will be from supplies of vaccine delivered to and accepted by the Government. To the extent the Government commits to deliver doses that have not yet been physically delivered to the Government, such donation will not occur until such doses have been delivered to the Government. The Government will be responsible for delivery of the donated doses to, and coordination of delivery with, the receiving foreign nation, clinical study sponsor, or NGO, as applicable. The Government or the receiving foreign nation, clinical study sponsor, or NGO, as applicable, will (i) satisfy all customs shipping requirements for import and export of the product; and (ii) as the exporter, file any required FDA export notifications. To the extent not already provided to the Government, the Contractor will provide all information necessary to complete any requirements identified in this paragraph in advance of shipment.

e. When the conditions above are met for any donation, the Parties will [***].

f. [***].

g. Shipment of any donated doses under this Article does not constitute a violation of the Defense Production Act.

H.21 CDC Healthcare Provider List

To ensure timely communication is provided to health care providers, the USG has provided Moderna the mailing list for the Centers for Disease Control and Prevention (CDC) healthcare providers administering Moderna's vaccine and boosters in order for Moderna to send information regarding boosters that were authorized by the FDA on October 20, 2021. Moderna agrees to the terms below of the handling of the CDC Healthcare Provider List.

1. Moderna shall use the CDC Healthcare Provider List only for the express purpose of the specific mailing regarding Moderna's FDA-authorized booster product/EUA expansion;

2. Moderna shall not share or provide this list to any outside parties other than those who are supporting this specific mailing; and

3. Moderna shall delete (and require any other parties to delete) the list once they have completed the mailing.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 February 2021
Exhibit B	Donation of Excess Product	8	1 November 2021
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	Security Plan	7	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	3	7 August 2020
Attachment 0005	[***]	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	1	14 June 2021
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	3 September 2021
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

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2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00020	22 DEC 2021	See Schedule	

6. ISSUED BY CODE W58P05

ACC-APG - COVID RESPONSE - W58P05
6472 INTEGRITY COURT (BUILDING 4401)
ABERDEEN PROVING GROUND MD 21005-3013

7. ADMINISTERED BY (If other than item 6) CODE S2206A

DCMA BOSTON
495 SUMMER STREET
BOSTON MA 02210-2138

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)

MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE 8PTM0 FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100

X 10B. DATED (SEE ITEM 13) 09-Aug-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended, is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT /ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return __1___ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT /MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: [***]
See Block 14 Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)
Shaun Ryan, SVP & Deputy General Counsel

16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
[***]
TEL: [***] EMAIL: [***]

15B. CONTRACT OR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Shaun Ryan	12/21/2021	BY [***]	22 December 2021
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00020

OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00020) is to:

- Update Section G Contracting Officer and Government Technical Point of Contract (FAR 43.103(b)

- Update Moderna Contractor's Contract Administration in Section G and Key Personnel in H.1 (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Update Exhibit B as outlined in clause H.20 with donation information for multiple recipients identified (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount remain unchanged.

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

G.1 GOVERNMENT CONTRACT ADMINISTRATION

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the Contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

Procuring Contracting Officer:
[***]
Joint COVID-19 Response Division
US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

Contract Specialist:
[***]
Joint COVID-19 Response Division
US Army Contracting Command

6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

Contract Specialist:
[***]
Joint COVID-19 Response Division
US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

[***]
Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

[***]
Moderna US, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.4 PLACES OF PERFORMANCE

Moderna US, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.5 NOTIFICATION OF REVISIONS AND CHANGE

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

G.6 PERFORMANCE BASED PAYMENT

Performance-based payments (PBP) are authorized under this contract in accordance with FAR 52.232-32. The contractor shall bill for the PBP upon achievement of the completion criteria identified in Attachment 0007, Performance-based Payment Milestone Table dated 4 May 2021. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option IAW the following schedule:

CLIN	Period	Amount	
0001AA	BASE	$90,210,000	
0001AB	BASE	$132,308,000	
0001AC	BASE	$180,420,000	
0001AD	BASE	$198,462,000	
	TOTAL		$601,400,000
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	

	TOTAL	$[***]
[***]	[***]	$[***]
[***]	[***]	$[***]
[***]	[***]	$[***]
[***]	[***]	$[***]
	TOTAL	$[***]
[***]	[***]	$[***]
[***]	[***]	$[***]
[***]	[***]	$[***]
[***]	[***]	$[***]
	TOTAL	$[***]

Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0008, Performance- based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0008.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

H.1 Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Name	Title
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

H.2 Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

a. Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

b. Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

c. The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

d. The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

H.5 Confidentiality of Information

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.6 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within [***] award.

b. [***].

H.7 Performance Based Payment Liquidated under Termination

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

H.8 Public Readiness and Emergency Preparedness (PREP) Act:

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and

(iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act

Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

H.9 [***].

H.10 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government [***], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.11 [***].

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. [***].

H.13 Validation of IP/Data

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

H.14 Novation

Upon Moderna, US, Inc.'s registration in the System for Award Management, the Government will, at the Contractor's request, complete a novation of this Contract to recognize Moderna US, Inc. as a counterparty instead of Moderna TX, Inc. This novation will be completed through a modification executed by the Government that identifies Moderna US, Inc. as the contracting party for all purposes as if it had originally executed the Contract.

H.15 Base & Option 1 Delivery Acceleration

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract.

If these manufacturing slots are successfully utilized, [***] above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by $[***] for each successfully accelerated drug product fill under the Base Period ([***]) and $[***] for each successfully accelerated drug product fill under Option 1 ([***]).

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government $[***] for [***] and $[***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,
ii.) The basis of the cancellation, and
iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 Delivery Schedule, as revised 11Feb2021 via modification P00004

[***].

H.17 Post-Termination Disposition of Undelivered Product

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

H.18 [***]

In order to facilitate projections and invoicing, the Government shall provide or direct a third party ([***]) to provide to Moderna (1) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; (2) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; and (3) the number of [***] remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with a [***].

Both parties acknowledge that the delivery schedule is based on an [***] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, [***]. Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

H.19 Product [***] (as added via P00018)

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government [***]:

a. Adult Primary Series (mRNA-1273 or other, as determined by EUA/BLA and any related supplement or amendment thereto accepted and authorized/licensed by FDA and mutually agreed upon; [***]

b. [***]

c. [***]

For avoidance of doubt, all doses delivered to the Government must be suitable for use in the United States pursuant to an active EUA or approved BLA at the time of product delivery. [***].

If US regulatory authorities determine there is a need for an updated vaccine containing one or more variant mRNA sequences for any reason, including improved efficacy against new or emerging virus strains, the Parties agree to work together in good faith to discuss any such situation and any potential impact on this contract. [***].

Both parties acknowledge that the EUA for mRNA-1273 may be expanded such that doses procured under this contract may have utility beyond the currently authorized indications/populations, and in the event of any such expansion, the Government will not be restricted hereunder from use of mRNA-1273 in accordance with the full scope of any FDA authorization and CDC recommendation to the extent consistent with the Government's obligations under Section H.8 and the terms of Section H.20.

The Government and Moderna agree that the total monthly delivery quantities for CLIN 3001 and 4001 will follow the following Delivery Schedule:

[***]

The Government and Moderna agree as follows:

- [***].
- *Sale of doses to the African Union.* The Government is agreeing to defer delivery of 33,000,000 doses previously scheduled for delivery in December and February to facilitate Moderna's supply of 50,000,000 doses of mRNA-1273 to the African Union (AU) at a not-for-profit price.
- [***].

EUA Wind Down. It is anticipated that all mRNA-1273 under this contract will be delivered in accordance with an active EUA. If a BLA is issued during the term of this Contract for the mRNA-1273 vaccine, the Government and Moderna shall discuss an appropriate transition of mRNA-1273 to BLA which will include that any doses subsequently provided to the Government under this Contract are appropriately labeled and are otherwise suitable for use in the United States under the terms of the EUA (before expiration) or the BLA.

H.20 Donation of Excess Product

a. If the Government determines that a quantity of doses of mRNA-1273 supplied to the Government under this contract is no longer needed by the Government, the Government may donate such doses to a foreign nation or nongovernmental organization (NGO) facilitating donation to a foreign nation, subject to the remainder of this Clause H.20. The Government shall notify Contractor in writing prior to any proposed donation to a foreign nation or NGO, which notice will include [***].

b. Contractor must verify in writing that all of the required conditions below are met before any such donation is made, [***]:

(i) [***];

(ii) [***];

(iii) [***]; and

(iv) [***].

c. Additionally, the Government may donate product for use in the clinical study to be conducted pursuant to the Clinical Trial Agreement (as amended on October 28, 2021) between The National Institute of Allergy and Infectious Disease ("NIAID") and the South African Medical Research Counsel ("SAMRC") under Protocol CoVPN 3008 (the "CoVPN 3008 Study"), subject to the Government's having a binding written agreement(s) in place with the sponsor that satisfies the conditions set forth below in this clause (c):

(i) [***],

(ii) [***];

(iii) [***].

(iv) [***];

(v) [***];

(vi) [***];

(vii) [***];

(viii) [***];

(ix) [***]; and

(x) [***].

d. The Government's donations will be from supplies of vaccine delivered to and accepted by the Government. To the extent the Government commits to deliver doses that have not yet been physically delivered to the Government, such donation will not occur until such doses have been delivered to the Government. The Government will be responsible for delivery of the donated doses to, and coordination of delivery with, the receiving foreign nation, clinical study sponsor, or NGO, as applicable. The Government or the receiving foreign nation, clinical study sponsor, or NGO, as applicable, will (i) satisfy all customs shipping requirements for import and export of the product; and (ii) as the exporter, file any required FDA export notifications. To the extent not already provided to the Government, the Contractor will provide all information necessary to complete any requirements identified in this paragraph in advance of shipment.

e. When the conditions above are met for any donation, the Parties [***].

f. [***].

g. Shipment of any donated doses under this Article does not constitute a violation of the Defense Production Act.

H.21 CDC Healthcare Provider List

To ensure timely communication is provided to health care providers, the USG has provided Moderna the mailing list for the Centers for Disease Control and Prevention (CDC) healthcare providers administering Moderna's vaccine and boosters in order for Moderna to send information regarding boosters that were authorized by the FDA on October 20, 2021. Moderna agrees to the terms below of the handling of the CDC Healthcare Provider List.

1. Moderna shall use the CDC Healthcare Provider List only for the express purpose of the specific mailing regarding Moderna's FDA-authorized booster product/EUA expansion;

2. Moderna shall not share or provide this list to any outside parties other than those who are supporting this specific mailing; and

3. Moderna shall delete (and require any other parties to delete) the list once they have completed the mailing.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 February 2021
Exhibit B	Donation of Excess Product	11	5 December 2021
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	Security Plan	7	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	3	7 August 2020
Attachment 0005	[***]	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	1	14 June 2021
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	3 September 2021
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES 1 13

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00021	21-JAN-2022	See Schedule	

6. ISSUED BY CODE W58P05

ACC-APG - COVID RESPONSE - W58P05
6472 INTEGRITY COURT (BUILDING 4401)
ABERDEEN PROVING GROUND MD 21005-3013

7. ADMINISTERED BY (If other than item 6) CODE S2206A

DCMA BOSTON
495 SUMMER STREET
BOSTON MA 02210-2138

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)

MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE 8PTM0 FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100

X 10B. DATED (SEE ITEM 13) 09-Aug-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended, is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT /ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return __1___ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT /MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: [***]
See Block 14 Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)
Shaun Ryan, SVP & Deputy General Counsel

16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
[***]
TEL: [***] EMAIL: [***]

15B. CONTRACT OR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Shaun Ryan	1/20/2022	BY [***]	21-JAN-2022
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:
P00021

OBLIGATION AMOUNT: $203,142.00

a. The purpose of this modification (P00021) is to:

- Revise Statement of Work in sections C.3.4, C.3.5, and C.7 (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Extend and fund VMI Storage by six month from 1 January 2022 to 30 June 2022 on CLIN 0006 (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Update Exhibit B as outlined in clause H.20 with donation information for multiple recipients (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total funded amount and total contract value amount increase by $203,142.00 from $8,145,591,662.60 to $8,145,794,804.60.

All other terms and conditions remain unchanged.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $203,142.00 from $8,145,591,662.60 to $8,145,794,804.60.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0006 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006		6	Months	$33,857.00	$203,142.00

Vendor Managed Inventory Extentions FFP
a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011737324
PSC CD: 6505

NET AMT $203,142.00

ACRN AP $203,142.00
CIN: GFEBS001173732400001

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

STATEMENT OF WORK
LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE

C.1 **SCOPE**. The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 **Background**. In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 **Objective**: The objective of this effort is to obtain the following:

a. Base Period: Large scale manufacturing of 100 million vaccine doses
b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

C.1.3 Consistent with the Updated EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) dated 01 April 2021, up to 15 doses may be extracted from Moderna's newly authorized multidose vials with 8.0mL fill volume (1600mcg). The Government and Moderna agree that 15 doses per vial are only attainable using premium low dead volume (LDV) syringes, which are in short supply globally. Utilizing initial ancillary equipment, vaccine administration personnel can reliably extract 13 doses from these vials; however, the Government has identified needle/syringe combinations that can be used to extract 14 doses.

C.1.3.1 Given the two parties' shared interest in reducing vaccine waste and accelerating the availability of Moderna's SARS-CoV-2 vaccine doses, the Government and Moderna intend that the Moderna vaccines doses be administered with needles and syringes compatible with extraction of 14 doses when possible. Toward this end, the Government shall maintain a list of syringe and/or needle combinations which will allow extraction of 14 doses per 8.0mL vial, which list shall be updated jointly by the Government and Moderna as any additional syringe and/or needle combinations compatible with extraction of 14 doses/vial are identified. Furthermore, the Government will, to the extent that appropriate needles and syringes are available, assemble and ship kits containing sufficient quantities of syringes and needles compatible with extraction of 14 doses per vial (Kit Moderna 140) with Moderna's SARS-CoV-2 vaccine. The Government expects that these kits will be available beginning 01 May 2021 for a significant portion of Moderna's remaining deliveries. If, however, appropriate syringes and needles are not available, the Government will revert to shipping the Kit Moderna 130 with Moderna's SARS-CoV-2 vaccine.

C.2 **APPLICABLE DOCUMENTS**.

C.2.1 **Federal Documents**:

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General. (https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0)

C.3 **REQUIREMENTS**. Independently, and not as an agent of the USG, in accordance with the Proposal submitted by Moderna US, Inc. in response to Solicitation Number W911QY20R0043, Titled, "Advanced Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)"), dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services, qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

C.3.1 **Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.1.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million Final Drug Product (FDP) doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include, the following tasks and other activities reasonably contemplated by such task:

C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.1.1.2 cGMP manufacturing of 100 million doses fully compliant with 21 CFR 210 and 211.

C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).

C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including "Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act" (April 2020).

C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.

C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.

C.3.1.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.1.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer's Representative (COR) within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.2 **CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.3 **CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581- 585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.4 **CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract per C.7. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf- life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial

Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.5 **CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract per C.7. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf- life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.4 **CLIN 0002: Data Deliverables**. The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, formulated LNPs, and the fill, finish, and released product.

C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.

C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.

C.4.5 Key Personnel Listing (CDRL A007).

C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.

C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.

C.4.8 Supply Chain Resiliency Plan (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.

C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance. The following RMP information shall be included in the Monthly Technical Progress Report (CDRL A008).

Risk Register content:
a. Manuf/FF -risks or possible delays. If none N/A
b. Supply chain – same as above
c. Distribution challenges – same as above
d. Regulatory – same as above

C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided “COVID-19 Dose Tracking Template” (CDRL Attachment 0003).

C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.

C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. “Significant” is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.

C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.

C.4.14 Press Releases. The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.

C.4.15 Manufacturing Development Plan. The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP).

C.5 **Administration**.

C.5.1 **Post Award Teleconference**. The contractor shall host a Post Award Teleconference within 15 calendar days after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 **Post Award Kickoff Meeting**. The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 **Bi-Weekly Teleconference**. The contractor shall participate in bi-weekly teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 **Daily "Check-In"**. The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

C.6 **Security**.

C.6.1 **Access and General Protection/Security Policy and Procedures**. The contractor shall provide all information required for background checks necessary to access critical information related to OWS, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change the USG may require changes in the contractor's security matters or processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.

C.6.2 **Security Program and Plan**. The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Security Plan comments, and, submit a final Security Plan to the U.S. USG within thirty (30) calendar days after receipt of the comments. The Security Plan shall include a timeline for compliance of all the required security measures outlined in CDRL Attachment 0002.

C.6.3 **Operational Security (OPSEC)**. The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP)/Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

C.7 **Vendor Managed Inventory (VMI)**. The Contractor shall provide the capability to store up to 100M doses of mRNA-1273 vaccine until 30 June 2022, in support of the extension of the delivery schedule for option 3 and 4. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months, in accordance with product labeling, and prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. [***]. The contractor shall store the product to insure product quality with audible alarms and contacting. The contractor shall notify the USG within [***] of detection of an incident with the potential to impact product quality, and implement corrective actions to mitigate the incident. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within [***] of detection of an incident with potential to impacts product quality.

C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. The contractor shall ship mRNA-1273 vaccines to designated locations [***] in the United States. The contractor shall be responsible for shipment of all vaccine product whether acceptance is conducted at origin or destination. [***].

C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.

C.7.3 [***]. Implementation of a Vendor Managed Inventory Plan/SOP (CDRL A012) shall be provided to the USG. [***]. Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0006:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0006 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-JUN-2022	6	N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $203,142.00 from $8,145,591,662.60 to $8,145,794,804.60.

CLIN 0006:
Funding on CLIN 0006 is initiated as follows:

ACRN: AP

CIN: GFEBS001173732400001

Acctng Data: 021202120222040000665654260 S.0074658.5.44 6100.0152021001

Increase: $203,142.00

Total: $203,142.00

Cost Code: A5XAH

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 February 2021
Exhibit B	Donation of Excess Product	10	19 January 2022
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	Security Plan	7	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	3	7 August 2020
Attachment 0005	[***]	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	1	14 June 2021
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	3 September 2021
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

Exhibit 21.1

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
Brizo Ltd.	Bermuda
Moderna Australia Pty Ltd	Australia
Moderna Austria GmbH	Austria
Moderna Biopharma Canada Corporation	Canada
Moderna Biotech Ireland Limited	Ireland
Moderna Biotech Securities, Inc.	Massachusetts
Moderna Biotech Spain, S.L.U.	Spain
Moderna Biotech UK Limited	United Kingdom
Moderna Charitable Foundation, Inc.	Delaware
Moderna France	France
Moderna Germany GmbH	Germany
Moderna Italy S.r.l.	Italy
Moderna Japan Co., Ltd.	Japan
Moderna Korea Limited	South Korea
Moderna Netherlands B.V.	Netherlands
Moderna Poland sp. z o.o.	Poland
Moderna Services, Inc.	Delaware
Moderna Sweden AB	Sweden
Moderna Switzerland GmbH	Switzerland
ModernaTX, Inc.	Delaware
Moderna US, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-228718) pertaining to the Moderna Therapeutics, Inc. 2016 Stock Option and Grant Plan and the Moderna, Inc. 2018 Employee Stock Purchase Plan,
(2) Registration Statement (Form S-8 No. 333-230245) pertaining to the Moderna, Inc. 2018 Stock Option and Incentive Plan,
(3) Registration Statement (Form S-3 No. 333-236348) of Moderna, Inc.,
(4) Registration Statement (Form S-8 No. 333-236713) pertaining to the Moderna, Inc. 2018 Stock Option and Incentive Plan and the Moderna, Inc. 2018 Employee Stock Purchase Plan, and
(5) Registration Statement (Form S-3 No. 333-238467) of Moderna, Inc.;

of our reports dated February 25, 2022, with respect to the consolidated financial statements of Moderna, Inc. and the effectiveness of internal control over financial reporting of Moderna, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 25, 2022

EX-31.1 Section 302 Certification of CEO

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Stéphane Bancel, certify that:

1. I have reviewed this Annual Report on Form 10-K of Moderna, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2022

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

EX-31.2 Section 302 Certification of CFO

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, David W. Meline, certify that:

1. I have reviewed this Annual Report on Form 10-K of Moderna, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2022

By: /s/ David W. Meline

David W. Meline
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Stéphane Bancel, Chief Executive Officer of Moderna, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2021 (Annual Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2022

By: /s/ Stéphane Bancel
Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, David W. Meline, Chief Financial Officer of Moderna, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2021 (Annual Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2022

By: /s/ David W. Meline
David W. Meline
Chief Financial Officer
(Principal Financial Officer)