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, 2022

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, 2022, the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $48.8 billion based on the closing sale price on that date of $142.85. 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 17, 2023, there were 386,339,594 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 2023 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 vaccines consistent with our existing or potential contractual obligations, including due to delays or difficulties experienced by our third-party commercial partners;
- We have limited sales, distribution and marketing experience, and if we cannot effectively establish such capabilities or supplement our capabilities by entering into agreements with third parties, our ability to generate revenues may be adversely affected;
- Evolving dynamics in the market for COVID-19 vaccines are likely to impact our financial results, including increased production costs per dose and lower product revenues than we have experienced in recent years;
- The pharmaceutical market is intensely competitive, and we may not compete effectively in the market for existing products, new treatment methods and new technologies;
- We may be unsuccessful or delayed in developing updates to our COVID-19 vaccines to protect against future variants of the SARS-CoV-2 virus, or booster doses of our COVID-19 vaccines may not protect against such variants, and a market for vaccines and boosters against these variants may not develop or may be weaker than anticipated;
- We have only recently established capabilities to facilitate our compliance with global pharmacovigilance obligations, and failure to build out and maintain this infrastructure may result in increased costs, reputational harm or the loss of our ability to commercialize our products;
- 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;
- The regulatory pathway for COVID-19 vaccines is continually evolving and may result in unexpected or unforeseen challenges;
- Preclinical development is lengthy and uncertain, especially for mRNA medicines, and our preclinical programs or development candidates may be delayed or terminated, which may have a material adverse impact on our platform or our business;
- Clinical development is lengthy and uncertain, and our clinical programs may be delayed or terminated, 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 products;
- As we grow as a commercial company and 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 third-party 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 vaccines and investigational medicines. Our manufacturing facilities or those of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet current Good Manufacturing Practice (cGMP) requirements could result in significant delays in any approval of and costs of our products;
- Our personalized cancer vaccine (PCV) investigational medicine is uniquely manufactured for each patient using a novel, complex manufacturing process and we may encounter difficulties in production;
- We have 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 and the intellectual property rights therein, 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 related to intellectual property rights and requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs;

- We have a limited history of recognizing revenue from product sales and may be unable to achieve 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, including from cybersecurity incidents, 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 or criminal penalties and damage our reputation;
- The price of our common stock has been volatile, which could result in substantial losses for stockholders; and
- Unfavorable U.S. or global economic conditions, including as a result of disease outbreak, war, conflict or other political instability, 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 vaccines, and our plans and expectations regarding future generations of our COVID-19 vaccines that we may develop in response to variants of the SARS-CoV-2 virus, ongoing clinical development, manufacturing and supply, pricing, commercialization, regulatory matters and third-party and governmental arrangements and potential arrangements;

- our expectations regarding an endemic, commercial market for COVID-19 and our preparations for and ability to effectively compete in such a market, as well as the impact that the evolving market will have on our financial returns;

- our expectations regarding execution of new COVID-19 vaccine sales contracts;

- expected sales and delivery of our COVID-19 vaccines in 2023;

- our ability to successfully contract with third-party suppliers, distributors and manufacturers;

- our ability and the ability of third parties with whom we contract to successfully manufacture, supply and distribute our COVID-19 vaccines and boosters, and any future 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, development candidates, investigational medicines and technology, including our ability to enter into license agreements, and our expectations regarding pending legal proceedings related to our intellectual property;

- our intention to submit our respiratory syncytial virus (RSV) vaccine candidate to the FDA for regulatory approval for older adults in the first half of 2023;

- our plans with respect to our PCV candidate, including our plan to initiate a Phase 3 study in adjuvant melanoma in 2023 and rapidly expand to additional tumor types, including non-small cell lung cancer;

- the timing of initiation, progress, completion, results (including interim data) and cost of our clinical trials, preclinical studies and research and development programs, as well as those of our collaborators, including Merck and Vertex Pharmaceuticals;

- participant enrollment in our clinical trials, including enrollment demographics and timing;

- 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;
- potential advantages of mRNA as compared to traditional medicine;
- our ability to obtain and maintain regulatory approval of our investigational medicines;
- the implementation of our business model and strategic plans for our business, investigational medicines and technology, including our expectations for ongoing pipeline expansion;
- potential product launches;
- our ability to successfully commercialize our products, if approved, including in light of the size and growth potential of the markets for our products and the degree of market acceptance of our products;
- the pricing and reimbursement of our medicines, if approved;
- the buildout of our manufacturing and commercial operations, including our partnerships with various governments to establish mRNA vaccine manufacturing facilities;
- estimates of our future expenses, revenues and capital requirements;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic collaborations or other agreements with collaborators with development, regulatory and commercialization expertise;
- our financial performance;
- 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;
- our ability to attract and retain key scientific, manufacturing, regulatory, commercial and 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 (mRNA). The potential advantages 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 and integrated manufacturing capabilities that allow for rapid clinical and commercial production at scale. We have established relationships with government and commercial collaborators, which has allowed us to pursue both groundbreaking science and rapid scaling of our manufacturing capabilities.

In 2020, mRNA technology emerged as a new class of medicines. Moderna's capabilities came together to secure the authorization and approval of one of the earliest and most-effective vaccines against the COVID-19 pandemic, progressing from vaccine design, through testing and to authorization and distribution in less than a year. Hundreds of millions of doses of our COVID-19 vaccines were distributed in each of 2021 and 2022, providing countries around the globe a key tool to combat the pandemic. In January 2022, our original COVID-19 vaccine, Spikevax®, for individuals 18 years of age and older in the United States, received our first Biologics License Application (BLA) approval from the U.S. Food and Drug Administration (FDA).

In December 2022, we announced positive Phase 2b results for mRNA-4157, our personalized cancer vaccine (PCV), as well as positive Phase 3 results in older adults for mRNA-1345, our vaccine for respiratory syncytial virus (RSV), in January 2023. Looking forward, we are continuing to advance a broad pipeline of mRNA medicines, with three programs beyond COVID-19 undergoing Phase 3 trials as of February 2023: RSV, cytomegalovirus (CMV) and seasonal flu. Our commercial priorities for 2023 include planning for the potential of an endemic COVID-19 market, advancing our respiratory vaccine portfolio of single-agent and combination vaccines for RSV, seasonal flu and COVID-19, executing on our bold campaign of cancer vaccine studies, advancing our rare metabolic disease programs and driving advancement and growth in our latent vaccine portfolio. To support our growing pipeline and our commercial activities, we are expanding our manufacturing and research and development footprint around the world. For example, we have entered into agreements with the governments of Australia, Canada and the United Kingdom, and entered into a Memorandum of Understanding with the Government of the Republic of Kenya, to establish state-of-the-art mRNA manufacturing facilities in those countries, which we expect will provide direct access to rapid pandemic response capabilities for future pandemics.

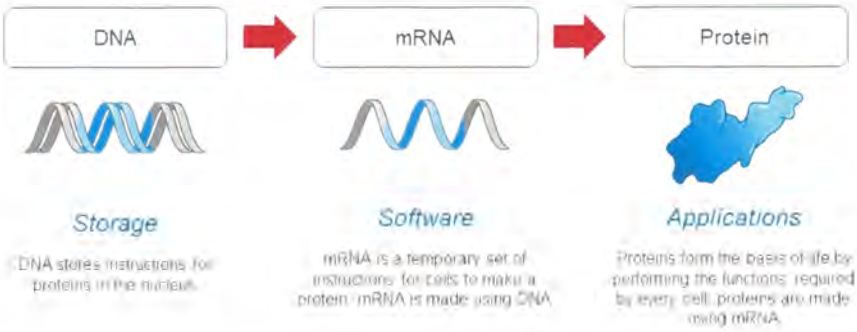
THE mRNA OPPORTUNITY

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 cell's 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.

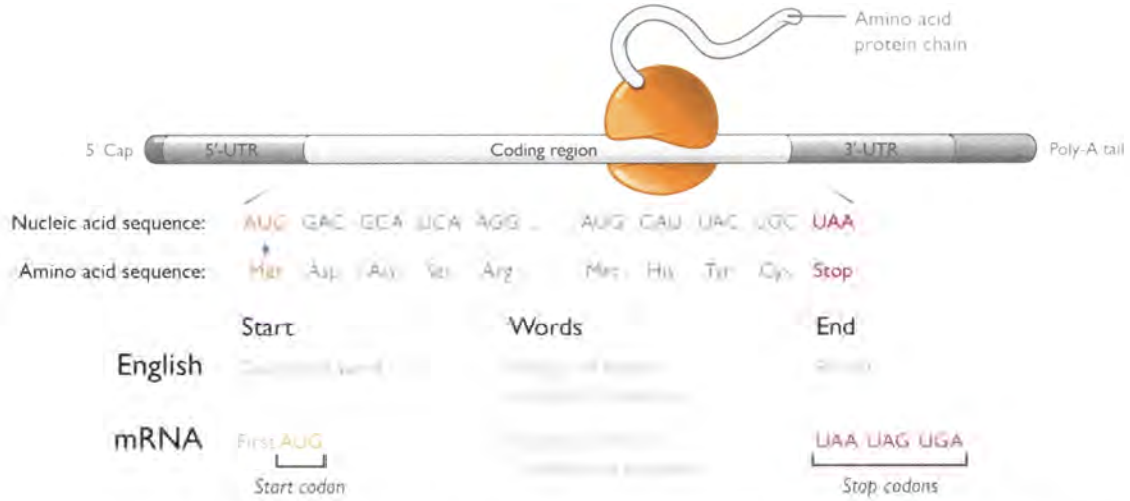
We see mRNA functioning as the "software of life." Every cell uses mRNA to provide real time instructions to make the proteins necessary to drive all aspects of biology, including in human health and disease. This was codified as the central dogma of molecular biology over 50 years ago, and is exemplified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



The structure of mRNA

mRNA 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 (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 (5'-UTR); (2) the 3' untranslated region (3'-UTR); (3) the 5' cap; and (4) a 3' polyadenosine (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 position it to have a profound impact on human health:

- **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:** Tailored mRNA can be sent into cells to instruct them to produce specific protein therapeutics or vaccine antigens and provides certain advantages over traditional approaches to medicine, where a protein or chemical is introduced to the 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, instead of starting from scratch for each new vaccine or therapy.
- **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 promote safety and tolerability.

Our ability to rapidly develop, manufacture and commercialize vaccines against COVID-19 demonstrates the potential mRNA medicines have to help people and patients in far-reaching ways that could exceed the impact of traditional approaches to medicine.

We believe that the main advantages of mRNA as compared to traditional medicine are:

1. **mRNA could create an unprecedented abundance and diversity of medicines.** mRNA's breadth of applicability has the potential to create an extraordinary number of new mRNA 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 leveraged across our 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 medicines represents a significant breakthrough for patients, our industry and human health globally. 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, and subsequently receiving BLA approval from the FDA, provides a visible example of the promise of mRNA medicine. The Moderna COVID-19 Vaccine/Spikevax has been authorized for use or approved in over 70 countries. As our first approved product, Spikevax has helped hundreds of millions of people worldwide combat the COVID-19 pandemic. We believe our success in developing our COVID-19 vaccines has positive implications beyond infectious disease vaccines and across our entire pipeline. We currently have 48 programs in development, and our pipeline spans infectious diseases, including vaccines against respiratory diseases, latent diseases and public health pathogens, as well as four therapeutic areas: 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 formulated strategic priorities that guide our near-term and long-term goals:

BioNTech-Pfizer Exhibit 1272
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358
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1. **Execute our commercialization plans for our COVID-19 vaccines.** Our COVID-19 vaccines have been approved in more than 70 countries. We are transitioning to prepare for an endemic, commercial market for COVID-19 vaccines in the United States and other countries. We are working to build a differentiated commercial model, with active commercial subsidiaries across North America, Europe and the Asia-Pacific region, providing us with local commercial teams in key markets around the world.

2. **Build an unrivaled seasonal respiratory vaccine franchise.** As we build our respiratory franchise, we are applying our experience and using our mRNA platform to develop medicines that can help prevent hospitalizations and deaths from the most prevalent respiratory viruses. We are currently developing vaccines against COVID-19, seasonal flu and RSV individually, while pursuing parallel development of combination vaccines. In January 2023, we announced that our older adult RSV vaccine candidate had met its primary efficacy endpoints in a Phase 3 trial. 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 that combination vaccines have the potential to improve health outcomes at lower costs due to higher compliance, better uptake, a larger benefit to the healthcare system (including through reduced vaccine administration costs) and increased consumer convenience. We have preparations underway for multiple potential vaccine launches globally over the next several years.

3. **Execute on a bold campaign of cancer vaccine studies.** In 2022, our platform technology delivered the world's first-ever investigational mRNA cancer treatment to show efficacy in a randomized Phase 2 clinical study in melanoma. Our personalized cancer vaccines, which we are developing with Merck Sharp & Dohme LLC (Merck), target an individual patient's unique tumor mutations to selectively treat their cancer. By making an individualized medicine for each unique patient, we are pioneering a new frontier in the fight against cancer. Under our strategic alliance, we and Merck expect to begin additional studies in melanoma, non-small cell lung carcinoma (NSCLC) and other forms of cancer with the goal of bringing truly individualized cancer treatment to patients.

4. **Advance rare metabolic disease programs.** We are seeing early promise in two of our rare disease programs targeting propionic acidemia (PA) and glycogen storage disease 1a (GSD1a). Our development candidate for methylmalonic acidemia (MMA) is also in the clinic. Based on proof-of-concept data and leveraging our learnings from our other rare disease programs, we recently announced a new development candidate for ornithine transcarbamylase (OTC) deficiency, which uses the same lipid nanoparticle (LNP) as our GSD1a program.

5. **Drive rapid advancement and growth in our latent vaccine portfolio.** Once a human is infected by a latent virus, the virus remains in the body and can lead to lifelong medical complications. We are committed to developing a portfolio of vaccine and therapeutic candidates against latent viruses, including CMV, Epstein-Barr virus (EBV), human immunodeficiency virus (HIV) and varicella-zoster virus (VZV).

   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 and higher risk of developing cancer/autoimmune diseases. Untreated HIV infection causes impairment of the immune system, leading to acquired immunodeficiency syndrome (AIDS). VZV causes shingles, which occurs in one of three adults in their lifetime.

6. **Deliver the next-generation pipeline and platform.** Our platform goes beyond a single pathogen, disease or pandemic. Our platform is about maximizing the impact of mRNA medicines on global human health. 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. This also includes developing and advancing innovative LNP delivery technologies. We currently have 48 mRNA development programs in our pipeline and 38 development programs in active clinical trials. Next on the horizon are innovative therapeutics based on mRNA-encoded gene editing enzymes. Moderna Genomics is our effort to expand the use of our platform to help patients with new cures for diseases. Our vision is to be a leader in large, complex genomic editing. We are investing internally and through strategic collaborations with other next-generation gene editing companies, such as our collaboration with Metagenomi, Inc. (Metagenomi) focused on advancing new gene editing systems for *in vivo* human therapeutic applications.

7. **Build a culture of perpetual learning, and strengthen our processes and digital systems.** The Moderna Mindsets are a set of beliefs by which we govern Moderna. Two of the Mindsets are "We obsess over learning" and "We digitize everywhere possible." Having a learning Mindset brings us new opportunities to get smarter and innovate faster. 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 learnings. By digitizing everywhere possible, we seek to use the power of digital information to maximize our impact on patients.

BioNTech-Pfizer Exhibit 1272
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358
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OUR PLATFORM

Overview of our platform

Our mRNA "platform" refers to our accumulated knowledge and capabilities in basic and applied sciences. Our platform incorporates advances across three key components—mRNA, delivery and the manufacturing process— to advance our medicines. We integrate these components and combine different versions of mRNA delivery and process into each of our medicines.

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 lipid nanoparticles (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.

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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 clinical studies 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 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. See "—Manufacturing."

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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, all of which have led to development candidates 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 vision for harnessing the power of mRNA through modalities

Within our platform, we invest in science to invent novel ways to deliver mRNA into various cell types. Each novel delivery system is a new application, which we call a "modality." While the programs within a modality may target diverse diseases, they share similar mRNA characteristics and manufacturing processes to achieve shared product features.

We believe that the high technological correlation within a modality allows us to rapidly accelerate the expansion of programs within that modality based on learnings from the earlier programs, while the lower technology correlation between modalities allows us to compartmentalize the technology risks. Additionally, because programs within a modality pursue diverse diseases, they often have uncorrelated biology risk. Each time we add a modality and a new investigational medicine to our portfolio, we create a network effect because each incremental program can help us gain additional insight into the other programs in our pipeline.

Although developing a new modality is difficult, time-consuming and expensive, we believe our experience and technology provide us with unique advantages in the development of mRNA medicines. Over the last decade, we have developed seven modalities, each with one or many investigational medicines in the clinic. We believe that our ongoing investments in our platform will lead to the identification of additional modalities and expand the utility of our existing modalities and the diversity of our pipeline.

Our current modalities

We have developed seven modalities to date, as described below. More detail regarding our current programs in each modality is provided below under "—Our Pipeline."

- **Infectious disease vaccines**: The goal of our infectious disease vaccines 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. Our infectious disease vaccines include those targeting respiratory viruses, latent viruses and public health pathogens. We believe mRNA vaccines have several advantages, including the ability to mimic many aspects of various infections, the ability to combine antigens for compelling product profiles, the rapid discovery and advancement of programs into the clinic and the 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 for several reasons, including the ability to deliver multiple personalized neoantigens in a single mRNA molecule, and that mRNA encoding for neoantigens is translated and processed by patients' endogenous cellular mechanisms for presentation to the immune system.

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- **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 patients with 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 intratumoral immuno-oncology using mRNA medicines could complement checkpoint inhibitors and has several advantages over recombinant protein-based drugs, including production of membrane-associated immune stimulatory proteins, multiplexing of mRNA to access multiple immune stimulatory pathways and creation of engineered mRNA sequences to reduce off-target effects.

- **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, including localized dose-dependent protein production for focused activity.

- **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 encoding for hard-to-make or complex secreted or membrane-associated proteins, multiplexing of mRNA to encode for multiple proteins with complementary activity, native post-translational modifications and sustained production of proteins, which can increase exposure to proteins with short half-lives.

- **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 encoding for intracellular and organelle-specific proteins and the production of hard-to-make or complex proteins with native post-translational modifications.

- **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 LNP 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 lung-associated production of secreted, membrane-associated or intracellular hard-to-make or complex proteins.

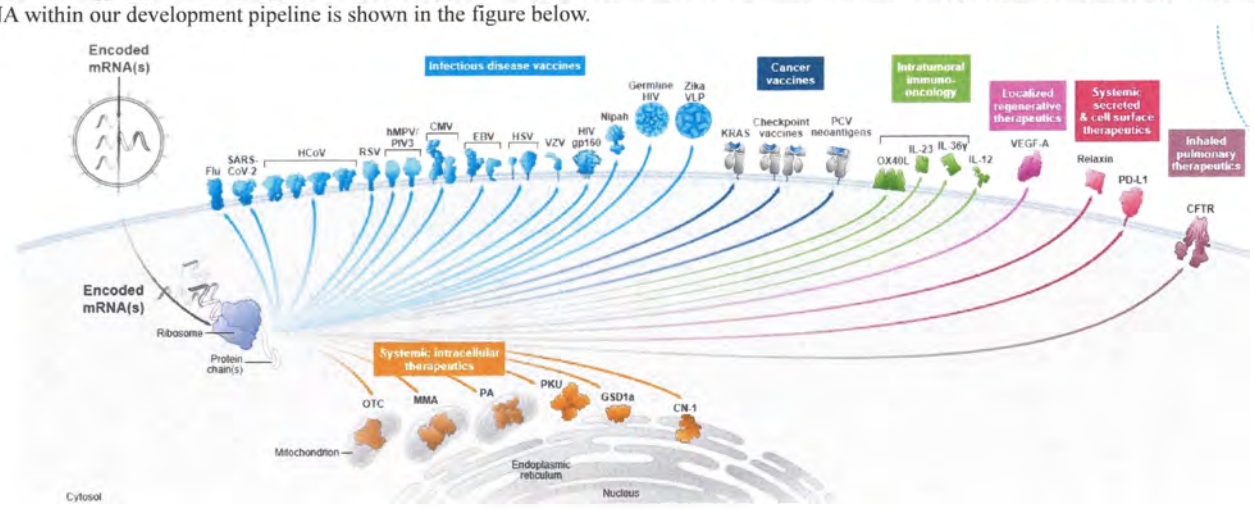
OUR PIPELINE

Since we nominated our first program in late 2014, we have advanced in parallel a diverse development pipeline that currently consists of 48 development programs across our 45 development candidates, with 38 programs having entered the clinic. To count our development programs, we separately track each indication of our COVID-19 and RSV vaccine candidates. We have entered eight other development candidates into the clinic that are no longer being pursued for further clinical development. Some candidates in our pipeline have been supported through strategic alliances, including with Merck and Vertex Pharmaceuticals, and government-sponsored organizations and private foundations focused on global health initiatives, including Biomedical Advanced Research and Development Authority (BARDA), the U.S. Government's Defense Advanced Research Projects Agency (DARPA), the National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation.

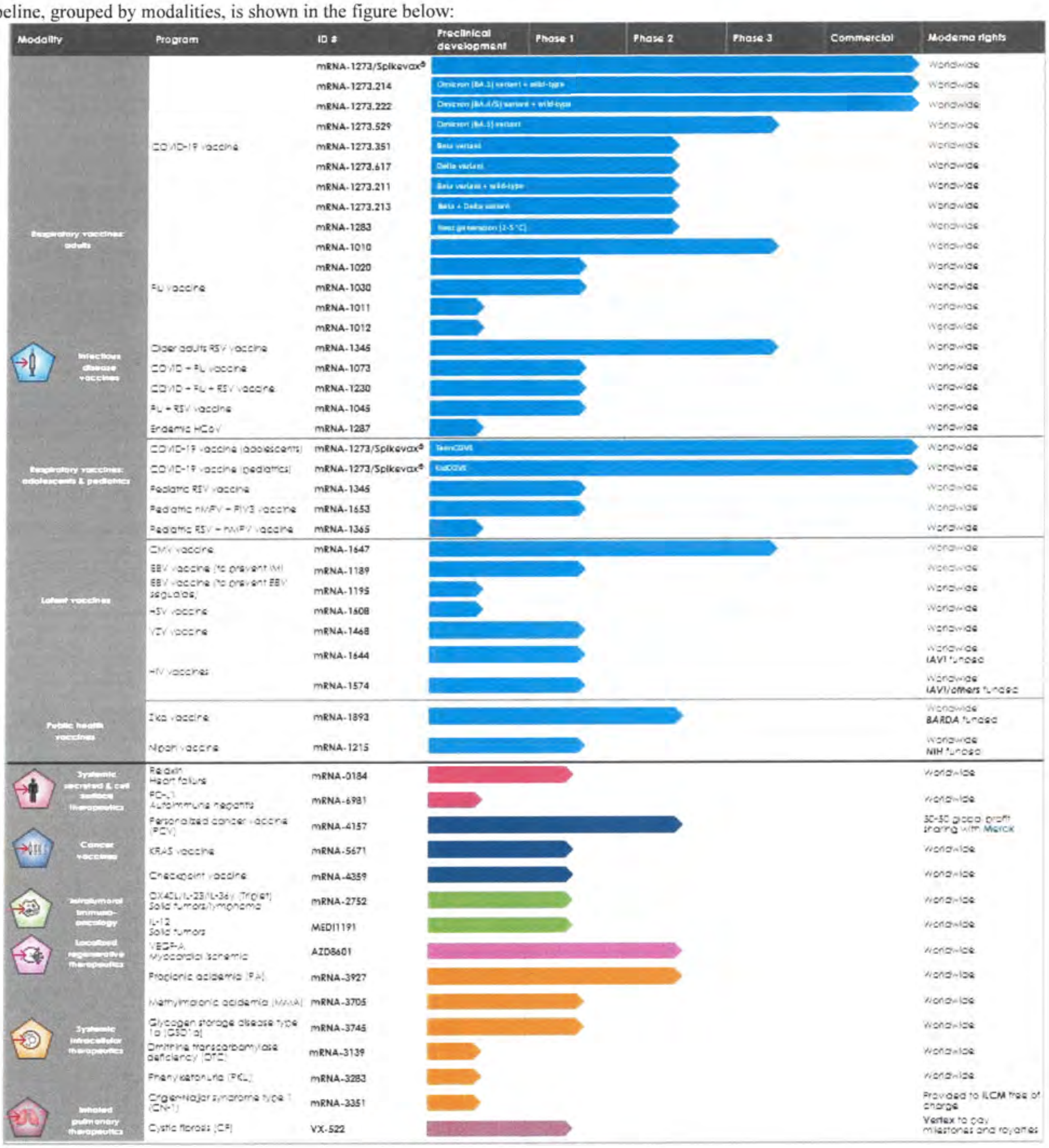
Our selection process for advancing new development candidates reflects both program-specific and portfolio-wide considerations. Program-specific criteria include, among other relevant factors, the severity of the unmet medical need, the biology risk of our chosen target or disease, the feasibility of 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.

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The breadth of biology addressable using mRNA technology is reflected in our current development pipeline of 48 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:



INFECTIOUS DISEASE VACCINES MODALITY

We have 33 different infectious disease vaccine programs, of which 27 have entered the clinic. We separate our infectious disease vaccines modality into three categories: (1) vaccines against respiratory viruses, (2) vaccines against latent viruses and (3) public health vaccines.

Infectious disease vaccines: Vaccines against respiratory viruses

COVID-19 vaccines (mRNA-1273/Spikevax®, mRNA-1273.214, mRNA-1273.222 and additional programs)

Our original COVID-19 Vaccine/Spikevax is approved or authorized for use in more than 70 countries. We have also launched two variant-matched bivalent vaccine boosters, mRNA-1273.214 and mRNA-1273.222

Our original COVID-19 vaccine, which is also marketed under the brand name Spikevax, was our first commercial product. In 2022, to address the evolution of the SARS-CoV-2 virus and to meet different needs across the largest markets, we launched two variant-matched bivalent booster vaccines, mRNA-1273.214 and mRNA-1273.222, to provide stronger protection against COVID-19 variants.

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 670 million confirmed cases and over 6.8 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 certain pre-existing diseases or comorbid conditions (e.g. cardiovascular disease, diabetes, chronic lung disease, obesity).

Spikevax was designed, manufactured, evaluated in Phase 1, Phase 2 and Phase 3 clinical trials, authorized for use, and supplied to the market in less than a year, and it continues to be a key tool in fighting the global COVID-19 pandemic. The SARS-CoV-2 virus continues to evolve, and as part of our strategy to combat the virus, 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.

In addition to our approved or authorized COVID-19 vaccines and boosters, we have advanced several other COVID-19 vaccine candidates into the clinic as part of effort to fight the evolving SARS-CoV-2 virus. Below is a summary of the status of our various COVID-19 vaccine development programs.

Spikevax/mRNA-1273 Programs

- Spikevax/mRNA-1273 has been approved or authorized for individuals 18 years and older in more than 70 countries and for adolescent and pediatric populations in more than 50 countries.

Omicron-targeting Bivalent Booster Vaccines

- We developed mRNA-1273.222 in accordance with FDA guidance to develop an Omicron BA.4/BA.5-targeting bivalent vaccine. mRNA-1273.222 is tailored to the BA.4/BA.5 Omicron subvariants and wild-type virus. In August 2022, we received an Emergency Use Authorization (EUA) from the FDA for mRNA-1273.222 as a booster dose for individuals 18 years and older, followed by adolescent and pediatric approvals. mRNA-1273.222 has been authorized as a booster vaccine for individuals 18 years and older in key markets, including the EU, Canada and Japan, with the EU, Japan and several other countries also authorizing boosters for adolescent populations.
    - In November 2022, we announced that mRNA-1273.222 had met the primary endpoint of superiority against Omicron variants compared to a booster dose of mRNA-1273 in a Phase 2/3 clinical trial.
    - In January 2023, the U.S. Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted unanimously to harmonize primary series and booster doses of COVID-19 vaccines. VRBPAC is expected to meet in the second quarter of 2023 for strain selection. Both the FDA and the Center for Disease Control must approve VRBPAC's recommendation before implementation.
- mRNA-1273.214 is tailored to the BA.1 Omicron subvariant and the wild-type virus. mRNA-1273.214 has been authorized as a booster vaccine in many jurisdictions, including the UK, the EU, Canada, Japan, Switzerland and Australia.

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Other COVID-19 Vaccine Programs

- mRNA-1283 is a next-generation COVID-19 vaccine candidate that we are developing as a potential refrigerator-stable mRNA vaccine that will facilitate easier distribution and administration by healthcare providers. It is currently being evaluated in a Phase 2 trial.
- As SARS-CoV-2 has continued to evolve, we have proactively made new mRNA development candidates in case they are needed for any variants. We have taken several of these candidates to clinical trials, targeting Omicron (mRNA-1273.529), Beta (mRNA-1273.351) and Delta (mRNA-1273.617), as well as bivalent vaccines against Beta and the wild-type (mRNA-1273.211) and Beta and Delta (mRNA-1273.213).
- We perform continuous epidemiological monitoring and risk assessment of SARS-CoV-2 variants to select which variant-targeted vaccines to evaluate in preclinical and clinical studies. Our monitoring activities allow for expedited delivery of new vaccines in the event that regulatory agencies request specific vaccine composition updates to address public health needs.

COVID-19 Commercial, Manufacturing and Supply Updates

Commercial sales of our COVID-19 vaccines accounted for $18.4 billion in revenues for the year ended December 31, 2022, which accounted for all of our commercial revenues. We anticipate that sales of our COVID-19 vaccines and boosters in 2023 will similarly provide all of our commercial revenues for the coming year. Sales for both 2021 and 2022 were primarily made to governments and international organizations engaged in the purchase of vaccines to combat the COVID-19 pandemic. We are preparing for the transition to a commercial market in 2023 and we expect to initiate sales in the U.S. private market. See "—Commercial" below. As the COVID-19 pandemic likely 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 provide booster vaccinations to their populations. For further information on the sales and manufacturing of our COVID-19 vaccines, see "—Manufacturing" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

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

We are advancing different approaches to developing seasonal influenza vaccines in parallel. We announced interim Phase 3 safety and immunogenicity results for mRNA-1010 in February 2023.

The World Health Organization (WHO) estimates that seasonal influenza viruses cause three to five million cases of severe illness and 290,000 to 650,000 deaths each year, resulting in a severe challenge to public health. Currently licensed seasonal influenza 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 influenza vaccine (mRNA-1010) based on WHO strain recommendations, including the hemagglutinins (HAs) of influenza A/H3N2 and A/H1N1 and the influenza B/Victoria- and B/Yamagata-lineage strains. Our second approach – expanded coverage – is to provide an enhanced antigen selection opportunity to public health authorities with the potential for regional variation through addition of HA antigens. Our third approach – immunologic breadth – is to provide immunity by targeting additional antigens beyond HA to provide the broadest coverage. We also aim to work with the WHO, regulators and public health authorities to enable strain selection closer to the influenza season to provide a better match to the circulating viruses.

Although both influenza A and B cause seasonal epidemics, influenza A viruses lead to the majority of influenza-related hospitalization in adults. The influenza A/H3N2 subtype, in particular, is a significant cause of illness in older adults and is responsible for most of the recent influenza outbreaks and excess morbidity caused by the virus.

mRNA-1010 is a single investigational vaccine consisting of four distinct mRNA sequences that encode for the HAs of A/H1N1, A/H3N2 and influenza B/Yamagata and B/Victoria lineages encapsulated 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 HA antigens (e.g. H3, H1). mRNA-1020 and mRNA-1030 are investigational vaccines that will add neuraminidase (NA) antigens.

Latest data and next steps

mRNA-1010 is currently being evaluated in two ongoing Phase 3 studies. One of these is a safety and immunogenicity study in adults 18 years and older in the Southern Hemisphere (P301) and the other is an efficacy study in adults 50 years and older in the Northern Hemisphere (P302). In February 2023, we announced interim results from the P301 study. Interim results indicate that mRNA-1010 achieved superiority on seroconversion rates for A/H3N2 and A/H1N1, as well as superiority on geometric mean titer ratios for A/H3N2 and non-inferiority on geometric mean titer rations for A/H1N1. Non-inferiority was not met for either endpoints for the influenza B/Victoria- or B/Yamagata-lineage strains. mRNA-1010 showed an acceptable safety and tolerability profile.

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The ongoing P302 study in the Northern Hemisphere has accrued more than 200 PCR-confirmed cases. Consistent with the predominant circulation of A/H3N2 and A/H1N1 viruses during the current influenza season, more than 99% of confirmed cases in the study are caused by influenza A viruses. The first per protocol interim analysis of efficacy is expected to be reviewed by an independent Data and Safety Monitoring Board (DSMB) before the end of the first quarter of 2023. Based on those results, the DSMB will notify us whether the primary efficacy endpoint has been met or whether the study should continue accruing further cases towards the final analysis.

Our immunologic breadth influenza vaccines (mRNA-1020 & mRNA-1030) are currently being evaluated in an ongoing Phase 1/2 trial, which is fully enrolled. Our expanded coverage influenza vaccines (mRNA-1011 & mRNA-1012) are in preclinical studies.

RSV vaccine (mRNA-1345)

We are developing an RSV vaccine for children and adults. In older adults, mRNA-1345 reported positive topline Phase 3 efficacy results in January 2023; in pediatrics, mRNA-1345 is ongoing in a Phase 1 study.

RSV is one of the most common causes of respiratory disease in children under the age of five and in older adults. Most children are infected at least once by age two. In the United States, it is estimated that over two million children younger than five 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 177,000 hospitalizations and 14,000 deaths per year in adults aged 65 years or older 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

In January 2023, we announced that mRNA-1345 had met primary efficacy endpoints in the pivotal Phase 3 trial in older adults, ages 60 and older. mRNA-1345 demonstrated vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; $p<0.0001$) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms. The other primary efficacy endpoint against RSV-LRTD defined by three or more symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%; $p=0.0078$). mRNA-1345 was generally well-tolerated with no safety concerns identified by the DSMB. The overall rate of severe (Grade 3 or greater) solicited systemic adverse reactions was 4.0% for mRNA-1345 and 2.8% for placebo. The overall rate of Grade 3 or greater solicited local adverse reactions was 3.2% for mRNA-1345 and 1.7% for placebo. The study is ongoing, and an updated analysis of safety and tolerability will be provided at the time of regulatory submission.

Based on the positive topline data from the pivotal Phase 3 efficacy trial, the FDA granted mRNA-1345 Breakthrough Therapy Designation for the prevention of RSV-LRTD in adults 60 years or older. We intend to submit mRNA-1345 to the FDA for regulatory approval for older adults in the first half of 2023.

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 fully enrolled and safety follow-up is ongoing. The age range of children in this de-escalation Phase 1 study is 12 to 59 months. Phase 1 interim data from the older adult cohort showed that a single mRNA-1345 vaccination at 12.5, 25, 50, 100 or 200 µg increased neutralizing antibody titers against RSV-A and RSV-B and remained above baseline through at least six months. The 50 µg dose level was generally well-tolerated and increased neutralizing antibody titers against RSV-A by approximately 12-fold and against RSV-B approximately 9-fold and was selected for evaluation in a pivotal Phase 2/3 safety and efficacy study.

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, older adults 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.

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Latest data and next steps

A first-in-human dose-ranging study, mRNA-1653-P101, in healthy adults was completed in January 2020. This study evaluated the safety, reactogenicity and immunogenicity of a range of dose levels administered on a 1- or 2-dose vaccination schedule compared with a placebo control, with a 13 month follow-up period. mRNA-1653 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 to 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 to 49 years of age) and two dose levels in children (12 to 59 months of age) with serologic evidence of prior hMPV and PIV3 exposure. The study is fully enrolled.

Combination vaccines (mRNA-1073, mRNA-1230, mRNA-1045 and mRNA-1365)

Our vision is to develop combination respiratory products to protect against a range of respiratory diseases.

mRNA-1073, our COVID-19 and seasonal flu combination vaccine, is fully enrolled in a Phase 1/2 study. mRNA-1073 encodes for the COVID-19 spike protein and the flu HA glycoproteins. Phase 1 studies have started for both mRNA-1230, our COVID-19, seasonal flu and RSV combination vaccine, and mRNA-1045, our seasonal flu and RSV combination vaccine. mRNA-1230 encodes for the COVID-19 spike protein, the flu HA glycoproteins and the RSV prefusion F glycoprotein. mRNA-1045 encodes for RSV prefusion F glycoprotein and the flu HA glycoprotein.

We are conducting a Phase 1 trial of mRNA-1365, our pediatric RSV and hMPV combination vaccine, which has dosed its first participants. mRNA-1365 encodes for the RSV prefusion F glycoprotein and the hMPV F protein.

Infectious disease 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 candidate, mRNA-1647, combines six mRNAs in one vaccine, which encode for two proteins located on the surface of CMV: five mRNAs encode the subunits that form the membrane-bound pentamer complex and one mRNA encodes the full-length membrane-bound glycoprotein B (gB). Both 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 pentamer and gB for the prevention of CMV infection.

Adult population: 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 data from the Phase 2 study of mRNA-1647 showed that mRNA-1647 was generally well-tolerated at the 50, 100 and 150 µg dose levels. In CMV-seronegative participants, 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 the total mRNA-1647 treatment groups after the third vaccination. In CMV positive participants, 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 in mRNA-1647 treatment groups after the third vaccination.

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Based on the safety and immunogenicity data from 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 enrolled in October 2021. The study is evaluating the safety and efficacy of mRNA-1647 against primary CMV infection in female participants 16 to 40 years of age and seeks to enroll 7,300 participants. The study is over 40% enrolled in the United States, Japan and internationally. Timing of the readout will depend upon the number of CMV cases accrued in the study.

Pediatric population: Clinical update

A Phase 1/2a study of mRNA-1647 at the 25, 50 and 100 ug dose levels in participants nine to 15 years of age enrolled the first participant in November 2022. The study is evaluating the safety and immunogenicity of mRNA-1647 to select a dose level for subsequent development in this age group.

EBV vaccine (mRNA-1189 & mRNA-1195)

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

EBV is a member of the herpesvirus family that is related to CMV and infects approximately 90% of people in the U.S. by adulthood, with primary infection typically occurring during childhood or late adolescence (approximately 50% and 89% seropositivity, respectively). EBV is the major cause of infectious mononucleosis in the U.S., accounting for over 90% of the approximately one to two 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 due to complications such as splenic rupture. EBV infection is also 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 one of our EBV vaccine candidates, 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 will be investigated in the context of post-transplant lymphoproliferative disorders and multiple sclerosis.

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 candidate, 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, an estimated 492 million persons have HSV-2 infection, representing 13% of the world's population aged 15 to 49 years.

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 candidate (mRNA-1608) is currently in preclinical studies.

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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 approximately one in three adults in their lifetime and incidence significantly increases at approximately 50 years of age. Protective immunity against VZV wanes as the immune system ages, 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. People with immunocompromising conditions, people with autoimmune disease using immunosuppressive therapies, people living with HIV and hematopoietic stem cell (HSCT) and organ transplant recipients have an increased risk of developing herpes zoster. 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 candidate (mRNA-1468) is designed to express VZV glycoprotein E (gE) to reduce the rate of herpes zoster, and uses our proprietary LNP.

Latest data and next steps

In February 2023, the first participant was dosed in our Phase 1/2 head-to-head study of mRNA-1468 against Shingrix.

HIV vaccine (mRNA-1644 & mRNA-1574)

We are developing two HIV vaccine candidates – 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

Both mRNA-1644 and mRNA-1574 are in ongoing Phase 1 clinical trials.

Infectious disease vaccines: Public health vaccines

Zika vaccine (mRNA-1893)

In partnership with BARDA, we are conducting 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 Zika 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.

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Our Zika vaccine candidate, 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 conducting a Phase 2 study in the United States and Puerto Rico to evaluate mRNA-1893 in approximately 800 participants. The randomized, placebo-controlled study aims to evaluate the safety, tolerability and reactogenicity of mRNA-1893, as well as evaluate the immunogenicity of two dose levels of mRNA-1893 (one-dose or two-dose schedule) compared to placebo. The study is fully enrolled.

Nipah vaccine (mRNA-1215)

In collaboration with the NIH-Vaccine Research Center (VRC), we have started 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 NiV, was co-developed along with the NIH's VRC. The Phase 1 clinical trial is ongoing, and testing will be focused on pandemic preparedness. This Phase 1 dose-escalation, open-label clinical trial is the first study of mRNA-1215 in healthy adults to evaluate the safety, tolerability and immunogenicity of a NiV mRNA vaccine candidate. The trial is sponsored and funded by NIAID.

SYSTEMIC SECRETED AND CELL SURFACE THERAPEUTICS MODALITY

Our systemic secreted and cell surface therapeutics modality currently has two active development programs, of which one has entered the clinic. We have discontinued the IL-2 mutein program (mRNA-6231) that was previously in this modality.

Relaxin (mRNA-0184)

Relaxin is a vasoactive peptide associated with cardiovascular remodeling; mRNA-0184 encodes for a relaxin fusion protein which is being developed to treat decompensated heart failure.

Relaxin is a naturally occurring hormone that has been shown to promote vasodilation and angiogenesis, regulate extracellular matrix turnover, and suppress arrhythmias post myocardial infarction. Relaxin plays an important role in women in pregnancy, but in addition, studies have pointed to its vasodilatory, antifibrotic, anti-inflammatory and other protective effects on multiple organs. 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 is defined as the new onset or worsening of symptoms and signs of heart failure. In developed countries, heart failure has become a substantial public health problem, affecting 2% of the adult population and acute heart failure is the most frequent cause of unplanned hospital admission in patients over 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.

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Latest data and next steps

In December 2022, we initiated dosing in a Phase 1 trial for mRNA-0184. Our Phase 1 trial is an adaptive, open-label, single ascending dose to single-blind, placebo-controlled, multiple ascending dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of mRNA-0184 in participants with chronic heart failure.

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 have determined that the current design of mRNA-6981 does not meet our criteria for advancement to the clinic. PD-L1 continues to be an area of interest, and we are currently evaluating other preclinical mRNA candidates.

CANCER VACCINES MODALITY

Our cancer vaccines modality currently has three development programs, all of which have entered the clinic. We have regained all rights to our KRAS vaccine candidate (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 patient's tumor mutations. We reported positive top-line data for our Phase 2 trial in December 2022; in February 2023, mRNA-4157 received a Breakthrough Therapy Designation from the FDA.

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.

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We are developing mRNA-4157 in collaboration with Merck. In September 2022, Merck exercised its option for personalized cancer vaccines, including mRNA-4157, pursuant to the terms of our existing PCV Collaboration and License Agreement with Merck, which was amended and restated in 2018 (PCV Agreement). Pursuant to the PCV Agreement, we and Merck will collaborate on further development and commercialization of mRNA-4157, and we will share costs and any profits and losses worldwide related to mRNA-4157 equally.

Latest data and next steps

In December 2022, we announced that the randomized Phase 2 trial of mRNA-4157 had met its primary endpoint. The open-label 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. The study showed that mRNA-4157 in combination with KEYTRUDA reduced the risk of recurrence or death by 44% (HR=0.56 [95% CI, 0.31-1.08]; one-sided p value=0.0266) compared with KEYTRUDA alone. The results are the first demonstration of efficacy for an investigational mRNA cancer treatment in a randomized clinical trial in melanoma. Adverse events observed were consistent with those previously reported in a Phase 1 clinical trial, which showed mRNA-4157 to be well-tolerated at all dose levels. We and Merck plan to discuss results with regulatory authorities and to initiate a Phase 3 study in adjuvant melanoma in 2023 and rapidly expand to additional tumor types, including non-small cell lung cancer (NSCLC). In February 2023, mRNA-4157 received a Breakthrough Therapy Designation from the FDA.

KRAS Vaccine (mRNA-5671)

Enrollment has closed in the Phase 1 study led by Merck; 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

Enrollment has closed in the Phase 1 open-label, multi-center study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with pembrolizumab, led by Merck. 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 candidate 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 candidate are advanced or metastatic cutaneous melanoma and 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%. Current standard of care pembrolizumab, nivolumab or the combination of nivolumab + ipilimumab.

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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 directed by 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

We started dosing the first patients in a Phase 1 study of mRNA-4359 in September 2022.

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-36γ (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 in superficial/palpable lesions (Arms A and B) and dose confirmation of safety in deep-seated lesions (Arm B), followed by dose expansion in select advanced solid tumors, including triple negative breast cancer (TNBC), urothelial carcinoma, lymphona, immune checkpoint refractory melanoma and NSCLC. An additional Arm C has been added in neoadjuvant cutaneous melanoma to explore an alternate administration schedule.

We previously announced the interim results of Arm 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 RDE is up to of 4 mg 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.

Interim efficacy data were reported in 2022 for the TNBC and melanoma expansion cohorts. mRNA-2752 given as monotherapy and in combination with durvalumab was generally well-tolerated at all dose levels studied. Administration of intratumoral mRNA-2752 was associated with tumor shrinkage in both injected and non-injected lesions in both monotherapy and in combination with durvalumab. Durable responses have been observed across multiple tumor types and enrollment is ongoing in the lead indications in TNBC and melanoma. These data support the ongoing testing of mRNA-2752 in combination with durvalumab in Arm B of the Phase 1 study.

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IL-12 (mRNA-2905)

We are developing a mRNA that encodes for IL-12 encapsulated in our proprietary LNP delivered intratumorally. In the third quarter of 2022, AstraZeneca terminated our collaboration for the IL-12 program, and we are evaluating next steps for the program.

One 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 worked to develop 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 was 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. 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. We are currently evaluating next steps for the program after its return from AstraZeneca.

REGENERATIVE THERAPEUTICS MODALITY

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

VEGF-A (AZD8601)

VEGF-A is a localized therapeutic encoding for the VEGF-A protein and addressing ischemic heart failure. In the third quarter of 2022, AstraZeneca terminated our collaboration for the VEGF-A program, and we are evaluating next steps for the program.

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.

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Latest data and next steps

In preclinical studies 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 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. 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. We are currently evaluating next steps for the program after its return from AstraZeneca.

SYSTEMIC INTRACELLULAR THERAPEUTICS

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

Propionic acidemia (PA) (mRNA-3927)

PA is an inherited metabolic disorder with significant morbidity and mortality; our mRNA therapy is ongoing in a Phase 1/2 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. These metabolic decompensation events (MDEs) occur when there is a build-up of toxic metabolites. 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 methylmalonic acidemia (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 affected individuals generally having loss-of-function mutations in either PCCA or PCCB enzyme (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 therapy, 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.

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Latest data and next steps

The Phase 1/2 clinical trial for mRNA-3927, the Paramount Study, is ongoing and we have fully enrolled the first four cohorts. An independent safety monitoring committee has approved moving to fifth cohort (0.9 mg/kg). The objective of the study 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 Designation from the European Commission for the PA program. Several critical milestones have been reached in the trial. mRNA-3927 has been generally well-tolerated to date with no drug-related serious adverse events, no discontinuations due to safety and only mild-to-moderate infusion related reactions (<10% of doses). Due to the objective and disease-defining nature of MDEs, regulators have provided initial support for MDE as a clinically meaningful, preferred primary clinical endpoint for development. Based on the preliminary data, there was a decrease in the number of MDEs post-mRNA-3927 treatment. We will continue to enroll additional cohorts and escalate dose, identify optimal dose for expansion and continue to engage with regulators on the registration path.

Methylmalonic acidemia (MMA) (mRNA-3705)

MMA is an inherited metabolic disorder with significant morbidity and mortality and our mRNA therapy is ongoing in a Phase 1/2 trial, aiming to produce an intracellular, mitochondrial enzyme complex to treat the disorder.

There are an estimated 500-2,000 people with MMA MUT deficiency 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 those 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. Survivors 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, multiple ascending dose (MAD) study and is designed to evaluate the safety and tolerability of up to five different dosing regimens of mRNA-3705 administered via intravenous infusion in participants 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. Secondary endpoints include incidence and severity of AEs and change in plasma biomarkers. We are recruiting patients in the United Kingdom, Canada, Australia and the United States. We are enrolling our third cohort.

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

GSD1a is an inborn error of glycogen metabolism caused by abnormalities of the intracellular protein glucose-6-phostphatase (G6Pase). Our approach is to replace the abnormal protein using an mRNA encoding for human G6Pase.

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 – processes that are critical for maintaining energy supply to our bodies – that mainly take 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 FDA as well as the European Medicines Agency (EMA) and has an open IND. We dosed our first participants in June 2022 in an ongoing Phase 1/2 study to evaluate the safety and pharmacology of mRNA-3745 in patients 18 years of age and older with GSD1a. The Phase 1 Balance clinical trial, is a single ascending dose 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 through improvement of fasting tolerance.

Ornithine transcarbamylase (OTC) deficiency (mRNA-3139)

Ornithine transcarbamylase (OTC) deficiency (OTCD) is monotonic X-linked recessive disorder caused by mutations in ornithine transcarbamylase, a key urea cycle enzyme involved in the detoxification of ammonia into urea.

With an incidence of approximately 1:57,000 live births, OTCD is the most common inborn error of urea metabolism, accounting for nearly half of all Urea Cycle Disorders (UCDs). OTC is a mitochondria protein that promotes the synthesis of citrulline and urea. OTCD leads to the accumulation of ammonium, glutamine, and other amino acids in the plasma, as well as low levels of plasma citrulline and the diversion of carbamoylphosphate into pyrimidine synthesis, leading to increased excretion of urinary orotic acid. The clinical presentation of OTCD is heterogeneous, depending on the degree of OTC deficiency. Severe OTCD is typically seen in affected males and presents in the neonatal period with acute hyperammonemic coma and is associated with a high mortality rate. Male and female patients with partial OTC deficiency have delayed symptom onset and can be asymptomatic for months or even years before suffering from their first bout of metabolic decompensation leading to hyperammonemic crises in early childhood or adulthood. Hepatodigestive, neurological or psychiatric symptoms can also occur. OTCD treatment consists of dietary protein restriction, arginine and citrulline supplementation, and the induction of alternate nitrogen excretion pathway with sodium phenylbutyrate and/or sodium benzoate. Surviving neonates often suffer from cognitive deficits and experience repeated episodes of hyperammonemic crises throughout their lives. Liver transplantation is an alternative to medical therapy for severe OTCD in the neonatal form, or in the case of frequent episodes of recurrent hyperammonemia or poor metabolic status for patients with late onset disease. Liver transplantation for severe neonatal OTCD is usually performed in the first year of life and there is a high incidence morbidity and mortality.

Our mRNA-3139 program is a chronic intravenous, mRNA, enzyme replacement therapy for Ornithine Transcarbamylase Deficiency, which may act as a bridge to liver transplant or a standalone therapeutic depending on efficacy. mRNA-3139 uses the same LNP as in our GSD1a program.

Latest data and next steps

We have conducted several *in vitro* and *in vivo* pharmacology studies for mRNA-3139, which remains in preclinical studies.

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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. Preclinical development of our program is ongoing.

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. Moderna and ILCM are collaborating in developing a preclinical package for Investigational New Drug application and Clinical Trial Application filings. ILCM will be responsible for the clinical development of mRNA-3351.

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INHALED PULMONARY THERAPEUTICS

Our inhaled pulmonary therapeutics modality currently has one development candidate.

Cystic Fibrosis (CF) (VX-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. This would be the first demonstration of a nebulized mRNA therapy produced by Moderna.

Latest data and next steps

We are collaborating with Vertex on our CF candidate, VX-522. In January 2023, Vertex announced that it has initiated a Phase 1, single ascending dose clinical trial in CF patients who cannot benefit from CFTR modulators, and the FDA has granted VX-522 Fast Track designation. The trial is active and enrolling patients. Vertex expects to complete the single ascending dose study and to initiate the multiple ascending dose study.

MANUFACTURING

Manufacturing plays a critical role in our value chain and our ability to develop our medicines. Our manufacturing capabilities support every stage of the development of our products, from discovery 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 trials. At the commercial stage, we manufacture drug substance and drug product in collaboration with our contract manufacturing organizations (CMOs), both in the United States and internationally.

We proactively invest in and build both internal and external manufacturing capacity in anticipation of demand. This approach was immediately leveraged and expanded during the commercial ramp up of our COVID-19 vaccine in response to the COVID-19 pandemic. Our ability to rapidly accelerate our manufacturing capabilities allowed us to produce and ship hundreds of millions of doses of our COVID-19 vaccine globally in 2021 and 2022, compared to 17 million doses in December 2020. We continue to invest in building global manufacturing capabilities to support future product launches.

Overview of our manufacturing operating model

Our manufacturing activities generally focus on the following:

- **Commercial Production:** Our manufacturing capabilities include state-of-the-art technologies for mRNA and drug substance 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 production of products for commercial approval. Our platform allows for efficient manufacturing at scale.
- **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 have built a dedicated in-house, multi-building manufacturing campus in Norwood, MA, the Moderna Technology Center (MTC). 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 commercial production. The MTC has been designed to allow us to continue to optimize our mRNA products as we explore new pharmaceutical delivery forms in our manufacturing network such as prefilled syringes and lyophilized products.

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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 our COVID-19 vaccines. Our COVID-19 vaccine production for the U.S. market is completed at our MTC campus. We have also partnered with Lonza in Switzerland and ROVI in Spain for COVID-19 vaccine production for markets outside the United States. Fill-finish services for our COVID-19 vaccine are provided by Catalent Inc. and Thermo Fisher Scientific in the United States, and by ROVI (in Spain), Thermo Fisher Scientific (in Italy) 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 2022, we entered into a ten-year collaboration with ROVI 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. We also entered into a fifteen-year collaboration with Thermo Fisher in 2022 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, we are working to build manufacturing capability globally to prepare for the future. We have announced agreements with the governments of Australia, Canada and the United Kingdom to establish state-of-the-art mRNA manufacturing facilities in those countries. We expect that these local manufacturing facilities will provide direct access to rapid pandemic response capabilities and our respiratory virus vaccine candidates in exchange for each government entering into multi-year commitments to purchase those products from us, once approved. We may seek to enter into future agreements other governments to provide similar manufacturing capabilities in other geographies.

We have further committed to building a state-of-the-art mRNA manufacturing facility in Kenya to provide a local source of mRNA medicines for the African continent, in part to prepare for future pandemics. We 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., systemic, intramuscular, intratumoral and pulmonary), 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 our COVID-19 vaccines.

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, due 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.

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Supply for Clinical 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 many patient batches, each with unique mRNA sequences. Additionally, as we prepare for a potential Phase 3 trial for our PCV candidate, we anticipate an increase in manufacturing demand that will require significant additional investments, including in additional custom-made equipment.

Our manufacturing capabilities have allowed us to build our broad pipeline of 48 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 original 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 vaccines, 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. mRNA manufacturing is flexible and one plant can manufacture multiple vaccines and therapeutics—mRNA vaccines and mRNA therapeutics use the same process, same equipment, same people and approximately 95% of the same raw materials. 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.

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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 vaccines 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, and we have invested heavily in these technologies. We aspire to digitize our operations wherever possible, with the goal of using the power of digital technology to maximize our impact on human health. To facilitate our growth, we will continue to invest in our digital infrastructure. For example, our new Moderna Science Center in Cambridge is being designed to integrate digital-first scientific research and development labs. Our approach to bring these digital technologies into our workflows and processes has involved:

- 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 48 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.

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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 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 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.

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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 thirty-four 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 production of our COVID-19 vaccine in response to the COVID-19 pandemic. 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.

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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 are working to build a differentiated commercial model, with active commercial subsidiaries in 16 countries, including in North America, Europe and the Asia-Pacific region. Our growing commercial footprint provides us with local commercial teams in key markets around the world. We have a direct presence in almost all major markets where respiratory vaccines have high utilization rates and sales. In 2023, we expect to expand our commercial presence by hiring commercial personnel in additional markets in Europe and Asia. To support our growth as we build out our commercial activities in markets around the globe, we have focused our hiring on talent with experience at other pharmaceutical companies.

This commercial presence is supported by the Moderna International Business Service center in Warsaw, Poland, which provides critical functions, including finance, pharmacovigilance, human resources and digital systems, and our Enterprise Solutions Hub in Atlanta, Georgia, which hosts finance, human resources, procurement and digital functions. Our commercial teams also work in conjunction with third-party distributors and other partners in countries where we do not have a presence. Our commercial activities are dependent on regulatory approvals and on agreements that we have made or may make in the future with strategic collaborators.

Before 2023, we sold our COVID-19 vaccines to the U.S. Government, other international governments, Gavi, on behalf of the COVAX Facility and other supranational organizations. During the pandemic, these sales were characterized by a relatively limited number of customers who purchased multi-dose vials for distribution through mass vaccination campaigns. In 2023, the COVID-19 vaccine market is transitioning to a commercial market in the United States, which will affect us in many ways, characterized by a fragmented customer base, less predictability in orders, seasonality of deliveries and the assumption by us of full distribution costs. We will also be impacted by other factors that characterize the U.S. private market for vaccines, including market practices regarding rebates, discounts and returns. We are also transitioning from multi-dose vaccine vials to a single-dose presentation, and expect to continue to invest in innovation and research and development associated with bivalent vaccine approaches as the SARS-CoV-2 virus evolves. Outside of the United States, we expect to execute new government COVID-19 vaccine sales contracts in 2023, but anticipate future sales to private customers if and as we gain marketing approval in various jurisdictions. The market for our vaccines for the likely transition to an endemic COVID-19 market will depend on many evolving factors such as medical need, viral evolution, public health authority recommendations and consumer motivation to vaccinate.

Additionally, we are advancing a broader seasonal respiratory vaccine franchise, consisting of single-agent and combination vaccines against RSV, influenza and COVID-19, which have the highest medical burden among respiratory vaccines. We believe that combination vaccines could provide us with competitive advantages and have the potential to transform the vaccine market due to higher compliance, better uptake, a larger benefit to the healthcare system and increased consumer convenience. Preparations are underway for multiple vaccine launches globally over the next several years.

We have also announced agreements with the governments of Australia, Canada and the United Kingdom to establish state-of-the-art mRNA manufacturing facilities in those countries, pursuant to which each government has entered into a multi-year commitment to purchase mRNA products from us, once approved. See "—Manufacturing" above for further detail.

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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 (i) Merck, for the PCV program (mRNA-4157) in the cancer vaccines modality, and (ii) Vertex, for the cystic fibrosis (CF) program (VX-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 ongoing collaborations. In August 2022, AstraZeneca terminated our collaborations with them for our VEGF-A (AZD8601) and IL-12 (MEDI1191) programs. Additionally, Merck terminated our collaboration with them for our KRAS program (mRNA-5671) in February 2022. All rights to these programs have reverted to us. 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.

Merck (NYSE: MRK)—Strategic Alliance for Personalized mRNA Cancer Vaccines

In June 2016, we entered into a personalized mRNA cancer vaccines (PCV) Collaboration and License Agreement with Merck (PCV Agreement), which was subsequently amended and restated in 2018, 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 were 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.

In September 2022, Merck exercised its option for PCVs, including mRNA-4157, pursuant to the terms of the PCV Agreement and in October 2022 paid us an option exercise fee of $250 million. Pursuant to the PCV Agreement, we and Merck have agreed to collaborate on further development and commercialization of PCVs, and we will share costs and any profits or losses worldwide equally.

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.

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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 upfront cash payment and make an equity investment in Metagenomi in the form of a convertible note, which has since converted to a minority equity stake in the company. In December 2022, we made an additional equity investment in Metagenomi. 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 upfront cash payment and make an equity investment in Carisma in the form of a convertible note, which we have since agreed to convert to a minority equity stake in the company. 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.

CytomX Therapeutics—2022 Collaboration and License Agreement for mRNA-Base Conditionally Activated Therapeutics

On December 30, 2022, we entered into a collaboration and licensing agreement with CytomX Therapeutics (CytomX) to create investigational mRNA-based conditionally activated therapies utilizing our mRNA technologies and CytomX's Probody® platform. Under the agreement, we agreed to pay CytomX an upfront cash payment, including a portion for pre-paid research funding. CytomX will receive research funding and is eligible to receive certain milestone payments, plus tiered royalties on global net sales of any products that are commercialized under the agreement. We and CytomX will collaborate on discovery and preclinical development and we will lead clinical development and commercialization of therapeutics under the agreement. The agreement further provides us with an option to participate in a future equity financing by CytomX subject to certain terms, conditions and regulatory requirements.

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Strategic alliances with government organizations and foundations

Defense Advanced Research Projects Agency (DARPA)

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, 2022, the committed funding, net of revenue earned was $6 million, with an additional $24 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, subsequently adjusted to $117 million in 2021, 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. In September 2022, the performance period of the grant expired, and BARDA was released of the obligation to fund the remaining $36 million of the award.

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 original COVID-19 vaccine. The agreement was amended in both 2020 and 2021 to provide for additional commitments to support various late-stage clinical development efforts of mRNA-1273, including a 30,000 participant Phase 3 study, pediatric clinical trials and pharmacovigilance studies. In March 2022, we entered into a further amendment to the BARDA agreement, increasing the amount of potential reimbursements by $308 million, in connection with costs associated with the clinical development for adolescent and pediatric studies and the Phase 3 pivotal study. The maximum award from BARDA, inclusive of all amendments, was approximately $1.7 billion. All contract options have been exercised. As of December 31, 2022, the remaining available funding net of revenue earned was $137 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 type 1 Crigler-Najjar syndrome (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 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 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.

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With respect to our IP estate, our solely-owned patent portfolio consists of more than 190 issued or allowed U.S. patents or patent applications and more than 150 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 1,050 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 positions.

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 and where 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 related to the design, manufacturing and formulating 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 delivery and expression of both therapeutic and vaccine nucleic acids, in particular, prophylactic infectious disease and cancer vaccine nucleic acids, 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

Our IP estate provides protection for the multiple programs 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 preventing or treating infectious diseases, including those caused by respiratory and latent viruses, as well as bacterial, viral and parasitical diseases known to threaten public health. Our mRNA chemistry, formulation and manufacturing patent applications and related know-how, along with trade secrets, may also provide us with additional IP protection relating to our development candidates.

Respiratory vaccines

For our respiratory vaccines programs, 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 directed to 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 mRNA-1273 vaccine, are featured in several patent families, three of which have been abandoned in all jurisdictions. A single Patent Cooperation Treaty (PCT) application is pending. Priority dates for these applications span a period from late January 2020 through January 2021. 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.

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Spikevax

Patent Number	Country/Region*	Patent Type	Expiration Date**
11,524,023	United States	Composition of Matter	October 22, 2041
11,485,972	United States	Composition of Matter	May 18, 2038
10,898,574	United States	Composition of Matter and Method of Use	April 2, 2032
10,703,789	United States	Composition of Matter	March 9, 2033
10,702,600	United States	Composition of Matter	October 21, 2036
10,577,403	United States	Composition of Matter	March 9, 2033
10,442,756	United States	Composition of Matter	September 16, 2036
10,266,485	United States	Composition of Matter	September 16, 2036
10,064,959	United States	Composition of Matter	October 3, 2031
9,868,692	United States	Composition of Matter	September 16, 2036
3 590 949	Europe	Composition of Matter and Method of Use	October 3, 2031
3 718 565	Europe	Composition of Matter	October 21, 2036

* Selected granted patents in the U.S. and Europe only. Additional granted and pending patents in the U.S., Europe and other countries may be available.
** Expiration dates listed here include any granted or anticipated patent term adjustment (PTA), but not any patent term extension (PTE) or supplementary protection certificates (SPC).

RSV

We have filed multiple patent families directed to RSV vaccines. For example, a U.S. patent issued on October 11, 2022, and is pending in Europe. Our RSV patent portfolio includes multiple families of differing patent breadth and are filed in many foreign jurisdictions where RSV vaccines are needed. At least four U.S. and European patent applications are pending, as are applications in Canada, Australia and several Asian jurisdictions.

Influenza

We have multiple patent families spanning different levels of breadth, design and antigen valency pending in the U.S., Europe and around the world. The first level includes the influenza vaccine patents derived from our vaccine platform filings.

Since the SARS-CoV-2 pandemic began, we have introduced several multivalent designs for advanced flu vaccines, which can be used in combination vaccines with other respiratory viruses. There is a pending PCT patent application on our multivalent design that includes claims covering our vaccine program for the prevention of infection with seasonal influenza virus.

hMPV/PIV3

Human metapneumovirus (hMPV) and parainfluenza virus 3 (PIV3) are both single-stranded RNA viruses like RSV. We have patent applications directed to our hMPV/PIV3 vaccine pending in the U.S., Europe and Hong Kong. Moreover, five U.S. patents have issued featuring hMPV/PIV3 vaccines, with claims covering: LNP-encapsulated mRNA vaccines that encode the PIV3 and hMPV fusion proteins, administration methods for these LNP-encapsulated mRNA vaccines, vaccines that include hMPV-encoding mRNA formulated in LNPs, vaccines that include PIV3-encoding mRNA formulated in LNPs and specific hMPV- and PIV3-encoding mRNAs for use as vaccines. A pending U.S. 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.

Latent vaccines

We have vaccine programs and patent applications directed to both the acute and latent forms of diseases caused by various viruses, including CMV, EBV, HSV, VZV and HIV, using both preventative vaccines targeting the acute phase and therapeutic vaccines for treating the latent diseases in those who do become infected.

CMV

The patent coverage for our human CMV vaccine candidate is extensive and is based on a vaccine with six mRNAs encoding a pentamer surface glycoprotein complex and the gB surface glycoprotein. Both pentamer and gB facilitate entry of the virus into different cell types and therefore immune responses targeting these proteins can block virus entry, spread and reactivation. The current patent portfolio contains both compositions of matter and methods of treating subjects using the vaccine. In the U.S., our CMV vaccine is covered by multiple issued U.S. patents of differing breadth. Each family has counterparts consisting of pending applications and issued patents in many non-US jurisdictions, including Australia, Canada, Europe and Japan. A separate family of CMV patents, which includes mRNA-1647 plus mRNA-1443 for use in CMV vaccines for transplant indications, is also yielding patents and with many foreign jurisdictions pending.

EBV, HSV and VZV

Similar to CMV, we have multiple patent families pending for each of EBV, HSV and VZV, covering both prophylactic and therapeutic indications. These patent families have also been filed across a broad list of foreign jurisdictions including Australia, Canada, Europe and Japan.

Public health vaccines

We maintain a multi-program effort at developing vaccines for potential future pandemics and for use in parts of the world with less well-established health care systems. This group of programs include infectious diseases such as flaviviruses like Zika and dengue viruses, HIV, Nipah virus, Ebola and Marburg viruses and monkeypox and smallpox viruses. In addition, programs are ongoing in many bacterial diseases including tuberculosis and in parasitical diseases, such as leishmaniasis and malaria. Specific patent families are being filed on most potential public health programs where possible, but in some scenarios, platform patents may be used to augment patent protection for public health target vaccines.

Personal cancer vaccines

Composition of matter and method claims are being pursued to protect programs within our cancer vaccines modality. Proprietary methods around the making and therapeutic use of our PCVs and resulting vaccine compositions are described and claimed in eight pending U.S. patent applications, six pending European patent applications, five pending patent applications in each of Australia, Canada and Japan, three pending patent applications and one granted patent in China, and several pending patent applications in New Zealand, South Africa, as well as other European, Asian and South American countries. These applications also relate to various vaccine design formats, in particular, polyepitopic vaccine formats, and methods of treating cancer with such PCVs. 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 an issued U.S. patent, which includes claims to LNP-encapsulated mRNA encoding mutant KRAS antigens, and in a pending U.S. patent application and pending applications in Australia, Brazil, Canada, Europe, Japan, Mexico, New Zealand and South Africa, as well as in several other European, Asian and Middle Eastern jurisdictions.

Intratumoral immuno-oncology

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 two granted European patents, by twelve issued U.S. patents, by several pending U.S. and European patent applications and by several pending patent applications in other foreign 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 using these development candidates. Similar claims cover our IL-12 development candidate, which can be found in two issued U.S. patents, a granted European patent, in pending patent applications in the U.S. and Europe and in issued and pending applications in other foreign jurisdictions.

Cardiovascular

Our localized regenerative therapeutics modality is focused on regenerative therapeutics. Our sole program, VEGF-A, is covered by a granted European patent, granted Japanese patents and by pending U.S. and European patent applications and by pending and issued national phase patent applications in additional foreign jurisdictions.

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Rare diseases

We have programs featuring expression of therapeutic proteins, e.g., 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 is for PA. For this 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 MMA, we have patent applications issued and pending in the U.S. and foreign applications filed in Australia, Canada, Japan, Europe and the Middle East.

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 filed several patent families, including pending U.S. and European patent applications, as well as applications pending in Australia, Canada, China, Japan, Israel and several Middle Eastern jurisdictions 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.

Our ornithine transcarbamylase deficiency (OTC) development candidate is covered by a pending PCT application.

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 to 2042 for the remaining MMA, PA, PKU, GSD1a and CN-1 patents, excluding any patent term adjustments, any patent term extensions and any terminal disclaimers.

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 immune 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 patent families, including granted patents in Japan, China and the U.S., and by additional applications in the U.S. and additional foreign jurisdictions and a pending PCT application.

Our PD-L1 development candidate is covered in pending patent applications filed in the U.S., Japan, Europe, Canada and Australia.

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.

Gene editing

Our gene editing program currently has one filed patent family that includes issued patents in the U.S., Australia, Europe, Canada and Japan, and also pending applications in these jurisdictions. We plan to file patent applications on development candidates and other aspects of gene editing technology as we continue to innovate both internally and through strategic collaborations.

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Trademarks

Our trademark portfolio currently contains at least 450 trademark registrations, including at least 15 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 925 pending trademark applications in more than 95 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 2022, we paid $635 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.

Patent license agreement with NIAID

In December 2022, we entered into a non-exclusive patent license agreement with the National Institute of Allergy and Infectious Diseases (NIAID), an Institute or Center of the National Institutes of Health (NIH) to license certain patent rights concerning stabilizing prefusion coronavirus spike proteins and the resulting stabilized proteins for use in COVID-19 vaccine products. Pursuant to the agreement, we have agreed to pay low single-digit royalties on future net sales, a minimum annual royalty payment and certain contingent development, regulatory and commercial milestone payments on a licensed product-by-licensed product basis.

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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 3,900 full-time employees as of December 31, 2022, representing a substantial increase from 2,700 full-time employees as of the end of the prior year. We have undertaken significant hiring of talent 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. While much of this growth has occurred at our headquarters in Cambridge, Massachusetts and our manufacturing facility in Norwood, Massachusetts (outside Boston), we also continued to increase our hiring elsewhere in the United States and internationally during 2022. At year-end, we had employees in 17 countries around the world, with a presence in North America, Europe and the Asia-Pacific region. To support our growth as we build out our commercial and regulatory capabilities, we have focused our hiring on talent with experience at other pharmaceutical companies, 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 our entire pipeline.

We operate in a highly competitive environment for talent, 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, 2022, 48% of our employees hold Ph.D., Doctorate, M.D., J.D. or Master's degrees. Among our employees, as of December 31, 2022, 50% are female. Among our leadership (which we define as employees at the vice president level and above), as of December 31, 2022, approximately 41% are female, a slight increase from the prior year. 41% of our U.S. employees identify as racially or ethnically diverse as of December 31, 2022, a slight increase from the prior year. In 2022, we engaged a third-party consultant to conduct a statistical pay equity analysis, which showed zero statistically significant differences in pay, based on role, across gender globally and across gender, race and ethnicity in the United States.

Our focus on belonging, inclusion & diversity

We believe that our strength comes from our diversity, and we are committed to building a culture of inclusion and belonging for all. In 2022, we continued to act on our commitment to belonging, inclusion & diversity by, among other things:

- increasing our monitoring and reporting of company-wide gender and ethnicity data;
- including a belonging, inclusion and diversity focus in every employee engagement survey;
- continuing to invest in our Employee Resource Groups, which are voluntary, employee-led groups that harness the power of belonging in service to our people, our company and the community at large;
- joining the Disability:IN Inclusion Works Program, an initiative that assists employers in all aspects of disability inclusion at work; and
- conducting diversity-related events, celebrations and learning opportunities for all employees throughout the year.

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 substantially through Moderna University in the development of our people.
- **Well-being**: We are committed to the health and well-being of our employees and their families and provide numerous family-friendly benefits and opportunities to be healthy, including monthly contributions to employee lifestyle spending accounts.
- **Inclusion**: 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. We measure and hold management accountable to creating an environment of psychological safety.
- **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.
- **Giving and volunteering:** Our people have the opportunity to give back to their communities and directly support causes that they are passionate about through volunteer and employee matching donation programs.

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To help promote alignment between our employees and our shareholders, all employees participate in our corporate 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 and embed our "We act like owners" mindset.

None of our employees are represented by a labor union or works councils, and none of our employees have entered into a collective bargaining agreement with us. A small number of employees in Belgium, France, Italy and Spain are covered by statutory 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 our company and team have been publicly recognized for our leadership, innovation and good corporate citizenship. *Science* magazine ranked us as a top employer for each of the last eight years. Additionally, in 2022, *Biospace* ranked us the number one large employer in its 2023 Best Places to Work in Biopharma report. We measure employee engagement through a vendor-supplied engagement software, using validated external benchmarks to track employee engagement factors.

We continually monitor employee turnover rates, as our success depends upon retaining our highly trained personnel. We believe that the competitive compensation we offer, along with the combination of the factors listed above, among other factors, have helped reduce voluntary turnover. In 2022, our voluntary turnover rate was approximately 8%.

Our approach to training our employees

To further invest in our teams, we have established a structured training curriculum for our employees through Moderna University and have a full-time team dedicated to developing its curriculum and conducting activities. 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 innovation. In addition, Moderna University is also focused on creating strong leaders through management and leadership training. There are four core areas within Moderna University:

- **Professional development**: This program provides on-site training programs, 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 at in-house scientific seminars;
    - 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**: Moderna ONE is our program for onboarding all new employees. During this intensive learning program, new employees from across the globe meet with members of the management team and senior functional leaders at our headquarters in Cambridge, Massachusetts to learn about Moderna, our culture and how we operate.

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 employees to identify and integrate AI and machine learning solutions into every Moderna system and processes to bring mRNA medicines to patients.

Our culture

As an organization, we are bold, collaborative, curious and relentless. These values are underpinned by a core set of what we call "basecamp" values—they are non-negotiable for every Moderna employee: integrity, quality, respect. Additionally, with the continued rapid growth of our company, we articulated the Moderna Mindsets in 2021. The Moderna Mindsets are a set of beliefs by which we govern Moderna. They define how we behave, how we lead and how we make decisions. We believe the Mindsets will be integral to our future success, and we are working to integrate them into every facet of how we identify, onboard, grow and manage the highest impact talent. 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. We have also rolled out a new coaching and development program for our senior leaders that is based on our Mindsets. This program represents a significant investment in our growing senior leader cohort, providing every senior leader with individualized coaching to help them become stronger leaders for Moderna's future.

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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, and provide our employees an opportunity to continuously grow and advance in a way that meets their aspirations and talents.

CORPORATE SOCIAL RESPONSIBILITY

As we pursue our mission to deliver the greatest possible impact to people through mRNA medicines, we have developed a corporate social responsibility (CSR) program that demonstrates our commitment to patients, employees, the environment and local communities. Our CSR framework consists of five key focus areas: medicines for patients, community, governance and ethics, employees and environment. Please refer to our 2021 ESG Report under the "Responsibility—Corporate policies" section of our website, which can be found at www.modernatx.com/responsibility/corporate-policies, as well as our proxy statement related to our 2023 Annual Meeting of Stockholders that we will file with the SEC, for a description of some of the measures we have taken to progress 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 Vaccines

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. The mRNA field is growing rapidly, which is leading to increased competitive pressure, including from large and more established pharmaceutical companies. 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 vaccines, particularly from established pharmaceutical companies with longer operating histories and significant experience in producing and marketing pharmaceutical products. Our COVID-19 vaccines compete against vaccines that have been approved or authorized in various jurisdictions, including the Pfizer/BioNTech COVID-19 vaccine, which is also based on mRNA technology.

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 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 vaccines 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 vaccines, 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 technology; storage and handling conditions for our vaccines and the ease or difficulty with which they can be distributed; the timing and scope of regulatory approvals; reimbursement coverage; our costs to produce and distribute our vaccines; and our ability to scale our manufacturing and distribution effectively as we continue to expand shipments internationally. The competitiveness of our COVID-19 vaccines in the future may also depend upon whether we are successful in our efforts to produce combination respiratory vaccines, which would combine protection against various respiratory diseases, such as seasonal flu, RSV and COVID-19 in a single shot. We will also be impacted by the degree of success that our competitors have with 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.

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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, Beam Therapeutics and others). Others include Sanofi, GlaxoSmithKline and CureVac. We also compete against other pharmaceutical companies in the market for COVID-19 vaccines that do not utilize mRNA technologies, including AstraZeneca, Johnson & Johnson and Novavax, 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.

Our Growing Commercial Footprint

Our commercial organization was only established in 2020 in connection with the launch of our COVID-19 vaccine. Accordingly, we have less commercial experience than many of our competitors and are still in the process of growing our commercial footprint. Additionally, we may compete against other companies who have certain competitive advantages over us, such as an ability to bundle the sale of their COVID-19 vaccines with other products. See "Risk Factors—Risks related to commercialization and our products."

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, development candidates and investigational medicines. 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 us 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 development candidates may be tested in humans, the development 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.

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Clinical trials

The clinical stage of development involves the administration of the investigational medicine 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 Institutional Review Board (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 (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 investigational medicine.
- Phase 2 clinical trials generally involve 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 disease-affected patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the investigational medicine for its intended use, its safety in use and to establish the overall benefit/risk relationship of the investigational medicine, 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 clinical trial site 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 clinical trial may move forward at designated check points based on access to certain data from the clinical 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.

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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 the facilities 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 BLA or NDA. 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 as 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 investigational medicine 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, such product 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 with due diligence. 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. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Additionally, under FDORA, the FDA has increased authority for expedited procedures to withdraw its accelerated approval for such drug or biologic if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

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 that 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.

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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 thereafter, 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. The FDA has subsequently reissued the EUA for our COVID-19 vaccine on multiple occasions, and we currently operate under the EUA provided by the FDA for our COVID-19 vaccines for pediatric and adolescent populations and for our boosters. 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 (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 to provide liability immunity for activities related to certain countermeasures against the ongoing COVID-19 pandemic. While we believe our products sold to the U.S. Government 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 that 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 product'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.

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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 product 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 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 since January 2022, the European Commission adopted a new Clinical Trials Regulation (No. 536/2014) 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 (known as the Paediatric Regulation) and formulates an opinion thereon.

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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 from the applicable regulatory authority in the EU. 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, advanced therapy medicinal products (ATMPs), orphan medicinal products, or those medicines containing a new active substance and intended to treat HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and other immune dysfunctions and viral diseases, and optional for those medicines that are highly innovative or contain a new active substance, provides for the grant of a single marketing authorization that is valid throughout the EEA. In addition to the centralized procedure, a marketing authorization can also be obtained in the EEA through a national 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.

A conditional marketing authorization may be granted in the EU when comprehensive clinical data for the safety and efficacy of the medicinal product have not been supplied but all the following requirements are met: (i) the risk-benefit balance of the medicine is positive; (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data post-authorization; (iii) the medicine fulfills an unmet medical need; and (iv) the benefit to public health of the immediate availability on the market of the medicine outweighs the risk that additional data is still required. Conditional marketing authorizations are valid for one year, on a renewable basis. The marketing authorization holder will be required to fulfil specific obligations within certain timeframes, which may include completing ongoing trials or conducting new trials to confirm that the benefit-risk balance is positive. Once such obligations are fulfilled, provided the benefit-risk balance is still positive, a conditional marketing authorization can be converted into a standard marketing authorization.

European exclusivity

In the EU, 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 generic or biosimilar applicants from referencing the innovator's data when applying for a generic or biosimilar marketing authorization. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. There is no guarantee that a product will be considered by the EU'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 EU 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. This period may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met. During the period of market exclusivity, marketing authorization may only be granted to a "similar medicinal product" (a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication) for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product

The aforementioned EU rules are generally applicable in the EEA.

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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

Similar to 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.

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- 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.

In August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.

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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, breach of our regulatory obligations or expose individuals to harm, 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 free of charge on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. 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.

The SEC also maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC.

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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 commercialization and our products

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

We continue to pursue the rapid manufacture, distribution and clinical testing of our COVID-19 vaccines, which are our only commercial products and source of product revenues. We may encounter difficulties producing COVID-19 vaccines on the timelines and in the quantities set forth in our supply agreements. We may also be unsuccessful in entering into contracts for future sales of COVID-19 vaccines. Our ability to commercialize our vaccines depends on our manufacturing capability, both at our own facilities and those of our partners. We are committing substantial financial resources and personnel to the development, manufacture and distribution of our COVID-19 vaccines, including updating our vaccines in response to new variants of concern, and these efforts may delay or otherwise negatively impact our other development programs.

Although we have expanded our internal manufacturing capacity, we rely on third-party manufacturing partners to produce our COVID-19 vaccines. We have entered into strategic collaborations for the production, as well as for commercial fill-finish manufacturing, of our COVID-19 vaccines to supply markets both in and outside the United States. We may need to engage additional partners in the future, including additional contract manufacturing organizations (CMOs), to assist in meeting our production needs. If we cannot enter into such arrangements on favorable terms, or at all, our ability to develop, manufacture and distribute our COVID-19 vaccines would be adversely affected.

Adapting our COVID-19 vaccines to new variants requires significant coordination with our partners and rapid adaptation. During the height of the pandemic, we were also subject to challenges sourcing sufficient raw materials to produce our vaccine and other supply chain pressures, and we may experience such challenges again in the future. Any capacity or production issues or delays experienced by our partners, whether in connection with updates to our COVID-19 vaccines, satisfying regulatory or quality requirements or other issues, may cause us to fail to meet certain product volume or delivery timing obligations under our supply agreements. Further, we will require significant additional investment, whether from our own capital resources or other sources of funding, as we continue to expand our commercial efforts.

We have limited sales, distribution and marketing experience, and if we cannot effectively establish such capabilities or supplement our capabilities by entering into agreements with third parties, our ability to generate revenues may be adversely affected.

Our commercial organization was only established in 2020 in connection with the launch of our COVID-19 vaccine. Accordingly, we have limited experience with the commercialization of our products, and we face risks and uncertainties as we likely shift to an endemic market for COVID-19 vaccines and as we prepare for the commercial launch of other medicines. We continue to invest in the development of sales, marketing, distribution, managerial and other non-technical capabilities in and out of the United States. We may seek to enter into agreements with others 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 others to commercialize our products, our revenues will be lower 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 partners commit insufficient resources to commercialize our products, and we cannot independently develop necessary marketing capabilities, we may be unable to generate sufficient product revenue to sustain our business.

Evolving dynamics in the market for COVID-19 vaccines are likely to impact our financial results, including increased production costs per dose and lower product revenues than we have experienced in recent years.

To date, our product sales have consisted of sales of our COVID-19 vaccines to the U.S. Government, other international governments and organizations. We will face many factors that are likely to impact our results as we likely transition to an endemic, commercial market in the United States and globally, including a more fragmented customer base, less predictability in orders, greater seasonality of demand, increased distribution costs, higher costs of goods sold due to single-dose or lower-dose presentations and increased research and development costs, including for clinical trials, when updating our COVID-19 vaccines for new variants of concern. In addition, we will be exposed to market practices that characterize the U.S. private market for vaccines, including practices regarding discounts, rebates and returns, which can result in the realization of significantly lower revenues than list prices.

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As we likely shift to an endemic market for COVID-19 vaccines, we have in the past and may in the future experience increased costs associated with exiting commitments with suppliers for raw materials and CMOs. As a result of potentially lower demand, and shifting to a lower dose for boosters than our primary series, we may experience increased costs with raw material suppliers as we seek to exit or modify our purchase commitments. Additionally, decreased overall demand for COVID-19 vaccines, as well as a shift in demand to the fall and winter seasons in each hemisphere, is also likely to result in our need to exit or modify commitments with certain CMOs, which could also result in increased costs. Further, we have entered and may in the future enter into significant non-cancellable or take-or-pay purchase commitments for raw materials that require a long lead time to procure, which increases our commitment exposure. If we cannot effectively manage evolving demand dynamics, our business, financial condition, results of operations and prospects may suffer.

Additionally, although we anticipate a decline in demand for COVID-19 vaccines compared to recent years, the medical burden for the likely shift to an endemic COVID-19 and annual booster volumes may not be as large as we currently expect. The market for our vaccines will depend on many evolving factors, such as medical need, viral evolution, public health authority recommendations and consumer motivation to vaccinate. We may be unsuccessful in entering into contracts for the supply of COVID-19 vaccines, and existing contracts may be subject to cancellation or deferrals.

The pharmaceutical market is intensely competitive, and we may not compete effectively in the market for existing products, new treatment methods and new technologies.

The pharmaceutical market is intensely competitive and rapidly changing. Many 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 and many of these institutions and competitors have:

- greater resources and experience than we have at every stage of the discovery, development, testing, approval, manufacturing and commercialization of products;
- multiple products that have been approved or are in late stages of development; and
- arrangements in our target markets with purchasers, leading companies and research institutions.

We face intense competition with respect to our COVID-19 vaccines, which may not continue to compete favorably with existing or future vaccines and treatments. Many COVID-19 vaccines have been authorized in various jurisdictions, including the mRNA COVID-19 vaccine produced by Pfizer/BioNTech. These vaccines and other treatments, such as Pfizer's antiviral pill, 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 vaccines. Even if our products demonstrate superiority to those of competitors, consumers and the public may fail to appreciate that benefit. These factors, or the perception of these factors, could lead to a competitor's vaccine or treatment being more successfully commercialized, and we may be unable to compete effectively for future sales of our COVID-19 vaccines. Further, the mRNA medicines field is growing rapidly, with increased competitive pressure from large and more established pharmaceutical companies. The actual or perceived success or failure of other entities may adversely impact our ability to commercialize our COVID-19 vaccines and future products.

We also will face competition from products that have already been approved and accepted by the medical community for the treatment of certain 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, and these 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. 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 unsuccessful or delayed in developing updates to our COVID-19 vaccines to protect against future variants of the SARS-CoV-2 virus, or booster doses of our COVID-19 vaccines may not protect against such variants, and a market for vaccines and boosters against these variants may not develop or be weaker than anticipated.

Our original COVID-19 vaccine was developed based upon the genetic sequence of the SARS-CoV-2 virus that was first detected in Wuhan, China. As the 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 earlier strains. There is a risk that our current COVID-19 vaccines and boosters will be ineffective, or less effective than desired, in protecting against these new variants. Additionally, our decisions regarding booster development may be directed by guidance from the FDA or other foreign regulatory authorities, which may impact the timing of development for our COVID-19 vaccines. For example, we developed mRNA-1273.222 in accordance with FDA guidance from June 2022 to develop a BA.4/BA.5-targeting bivalent COVID-19 vaccine.

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In the future, we may not adequately anticipate demand for, or we may experience delays in producing, variant-specific boosters. Further, different regulators may issue differing guidance regarding composition of variant-specific boosters. If our efforts to develop variant-specific vaccines against future variants are unsuccessful, we are slower than competitors to develop such vaccines or our vaccines prove less effective than competitors' vaccines, we could suffer reputational harm, loss of market share and adverse financial results. Additionally, we may expend significant resources adapting our vaccines or conducting clinical trials to protect against COVID-19 variants, but a market for our adapted vaccines fails to develop or demand does not align with our projections or cost expenditures.

We have only recently established capabilities to facilitate our compliance with global pharmacovigilance obligations, and failure to build out and maintain this infrastructure may result in increased costs, reputational harm or the loss of our ability to commercialize our products.

The commercialization and distribution of our COVID-19 vaccines subjects us to pharmacovigilance obligations under regulatory regimes in the jurisdictions where our vaccine is distributed, and we will also be subject to these requirements in connection with future products. These regulations require us to collect, process, analyze and monitor safety data and to identify and evaluate adverse reactions to our vaccines as they are 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 regulatory authorizations to distribute our vaccines in the relevant jurisdiction may be revoked or curtailed. There are a limited number of service providers who are qualified and capable of providing global pharmacovigilance services, and our inability to identify or contract with them may impede our commercial activities.

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.

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 will depend on numerous factors, including:

- the potential efficacy and advantages over alternative treatments;
- the ability to offer products 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 our products may require significant resources, especially due to the complexity of our programs, and may never be successful.

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 vaccines 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 be unable 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. 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 our PCVs, 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.

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 estimates of the number of people who have these diseases, as well as the subset of those with the potential to benefit from treatment with our medicines, are based on our beliefs, and 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, these medicines may never be profitable.

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

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Some customers for our COVID-19 vaccines 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. 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, we may be required to pay refunds or other obligations based on the number of days we are late, or a customer may reduce the volume of vaccine doses that it commits to purchase or terminate the contract. Upon termination, we may be required to refund a portion of that customer's prepayment. Customers may not agree to prepay us for our services in the future.

Risks related to our pipeline, product development and regulatory review

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

Our COVID-19 vaccines have advanced rapidly through the regulatory review, authorization and approval processes in the U.S. and other jurisdictions. The speed at which COVID-19 vaccines have been created and tested is atypical as compared to other vaccine development processes. Evolving or changing plans or priorities within the FDA or other regulatory authorities, including changes based on new knowledge of how the SARS-CoV-2 virus, and new variants thereof, affect the human body, may significantly affect the regulatory timeline for further authorizations or approvals for our COVID-19 vaccines, including variant-specific versions. We cannot predict with certainty the timelines or types of clinical trials or regulatory processes that may be required for the authorization or approval of updated versions of our COVID-19 vaccines.

We currently operate under a BLA approved by the FDA for our COVID-19 vaccine in certain demographics and an EUA provided by the FDA for our COVID-19 vaccines that are administered as boosters and as a primary series in certain demographics. The FDA may revoke these authorizations for a variety of reasons, including if it determines that the underlying health emergency no longer exists or warrants such authorization. Additionally, we have received certain conditional marketing authorizations in the EEA. Although a conditional marketing authorization is a formal marketing authorization and covers all of our current COVID-19 vaccines produced for the EU, we must provide certain additional information and data by specified timelines as conditions of the conditional authorization in the EU, and the EMA can take regulatory action if we fail to comply. Conditional marketing authorizations are valid for one year and must be renewed annually to remain valid; 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 conditional marketing authorization. Similar temporary, emergency authorizations that we have received for our COVID-19 vaccines in other jurisdictions could be revoked if the conditions for granting such authorizations no longer apply. If such authorizations were revoked, without receiving final approval to distribute our COVID-19 vaccines, our business would be adversely impacted.

Preclinical development is lengthy and uncertain, especially for mRNA medicines, and our preclinical programs or development candidates may be delayed or terminated, 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 advanced 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. We must also complete extensive work on Chemistry, Manufacturing, and Controls (CMC) activities to be included in an IND submission. CMC activities for mRNA medicines require extensive manufacturing processes and analytical development, which is uncertain and lengthy. We have had 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, our preclinical studies 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 further development of our programs. As a result, we may be unable to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and such applications may not result in the FDA or other regulators allowing clinical trials to begin.

Clinical development is lengthy and uncertain, and our clinical programs may be delayed or terminated, 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. Most investigational medicines that commence clinical trials are never approved as products. We may be unable 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. Events that might prevent us from proceeding with clinical trials could 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 or site of our manufacturing could cause 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 may 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;
- 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 to immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions or reactions to PEG-lipids;
- significant adverse events or other side effects could be observed in our clinical trials, including those involving dosing young, human subjects;
- 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 applicable clinical trial protocol or withdraw from the applicable clinical trial, which may require that we add new clinical trial sites;
- regulators may impose a complete or partial clinical hold on a clinical trial, or we or our investigators, IRBs or ethics committees may suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that 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 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.

Before commencing later-stage clinical trials for our programs, we must 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. Further, the assays used to estimate the effectiveness of our COVID-19 vaccines continue to evolve. Validation reports for these assays have been submitted for review to regulatory agencies. Results obtained in clinical trials of our COVID-19 vaccines with later versions of these assays may be less positive than the results observed to date.

Additionally, we have conducted and may conduct in the future "open-label" clinical trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate, an approved drug or a placebo. The results from an open-label clinical 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 and could 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 commercialize our products, or cause us to experience significant delays in doing so, any of which may materially harm our business.

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 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.

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We utilize earlier programs in a modality to understand the technology risks within the modality, including the program's 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 or biology risk unique to that 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.

There are many clinical and manufacturing challenges specific to our PCV candidate, mRNA-4157, and any other neoantigen cancer vaccines we may develop. 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 PCV candidate 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 clinical 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 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 enrolling participants in our clinical trials, which would delay the progress of our investigational medicines and result in increased expenses.

Enrolling participants in our clinical trials is critical to our success. Difficulties or delays in enrolling a sufficient number of clinical trial participants, or those with required or desired characteristics to achieve diversity in a clinical trial, may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our investigational medicines and obtain regulatory approval of potential products. We may slow enrollment in a trial to focus on achieving greater diversity in the subject population, as we did in our Phase 3 clinical trial of our COVID-19 vaccine.

Participant enrollment is affected by factors, including:

- severity of the disease under investigation;
- complexity and design of the clinical trial protocol;
- size of the patient population;
- eligibility criteria for the clinical trial in question, including age-based eligibility criteria limiting subject enrollment to adolescent or pediatric populations;
- proximity and availability of clinical trial 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 qualified clinical trial investigators;
- 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, could discourage potential clinical trial participants and their doctors from participating in our trials;
- in the case of PCV, the need to wait for the manufacture of the personalized drug product; and
- our ability to obtain and maintain participant informed consent.

Additionally, we may have limited or no ability to influence enrollment in clinical trials where we have entered into strategic alliances pursuant to which our collaborators control development of certain of our investigational medicines. Even if we or our strategic collaborators are able to enroll clinical trial participants, there is no guarantee that such participants 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.

COVID-19 vaccines are the only mRNA medicines that have been authorized or approved to date by the FDA or other regulators, and efficacy, safety and immunogenicity data with respect to our COVID-19 vaccines, 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. Additionally, we may observe new, more frequent or more severe adverse events in subjects participating in ongoing clinical trials or individuals vaccinated with our COVID-19 vaccines. For example, some studies have suggested that our COVID-19 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 FDA and other regulators may interpret data from our clinical trials differently than we do and such agencies may require us to conduct additional studies or analyses, which could cause delays in obtaining regulatory authorizations. 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 prior to receiving regulatory authorization. These factors could delay or prevent us from receiving full regulatory approval of our COVID-19 vaccines in certain jurisdictions or for certain demographics.

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 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 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 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;

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- 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 are currently attempting 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 clinical 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 are only a 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 therapy products have evolved and may continue to change in the future, and the implications for mRNA therapies are unknown. For example, the FDA has established an office, now called the Office of Therapeutics Products (OTP), 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 of mRNA therapies. 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 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 clinical trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory 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.

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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 its 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.

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 (BPCI Act), another company may market a competing version of one of our products if the FDA approves a BLA for the competing product containing the company's own preclinical data and data from adequate and well-controlled clinical trials demonstrating 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 U.S. 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 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 foreign regulators, for each investigational medicine and, consequently, the ultimate approval and commercial marketing of any investigational medicines.

To date, we have only received regulatory authorizations for our COVID-19 vaccines, and our current or future 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 parties to assist us in this process. Although we expect to submit BLAs for our mRNA investigational medicines in the United States, other jurisdictions may consider our mRNA investigational medicines to be new drugs, not biologics, and require different marketing approval 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.

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 law or changes in regulatory review may delay the review of a submitted product application. The FDA and comparable foreign regulators have substantial discretion in the approval process and may refuse to accept any marketing approval application or may decide that our data are insufficient for marketing 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.

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The FDA and other foreign 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 negative 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 regulatory approval or if we fail to obtain regulatory 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, we may remain subject to significant restrictions on the indicated uses or marketing of our product and ongoing requirements for potentially costly post-approval studies—such as those required under an accelerated approval by the FDA or other similar type of approval—or post-market surveillance. For example, the holder of an approved BLA must monitor and report adverse events and monitor and report any failure of a product to meet the specifications in the BLA, as well as 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 regulations 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.

For mRNA-1273, we are required by the FDA to conduct post-marketing studies to further assess the risks of myocarditis and pericarditis following vaccination. Additionally, we have committed to conducting additional post-marketing safety studies, including conducting a pregnancy registry to evaluate pregnancy and infant outcomes after receipt of mRNA-1273 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 trials or earlier post-marketing periods. If we, our contract manufacturers or other strategic collaborators fail to comply with applicable post-approval regulatory requirements, 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 require field alerts to physicians, pharmacists and hospitals or refuse to allow us to enter into supply contracts. We could also be required to conduct additional nonclinical studies or clinical trials, or implement changes in labeling or to our manufacturing processes, specifications or facilities. Initiation of any government investigation or lawsuit, including class-action lawsuits, would require us to expend significant time and resources in response and would likely generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize mRNA-1273, or any future approved products, and generate revenues.

Additionally, the FDA or other foreign regulators could require us to adopt a REMS 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 to us. 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.

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

Our mRNA products, including our COVID-19 vaccines, 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 products.

The manufacturing processes for our mRNA medicines are novel and complex. 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, including delays as our supply chain expands and grows more complex. We could experience issues resulting from 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.

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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 clinical trials 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 high rate of innovation causes 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 supply requirement of a single preclinical study or clinical trial. Failure in our ability to scale up batch size or failure in any batch, which we have experienced in the past, 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 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 we grow as a commercial company and 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 third-party providers, all of whom have inherent risks in their operations that may adversely impact our operations.

We have limited experience at larger scale production necessary to support large-scale clinical trials and commercial sales. Completion of our 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 expect to continue to make significant investments in our manufacturing capacity and commercial network as we continue to expand our commercial launch efforts. We are building regional manufacturing capability globally and are subject to risks associated with building and operating in foreign jurisdictions.

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To supplement our internal manufacturing infrastructure, we have entered into agreements for the production, as well as for commercial fill-finish manufacturing, of our products to supply markets globally. We may need to engage additional third parties in the future 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 vaccines and any future products would be adversely affected. Further, 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, we may encounter difficulties producing our products on the timelines and in the quantities set forth in our supply agreements or to meet potential future demand. 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:

- 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 poses risk of process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, design issues, system compatibility or potential cybersecurity compromises, incidents or breaches. Upgrades or changes to our systems, infrastructure or the software that we implement, use, or upon which our business relies, may result in the introduction of new cybersecurity vulnerabilities and risks.

Our facilities and infrastructure or those of our contract manufacturers or other third-party providers 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, cause us to fail to meet certain product volume or delivery timing obligations, 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, Canada and the United Kingdom. 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 or manage our growth effectively, the development and production of commercial products or our investigational medicines could be delayed or curtailed. We will require significant additional investments in our manufacturing processes as we expand the MTC and our other manufacturing infrastructure.

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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 vaccines and 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 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 vaccines. If we or third-party distributors do not maintain effective cold-chain supply logistics, then we may experience returned or out of date products and product may be rendered unusable. This has led and could lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or commercial sale. 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 vaccines and investigational medicines. Our manufacturing facilities or those of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet current Good Manufacturing Practice (cGMP) requirements 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 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:

- 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 vaccines, 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 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. 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 affect the regulatory status of their facilities. In addition, to the extent that we rely on foreign contract manufacturers, including for our COVID-19 vaccines, we are subject to additional risks, including the need to comply with import and export regulations.

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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 resulting in product recalls of our COVID-19 vaccine. Lot failures have 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 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. Additionally, as we prepare for a potential Phase 3 trial for our PCV candidate, we anticipate an increase in manufacturing demand that will require significant additional investments. Some of the additional equipment that will be required will be custom made for us, which will lead to long lead times and expedited procurement to meet our timelines. 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 resulted 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.

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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 vaccines, 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 could lead to supply delays or interruptions that would damage our business, financial condition, results of operations and prospects.

There are, in general, 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. 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 manufacturing processes and facilities of our single-source suppliers.

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

- 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 with our products or investigational medicines if such collaborators believe that competitive products are more likely to be successfully developed or can be commercialized on more economically attractive terms than ours;
- products or investigational medicines developed in strategic alliances with us may be viewed by our collaborators as competitive with their own investigational medicines or products, which may cause them to cease to devote resources to development or commercialization;
- a strategic collaborator with marketing and distribution rights to one or more of our products 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; 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.

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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 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 and the intellectual property rights therein, or protect the confidentiality of our trade secrets, our ability to effectively compete using our development candidates will be harmed.

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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, 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. We therefore 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 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 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 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 March 2022, we announced that we will not enforce our patents for COVID-19 vaccines against companies manufacturing in or for the Gavi COVAX Advance Market Commitment countries, provided that the manufactured vaccines are solely for use in the AMC 92 countries. In addition, we are willing to license our IP for COVID-19 vaccines to manufacturers, but we may never enter into such licenses of our IP, and our business may be otherwise adversely impacted if we are unable to enforce our IP.

In August 2022, we filed patent infringement lawsuits against Pfizer and BioNTech in the United States, Germany and other jurisdictions, alleging that their COVID-19 vaccine Comirnaty® infringes patents we filed between 2010 and 2016 covering our foundational mRNA technology. We have invested billions of dollars in creating our patented mRNA platform, which is integral to the development of our mRNA medicines. We expect to expend substantial financial and managerial resources pursuing this litigation and defending against counterclaims filed by Pfizer and BioNTech, and the ultimate outcome of the litigation is uncertain.

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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. Litigation is ongoing over the underlying technology to mRNA vaccines. In addition to our ongoing litigation against Pfizer and BioNTech, CureVac has filed suit against BioNTech, Alnylam Pharmaceuticals has sued Pfizer and us and Acuitas Therapeutics has sued Arbutus Biopharma Corporation and Genevant Sciences. It is likely that there will continue to 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 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.

We are, and may in the future 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.

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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 our pipeline, product development and regulatory review—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 related to intellectual property rights and 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 our financial condition and results of operations

We have a limited history of recognizing revenue from product sales and may be unable to achieve long-term sustainable profitability.

Before 2021, we incurred net losses in each year since our inception. Currently, our COVID-19 vaccines are our only commercial products. While preparations are underway for additional potential product launches, it will be years, if ever, before most of the candidates in our pipeline are ready for commercialization. Our ability to generate revenue and maintain profitability depends on our ability to successfully develop and obtain the regulatory approvals necessary to commercialize our products and investigational medicines.

We have incurred, and expect to continue to incur, significant costs associated with commercializing our COVID-19 vaccines and our clinical and preclinical development activities. We may be unable to achieve long-term sustainable profitability and may need 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 with collaborators;
- 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 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 may fluctuate from quarter-to-quarter and year-to-year due to many factors, many of which are beyond our control. As such, a period-to-period comparison of our operating results may not be predictive 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. Our stock price could be affected by events not necessarily tied to our actual operating results, including recommendations by securities analysts, the timing of certain public disclosures by us, our collaborators or our competitors and our ability to accurately report our financial results in a timely manner. Other factors relating to our business that may contribute to these fluctuations include those described in these *Risk Factors* and elsewhere in this Annual Report on Form 10-K.

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, 2022, we had approximately $18.2 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.

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As of December 31, 2022, we had approximately 3,900 full-time employees in 17 countries, and we expect to continue to increase our employees and the scope of our operations. To manage this global expansion, 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 significant attention away from our day-to-day activities to manage these development activities.

Successfully developing products for and fully understanding the regulatory and manufacturing pathways for the many therapeutic areas and diseases we seek to address requires significant depth of talent, resources and corporate processes to allow simultaneous execution across multiple areas. We may be unable to effectively manage this simultaneous execution and expansion of our operations or recruit and train qualified personnel, which could cause 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 development and expansion, our financial performance and ability to commercialize our products may be affected negatively, and we may not be able to implement our business strategy.

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

Our business is subject to risks associated with doing business outside of the United States, and we have limited experience operating internationally. 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. To obtain regulatory approval in various jurisdictions, we must comply with numerous 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 may fail to obtain approval. We are rapidly expanding our global operations, establishing commercial subsidiaries and entering into arrangements to support the worldwide manufacture and distribution of our products, which is a complex task. For example, we are building regional manufacturing facilities and investing in research and development in several countries. Our business may be adversely affected by many 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;
- our customers' ability to obtain reimbursement for our products in foreign markets;
- our inability to directly control commercial activities because we rely 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;
- 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;
- 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 UK Bribery Act and similar laws in other countries. Compliance with the FCPA is expensive and difficult, particularly in countries where corruption is a recognized problem. Additionally, the FCPA presents particular challenges to 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.

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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 where 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.

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

We are upgrading our global ERP system to support our continued growth 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 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 controls could cause our non-compliance 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's 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, regulatory and commercial personnel. The turnover rate in our industry is high. In addition to competition from other companies, we compete with academic institutions for individuals with certain 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, including as the result of failure to succeed in preclinical studies or clinical trials or applications for marketing approval, may make it difficult to recruit and retain qualified 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 they 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 executives, 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 help us formulate 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 limit their availability to us. The loss of the services of these individuals might impede the achievement of our research, development, regulatory approval, manufacturing and commercialization objectives.

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. The dramatic growth of our workforce, coupled with recent 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.

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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, including from cybersecurity incidents, which could materially disrupt our product development programs and manufacturing operations.

Our internal computer systems and infrastructure and those of our strategic collaborators, vendors, contractors, consultants or regulatory authorities with whom we share confidential, protected or sensitive data or information, or upon which our business relies, are vulnerable to damage from computer viruses, unauthorized access, misuse, 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, as well as security compromises or breaches, which may compromise our systems, infrastructure, data or that of our strategic collaborators, vendors, contractors, consultants or regulatory authorities with whom we share confidential, protected or sensitive data or information or upon which our business relies, or lead to data compromise, misuse, misappropriation or leakage. We have experienced, and may experience additional, cyber-attacks on our information technology systems and infrastructure by threat actors of all types (including nation states, criminal enterprises, individual actors or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by these threat actors. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, digital extortion, business email compromise and denial-of-service attacks, social engineering and other means to affect serve reliability and threaten the confidentiality, integrity and availability of information, systems or infrastructure. If any such cyber-attack or physical intrusion against us or our strategic collaborators, vendors, contractors, consultants or regulatory authorities with whom we share confidential, protected or sensitive data or information, or upon which our business relies, were to result in a loss of or damage to our data, systems or infrastructure, or interrupt 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 adverse effect on us. For example, the loss of clinical trial data could delay 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 infrastructure or physical premises may result in a loss of data or compromised data integrity across multiple programs in many stages of development. Our cybersecurity liability insurance may not cover all damages we would sustain based on any breach or compromise of our computer security protocols or cybersecurity attack.

Any data breach, security incident or compromise of confidential, protected or personal information, including any clinical trial participant personal data, may also subject us to civil fines and penalties, litigation, regulatory investigations or enforcement actions, or claims for damages 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, as amended by the California Privacy Rights 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, including by nation states and affiliated cyber actors. To the extent that any disruption or security compromise incident or breach were to result in a loss of, or damage to, our data, systems, infrastructure or applications, or inappropriate use or disclosure of confidential or proprietary information, including information related to the research and manufacturing of our products, 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 security incidents or breaches involving personal information, the CCPA is of particular concern since it provides for a private right of action 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 other opportunities that could later prove to have greater commercial potential. For example, we have focused a significant amount of resources on our COVID-19 vaccines and other respiratory programs, for which preparations are underway for multiple vaccine launches. Additionally, we are increasing our investments in production capacity for our PCV program. Our resource allocation decisions, or our contractual commitments to provide resources to our strategic collaborators, may cause us to fail to capitalize on certain commercial products or profitable market opportunities. Our spending on 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 where it would have been more advantageous for us to retain sole development and commercialization rights, 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, 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 commercialize 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 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, which would impair our potential for growth.

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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 regulators could require the recall of our commercial 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 or other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, foreign governmental bodies may 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 adversely affect our financial condition and results of operations. A recall announcement could harm our reputation 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 vaccines 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 vaccines or investigational medicines. For example, we may be sued if any product or 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 our COVID-19 vaccines or investigational medicines. Any such claims may include allegations of defects in manufacturing or 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. For any marketed products, 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 cause 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. 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.

With respect to our COVID-19 vaccines, 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 be unavailable to cover potential claims or liabilities resulting from the research, development, manufacture, distribution or commercialization of the vaccine. Additionally, other foreign governments that we contract with in the future may not provide us with similar contractual indemnity or statutory immunity, and we will not have the benefit of such indemnities or immunities in the future as the COVID-19 market transitions to a commercial market in the United States and elsewhere. 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 be unable to maintain our product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. 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.

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

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We may face competition in the United States for our products 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 a joint federal lawsuit requesting injunctive relief to prevent the rule from taking effect and challenging multiple aspects of the final rule. This litigation was dismissed in February 2023 for lack of standing, and the market implications of the final rule 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. Additionally, the Inflation Reduction Act of 2022 includes several provisions such as drug pricing controls and Medicare redesign that are likely to impact our business to varying degrees, but its ultimate effect on our business and the healthcare industry in general is not yet known. See "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.

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 "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 UK. 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 Bribery Act 2010 in the UK. 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 UK 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 or criminal penalties and damage our reputation.

Privacy and data security have become significant issues in the United States, Europe and many other jurisdictions where we operate 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 and privacy 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 receive increased focus.

The GDPR imposes stringent obligations on us with respect to our processing and the cross-border transfer of personal 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. We could be subject to fines and penalties, litigation and reputational harm in connection with any activities falling within the scope of the GDPR.

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In the United States, California has passed the CCPA and Connecticut, Colorado, Utah and Virginia each passed their own comprehensive consumer privacy laws. In addition, numerous states and the federal government are actively considering proposed legislation governing the protection of personal data. Additionally, many foreign jurisdictions have passed data privacy legislation and others are considering various proposals for new privacy and data protection laws. Data privacy remains an evolving landscape at the domestic and international levels, with new laws and regulations being considered and coming into effect and continued legal challenges. We must devote significant resources to understanding and complying with the changing landscape in this area. Each law is also subject to various interpretations by courts and regulatory agencies, creating additional uncertainty, and we may fail to comply with the evolving data protection laws, which 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. 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 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 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.

Our business has been, and may in the future be, adversely affected by outbreaks of epidemic, pandemic or other contagious diseases, including the COVID-19 pandemic.

Certain of our clinical trials were adversely affected by the COVID-19 pandemic, resulting in paused enrollment or delayed site initiations. In the future, site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis could 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. Future quarantines or travel limitations could impede participant movement, affect sponsor access to study sites or interrupt healthcare services, impairing our ability to conduct clinical trials. Such travel limitations could also create challenges and potential delays in our development and production activities, increasing the expense and timelines for producing our products and development candidates.

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 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. Certain of our third-party manufacturers and suppliers have encountered, and may in the future encounter, delays in providing their services in response to an epidemic or pandemic. If we or any third parties in our supply chain are adversely impacted by restrictions resulting from an epidemic or pandemic, our supply chain may be disrupted, limiting our ability to manufacture and sell our products and manufacture investigational medicines for our clinical trials, as well as negatively impacting our research and development operations. In addition, delays and disruptions experienced by our strategic collaborators due to an epidemic or pandemic could adversely impact their ability to fulfill their obligations, which could affect the clinical development or regulatory approvals of development candidates and investigational medicines under joint development.

In addition, during a global health crisis, one or more government entities could take actions (such as via the Defense Production Act in the U.S.) that diminish our rights or economic opportunities with respect to our products. Our third-party service providers could be impacted by government-imposed restrictions on services they might otherwise offer. Any such action could cause us to experience delays in the development, production, distribution or export of our products and development candidates and increased expenses.

Engaging in acquisitions, joint ventures or strategic collaborations 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 engage in acquisitions, joint ventures and collaborations, including licensing or acquiring complementary products, IP rights, technologies or businesses. Such transactions and relationships 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;

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- 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 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.

In the first quarter of 2023, we acquired OriCiro Genomics K.K., a pioneer in cell-free DNA synthesis and amplification technologies. We may fail to recognize the potential benefits of this acquisition or integrating OriCiro's business into our own may prove more difficult or costly than anticipated.

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 negatively impact 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 medicines may contain harmful substances or the wrong dose, are frequently unsafe or ineffective and could be life-threatening. 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. Adverse events caused by unsafe counterfeit or other non-mRNA products could 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.

Our aspirations, goals and disclosures related to environmental, social and governance (ESG) matters expose us to numerous risks, including risks to our reputation and stock price.

Institutional and individual investors are increasingly using ESG screening criteria to determine whether we qualify for inclusion in their investment portfolios. We are frequently asked by investors and other stakeholders to set ambitious ESG goals and provide new and more robust disclosure on goals, progress toward goals and other matters of interest to ESG stakeholders. In response, we have adapted the tracking and reporting of our corporate responsibility program to various evolving ESG frameworks, and we have established and announced goals and other objectives related to ESG matters. Statements about these goals reflect our current plans and aspirations and are not guarantees that we will be able to achieve them. Our efforts to accomplish and accurately report on these goals and objectives, including with respect to environmental and diversity initiatives, are subject to numerous risks, many of which are outside of our control, which could have a material negative impact, including on our reputation and stock price.

Further, the standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. Our selection of disclosure frameworks that seek to align with various reporting standards may change from time to time and may result in a lack of consistent or meaningful comparative data from period to period. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals.

If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our attractiveness as an investment, business partner or acquiror could be negatively impacted. Similarly, our failure or perceived failure to pursue or fulfill our goals, targets and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could also have similar negative impacts and expose us to government enforcement actions and private litigation.

Risks related to ownership of our common stock

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

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Our stock price has been, and is expected to continue to be, subject to substantial volatility. From December 7, 2018, our first day of public trading, through December 31, 2022, our stock price has ranged from a high of $497.49 to a low of $11.54 per share. Since we began our COVID-19 vaccine development efforts in early 2020, our stock has experienced pronounced and extended periods of volatility, which could cause our stockholders to 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 resulted, and may result, in significant fluctuations in our stock price. 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.

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, and you may not be able to sell your shares 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;
- the commercial launch of any additional products;
- timing and results of clinical trials or progress 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;
- developments regarding our manufacturing, regulatory and commercialization efforts, or information regarding such efforts by competitors;
- 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;
- economic, industry and market conditions generally, and in the biopharmaceutical sector specifically;
- 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; and
- announcement by us or our competitors of the commencement or termination of significant acquisitions, strategic partnerships, joint ventures or capital commitments.

Securities class-action litigation often has been instituted against companies following periods of volatility in their stock price. If such litigation were instituted against us, we could incur substantial costs in defense and management's attention and resources could be diverted, which could adversely affect 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 17, 2023, our executive officers, directors, and affiliated stockholders owned, directly or indirectly, approximately 13% of our outstanding common stock. In addition, non-affiliated five percent or greater stockholders owned approximately 25% of our outstanding common stock. These stockholders will have the ability to influence us through their ownership positions. For example, if they 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 our stockholders may believe to be in their best interests.

Provisions in our organizational documents, as well as provisions of Delaware law, could make it more difficult or costly for a third party to acquire us or remove our current management, even if doing so would benefit our stockholders.

Our amended and restated certificate of incorporation (charter), amended and restated by-laws (by-laws) and Delaware law contain provisions that could delay or prevent a hostile takeover or change in control of us or changes in our management. Our charter and 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;

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- 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 by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our charter and 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 charter, 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, 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 by-laws designate the Court of Chancery of the State of Delaware or the U.S. 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 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 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 by-laws further provide that the U.S. 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 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 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 U.S. 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.

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We are exposed to the risk of fraud or other misconduct by our employees, principal investigators leading our clinical trials and consultants. Such misconduct could include failures to: comply with FDA regulations or similar regulations in 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 we may fail to control unknown or unmanaged risks or losses or take steps that protect 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, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including through the imposition of significant fines or other sanctions.

Unfavorable U.S. or global economic conditions, including as a result of disease outbreak, war, conflict or other political instability, 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 disruptions caused by the COVID-19 pandemic or any other health epidemic, war, conflict or other political instability, including Russia's invasion of Ukraine and resulting sanctions against Russia. Adverse macroeconomic conditions, and perceptions or expectations about current or future conditions, such as inflation, slowing growth, rising interest rates, rising unemployment and recession, could negatively affect our business and financial condition. Additionally, global events, including war, conflict, political instability or other adverse economic conditions have and may in the future cause governments to divert spending away from healthcare, negatively impacting the marketability of our products.

The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A similar severe or prolonged economic downturn could create a variety of risks to our business, including weakened demand for our medicines, and negatively impacting 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. Recently, 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. 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 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, penalties or other sanctions for failure to comply with such laws and regulations. We may also incur substantial costs to comply with such laws and regulations, and these laws and regulations could impair our research, development or production efforts.

Our workers' compensation insurance may not provide adequate coverage against potential liabilities due to injuries to our employees resulting from the use of hazardous materials. 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.

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, local and non-U.S. income taxation are constantly under review by legislative and tax authorities. Changes to tax laws (which could apply retroactively) could adversely affect us and our stockholders. In recent years, such changes have been made and changes are likely to occur in the future, which could have a material adverse effect on our business, cash flow, financial condition and results of operations.

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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, commercial products and the diseases our development candidates and medicines are designed 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 be unable to defend our business in the face of 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 292,000 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 primarily comprised of three buildings (MTC South, MTC North and MTC East). The MTC campus is approximately 686,000 square feet which includes lab and office space, directly supporting improvement in our manufacturing capabilities and 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 own and lease land, office and lab spaces globally for our business operations.

We are also investing in a new Moderna Science Center (MSC) in Cambridge, Massachusetts, totaling approximately 462,000 square feet of leased space. The MSC is expected to house scientific and non-scientific spaces, including our principal executive offices, and is built to support our growth as we continue to advance our pipeline of mRNA medicines. The building construction is currently on-going. We expect to begin a phased move-in process in the fourth quarter of 2023. Following completion of the building project, the lease term is 15 years, subject to our right to extend the lease for up to two seven-year terms.

Item 3. Legal Proceedings

We are involved in various claims and legal proceedings of a nature considered ordinary course in our business, including the intellectual property litigation described below. Most of the issues raised by these claims are highly complex and subject to substantial uncertainties. For a description of risks relating to these and other legal proceedings we face, see Part I, Item 1A, "Risk Factors," including the discussion under the headings entitled "Risks related to our intellectual property" and "Risks related to the manufacturing of our commercial products, development candidates, investigational medicines and our future pipeline."

The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. We describe below those legal matters for which a material loss is either (i) possible but not probable, and/or (ii) not reasonably estimable at this time.

Pfizer/BioNTech Patent Litigation

In August 2022, we filed a lawsuit in the U.S. District Court for the District of Massachusetts against Pfizer Inc. (Pfizer) and BioNTech SE, BioNTech Manufacturing GmbH and BioNTech US Inc. (collectively, BioNTech), asserting infringement of certain U.S. patents concerning our mRNA platform technology and disease-specific vaccine designs in Pfizer and BioNTech's manufacture and sale of their mRNA COVID-19 vaccines. The complaint seeks a judgment of infringement of the asserted patents and monetary damages.

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Also in August 2022, we initiated patent infringement proceedings in Germany (in the Dusseldorf Regional Court), the Netherlands (in the District Court of The Hague) and the UK (in the High Court of Justice of England & Wales) against Pfizer, BioNTech and related entities with respect to certain European patents that also concern our mRNA platform technology and disease-specific vaccine designs, including coronaviruses. As in the U.S. action, we seek a judgment of infringement of the asserted patents and monetary damages.

Pfizer Inc. and BioNTech SE have also filed an action seeking revocation of certain Moderna patents in the UK. In addition, the Moderna patents being asserted in the European actions are subject to notices of opposition, including by Pfizer and BioNTech SE and others. These actions seek to revoke the patents, which have been filed at the European Patent Office.

Proceedings Related to Patents Owned by Arbutus

In February 2022, Arbutus Biopharma Corporation (Arbutus) and Genevant Sciences GmbH (Genevant) filed a complaint against us in the U.S. District Court for the District of Delaware asserting that our manufacture and sale of our COVID-19 vaccine willfully infringes certain U.S. patents concerning lipid nanoparticles. The complaint seeks a judgment of infringement of the asserted patents and monetary damages, but does not seek to prevent or stop the marketing or sales of our COVID-19 vaccines.

Proceedings Related to Patents Owned by Alnylam

In March 2022, Alnylam Pharmaceuticals, Inc. (Alnylam) filed a complaint against us in the U.S. District Court for the District of Delaware asserting that our manufacture and sale of our COVID-19 vaccine infringes a U.S. patent concerning cationic lipids. The complaint seeks a judgment of infringement of the asserted patent and monetary damages, but does not seek to prevent or stop the marketing or sales of our COVID-19 vaccines.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market for Our Common Stock

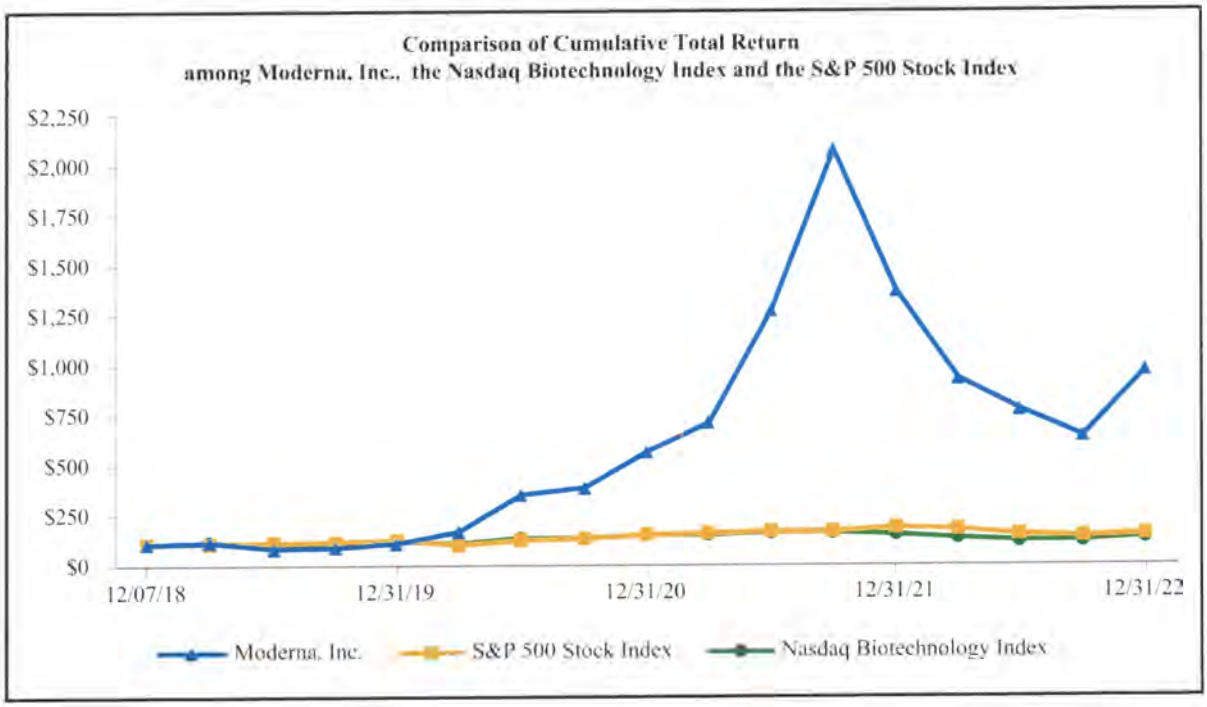
Our common stock began trading on the Nasdaq Global Select Market under the symbol "MRNA" on December 7, 2018. Prior to that time, there was no public market for our common stock.

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, 2022 of the cumulative total return for our common stock, the Nasdaq Biotechnology Index, and the Standard & Poor's 500 Stock Index (the "S&P 500") 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.

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 79 stockholders of record as of February 17, 2023. 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.

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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, 2022:

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 (in millions) [2]
October 1 - October 31, 2022	3,024,505	$ 124.27	22,523,999	$ 2,840
November 1 - November 30, 2022	177,169	$ 147.77	22,701,168	$ 2,814
December 1 - December 31, 2022	—	$ —	22,701,168	$ 2,814
Total	3,201,674			

[1] Average price paid per share includes related expenses.
[2] On February 22, 2022, our Board of Directors authorized a share repurchase program for our common stock of up to $3.0 billion, with no expiration date. This share repurchase program was increased by the Board of Directors by an additional $3.0 billion on August 1, 2022, also with no expiration date.

Refer to Note 14 to consolidated financial statements for information regarding our share repurchase programs.

Item 6. [Reserved]

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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 a new class of medicines made of messenger RNA (mRNA). 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.

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 and integrated manufacturing capabilities that allow for rapid clinical and commercial production at scale. We have a diverse and extensive development pipeline of 45 development candidates across our 48 development programs, of which 38 are in clinical studies currently.

We have three authorized marketed products: (1) Spikevax, the Moderna COVID-19 vaccine (mRNA-1273), (2) our bivalent vaccine targeting the BA.1 Omicron variant, combined with Spikevax (mRNA-1273.214), and (3) our bivalent vaccine targeting the BA.4/BA.5 Omicron variants combined with Spikevax (mRNA-1273.222).

2022 Business Highlights

Moderna COVID-19 Vaccines

In January 2022, the U.S. Food and Drug Administration (FDA) approved the Biologics License Application (BLA) for our COVID-19 vaccine, Spikevax. Prior to that approval, our COVID-19 Vaccine was marketed in the U.S. subject to an Emergency Use Authorization (EUA) that was first granted in December 2020 and similar authorizations in other markets. Spikevax is our first product to achieve licensure in the U.S., and it has been authorized for use or approved by regulators in more than 70 countries.

In August 2022, we received an EUA from the FDA for our Omicron BA.4/BA.5 targeting bivalent booster vaccine, mRNA-1273.222, for individuals 18 years and older, followed later by adolescent and pediatric approvals. mRNA-1273.222 has been authorized as a booster vaccine for individuals 18 years and older in key markets, including the European Union, Canada and Japan, with the European Union, Japan and several other countries also authorizing boosters for adolescent populations.

During the third quarter of 2022, we also received authorizations for the use of our Omicron BA.1 targeting bivalent COVID-19 booster vaccine, mRNA-1273.214, in the European Union, Japan, United Kingdom, Canada, Australia, and other markets globally.

For the year ended 2022, we recognized product sales of $18.4 billion from sales of our COVID-19 vaccines, compared to $17.7 billion and $200 million for the years ended 2021 and 2020, respectively.

Program Development

Respiratory Vaccines

As we build our respiratory franchise, we are applying our experience and using our mRNA platform to develop medicines that can help prevent hospitalizations and deaths from those respiratory viruses that impose the greatest burden on patients and healthcare systems. By pursuing combination products to protect against a range of diseases, we can potentially help decrease morbidity and mortality from respiratory disease, lower healthcare costs and increase health security globally.

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Our late-stage respiratory vaccine pipeline continues to progress. The Phase 3 study of our respiratory syncytial virus (RSV) vaccine candidate (mRNA-1345) in adults 60 years of age and older is fully enrolled, with more than 36,000 trial participants. In January 2023, we announced that the Phase 3 study for our RSV vaccine candidate met its primary efficacy endpoints, including vaccine efficacy of 83.7% (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms. Based on this positive topline data, the FDA granted mRNA-1345 Breakthrough Therapy Designation for the prevention of RSV-LRTD in adults 60 years or older. We intend to submit our RSV vaccine candidate for regulatory approval by the FDA in the first half of 2023. Since RSV also imposes a significant disease burden on children, we are studying our RSV vaccine candidate in an ongoing Phase 1 trial in pediatric populations.

In February 2023, we announced interim results from the Phase 3 immunogenicity and safety study in the Southern Hemisphere of mRNA-1010, our quadrivalent seasonal influenza vaccine candidate. Interim results indicate that mRNA-1010 achieved superiority on seroconversion rates for influenza A/H3N2 and A/H1N1, as well as superiority on geometric mean titer ratios for A/H3N2 and non-inferiority on geometric mean titer ratios for A/H1N1. Non-inferiority was not met for either endpoint for the influenza B/Victoria- or B/Yamagata-lineage strains. mRNA-1010 showed an acceptable safety and tolerability profile.

We are also conducting a Phase 3 efficacy trial of mRNA-1010 in the Northern Hemisphere to test the vaccine's efficacy compared to a currently licensed seasonal influenza vaccine.

We are also progressing several combination respiratory vaccine candidates. A Phase 1/2 study of our combination vaccine candidate targeting SARS-CoV-2 and influenza is fully enrolled and ongoing. We further initiated a clinical trial for a combination vaccine candidate targeting SARS-CoV-2, influenza, and RSV in the beginning of 2023.

Cancer

PCVs target an individual patient's unique tumor mutations to selectively treat their cancer. Our PCV program is being developed in collaboration with Merck and is designed to stimulate an immune response by boosting T cells, which are believed to be necessary for recurrence-free survival. Primary data from our Phase 2 study of mRNA-4157, which were released in December 2022, showed that the investigational personalized cancer vaccine in combination with KEYTRUDA® (pembrolizumab) can improve recurrence-free survival in patients with resected melanoma at high risk of recurrence, compared to KEYTRUDA alone. Adjuvant treatment with mRNA-4157 in combination with KEYTRUDA reduced the risk of recurrence or death by 44%. These results represent the first demonstration of the potential for mRNA to have an impact on outcomes in a randomized clinical trial in melanoma. We expect to initiate a Phase 3 study in adjuvant melanoma in 2023 and rapidly expand to additional tumor types, including non-small cell lung cancer (NSCLC). In February 2023, mRNA-4157 received a Breakthrough Therapy Designation from the FDA.

Latent Vaccines

Once a human is infected by a latent virus, the virus remains in the body and can lead to lifelong medical complications. We are committed to developing a portfolio of vaccine and therapeutic candidates against latent viruses, including cytomegalovirus (CMV), Epstein-Barr virus (EBV), human immunodeficiency virus (HIV) and varicella-zoster virus (VZV). To date, we have enrolled over 40% of anticipated participants in the Phase 3 study of our CMV vaccine candidate (mRNA-1647) and enrollment is ongoing in the U.S. and internationally. We are enrolling in Phase 1 trials for our EBV vaccine candidate (to prevent infectious mononucleosis) (mRNA-1189) and our HIV vaccine candidates (mRNA-1644 & mRNA-1574). We have also initiated a Phase 1/2 head-to-head study of our VZV vaccine candidate (mRNA-1468) against standard of care Shingrix.

Rare Diseases

The Phase 1/2 Paramount study of our propionic acidemia (PA) program is ongoing and the first two groups of patients are fully enrolled. Encouraging early data have shown a decrease in the number of metabolic decompensation events (MDEs) among participants and initial discussions with regulators are supportive of MDE as a primary endpoint for a pivotal study. We will continue to enroll additional cohorts and escalate dose, identify optimal dose for expansion and continue to engage with regulators on the registration path. The Phase 1/2 study of our methylmalonic acidemia candidate is ongoing and we are recruiting participants in the United Kingdom, Canada, and the U.S.

We are also evaluating the safety, tolerability and pharmacology of a single IV dose of our therapeutic candidate for glycogen storage disease 1a (GSD1a) in adult participants in a Phase 1 study. Enrollment is ongoing.

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Cardiovascular

We are developing novel mRNA medicines to address the significant unmet medical needs of heart failure patients. In December 2022, we dosed the first patient in our relaxin Phase 1B clinical trial, which we view as an important step in advancing a potential new treatment for cardiovascular disease. Our drug candidate is designed to produce the naturally occurring cardioprotective hormone relaxin and uses similar technology as our investigational treatment for propionic acidemia. Longer duration relaxin and repeated infusions could allow for improved outcomes with a treatment that matches the time course of the pathophysiology of heart failure, which large pharmaceutical companies have been unable to show in previous trials.

Inhaled Pulmonary

At the end of 2021, we announced our first program in a new modality with inhaled pulmonary therapeutics. We are collaborating with Vertex on our cystic fibrosis (CF) candidate, VX-522, our first inhaled mRNA candidate. In December 2022, the FDA cleared the Investigational New Drug application for VX-522. In January 2023, Vertex announced that it has initiated a Phase 1, single ascending dose clinical trial for VX-522, and the FDA has granted VX-522 Fast Track designation. The trial is active and enrolling patients.

Other Business Updates

During 2022, we executed and finalized strategic partnership agreements with the Australian Federal Government, the Government of Canada and the United Kingdom Government, respectively, to establish a state-of-the-art mRNA vaccine manufacturing facility in each of these countries. Each facility, when constructed, is expected to provide people in the country with access to a domestically manufactured portfolio of mRNA vaccines against respiratory viruses, including SARS-CoV-2, seasonal influenza, RSV, and other potential respiratory viruses, pending licensure. As part of these strategic collaborations, we expect to support expanded research and development programs in each of these countries.

We have committed to returning capital to our shareholders via share repurchase programs. During 2022, we repurchased approximately 23 million shares of common stock for $3.3 billion.

In December 2022, we purchased a Priority Review Voucher (PRV), which allows us to apply for expedited FDA review of a licensing application for one of our drug candidates. We were previously granted a PRV for mRNA-1273 and intend to use both PRVs to accelerate review of two expected BLA filings from our pipeline.

Financial Operations Overview

Revenue

The following table summarizes revenue for the periods presented (in millions):

	Years Ended December 31,		
	2022	2021	2020
Revenue:			
Product sales	$ 18,435	$ 17,675	$ 200
Grant revenue	388	735	529
Collaboration revenue	440	61	74
Total revenue	$ 19,263	$ 18,471	$ 803

We began to record product sales for our COVID-19 vaccines subsequent to its authorization for emergency use by the FDA and Health Canada in December 2020. For the years ended December 31, 2022, 2021, and 2020, we recognized $18.4 billion, $17.7 billion, and $200 million, respectively, of product sales from sales of our COVID-19 vaccines.

As of December 31, 2022, we had deferred revenue of $2.6 billion associated with customer deposits received or billable under supply agreements of which we expect $2.0 billion of our COVID-19 vaccines to be delivered in 2023. We believe that the SARS-CoV-2 virus is likely evolving to an endemic phase and as a result, we expect that COVID-19 vaccine market will likely shift to an endemic seasonal market and our product sales will decline in 2023 compared to 2022.

Other than product sales, our revenue in 2022, 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.

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The following table summarizes grant revenue for the periods presented (in millions):

	Years Ended December 31,		
	2022	2021	2020
BARDA	$ 372	$ 713	$ 522
Other grant revenue	16	22	7
Total grant revenue	$ 388	$ 735	$ 529

The following table summarizes collaboration revenue for the periods presented (in millions):

	Years Ended December 31,		
	2022	2021	2020
Collaboration revenue:			
Merck	$ 309	$ 23	$ 26
AstraZeneca	80	7	33
Vertex	48	26	15
Other	3	5	—
Total collaboration revenue	$ 440	$ 61	$ 74

In the third quarter of 2022, AstraZeneca elected to terminate our collaborations, effective on November 21, 2022. As a result of the termination, we recognized the remaining deferred revenue of $76 million as collaboration revenue during the third quarter of 2022.

In September 2022, Merck exercised its option for PCVs, including mRNA-4157, pursuant to the terms of the PCV/SAV Agreement. In the fourth quarter of 2022, in accordance with the PCV/SAV Agreement, we granted a worldwide license to Merck for future development and commercialization, upon receipt of the participation payment of $250 million from Merck, and recognized collaboration revenue of $250 million. Please refer to Note 5 to our consolidated financial statements.

As of December 31, 2022, the remaining available funding, net of revenue earned was $137 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 products. 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, indirect overhead costs associated with our product sales during the period, third-party royalties on net sales of our products, and charges for inventory valuation and losses on firm purchase commitments.

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;

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- 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;
- upfront fees and milestones paid to third-parties for licenses and technologies that had not reached technological feasibility and did not have an alternative future use; 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, 2022, 2021, and 2020 (in millions):

	Years Ended December 31,		
	2022	2021	2020
Program expenses by modality:			
Infectious disease vaccines	$ 1,734	$ 1,099	$ 707
Systemic secreted and cell surface therapeutics	23	3	2
Cancer vaccines	14	47	29
Intratumoral immuno-oncology	10	20	9
Systemic intracellular therapeutics	42	26	21
Inhaled pulmonary therapeutics	18	1	—
Total program-specific expenses by modality [1]	$ 1,841	$ 1,196	$ 768
Other research and development expenses:			
Discovery programs	$ 69	$ 85	$ 56
Platform research	169	125	93
Technical development and unallocated manufacturing expenses	464	275	279
Shared discovery and development expenses	658	242	118
Stock-based compensation	94	68	56
Total research and development expenses	$ 3,295	$ 1,991	$ 1,370

[1] Includes a total of 45 development candidates at December 31, 2022, 37 development candidates at December 31, 2021, and 21 development candidates at December 31, 2020. Program-specific expenses 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, certain collaborative and licensing arrangements, 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.

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 RSV vaccine, seasonal flu vaccine, CMV vaccine and our COVID-19 vaccines, 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 many 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 vaccines, and these expenses increased throughout the course of 2021 and 2022. 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 vaccines and the expansion of our footprint across the globe, with active subsidiaries in more than 17 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, gains (losses) related to changes in fair value of investments in equity securities, and other income and expense unrelated to our core operations.

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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. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, we consider the scheduled reversal of deferred tax liabilities, projected future taxable income and the effects of tax planning strategies in assessing the need for a valuation allowance. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our financial position and results of operations. 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. As of December 31, 2022, we maintained a valuation allowance against a portion of the state deferred tax assets based on management's evaluation of all available evidence.

We account for uncertain tax positions using a "more-likely-than-not" threshold for recognizing and resolving uncertain tax positions. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. We evaluate uncertain tax positions on a quarterly basis and consider various factors, that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions in the period when these changes are determined. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the "more-likely-than-not" threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews, we have no plans to appeal or litigate any aspect of the tax position, and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income 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.

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Results of operations

A discussion regarding our results of operations for the year ended December 31, 2022 compared to 2021 is presented below. A discussion regarding our results of operations for the year ended December 31, 2021 compared to 2020 can be found under Part II -Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission (SEC) on February 25, 2022.

The following tables summarize our consolidated statements of operations for the periods presented (in millions):

	Years Ended December 31,		Change 2022 vs. 2021	
	2022	2021	Change	%
Revenue:				
Product sales	$ 18,435	$ 17,675	$ 760	4 %
Grant revenue	388	735	(347)	(47)%
Collaboration revenue	440	61	379	621 %
Total revenue	19,263	18,471	792	4 %
Operating Expenses:				
Cost of sales	5,416	2,617	2,799	107 %
Research and development	3,295	1,991	1,304	65 %
Selling, general and administrative	1,132	567	565	100 %
Total operating expenses	9,843	5,175	4,668	90 %
Income from operations	9,420	13,296	(3,876)	(29)%
Interest income	200	18	182	1,011 %
Other expense, net	(45)	(29)	(16)	55 %
Income before income taxes	9,575	13,285	(3,710)	(28)%
Provision for income taxes	1,213	1,083	130	12 %
Net income	$ 8,362	$ 12,202	$ (3,840)	(31)%

Revenue

Total revenue increased by $792 million, or 4%, in 2022, primarily due to an increase in product sales. Product sales increased by $760 million, or 4%, in 2022 from sales of our COVID-19 vaccines to domestic and international government customers and organizations, largely attributable to a higher average selling price and customer mix. Grant revenue decreased by $347 million, or 47%, in 2022, mainly due to a decrease in grant revenue from BARDA related to our COVID-19 vaccine development in 2022. Collaboration revenue increased by $379 million, or 621%, in 2022, mainly attributable to the recognition of Merck's participation payment of $250 million related to our PCV collaboration, and the recognition of deferred revenue of $76 million in connection with the termination of our collaborations with AstraZeneca.

Operating expenses

Cost of sales

Our cost of sales was $5.4 billion, or 29% of our product sales, in 2022, including third-party royalties of $1.1 billion. 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.

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Cost of sales for 2022 increased by $2.8 billion, or 107%, compared to 2021. Cost of sales as a percentage of product sales for 2022 increased 14 percentage points to 29% from 15% in 2021. These increases were mainly due to write-downs for excess and obsolete inventory related to our COVID-19 vaccines, unutilized manufacturing capacity and losses on firm purchase commitments of raw materials, driven by a shift in product demand, as well as a catch-up royalty payment of $400 million to the National Institute of Allergy and Infectious Diseases, an Institute or Center of the National Institutes of Health (please refer to Note 12 to our consolidated financial statements). We expect our cost of sales as a percentage of product sales to increase in 2023 as we likely move from a pandemic to an endemic seasonal market environment for our COVID-19 vaccines.

Research and development expenses

Research and development expenses increased by $1.3 billion, or 65%, in 2022. The increase was primarily attributable to an increase in clinical trial expenses of $690 million, an increase in clinical manufacturing expenses of $173 million, an increase in personnel-related costs of $156 million, acquisition of a Priority Review Voucher for $101 million, and an increase in consulting and outside services of $71 million. The increase in 2022 was largely attributable to the late-stage clinical development associated with our RSV, seasonal flu and CMV vaccine programs. The increase in personnel-related costs was primarily driven by an increase in the number of employees supporting our increased research and development programs and activities.

We expect that research and development expenses will increase in 2023 as we continue to progress our Phase 3 studies for our RSV, seasonal flu and CMV vaccine programs, and continue to develop our pipeline and advance our product candidates into later-stage development.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $565 million, or 100%, in 2022. The inerease was mainly due to an increase in consulting and outside services of $169 million, an increase in personnel-related costs of $108 million, an increase in marketing expense of $89 million, an increase in technology- and facilities-related costs of $51 million, and an endowment to the Moderna Charitable Foundation of $50 million. The increase in 2022 was primarily related to our corporate expansion, particular in the commercial area and to a lesser extent, in support functions.

We expect that selling, general and administrative expenses will increase in 2023, as we continue to build out our global commercial, regulatory, sales and marketing infrastructure, and continue to expand the number of programs and our business operations.

Interest income

Interest income generated from our investments in marketable securities increased by $182 million in 2022, mainly attributable to an overall higher interest rate environment and increased investment balances.

Other expense, net

The following table summarizes other expense, net for the periods presented (in millions):

	Years Ended December 31,		Change 2022 vs. 2021	
	2022	2021	Change	%
(Loss) gain on investments	$ (20)	$ 1	$ (21)	(2,100)%
Interest expense	(29)	(17)	(12)	71 %
Other income (expense), net	4	(13)	17	(131)%
Total other expense, net	$ (45)	$ (29)	$ (16)	55 %

Total other expense, net increased by $16 million, or 55%, in 2022. The increase was primarily due to a net realized loss on available-for-sale debt securities as well as an increase in interest expense, partially offset by a gain on equity securities and a net gain related to our foreign currency balance sheet hedging activities, foreign currency transactions, and remeasurements. Our interest expense is primarily related to our finance leases. The increase in interest expense was driven by new finance leases that commenced in 2022. Please refer to Note 11 to our consolidated financial statements.

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Provision for income taxes

Provision for income taxes increased by $130 million, or 12%, in 2022, primarily due to the tax benefit recorded in 2021 related to the release of the valuation allowance on the majority of our deferred tax assets. Our effective tax rate for the year ended December 31, 2022 was 12.7%, which included tax benefits related to foreign-derived intangible income deductions and stock-based compensation. 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.

Liquidity and capital resources

The following table summarizes our cash, cash equivalents, investments and working capital for each period presented (in millions):

	December 31, 2022	December 31, 2021
Financial assets:		
Cash and cash equivalents	$ 3,205	$ 6,848
Investments	6,697	3,879
Investments, non-current	8,318	6,843
Total	$ 18,220	$ 17,570
Working capital:		
Current assets	$ 13,431	$ 16,071
Current liabilities	4,923	9,128
Total	$ 8,508	$ 6,943

Our cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Our investments, consisting primarily of government and corporate debt securities, are stated at fair value. Cash, cash equivalents and investments as of December 31, 2022 increased by $650 million, or 4%, compared to December 31, 2021. For the year ended December 31, 2022, we generated cash from operations of $5.0 billion, partially offset by repurchases of our common stock of $3.3 billion; purchases of property, plant and equipment of $400 million; and unrealized losses on available-for-sale debt securities of $412 million.

Working capital, which is current assets less current liabilities, as of December 31, 2022 increased by $1.6 billion, or 23%, compared to December 31, 2021, primarily due to a decrease in short-term deferred revenue of $4.2 billion, mainly driven by revenue recognized from deferred revenue in excess of customer deposits received, and a decrease in income taxes payable of $828 million. This was partially offset by a decrease in accounts receivable of $1.8 billion, a decrease in cash, cash equivalents and short-term investments of $825 million, primarily due to purchases of long-term marketable securities, repurchases of our common stock, and income tax payments, and a decrease in inventory of $492 million.

Cash flow

The following table summarizes the primary sources and uses of cash for the periods presented (in millions):

	Years Ended December 31,		
	2022	2021	2020
Net cash provided by (used in):			
Operating activities	$ 4,981	$ 13,620	$ 2,027
Investing activities	(5,176)	(8,523)	(1,672)
Financing activities	(3,448)	(873)	2,033
Net (decrease) increase in cash and cash equivalents	$ (3,643)	$ 4,224	$ 2,388

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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. Beginning in the third quarter of 2020, we entered into supply agreements with the U.S. Government, other international governments and organizations for the supply of our COVID-19 vaccines and received upfront deposits. As of December 31, 2022, we had $2.6 billion in deferred revenue related to customer deposits received or billable.

Net cash provided by operating activities in 2022 was $5.0 billion and consisted of net income of $8.4 billion and non-cash adjustments of $74 million, plus a net change in assets and liabilities of $3.5 billion. Non-cash items primarily included deferred income taxes of $559 million, depreciation and amortization of $348 million, stock-based compensation of $226 million, and amortization of investment premiums and discounts of $31 million. The net change in assets and liabilities was primarily due to a decrease in deferred revenue of $4.2 billion, an increase in prepaid expenses and other assets of $1.7 billion, and a decrease in income taxes payable of $828 million, partially offset by a decrease in accounts receivable of $1.8 billion, an increase in accrued liabilities of $612 million, a decrease in inventory of $492 million, and an increase in accounts payable of $240 million.

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 deferred income taxes of $318 million, depreciation and amortization of $232 million, stock-based compensation of $142 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 and 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 in accounts receivable of $1.4 billion, an increase in prepaid expenses and other assets of $241 million, an increase in inventory of $47 million, and an increase in operating lease right-of-use assets of $11 million.

Investing activities

Our primary investing activities consist of purchases, sales, and maturities of our investments and capital expenditures for land, leasehold improvements, manufacturing, laboratory, computer equipment, and software.

Net cash used in investing activities in 2022 was $5.2 billion, which included purchases of marketable securities of $11.4 billion, purchases of property, plant and equipment of $400 million, and investment in convertible notes and equity securities of $40 million, partially offset by proceeds from sales of marketable securities of $3.5 billion and proceeds from maturities of marketable securities of $3.2 billion.

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, plant 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, plant 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.

Financing activities

Our primary financing activities consist of repurchases of common stock, issuance of common stock related to our equity plans and finance leases.

Net cash used in financing activities in 2022 was $3.4 billion, primarily from repurchases of common stock of $3.3 billion and changes in financing lease liabilities of $184 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 $65 million.

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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 employee stock purchases under our equity plans of $186 million.

Operation and funding requirements

Our principal sources of funding as of December 31, 2022 consisted of cash and cash equivalents, investments, and cash we expect to generate from operations. We generated net income of $8.4 billion for the year ended December 31, 2022. We generated net income of $12.2 billion for the year ended 2021, following the authorization of our first commercial product in December 2020. From our inception to the end of 2020, prior to the authorization of our first commercial product in December 2020, we incurred significant losses from operations due to our significant research and development expenses. We have retained earnings of $18.3 billion as of December 31, 2022.

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, particularly 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 our RSV, seasonal flu, CMV vaccine candidates, and COVID-19 vaccines, including development of any new generations of boosters and vaccines against variants of SARS-CoV-2, late-stage clinical development, and buildout of global commercial, regulatory, sales and marketing infrastructure will require significant cash outflows, 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 also 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, 2022, 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, 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.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2022 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	$ 162	$ 43	$ 41	$ 36	$ 42
Financing leases [1]	1,665	195	253	129	1,088
MSC lease [2]	1,019	—	112	118	789
Purchase obligations [3]	2,318	1,642	666	10	—
Total contractual cash obligations	$ 5,164	$ 1,880	$ 1,072	$ 293	$ 1,919

[1] The amounts in the table include a total payment of $662 million associated with our MTC leases for the optional lease extension periods. For accounting purposes, 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.

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(2) We entered into a lease agreement in 2021 for approximately 462,000 square feet in Cambridge, Massachusetts (Moderna Science Center) and are currently undergoing 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 Commencement date defined in the lease agreement that is currently estimated to be the fourth quarter of 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. As of December 31, 2022, $268 million of the purchase commitments related to raw materials was recorded as an accrued liability for loss on future firm purchase commitments.

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, 2022, we had cancelable open purchase orders of $2.5 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, 2022, 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 $2.5 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.

As of December 31, 2022, we did not have any off-balance sheet arrangements that were material or reasonably likely to become material to our financial condition or results of operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

As of December 31, 2022 and 2021, we had cash, cash equivalents, restricted cash, and investments in marketable securities of $18.2 billion and $17.6 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, 2022, the net fair value of our marketable securities would decrease by approximately $169 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, 2022 was the equivalent of $5.4 billion in Euros and $1.0 billion in Japanese Yen. 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 and Japanese Yen, 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, 2022, carried at fair value, had maturities of up to one month.

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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, 2022, our outstanding balance sheet hedging derivatives, carried at fair value, had maturities of less than one month.

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, 2022, 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 $13 million. As of December 31, 2022, 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 $51 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.

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Item 8. Financial Statements and Supplementary Data

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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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 24, 2023, 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.

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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 and organizations. Under the supply agreements, including related amendments, 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, 2022, product sales revenue totaled $18.4 billion.

Auditing the Company's revenue recognition was especially challenging due to the volume of executed supply agreements, including related amendments, 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, including related amendments, 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, including related amendments, 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 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, including related amendments, 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 24, 2023

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MODERNA, INC.
CONSOLIDATED BALANCE SHEETS
(In millions, except per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 3,205	$ 6,848
Investments	6,697	3,879
Accounts receivable	1,385	3,175
Inventory	949	1,441
Prepaid expenses and other current assets	1,195	728
Total current assets	13,431	16,071
Investments, non-current	8,318	6,843
Property, plant and equipment, net	2,018	1,241
Right-of-use assets, operating leases	121	142
Deferred tax assets	982	326
Other non-current assets	988	46
Total assets	$ 25,858	$ 24,669
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 487	$ 302
Accrued liabilities	2,101	1,472
Deferred revenue	2,038	6,253
Income taxes payable	48	876
Other current liabilities	249	225
Total current liabilities	4,923	9,128
Deferred revenue, non-current	673	615
Operating lease liabilities, non-current	92	106
Financing lease liabilities, non-current	912	599
Other non-current liabilities	135	76
Total liabilities	6,735	10,524
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001; 162 shares authorized as of December 31, 2022 and 2021; no shares issued or outstanding at December 31, 2022 and 2021	—	—
Common stock, par value $0.0001; 1,600 shares authorized as of December 31, 2022 and 2021; 385 and 403 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	1,173	4,211
Accumulated other comprehensive loss	(370)	(24)
Retained earnings	18,320	9,958
Total stockholders' equity	19,123	14,145
Total liabilities and stockholders' equity	$ 25,858	$ 24,669

The accompanying notes are an integral part of these consolidated financial statements.

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MODERNA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In millions, except per share data)

	Years Ended December 31,		
	2022	2021	2020
Revenue:			
Product sales	$ 18,435	$ 17,675	$ 200
Grant revenue	388	735	529
Collaboration revenue	440	61	74
Total revenue	19,263	18,471	803
Operating expenses:			
Cost of sales	5,416	2,617	8
Research and development	3,295	1,991	1,370
Selling, general and administrative	1,132	567	188
Total operating expenses	9,843	5,175	1,566
Income (loss) from operations	9,420	13,296	(763)
Interest income	200	18	25
Other expense, net	(45)	(29)	(6)
Income (loss) before income taxes	9,575	13,285	(744)
Provision for income taxes	1,213	1,083	3
Net income (loss)	$ 8,362	$ 12,202	$ (747)
Earnings (loss) per share:			
Basic	$ 21.26	$ 30.31	$ (1.96)
Diluted	$ 20.12	$ 28.29	$ (1.96)
Weighted average common shares used in calculation of earnings (loss) per share:			
Basic	394	403	381
Diluted	416	431	381

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,		
	2022	2021	2020
Net income (loss)	$ 8,362	$ 12,202	$ (747)
Other comprehensive (loss) income, net of tax			
Available-for-sale securities:			
Unrealized (losses) gains on available-for-sale debt securities	(348)	(42)	2
Less: net realized losses (gains) on available-for-sale securities reclassified to net income (loss)	26	(1)	(1)
Net (decrease) increase from available-for-sale debt securities	(322)	(43)	1
Cash flow hedges:			
Unrealized gains on derivative instruments	130	74	—
Less: net realized (gains) on derivative instruments reclassified to net income (loss)	(154)	(58)	—
Net (decrease) increase from derivatives designated as hedging instruments	(24)	16	—
Total other comprehensive (loss) income	(346)	(27)	1
Comprehensive income (loss)	$ 8,016	$ 12,175	$ (746)

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 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	—	1853	—	—	1,853
Exercise of options to purchase common stock	14	—	179	—	—	179
Issuance 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
Issuance 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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	403	$ —	$ 4,211	$ (24)	$ 9,958	$ 14,145
Vesting of restricted common stock	1	—	—	—	—	—
Exercise of options to purchase common stock	4	—	50	—	—	50
Issuance of common stock under employee stock purchase plan	—	—	15	—	—	15
Stock-based compensation	—	—	226	—	—	226
Other comprehensive loss, net of tax	—	—	—	(346)	—	(346)
Repurchase of common stock	(23)	—	(3,329)	—	—	(3,329)
Net income	—	—	—	—	8,362	8,362
Balance at December 31, 2022	385	$ —	$ 1,173	$ (370)	$ 18,320	$ 19,123

The accompanying notes are an integral part of these consolidated financial statements.

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MODERNA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In millions)

	Years Ended December 31,		
	2022	2021	2020
Operating activities			
Net income (loss)	$ 8,362	$ 12,202	$ (747)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Stock-based compensation	226	142	93
Depreciation and amortization	348	232	31
Leased assets expensed	—	—	62
Amortization/accretion of investments	31	54	10
Deferred income taxes	(559)	(318)	—
Other non-cash items	28	—	—
Changes in assets and liabilities:			
Accounts receivable	1,790	(1,784)	(1,385)
Prepaid expenses and other assets	(1,699)	(489)	(241)
Inventory	492	(1,394)	(47)
Right-of-use assets, operating leases	21	(58)	(11)
Accounts payable	240	204	12
Accrued liabilities	612	989	388
Deferred revenue	(4,157)	2,824	3,842
Income taxes payable	(828)	876	—
Operating lease liabilities	(14)	17	12
Other liabilities	88	123	8
Net cash provided by operating activities	4,981	13,620	2,027
Investing activities			
Purchases of marketable securities	(11,435)	(12,652)	(2,956)
Proceeds from maturities of marketable securities	3,151	1,338	1,137
Proceeds from sales of marketable securities	3,548	3,105	215
Purchases of property, plant and equipment	(400)	(284)	(68)
Investment in convertible notes and equity securities	(40)	(30)	—
Net cash used in investing activities	(5,176)	(8,523)	(1,672)
Financing activities			
Proceeds from offerings of common stock, net of issuance costs	—	—	1,853
Proceeds from issuance of common stock through equity plans	65	124	186
Repurchases of common stock	(3,329)	(857)	—
Changes in financing lease liabilities	(184)	(140)	(6)
Net cash (used in) provided by financing activities	(3,448)	(873)	2,033
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,643)	4,224	2,388
Cash, cash equivalents and restricted cash, beginning of year	6,860	2,636	248
Cash, cash equivalents and restricted cash, end of year	$ 3,217	$ 6,860	$ 2,636
Supplemental cash flow information			
Cash paid for income taxes	$ 2,729	$ 480	$ 1
Cash paid for interest	$ 25	$ 14	$ 9
Non-cash investing and financing activities			
Purchases of property, plant and equipment included in accounts payable and accrued liabilities	$ 72	$ 111	$ 18

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) is a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new class of medicines to improve the lives of patients. 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 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 January 2022, we received full commercial approval for Spikevax in the United States.

As of December 31, 2022, Spikevax is authorized by the FDA and global regulators in more than 70 countries. In addition, our Omicron-targeting bivalent boosters, targeting the BA.1 Omicron variant combined with Spikevax (mRNA-1273.214) and targeting the BA.4/BA.5 Omicron variant combined with Spikevax (mRNA-1273.222), are authorized by regulatory agencies around the globe. We generate worldwide product sales from Spikevax and the two authorized Omicron-targeting boosters.

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, critical accounting policies or estimates related to revenue recognition, income taxes, valuation of deferred tax assets, inventory valuation, firm purchase commitment liabilities, fair value of financial instruments, derivative financial instruments, leases, useful lives of property, plant and equipment, research and development expense, and stock-based compensation. 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

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.

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Product Sales

Product sales are associated with our COVID-19 vaccine supply agreements with the U.S. Government, other international governments and organizations. These agreements and related amendments generally do not include variable consideration, such as discounts, rebates or returns. Under certain of 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 (*Revenue from Contracts with Customers*), 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 years ended December 31, 2022 and 2021. We did not have any distribution fees for the year ended December 31, 2020.

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 grant 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. Grant revenue 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. Restricted cash is classified as either current or non-current based on the terms of the underlying lease arrangement and is included in either prepaid expenses and other current assets or other non-current assets in our consolidated balance sheets.

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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,		
	2022	2021	2020
Cash and cash equivalents	$ 3,205	$ 6,848	$ 2,624
Restricted cash [1]	—	—	1
Restricted cash, non-current [2]	12	12	11
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 3,217	$ 6,860	$ 2,636

[1] Included in prepaid expenses and other current assets in the consolidated balance sheets.
[2] Included in other non-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.

Investments in publicly traded equity securities with readily determinable fair values are recorded at quoted market prices for identical securities, with changes in fair value recorded in other expense, net, in our consolidated statements of operations. Investments in equity securities without readily determinable fair values are recorded at cost minus impairment, if any, adjusted for changes resulting from observable price changes in orderly transactions for identical or similar securities. Such adjustments are recorded in other expense, net, in our consolidated statements of operations.

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, 2022 or 2021. There was no bad debt expense for the years ended December 31, 2022, 2021 or 2020.

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Concentrations of Credit Risk

Financial instruments that subject us to significant concentrations of credit risk consist primarily of 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.

We are also subject to credit risk from our accounts receivable related to our product sales and collaborators. We sell our products primarily to U.S. Government, other international governments and organizations. We do not require collateral or other security to support accounts receivable. To date, we have not experienced any losses with respect to the collection of our accounts receivable.

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 and organizations, grants made by government-sponsored and private organizations, and to a lesser extent, 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,	
	2022	2021	2020	2022	2021
European Commission	28 %	32 %	*	29 %	46 %
U.S. Government (excluding BARDA)	23 %	29 %	24 %	*	*
Takeda Pharmaceutical Company	10 %	*	*	*	*
BARDA	*	*	65 %	*	16 %
Ministry of Health, Labor, and Welfare of Japan	*	*	*	30 %	*
UK Health Security Agency	*	*	*	11 %	*

* - *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, 2022, 2021, and 2020.

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. We also assess whether we have any excess firm, non-cancelable, purchase commitment liabilities, resulting from our supply agreements with third-party vendors, on a quarterly basis. The determination of net realizable value and firm purchase commitment liabilities requires judgment, including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions, potential product obsolescence, expiration and utilization of raw materials under firm purchase commitments and contractual minimums, among others. We hold raw materials beyond our one year forecasted production plan, which were classified as non-current and included in other non-current assets in our consolidated balance sheets.

Pre-launch Inventory

Costs relating to raw materials and production of inventory in preparation for product launch prior to regulatory approval are capitalized when future commercialization is considered probable, the future economic benefit is expected to be realized, and we believe that material uncertainties related to the ultimate regulatory approval have been significantly reduced. For pre-launch inventory that is capitalized, we consider a number of factors based on the information available at the time, including the product candidate's current status in the drug development and regulatory approval process, results from the related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential impediments to the approval process such as product safety or efficacy, historical experience, viability of commercialization and market trends. As of December 31, 2022, we did not have any capitalized pre-launch inventory on our consolidated balance sheets.

Property, Plant and Equipment

Property, plant 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, plant and equipment are described below:

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	Estimated Useful Life
Land and land improvements	Not depreciated
Manufacturing and laboratory equipment	5 years
Leasehold improvements	Lesser of estimated useful life of improvement or remaining life of related lease
Computer equipment and software	3 to 5 years
Furniture and fixtures	5 years
Right-of-use asset, financing	Lease term

Construction in progress includes direct costs related to the construction of various property, plant and equipment, including leasehold improvements, and is stated at original cost. Once the asset is placed into service, these capitalized costs will be allocated to certain property, plant and equipment categories and will be depreciated over the estimated useful life of the underlying assets.

Impairment of Long-Lived Assets

We evaluate our long-lived assets, which consist of property, plant 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, 2022, 2021 and 2020 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 the statements of operations on a straight-line basis over the lease term.

Collaboration Arrangements

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808 (*Collaborative Arrangements*) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, we assess whether aspects of the arrangement between us and our collaboration partner are within the scope of other accounting literature. If we conclude that some or all aspects of the arrangement represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606. Please refer to our "Revenue Recognition" policy within Note 2 for additional discussion of revenue recognition under these types of arrangements. If we conclude that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, we recognize our allocation of the shared costs incurred with respect to the jointly conducted activities as a component of the related expense in the period incurred.

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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. Research and development costs also include costs and shared cost associated with third-party collaboration arrangements, including upfront fees and milestones paid to third-parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use.

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 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. We estimate the expected term of our stock options granted to employees and non-employees using the simplified method, whereby, the expected term equals the average of the vesting term and the original contractual term of the option. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected volatility is based on a blended average of average historical stock volatilities of selected guideline companies over the expected term of the stock options, historical volatility of our stock price, and implied stock price volatility derived from the price of exchange traded options on our stock. We will continue to apply this process until a sufficient amount of historical information regarding the expected term and historical volatility of our own stock price becomes available. 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.

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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 for the years ended December 31, 2022 and 2021 were as follows (in millions):

	Unrealized Gain (Loss) on Available-for-Sale Debt Securities	Net Unrealized Gain (loss) on Derivatives Designated As Hedging Instruments	Total
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)
Other comprehensive loss	(322)	(24)	(346)
Accumulated other comprehensive loss, balance at December 31, 2022	$ (362)	$ (8)	$ (370)

Share Repurchases

Shares of our common stock repurchased pursuant to our repurchase programs are retired. The purchase price of such repurchased shares of common stock is recorded as a reduction to additional paid-in-capital. If the balance in additional paid-in-capital is exhausted, the excess is recorded as a reduction to retained earnings.

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. 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 and organizations.

Product sales by customer geographic location were as follows for the periods presented (in millions):

	Years Ended December 31,		
	2022	2021	2020
United States	$ 4,405	$ 5,393	$ 194
Europe	6,732	6,834	—
Rest of world [1]	7,298	5,448	6
Total	$ 18,435	$ 17,675	$ 200

[1] Includes product sales recognized under the agreement with Gavi (on behalf of the COVAX Facility), which facilitates the allocation and distribution of our COVID-19 vaccines around the world, particularly for low- and middle-income countries.

As of December 31, 2022, our COVID-19 vaccine (marketed under the brand name Spikevax) and Omicron-targeting bivalent boosters (mRNA-1273.214 and mRNA-1273.222) were our only commercial products authorized for use. As of December 31, 2021 and 2020, our COVID-19 vaccine was our only commercial product authorized for use.

As of December 31, 2022 and 2021, we had deferred revenue of $2.6 billion and $6.7 billion, respectively, related to customer deposits. We expect $2.0 billion of our deferred revenue related to customer deposits as of December 31, 2022 to be realized in less than one year. Timing of product manufacturing, delivery and receipt of marketing approval will determine the period in which product sales is recognized.

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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, 2022, the committed funding, net of revenue earned was $6 million. An additional $24 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 original vaccine candidate against COVID-19. The agreement was amended in both 2020 and 2021 to provide for additional commitments to support various late-stage clinical development efforts of mRNA-1273, including a 30,000 participant Phase 3 study, pediatric clinical trials and pharmacovigilance studies. In March 2022, we entered into a further amendment to the BARDA agreement, increasing the amount of potential reimbursements by $308 million, in connection with costs associated with the clinical development for the adolescent and pediatric studies and the Phase 3 pivotal study. The maximum award from BARDA, inclusive of the 2020, 2021 and 2022 amendments, was $1.7 billion. All contract options have been exercised. As of December 31, 2022, the remaining available funding, net of revenue earned was $137 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. In September 2022, the performance period of the grant expired, and BARDA was released of the obligation to fund the remaining $36 million of the award.

In January 2016, we entered a global health project framework agreement with the Gates Foundation to advance mRNA development projects for various infectious diseases, including human immunodeficiency virus (HIV). As of December 31, 2022, the available funding, net of revenue earned was $6 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 December 31,		
	2022	2021	2020
BARDA	$ 372	$ 713	$ 522
Other grant revenue	16	22	7
Total grant revenue	$ 388	$ 735	$ 529

5. Collaboration Agreements

AstraZeneca – Strategic Alliances in Cardiovascular and Oncology

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. 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. 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).

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 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.

In the third quarter of 2022, AstraZeneca terminated our collaborations with them, including the development of VEGF-A and IL-12 programs, for which termination became effective on November 21, 2022. All rights to these two programs reverted to us. As a result of the termination, we recognized the remaining deferred revenue of $76 million as collaboration revenue in the period.

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Merck – Strategic Alliances in Infectious Diseases and Personalized mRNA 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 were 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. We received an upfront payment of $200 million from Merck upon execution of the agreement.

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). Under the PCV/SAV Agreement, Merck was responsible for conducting Phase 1 and Phase 2 clinical trials for mRNA-5671 and for all costs associated with such activities, and we were 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. In December 2021, Merck elected to terminate the Merck participation election with respect to the joint SAV program, including KRAS development candidate, mRNA-5671.

In September 2022, Merck exercised its option for PCVs, including mRNA-4157, pursuant to the terms of the PCV/SAV Agreement. In the fourth quarter of 2022, in accordance with the PCV/SAV Agreement, we granted a worldwide license to Merck for future development and commercialization, upon receipt of the participation payment of $250 million from Merck, and recognized collaboration revenue of $250 million. Under the PCV/SAV Agreement, we are principally responsible for providing manufacturing capacity and manufacturing PCVs for clinical trials and Merck is responsible for conducting the Phase 3 clinical trial for mRNA-4157. We and Merck will equally share the costs for the joint operations. A detailed joint development plan and budget are expected to be finalized in 2023. We concluded that the collaboration arrangement under the Merck Participation Term is within the scope of ASC808.

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, 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.

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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:	**2022**	**2021**	**2020**
Merck	$ 309	$ 23	$ 26
AstraZeneca	80	7	33
Vertex	48	26	15
Other	3	5	—
Total collaboration revenue	$ 440	$ 61	$ 74

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, 2022 (in millions):

	December 31, 2021	Additions	Deductions	December 31, 2022
Contract Assets:				
Accounts receivable	$ 9	$ 318	$ (310)	$ 17
Contract Liabilities:				
Deferred revenue	$ 204	$ 16	$ (139)	$ 81

As of December 31, 2022, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was $89 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.

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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, 2022 and 2021 (in millions):

	December 31, 2022						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 3,205	$ —	$ —	$ 3,205	$ 3,205	$ —	$ —
Available-for-sale:							
Certificates of deposit	188	—	—	188	—	188	—
U.S. treasury bills	767	—	—	767	—	767	—
U.S. treasury notes	7,781	—	(229)	7,552	—	4,182	3,370
Corporate debt securities	6,595	—	(226)	6,369	—	1,560	4,809
Government debt securities	148	—	(9)	139	—	—	139
Total	$ 18,684	$ —	$ (464)	$ 18,220	$ 3,205	$ 6,697	$ 8,318

	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

The amortized cost and estimated fair value of available-for-sale securities, by contractual maturity at December 31, 2022 and 2021 were as follows (in millions):

	December 31, 2022	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 6,792	$ 6,697
Due after one year through five years	8,687	8,318
Total	$ 15,479	$ 15,015

	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

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, 2022, 2021, and 2020. We did not recognize any credit-related allowance to available-for-sale securities as of December 31, 2022 and 2021.

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, 2022 and 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, 2022:						
U.S. treasury bills	$ —	$ 128	$ —	$ —	$ —	$ 128
U.S. treasury notes	(101)	3,956	(128)	3,541	(229)	7,497
Corporate debt securities	(138)	3,505	(88)	1,890	(226)	5,395
Government debt securities	(2)	46	(7)	93	(9)	139
Total	$ (241)	$ 7,635	$ (223)	$ 5,524	$ (464)	$ 13,159
As of December 31, 2021:						
U.S. treasury securities	$ —	$ 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

At December 31, 2022 and 2021, we held 582 and 384 available-for-sale securities, respectively, out of our total investment portfolio that were in a continuous unrealized loss position. 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.

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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, 2022 and 2021 (in millions):

	Fair value at December 31, 2022	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 1,079	$ 1,079	$ —
Certificates of deposit	188	—	188
U.S. treasury bills	767	—	767
U.S. treasury notes	7,552	—	7,552
Corporate debt securities	6,369	—	6,369
Government debt securities	139	—	139
Derivative instruments (Note 7)	6	—	6
Total	$ 16,100	$ 1,079	$ 15,021
Liabilities:			
Derivative instruments (Note 7)	$ 32	$ —	$ 32

	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

During the years ended December 31, 2022 and 2021, we did not have non-financial assets or liabilities measured at fair value on a recurring basis.

In addition, as of December 31, 2022, we had $42 million in equity investments without readily determinable fair values, which are recorded within other non-current assets in our consolidated balance sheets and excluded from the fair value measurement tables above. We did not have equity investments as of December 31, 2021.

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: (1) forecasted product sales that are denominated in foreign currencies and (2) 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 and Japanese Yen 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 prepaid expenses and 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, 2022, we had net deferred losses of $11 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 cash, accounts receivable, accounts payable, and lease liabilities in Euro, Swiss Franc and Japanese Yen, 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 prepaid expenses and other current assets or other current liabilities in 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, 2022		
		Fair Value	
	Notional Amount	Asset[1]	Liability[2]
Derivatives designated as cash flow hedging instruments:			
Foreign currency forward contracts	$ 120	$ —	$ 11
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	1,368	6	21
Total derivatives	$ 1,488	$ 6	$ 32

	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	$ 1,935	$ 21	$ 7

[1] As presented in the consolidated balance sheets 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 years ended December 31, 2022 and 2021 were as follows (in millions):

	Years Ended December 31,	
	2022	2021
Derivatives in cash flow hedging relationships:		
Foreign currency forward contracts	$ 130	$ 74

The effect of derivative instruments in our consolidated statements of operations for the years ended December 31, 2022 and 2021 was as follows (in millions):

	Statement of Operations Classification	Year Ended December 31, 2022	Year Ended December 31, 2021
Derivatives in cash flow hedging relationships:			
Foreign currency forward contracts			
Net gains reclassified from AOCI into income	Product sales	$ 154	$ 58
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts			
Net realized and unrealized gains (losses)	Other expense, net	$ 48	$ (8)

There were immaterial hedging gains and losses for the year ended December 31, 2020.

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8. Inventory

Inventory as of December 31, 2022 and 2021 consisted of the following (in millions):

	December 31, 2022	December 31, 2021
Raw materials	$ 575	$ 870
Work in progress	205	338
Finished goods	169	233
Total inventory	$ 949	$ 1,441
Inventory, non-current [1]	$ 910	$ —

[1] Consisted of raw materials with an anticipated consumption beyond one year. Inventory, non-current is included in other non-current assets in the consolidated balance sheets.

Inventory write-downs as a result of excess, obsolescence, scrap or other reasons, and losses on firm purchase commitments are recorded as a component of cost of sales in our consolidated statements of operations. For the year ended December 31, 2022, inventory write-downs were $1.3 billion. Inventory write-downs were immaterial for the years ended December 31, 2021 and 2020. For the year ended December 31, 2022, losses on firm purchase commitments were $617 million. As of December 31, 2022, the accrued liability for loss on firm future purchase commitments in our consolidated balance sheets was $268 million. There were no such charges in 2021 or 2020, or accrued liabilities at December 31, 2021.

9. Property, Plant and Equipment

Property, plant and equipment, net as of December 31, 2022 and 2021 consisted of the following (in millions):

	December 31,	
	2022	2021
Land and land improvements	$ 11	$ —
Manufacturing and laboratory equipment	284	175
Leasehold improvements	460	313
Furniture and fixtures	21	11
Computer equipment and software	38	25
Construction in progress	281	212
Right-of-use asset, financing	1,581	857
	2,676	1,593
Less: Accumulated depreciation	(658)	(352)
Property, plant and equipment, net	$ 2,018	$ 1,241

Depreciation and amortization expense for the years ended December 31, 2022, 2021, and 2020 was $348 million, $232 million, and $31 million, respectively.

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10. Other Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of December 31, 2022 and 2021 consisted of the following (in millions):

	December 31,	
	2022	2021
Down payments to manufacturing vendors	$ 229	$ 118
Down payments for materials and supplies	219	287
Prepaid services	216	126
Prepaid income taxes	187	23
Value added tax receivable	140	70
Interest receivable	61	27
Tenant improvement allowance receivable	42	51
Convertible note receivable	36	—
Other current assets	65	26
Prepaid expenses and other current assets	$ 1,195	$ 728

Other Non-Current Assets

Other non-current assets, as of December 31, 2022 and 2021 consisted of the following (in millions):

	December 31,	
	2022	2021
Inventory, non-current [1]	$ 910	$ —
Other	78	46
Other non-current assets	$ 988	$ 46

[1] Consisted of raw materials with an anticipated consumption beyond one year.

Accrued Liabilities

Accrued liabilities, as of December 31, 2022 and 2021 consisted of the following (in millions):

	December 31,	
	2022	2021
Manufacturing	$ 400	$ 227
Clinical trials	319	283
Raw materials	316	260
Loss on future firm purchase commitments[1]	268	—
Other external goods and services	264	79
Royalties	203	241
Compensation-related	190	126
Development operations	88	137
Other	53	119
Accrued liabilities	$ 2,101	$ 1,472

[1] Related to losses that are expected to arise from firm, non-cancellable, commitments for future raw material purchases (Note 8).

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Other Current Liabilities

Other current liabilities, as of December 31, 2022 and 2021 consisted of the following (in millions):

	December 31, 2022	December 31, 2021
Lease liabilities - financing (Note 11)	$ 161	$ 165
Lease liabilities - operating (Note 11)	35	46
Other	53	14
Other current liabilities	$ 249	$ 225

Deferred Revenue

The following table summarizes the activities in deferred revenue during the year ended December 31, 2022 (in millions):

	December 31, 2021	Additions	Deductions	December 31, 2022
Product sales	$ 6,658	$ 2,510	$ (6,542)	$ 2,626
Grant revenue	6	—	(2)	4
Collaboration revenue	204	16	(139)	81
Total deferred revenue	$ 6,868	$ 2,526	$ (6,683)	$ 2,711

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.

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 292,000 square feet. Our Cambridge campus leases have expiry ranges from 2024 to 2029. All our Cambridge leases are classified as operating leases.

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 (see Note 12). As of December 31, 2022, we did not gain the control of the underlying leased asset at the MSC, and therefore we did not recognize the related right-of-use asset and lease liability on our consolidated balance sheets. 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.

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, totaling approximately 686,000 square feet. Our MTC leases expire in 2042 and we have the option to extend the term for three extension periods of five years each. All our MTC leases are classified as finance leases.

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, 2022 and 2021, we had lease liabilities of $440 million and $166 million, respectively, related to the embedded leases. As of December 31, 2022 and December 31, 2021, we had right-of-use assets of $639 million and $173 million, respectively, related to the embedded leases. All our embedded leases are classified as finance leases.

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Operating and financing lease right-of-use assets and lease liabilities as of December 31, 2022 and 2021 were as follows (in millions):

	December 31,	
	2022	2021
Assets:		
Right-of-use assets, operating, net [1] [2]	$ 121	$ 142
Right-of-use assets, financing, net [3] [4]	1,150	665
Total	$ 1,271	$ 807
Liabilities:		
Current:		
Operating lease liabilities [5]	$ 35	$ 46
Financing lease liabilities [5]	161	165
Total current lease liabilities	196	211
Non-current:		
Operating lease liabilities, non-current	92	106
Financing lease liabilities, non-current	912	599
Total non-current lease liabilities	1,004	705
Total	$ 1,200	$ 916

[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, plant 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 were as follows for the periods presented (in millions):

	Years ended December 31,		
	2022	2021	2020
Operating lease costs	$ 48	$ 24	$ 17
Financing lease costs:			
Amortization of right-of-use assets, financing leases	280	189	1
Interest expense for financing lease liabilities	29	17	10
Total financing lease costs	$ 309	$ 206	$ 11
Short term lease costs	$ —	$ 49	$ 13
Variable lease costs	$ 165	$ 100	$ 5

Supplemental cash flow information relating to our leases was as follows for the periods presented (in millions):

	December 31,		
	2022	2021	2020
Cash paid for amounts included in measurement of lease liabilities:			
Operating cash flows used in operating leases	$ (57)	$ (19)	$ (15)
Operating cash flows used in financing leases	(25)	(14)	(9)
Financing cash flows used in financing leases	(184)	(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	20	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	777	126	—
Changes in financing lease liabilities	4	3	1

Weighted average remaining lease terms and discount rates as of December 31, 2022 and 2021 were as follows:

	December 31,	
	2022	2021
Remaining lease term:		
Operating leases	6 years	5 years
Finance leases	22 years	28 years
Discount rate:		
Operating leases	7.5 %	6.8 %
Finance leases	3.6 %	3.1 %

Future minimum lease payments under non-cancelable lease agreements as of December 31, 2022, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases [1]
2023	$ 43	$ 195
2024	22	126
2025	19	127
2026	18	106
2027	18	23
Thereafter	42	1,088
Total minimum lease payments	162	1,665
Less amounts representing interest	(35)	(592)
Present value of lease liabilities	$ 127	$ 1,073

[1] Include certain optional lease term extensions, predominantly related to the MTC leases, which represent a total of $662 million of undiscounted future lease payments.

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12. Commitments and Contingencies

Legal Proceedings

We are involved in various claims and legal proceedings of a nature considered ordinary course in our business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. We are not currently a party to any legal proceedings for which a material loss is probable, or for which a loss is reasonably estimable at this time.

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, 2022 and 2021, we had not experienced any significant 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, 2022, we had $2.1 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2026. As of December 31, 2022, $268 million of the purchase commitments related to raw materials was recorded as an accrued liability for loss on future firm purchase commitments. As of December 31, 2022, we had $177 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2027. 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, 2022, we had cancelable open purchase orders of $2.5 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, 2022, 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

In 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 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 2022, 2021, and 2020 we recognized $635 million, $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.

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In December 2022, we entered into a non-exclusive patent license agreement with the National Institute of Allergy and Infectious Diseases (NIAID), an Institute or Center of the National Institutes of Health (NIH) to license certain patent rights concerning stabilizing prefusion coronavirus spike proteins and the resulting stabilized proteins for use in COVID-19 vaccine products. Pursuant to the agreement, we have agreed to pay low single-digit royalties on future net sales, a minimum annual royalty payment, and certain contingent development, regulatory and commercial milestone payments on a licensed product-by-licensed product basis. In addition, in December 2022, we made a catch-up royalty payment of $400 million to NIAID, which was recorded to cost of sales in our consolidated statements of operations.

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, 2022.

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 is 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 are currently undergoing 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 $1.0 billion non-cancellable rent payments for the initial lease term. We expect to begin a phased move-in process in the fourth quarter of 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 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 Stock Option and Incentive Plan (the 2016 Equity 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 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 Equity Plan will be added back to the shares of common stock available for issuance under the 2018 Equity Plan.

The Board of Directors may grant to employees, nonemployee directors, consultants and independent advisors equity-based awards during their period of service, generally in the form of stock options, restricted stock units, and performance stock units. 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, 2022, we had a total of 51 million shares reserved for future issuance under our Equity Plans, of which 28 million shares were reserved for equity awards previously granted, and 23 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.

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Options

We have granted options generally through the 2018 Equity Plan and 2016 Equity Plan. The following table summarizes our option activity during the year ended December 31, 2022:

	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, 2021	27.41	$ 27.08	5.8 years	$ 6,247
Granted	2.69	150.05		
Exercised	(4.78)	10.51		
Canceled/forfeited	(0.39)	109.93		
Outstanding at December 31, 2022	24.93	42.23	5.7 years	3,478
Exercisable at December 31, 2022	16.91	22.12	4.8 years	2,677
Expected to vest at December 31, 2022	8.02	84.57	7.4 years	800

[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, 2022.

The total intrinsic value of options exercised was $714 million, $1.6 billion, and $786 million for the years ended December 31, 2022, 2021, and 2020, 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 $144 million and $325 million during the years ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2020, 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 $50 million, $112 million, and $179 million for the years ended December 31, 2022, 2021, and 2020.

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, 2022:

	Number of Units (in millions)	Weighted Average Grant Date Fair Value per Unit
Outstanding, non-vested at December 31, 2021	2.14	$ 88.55
Issued	1.83	149.82
Vested	(0.82)	66.56
Canceled/forfeited	(0.25)	102.66
Outstanding, non-vested at December 31, 2022	2.90	132.25

The total grant date fair value of RSUs and PSUs vested during the years ended December 31, 2022, 2021, and 2020, was $55 million, $18 million, and $5 million, respectively. The total intrinsic value of RSUs and PSUs vested during the years ended December 31, 2022, 2021, and 2020, was $125 million, $141 million and $14 million, respectively.

During 2022 and 2021, we granted an immaterial amount of PSUs, respectively, primarily 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.

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2018 Employee Stock Purchase Plan

In November 2018, we adopted the 2018 Employee Stock Purchase Plan (ESPP). We 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 usually begin every six months and continue for six-month periods, referred to as offering periods. The purchase price at which shares are sold under the ESPP equals 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. There were 123,308, 81,423, and 251,752 shares of common stock sold at a weighted average price of $122.83, $145.90, and $27.97 per share under the ESPP during the years ended December 31, 2022, 2021, and 2020, respectively. As of December 31, 2022, 3 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, 2022, 2021, and 2020 were as follows:

	Weighted Average Years Ended December 31,		
	2022	2021	2020
Options:			
Risk-free interest rate	2.46 %	0.84 %	0.83 %
Expected term	6.13 years	6.10 years	6.11 years
Expected volatility	50 %	46 %	58 %
Expected dividends	— %	— %	— %
Weighted average fair value per share	$ 76.02	$ 91.84	$ 19.30
ESPP:			
Risk-free interest rate	3.56 %	0.08 %	0.14 %
Expected term	0.50 years	0.50 years	0.50 years
Expected volatility	51 %	34 %	54 %
Expected dividends	— %	— %	— %
Weighted average fair value per share	$ 50.18	$ 64.25	$ 32.18

Stock-Based Compensation Expense

The following table presents the components and classification of stock-based compensation expense for the years ended December 31, 2022, 2021, and 2020 (in millions):

	Years Ended December 31,		
	2022	2021	2020
Options	$ 123	$ 96	$ 78
RSUs and PSUs	97	42	12
ESPP	6	4	3
Total	$ 226	$ 142	$ 93
Cost of sales	$ 45	$ 22	$ —
Research and development	93	68	56
Selling, general and administrative	88	52	37
Total	$ 226	$ 142	$ 93

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For the years ended December 31, 2022, 2021, and 2020, we recognized stock-based compensation expense of $18 million, $16 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, 2022, 2021, and 2020.

As of December 31, 2022, there were $571 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, 2022.

Share Repurchase Programs

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 were authorized to repurchase up to $1.0 billion of our outstanding common stock. By the end of January 2022, we had 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 an additional share repurchase program of our common stock, with no expiration date, for up to $3.0 billion. On August 1, 2022, our Board of Directors authorized an increase of $3.0 billion under the repurchase program for our common stock, with no expiration date (collectively with the February 22, 2022 authorization, the 2022 Repurchase Programs). The timing and actual number of shares repurchased under the 2022 Repurchase Programs 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 Securities Exchange Act of 1934, as amended.

The following table summarizes activity related to our share repurchase programs (in millions, except per share data):

	Years Ended December 31,	
	2022	2021
Number of shares repurchased	23	3
Average price per share [1]	$ 142.83	$ 245.76
Aggregate purchase price	$ 3,329	$ 857
Remaining authorization at end of period	$ 2,814	$ 143

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

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 100% of the first 3%, and 50% of the next 3% contributed by a participant. All matching contributions are immediately vested. Total matching contributions to the 401(k) Plan were $20 million, $10 million, and $5 million for the years ended December 31, 2022, 2021, and 2020, 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 $8 million and $9 million as of December 31, 2022 and 2021, respectively, which were recognized in other long-term liabilities in our consolidated balance sheets.

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16. Income Taxes

Income (loss) before income taxes for the years ended December 31, 2022, 2021, and 2020 consisted of the following (in millions):

	Years Ended December 31,		
	2022	2021	2020
United States	$ 9,433	$ 13,108	$ (745)
Foreign	142	177	1
Income (loss) before income taxes	$ 9,575	$ 13,285	$ (744)

The provision for income taxes for the years ended December 31, 2022, 2021, and 2020 consisted of the following components (in millions):

	Years Ended December 31,		
	2022	2021	2020
Current:			
Federal	$ 1,687	$ 1,304	$ —
State	47	35	—
Foreign	57	40	3
Total current	$ 1,791	$ 1,379	$ 3
Deferred:			
Federal	$ (569)	$ (288)	$ —
State	(7)	(6)	—
Foreign	(2)	(2)	—
Total deferred	(578)	(296)	—
Total provision for income taxes	$ 1,213	$ 1,083	$ 3

The reconciliation of the federal statutory income tax rate to our effective tax rate for the years ended December 31, 2022, 2021, and 2020 was as follows:

	Years Ended December 31,		
	2022	2021	2020
Federal statutory tax rate	21.0 %	21.0 %	21.0 %
Change in valuation allowance	— %	(5.4)%	(47.4)%
Foreign-derived intangible income	(7.4)%	(4.8)%	— %
Stock-based compensation windfall	(1.6)%	(2.6)%	19.8 %
Federal research and development credits	(0.5)%	(0.7)%	3.8 %
State taxes, net of federal benefits	0.4 %	0.5 %	3.6 %
Non-deductible items	— %	— %	(0.8)%
Other	0.8 %	0.1 %	(0.3)%
Effective tax rate	12.7 %	8.1 %	(0.3)%

Our effective tax rate for the year ended December 31, 2022 was 12.7% and was lower than the federal statutory tax rate, primarily due to the tax benefit of the foreign-derived intangible income deduction (FDII) and excess tax benefit related to stock-based compensation. Our effective tax rate for the year ended December 31, 2021 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, FDII and stock-based compensation. Our effective tax rate for the year ended December 31, 2020 was lower than the federal statutory tax rate primarily due to the valuation allowance on our deferred tax assets.

As of January 1, 2022, pursuant to the Tax Cuts and Jobs Act of 2017 ("TCJA"), research and development costs in the current period are required to be amortized over five or fifteen years, depending on where the research is conducted. The new capitalization requirement significantly increased our deferred tax assets and cash tax liabilities, but also decreased our effective tax rate by increasing the foreign-derived intangible income deduction.

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The President signed into law the Inflation Reduction Act (the "IRA") on August 16, 2022. The Act includes a new 15% corporate minimum tax and a 1% excise tax on the value of corporate stock repurchases, net of new share issuances, after December 31, 2022. We do not expect these provisions to have a material impact on our consolidated financial position; however, we will continue to evaluate their impact as further information becomes available.

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, 2022 and 2021 were as follows (in millions):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 59	$ 69
Stock-based compensation	68	44
Capitalized licenses, research and development and start-up costs	704	204
Tax credit carryforwards	97	80
Deferred revenue	16	43
Operating lease liabilities	26	32
Financing lease liabilities	135	136
Other comprehensive income	106	—
Inventory reserve and capitalization	86	—
Other	69	67
Total deferred tax assets	1,366	675
Less: valuation allowance	(155)	(149)
Net deferred tax assets	$ 1,211	$ 526
Deferred tax liabilities:		
Right-of-use assets, financing	$ (117)	$ (119)
Right-of-use assets, operating	(26)	(31)
Property, plant and equipment	(85)	(49)
Other	(1)	(1)
Total deferred tax liabilities	(229)	(200)
Net deferred tax assets	$ 982	$ 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. The valuation allowance increased by $6 million in the year ended December 31, 2022, primarily due to generation of state net operating losses and credits.

The table below summarizes changes in the valuation allowance for deferred tax assets for the periods presented (in millions):

	Years Ended December 31,		
	2022	2021	2020
Valuation allowance at beginning of the period	$ 149	$ 823	$ 471
Decreases recorded as benefit to income tax provision	(12)	(722)	—
Increases to valuation allowance	18	48	352
Valuation allowance at December 31	$ 155	$ 149	$ 823

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At December 31, 2022, we had $828 million of state net operating loss carryforwards, which begin to expire in 2032. At December 31, 2022, we also had state research and development tax credit carryforwards of $122 million, the majority of which will begin to expire in 2030.

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, 2022, 2021, and 2020 were as follows (in millions):

	Years Ended December 31,		
	2022	2021	2020
Unrecognized tax benefits at beginning of the period	$ 68	$ —	$ —
Decrease due to prior positions:			
Tax positions for prior years	(1)	—	—
Increase due to current year tax positions:			
Additions based on tax positions for current year	57	54	—
Additions based on tax positions for prior years	4	14	—
Unrecognized tax benefits at end of the period	$ 128	$ 68	$ —

As of December 31, 2022, we had $128 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.

We file U.S. federal income tax returns and income tax returns in various state, local and foreign jurisdictions. All tax years since our date of incorporation remain open to examination by the major taxing jurisdictions, as carryforward attributes generated in past years may be adjusted upon examination by the Internal Revenue Service or the state authorities. There are no open tax examinations at this time.

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, 2022, 2021 and 2020 were calculated as follows (in millions, except per share data):

	Years Ended December 31,		
	2022	2021	2020
Numerator:			
Net income (loss)	$ 8,362	$ 12,202	$ (747)
Denominator:			
Basic weighted-average common shares outstanding	394	403	381
Effect of dilutive securities	22	28	—
Diluted weighted-average common shares outstanding	416	431	381
Basic EPS	$ 21.26	$ 30.31	$ (1.96)
Diluted EPS	$ 20.12	$ 28.29	$ (1.96)

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The following common stock equivalents, presented based on amounts outstanding as of December 31, 2022, 2021 and 2020, 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,		
	2022	2021	2020
Options	3	1	34
RSUs and PSUs	—	—	2
Total	3	1	36

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,		
	2022	2021	2020
United States	$ 5,150	$ 6,177	$ 764
Europe	6,815	6,846	33
Rest of world [1]	7,298	5,448	6
Total	$ 19,263	$ 18,471	$ 803

[1] Includes product sales recognized under the agreement with Gavi, which facilitates the allocation and distribution of our COVID-19 vaccines around the world, particularly for low- and middle-income countries.

Our property, plant and equipment, including financing right-of-use assets, by geographic area was as follows (in millions):

	December 31,	
	2022	2021
United States	$ 1,267	$ 1,050
Europe	714	181
Rest of world	37	10
Total	$ 2,018	$ 1,241

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

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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, 2022. 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, 2022, 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, 2022. 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, 2022.

The effectiveness of our internal control over financial reporting as of December 31, 2022 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, 2022, 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.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Moderna, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Moderna, Inc.'s internal control over financial reporting as of December 31, 2022, 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, 2022, 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, 2022 and 2021, 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, 2022, and the related notes and our report dated February 24, 2023 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 24, 2023

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Item 9B. Other Information

Effective February 23, 2023, the Compensation and Talent Committee of the Board of Directors approved a new form of Executive Severance Plan (the Amended and Restated Executive Severance Plan) that would be applicable to the Company's Executive Committee members. Under the Amended and Restated Executive Severance Plan, Executive Committee members covered by the plan would continue to be eligible for the benefits previously provided for under the predecessor plan, except that in the event of termination (or than for Cause, death or Disability) other than in connection with a Change of Control (in each case as defined in the Amended and Restated Executive Severance Plan), eligible participants would be entitled to receive their full annual bonus at target, rather than a pro-rated bonus based upon weeks lapsed during the year. The Amended and Restated Executive Severance Plan also includes an expanded definition of the circumstances that would constitute termination for Cause and that would render a participant ineligible for benefits under the plan. The above summary is not complete and is qualified in its entirety by the Amended and Restated Executive Severance Plan, a copy of which is attached hereto as Exhibit 10.11 and is incorporated herein by reference.

On February 21, 2023, Juan Andres, the Company's President, Strategic Partnerships and Enterprise Expansion, announced his decision to retire from the Company in May 2023. Until December 31, 2022, Mr. Andres had served as the Company's Chief Technical Operations and Quality Officer. In connection with his retirement, Mr. Andres will be granted a period of one year from his date of retirement to exercise any stock options that are vested, but unexercised as of his retirement date.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None Applicable.

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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 2023 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 2023 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 2023 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 2023 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 2023 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.

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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 II, 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. (6)
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†	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)
10.7	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)
10.8	Fifth Amendment to Lease Agreement, by and between ModernaTX, Inc. and ARE-Tech Square, LLC, dated as of August 28, 2019. (3)
10.9	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)
10.10	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. (7)
10.11#*	Amended and Restated Executive Severance Plan and Form of Participation Letter, as amended on February 23, 2023.
10.12#	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)
10.13#	Letter Agreement by and between the Company and Stephen Hoge, dated as of October 17, 2017. (1)
10.14#	Employment Letter Agreement between ModernaTX, Inc. and Shannon Klinger, dated as of March 4, 2021. (7)
10.15#	Offer Letter by and between ModernaTX, Inc. and James Mock, dated as of August 15, 2022. (10)
10.16#*	Offer Letter by and between ModernaTX, Inc. and Arpa Garay, dated as of April 21, 2022.
10.17#	Updated Executive Retirement and Strategic Consulting Agreement, dated May 27, 2022, between ModernaTX, Inc. and David Meline. (9)

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10.18#	Executive Separation Agreement and Release, dated May 13, 2022, between ModernaTx, Inc. and Jorge Gomez. (8)
10.19#	Senior Executive Cash Incentive Bonus Plan. (1)
10.20#	Amended and Restated Non-Employee Director Compensation Policy, effective October 1, 2022. (10)
10.21#	Form of Indemnification Agreement between the Registrant and each of its officers. (1)
10.22#	2018 Employee Stock Purchase Plan. (1)
10.23#	Form of Employee Restricted Stock Unit Award Agreement. (7)
10.24#	Form of Employee Non-Qualified Stock Option Agreement. (7)
10.25#	Form of Non-Employee Director Restricted Stock Unit Award Agreement. (7)
10.26#	Form of Non-Employee Director Non-Qualified Stock Option Agreement. (7)
10.27#	Form of Performance-Based Restricted Stock Unit Award Agreement under the 2018 Stock Option and Incentive Plan. (4)
10.28†	Global Long Term Agreement, by and among ModernaTX Inc., Lonza Sales Ltd., and Lonza Ltd., dated September 4, 2020. (5)
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 October 30, 2020.

(6) 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.

(7) Incorporated by reference to the Annual Report on Form 10-K (File No. 001-38752) filed with the Securities and Exchange Commission on February 25, 2022.

(8) Incorporated by reference to the Current Report on Form 8-K/A (File No. 001-38753) filed with the Securities and Exchange Commission on May 13, 2022.

(9) Incorporated by reference to the Current Report on Form 8-K/A (File No. 001-38753) filed with the Securities and Exchange Commission on June 1, 2022.

(10) Incorporated by reference to the Quarterly Report on Form 10-Q (File No. 001-38753) filed with the Securities and Exchange Commission on November 3, 2022.

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Item 16. Form 10-K Summary

Not applicable.

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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 24, 2023

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer and Director

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POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints each of Stéphane Bancel and James M. Mock 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 24, 2023
/s/ James M. Mock James M. Mock	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 24, 2023
/s/ Noubar B. Afeyan, Ph.D. Noubar B. Afeyan, Ph.D.	Chairman and Director	February 24, 2023
/s/ Stephen Berenson Stephen Berenson	Director	February 24, 2023
/s/ Sandra Horning, M.D. Sandra Horning M.D.	Director	February 24, 2023
/s/ Robert Langer, Sc.D. Robert Langer, Sc.D.	Director	February 24, 2023
/s/ Francois Nader, M.D. Francois Nader M.D.	Director	February 24, 2023
/s/ Elizabeth Nabel, M.D. Elizabeth Nabel, M.D.	Director	February 24, 2023
/s/ Paul Sagan Paul Sagan	Director	February 24, 2023
/s/ Elizabeth Tallett Elizabeth Tallett	Director	February 24, 2023

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Exhibit 10.11

Moderna, Inc.
Amended and Restated Executive Severance Plan

1. Purpose. Moderna, Inc. (the "Company") considers it essential to the best interests of the Company to foster the continuous employment of key management employees. The Board of Directors of the Company (the "Board") recognizes, however, that, as is the case with many corporations, the possibility of an involuntary termination of employment, either before or after a Change in Control (as defined in Section 2 below), exists and that such possibility, and the uncertainty and questions that it may raise among key management employees, may result in the departure or distraction of management employees to the detriment of the Company. Therefore, the Board has determined that the Moderna, Inc. Amended and Restated Executive Severance Plan (the "Plan") should be adopted to reinforce and encourage the continued attention and dedication of the Company's Covered Executives (defined in Section 2 below) to their assigned duties without distraction. Nothing in this Plan shall be construed as creating an express or implied contract of employment and nothing shall alter the "at will" nature of the Covered Executives' employment with the Company.

2. Definitions. The following terms shall be defined as set forth below:

(a) *"Accounting Firm"* shall mean a nationally recognized accounting firm selected by the Company.

(b) *"Administrator"* means the Board or the Compensation Committee of the Board.

(c) "*Cause*" shall mean, and shall be limited to, the occurrence of any one or more of the following events:

(i) the Covered Executive's failure to comply with the requirements of the Company's Code of Ethics and Business Conduct or any other Company standards, policies, or practice(s) regarding acceptable workplace conduct;

(ii) the Covered Executive's material breach of their offer letter, their Employee Confidentiality, Assignment, Nonsolicitation, and Noncompetition Agreement, or any other agreement between the Covered Executive and the Company;

(iii) the Covered Executive's gross misconduct or fraudulent conduct in connection with the Executive's performance of their duties to the Company or otherwise if such conduct is reasonably determined to result in reputational harm to the Company;

(iv) the Covered Executive's continuing failure to perform assigned duties or negligence in performing such duties (other than by reason of Disability or death) after receiving written notification of the failure from the Company and, if curable, a period of thirty (30) days to cure such failure;

(v) the Covered Executive's conviction of, or the entry of a pleading of guilty or nolo contendere to, any crime involving fraud or embezzlement or any felony; or

(vi) the Covered Executive's failure to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers, or employees, if the Company has requested the Covered Executive's cooperation.

(d) "*Change in Control*" shall mean

(i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity;

(ii) a merger, reorganization, or consolidation pursuant to which the holders of the Company's outstanding voting power and the outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction;

(iii) the sale of all of the outstanding stock of the Company to an unrelated person, entity, or group thereof acting in concert; or

(iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

(e) "*Change in Control Period*" shall mean the period beginning on the date of a Change in Control and ending on the one-year anniversary of the Change in Control.

(f) "*Code*" shall mean the Internal Revenue Code of 1986, as amended.

(g) "*Covered Executives*" shall mean the individuals designated as such by the Administrator and who are listed in Exhibit A, attached hereto, as such exhibit is amended by the Administrator from time to time.

(h) "*Date of Termination*" shall mean the date that a Covered Executive's employment with the Company (or any successor) ends, which date shall be specified in the Notice of Termination. Notwithstanding the foregoing, a Covered Executive's employment shall not be deemed to have been terminated solely as a result of the Covered Executive becoming an employee of any direct or indirect successor to the business or assets of the Company.

(i) "*Disability*" shall mean the following: if through any illness, injury, accident, or mental or physical impairment or condition, the Covered Executive becomes unable to perform substantially all of their essential functions for a continuous period of sixteen (16) consecutive weeks or for a period of twenty-six (26) weeks within a rolling fifty-two (52) week period. Determinations as to whether Covered Executive is Disabled shall be made by a physician selected by the Board or its insurers and acceptable to the Covered Executive or the Covered Executive's legal representative, such agreement as to acceptability not to be unreasonably withheld or delayed.

(j) *"Good Reason"* shall mean that the Covered Executive has complied with the "Good Reason Process" following the occurrence of any of the following events:

(i) a diminution of at least 20% in the Covered Executive's annual base salary other than across-the-board decreases in annual base salary similarly affecting all executives of the Company;

(ii) the Company requiring the Covered Executive to relocate (other than for travel incident to the Covered Executive's performance of his or her duties on behalf of the Company) a distance of more than fifty (50) miles from the Covered Executive's current principal place of business; or

(iii) any material diminution in the Covered Executive's position, responsibilities, authority, or duties.

For purposes of Section 2(j)(iii), a change in the reporting relationship, or a change in a title will not, by itself, be sufficient to constitute a material diminution of responsibilities, authority, or duty.

(k) *"Good Reason Process"* shall mean:

(i) the Covered Executive reasonably determines in good faith that a "Good Reason" condition has occurred;

(ii) the Covered Executive notifies the Company in writing of the first occurrence of the Good Reason condition within sixty (60) days of the first occurrence of such condition;

(iii) the Covered Executive cooperates in good faith with the Company's efforts, for a period of not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition;

(iv) notwithstanding such efforts, the Good Reason condition continues to exist following the Cure Period; and

(v) the Covered Executive terminates his or her employment and provides the Company with a Notice of Termination with respect to such termination, each within sixty (60) days after the end of the Cure Period.

If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(l) *"Notice of Termination"* shall mean a written notice which shall indicate the specific termination provision in this Plan relied upon for the termination of a Covered Executive's employment and the Date of Termination.

(m) *"Participation Agreement"* shall mean an agreement between a Covered Executive and the Company that acknowledges the Covered Executive's participation in the Plan.

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(n) *"Qualified Termination Event"* shall mean (i) a termination of the Covered Executive's employment by the Company other than for Cause, death, or Disability or (ii) the Covered Executive's resignation from the Company for Good Reason.

(o) *"Restrictive Covenants Agreement"* shall mean the Employee Confidentiality, Non-Competition, Non-Solicitation, and Inventions Assignment Agreement or similar agreement entered into between the Covered Executive and the Company.

3. Administration of the Plan.

(a) Administrator. The Plan shall be administered by the Administrator.

(b) Powers of Administrator. The Administrator shall have all powers necessary to enable it properly to carry out its duties with respect to the complete control of the administration of the Plan. Not in limitation, but in amplification of the foregoing, the Administrator shall have the power and authority in its discretion to:

(i) construe the Plan to determine all questions that shall arise as to interpretations of the Plan's provisions;

(ii) determine which individuals are and are not Covered Executives, determine the benefits to which any Covered Executives may be entitled, the eligibility requirements for participation in the Plan, and all other matters pertaining to the Plan;

(iii) adopt amendments to the Plan which are deemed necessary or desirable to comply with all applicable laws and regulations, including but not limited to Code Section 409A and the guidance thereunder;

(iv) make all determinations it deems advisable for the administration of the Plan, including the authority and ability to delegate administrative functions to a third party;

(v) decide all disputes arising in connection with the Plan; and

(vi) otherwise supervise the administration of the Plan.

(c) All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Covered Executives.

4. Eligibility. All Covered Executives who have executed and submitted to the Company a Participation Agreement and satisfied such other requirements as may be determined by the Administrator, are eligible to participate in the Plan.

5. Termination Benefits Generally. In the event a Covered Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Covered Executive any earned but unpaid salary, unpaid expense reimbursements in accordance with Company policy, and any vested benefits the Covered Executive may have under any employee benefit plan of the Company

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in accordance with the terms and conditions of such employee benefit plan (collectively, the "Accrued Benefits"), within the time required by law but in no event more than sixty (60) days after the Date of Termination.

6. Termination Not in Connection with a Change in Control. In the event a Qualified Termination occurs at any time other than during the Change in Control Period, with respect to such Covered Executive, in addition to the Accrued Benefits, subject to his or her execution of a separation agreement in a form and manner satisfactory to the Company containing, among other provisions, a general release of claims in favor of the Company and related persons and entities, confidentiality, return of property, non-disparagement and reaffirmation of the Restrictive Covenants Agreement (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable, all within the time period outlined in the Separation Agreement and Release but in no event more than sixty (60) days after the Date of Termination, and subject to the Covered Executive complying with the Separation Agreement and Release, the Company shall:

(a) pay the Covered Executive salary continuation in an amount equal to the sum of (i) twelve (12) months of the Covered Executive's annual base salary in effect immediately before the Qualified Termination Event plus (ii) an amount equal to the Covered Executive's annual target bonus in effect immediately prior to the Qualified Termination Event (the "Severance Pay"); and

(b) if the Covered Executive was participating in the Company's group health plan immediately before the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Covered Executive a monthly cash payment for twelve (12) months or the Covered Executive's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Covered Executive if the Covered Executive had remained employed by the Company, based on the premiums as of the Date of Termination.

The amounts payable under Section 6(a) and (b) shall be paid out in substantially equal installments under the Company's payroll practice over twelve (12) months commencing within sixty (60) days after the Date of Termination; provided, however, that if the 60-day period begins in one (1) calendar year and ends in a second calendar year, the Severance Pay shall begin to be paid in the second calendar year by the last day of such 60-day period; provided further, that the initial Severance Pay payment shall, if necessary, include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment under this Plan is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

7. Termination in Connection with a Change in Control. In the event the Qualified Termination Event occurs within the Change in Control Period, then with respect to such Covered Executive, in addition to the Accrued Benefits, subject to his or her execution and non-revocation of the Separation Agreement and Release, all within the time period outlined in the Separation Agreement and Release, but in no event more than sixty (60) days after the Date of Termination, the Company shall:

(a) cause 100% of the outstanding and unvested equity awards with time-based vesting held by the Covered Executive to immediately become fully exercisable or nonforfeitable as of the Date of Termination. Notwithstanding the foregoing, in the event of a Change in Control where the parties to

such Change in Control do not provide for the assumption, continuation, or substitution of equity awards of the Company, any and all outstanding and unvested equity awards held by the Covered Executive shall be subject to Section 3(d) of the Company's 2018 Stock Option and Incentive Plan, if adopted by the Board.

(b) pay to the Covered Executive an amount equal to the sum of (i) 150% of the Covered Executive's annual base salary in effect immediately before the Qualified Termination Event (or the Covered Executive's annual base salary in effect immediately before the Change in Control, if higher) plus (ii) 150% of the Covered Executive's annual target bonus in effect immediately prior to the Qualified Termination Event (or the Covered Executive's target bonus in effect immediately prior to the Change in Control, if higher, (such higher annual target bonus, the "Applicable Bonus")) plus (iii) an amount equal to the Covered Executive's Applicable Bonus prorated to the Qualified Termination Event; and

(c) if the Covered Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Covered Executive a lump sum cash payment in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Covered Executive if the Covered Executive had remained employed by the Company for eighteen (18) months after the Date of Termination, based on the premiums as of the Date of Termination.

The amounts payable under Section 7(b) and (c), as applicable, shall be paid out in a lump sum within sixty (60) days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the amounts shall be paid in the second calendar year no later than the last day of the 60-day period. For the avoidance of doubt, the severance pay and benefits provided in this Section 7 shall apply in lieu of, and expressly supersede, the provisions of Section 6 and no Covered Executive shall be entitled to the severance pay and benefits under both Section 6 and 7 of this Plan.

8. Additional Limitation.

(a) Anything in this Plan to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Covered Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Plan or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Covered Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Covered Executive receiving a higher After Tax Amount (as defined below) than the Covered Executive would receive if the Aggregate Payments were not subject to such reduction. In the event of such reduction, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not

subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(b) For purposes of this Section 8, the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes (if any) which could be obtained from deduction of such state and local taxes.

(c) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 8(a) shall be made by the Accounting Firm, which shall provide detailed supporting calculations both to the Company and the Covered Executive within fifteen (15) business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Covered Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Covered Executive.

9. Restrictive Covenants Agreement. As a condition to participating in the Plan, each Covered Executive shall continue to comply with the terms and conditions contained in the Restrictive Covenants Agreements or similar agreement entered into between the Covered Executive and the Company and such other agreement(s) as designated in the applicable Participation Agreement. If a Covered Executive has not entered into a Restrictive Covenants Agreement or similar agreement with the Company, they shall enter into such agreement prior to participating in the Plan.

10. Withholding. All payments made by the Company under this Plan shall be subject to any tax or other amounts required to be withheld by the Company under applicable law.

11. Section 409A.

(a) Anything in this Plan to the contrary notwithstanding, if at the time of the Covered Executive's "separation from service" within the meaning of Section 409A of the Code, the Company determines that the Covered Executive is 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 the Covered Executive becomes entitled to under this Plan would be considered deferred compensation subject to the twenty (20) percent 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 (i) six (6) months and one (1) day after the Covered Executive's separation from service, or (ii) the Covered Executive's 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) The parties intend that this Plan will be administered in accordance with Section 409A of the Code and that all amounts payable hereunder shall be exempt from the requirements of such section as a result of being "short term deferrals" for purposes of Section 409A of the Code to the greatest extent possible. To the extent that any provision of this Plan is not exempt from Section 409A of the Code and ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner to comply with Section 409A of the Code. Each payment pursuant to this Plan is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Plan may be amended, as reasonably requested by either party, and as may be necessary to fully comply with 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.

(c) To the extent that any payment or benefit described in this Plan constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Covered Executive's termination of employment, then such payments or benefits shall be payable only upon the Covered Executive's "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) All in-kind benefits provided and expenses eligible for reimbursement under this Plan shall be provided by the Company or incurred by the Covered Executive during the time periods set forth in this Plan. 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.

(e) The Company makes no representation or warranty and shall have no liability to the Covered Executive or any other person if any provisions of this Plan 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. Notice and Date of Termination.

(a) Notice of Termination. A termination of the Covered Executive's employment shall be communicated by Notice of Termination from the Company to the Covered Executive or vice versa in accordance with this Section 12.

(b) Notice to the Company. Any notices, requests, demands, and other communications provided for by this Plan shall be sufficient if in writing and delivered in person or by overnight mailto a Covered Executive at the last address the Covered Executive has filed in writing with the Company, or to the Company at the following physical and/or email address:

Moderna, Inc.
Attention: Chief Human Resources Officer

200 Technology Square
Cambridge, MA 02139
tracey.franklin@modernatx.com

13. No Mitigation. The Covered Executive is not required to seek other employment or to attempt to reduce any amounts payable to the Covered Executive under Section 6 or 7 by the Company under this Plan.

14. Benefits and Burdens. This Plan shall inure to the benefit of and be binding upon the Company and the Covered Executives, their respective successors, executors, administrators, heirs, and permitted assigns. In the event of a Covered Executive's death after termination of employment but prior to the completion by the Company of all payments due under this Plan, the Company shall continue such payments to the Covered Executive's beneficiary designated in writing to the Company prior such death (or to the designated estate, if the Covered Executive fails to make a beneficiary designation).

15. Enforceability. If any portion or provision of this Plan shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Plan, 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 Plan shall be valid and enforceable to the fullest extent permitted by law.

16. Waiver. No waiver of any provision hereof 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 Plan, or the waiver by any party of any breach of this Plan, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

17. Non-Duplication of Benefits and Effect on Other Plans. Notwithstanding any other provision in the Plan to the contrary, the benefits provided in this Plan shall be in lieu of any other severance payments and/or benefits provided by the Company, including but not limited to any payments and/or benefits under an applicable employment agreement or offer letter between the Company and the Covered Executive. The provisions of sections 5, 6, and 7 of this Plan are subject to clawback under the circumstances detailed in the Company's February 9, 2021, Policy for Recoupment of Executive Incentive Compensation.

18. No Contract of Employment. Nothing in this Plan shall be construed as giving any Covered Executive any right to be retained by the Company for any specific period of time or shall affect the terms and conditions of a Covered Executive's at-will employment with the Company.

19. Amendment or Termination of Plan. The Company may amend or terminate this Plan at any time or from time to time, but no such action shall adversely affect the rights of any Covered Executive without the Covered Executive's written consent.

20. Governing Law. This Plan shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles.

21. Obligations of Successors. In addition to any obligations imposed by law upon any successor to the Company, any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company shall expressly assume and agree to perform this Plan in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

22. Effectiveness and Term. The Executive Severance Plan is effective as of June 13, 2018 and was amended and restated as of November 4, 2018, and again on February 23, 2023.

BioNTech-Pfizer Exhibit 1272
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358
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Exhibit A

Covered Executives

moderna

Exhibit 10.16

200 Tech Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

April 21, 2022

VIA ELECTRONIC MAIL

Arpa Garay
[***]
[***]

Re: Offer of Employment with Moderna

Dear Arpa:

On behalf of Moderna (ModernaTx, Inc. or, alternatively, one of its US-based subsidiaries to which you may be assigned, hereafter "Moderna" or the "Company"), it is my privilege to offer you the opportunity to join our mission: to boldly, curiously, and relentlessly deliver on the promise of mRNA technology to transform the lives of patients. We are confident that, as you leverage our Moderna Mindsets to help build and grow the best possible version of Moderna, you will experience challenge, satisfaction, collaboration, and opportunity for professional and personal growth.

Role and Start Date: You will join Moderna in the position of Chief Commercial Officer as a regular, full-time employee. Your first day of employment will be on May 31, 2022 (the "Start Date") and your regular place of work will be at the Company's offices in Cambridge, Massachusetts, although you will be working from your home office in Pennsylvania prior to your relocation, which is expected to occur before December 31, 2022.

Moderna Total Rewards: As a Moderna executive, you are eligible for a meaningful total compensation and rewards program, inclusive of:

Base Compensation: You will be paid an annualized base salary of USD$800,000.00 at the rate of USD$30,769.23 per bi-weekly pay period. Your salary is subject to deductions and withholdings as required by law. As a salaried, exempt employee, you will not be eligible for overtime payments. 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"). The Company acknowledges and agrees that you shall be a Participant in the current ESP upon your Start Date.

Sign On Cash Bonus: If you accept this offer, you will receive a one-time gross sign-on payment of $1,500,000 (the "Sign On Bonus") within thirty (30) days following the Start Date (the "Payment Date") unless you give notice of your resignation, resign, or your employment terminates for any reason prior to the Payment Date. If you resign or are terminated by the Company for Cause (as defined below), either within twenty-four (24) months of the Payment Date, you will be required to and agree to repay the Company for the total net amount of the Sign-On Bonus within one week of your separation date, and to the maximum extent permitted by law, you authorize the Company to deduct any owed Sign-On Bonus as a valid set-off from your final wages, any accrued and unused vacation pay, bonus, outstanding expense reimbursement, and/or any other payments or compensation owed to you by the Company. For purposes of this section, "Cause" means one or more of the following events, as determined in the Company's reasonable discretion: (i) your failure to perform or negligence in performing (other than by reason of disability or death) your duties and responsibilities as a Company employee; (ii) your failure to comply with the requirements of the Company's Code of Conduct or any other Company standards, policies, or

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practice(s) regarding acceptable workplace conduct; (iii) a breach by you of any provision of this offer letter (including its Exhibit A) or any of the other agreements you may have with the Company; (iv) your conviction of, or the entry of a pleading of guilty or nolo contendere to, any crime involving fraud or embezzlement or any felony; or (iv) any form of fraudulent conduct.

Benefits: Moderna is proud to provide you with a comprehensive suite of innovative health and wellbeing benefits to support our diverse and multigenerational workforce. As a regular employee working over 20 hours per week, you will be eligible for various employee benefit programs offered to Company employees in comparable positions in line with the eligibility requirements and other terms of the Company's benefit plans and/or policies. These benefits currently include paid vacation and sick time, group medical and dental insurance, group life insurance, short and long-term disability insurance, and a 401(k) plan with a Company match, along with many other wellness benefits. The eligibility requirements and other information regarding these benefits are set forth in the Company's Summary of Benefits and more detailed documents available from the Company. With the exception of the "employment at will" policy below, Moderna may, from time to time in its sole discretion, modify the benefits offered to employees and any associated plans or policies. Where a benefit is subject to a formal plan (for example, medical insurance or life insurance), eligibility to participate in and receive such benefit is controlled solely by the applicable plan document.

Relocation: Moderna, through its global mobility program, will assist you with your move you're your current location in Pennsylvania to the greater Cambridge, Massachusetts region by offering you a relocation benefits package through our relocation provider corresponding with your role (the "Relocation Expenses"). This relocation package, which is limited to one per household, is conditional on your acceptance of this offer of employment and will be available to you for up to twelve (12) months from the Start Date, depending on your function (with the actual date of your relocation designated as the "Relocation Date"). You understand and agree that in the event you terminate your employment with the Company for any reason (except due to your death or disability), or if you are involuntarily terminated by the Company (except due to job elimination or separation in connection with a reduction in force) within 24 months of the Relocation Date, you will reimburse the Company for 100% of all Relocation Expenses paid or reimbursed on your behalf (provided you separate within 12 months of the Relocation Date) or 50% of all Relocation Expenses paid or reimbursed on your behalf (provided you separate within 13-24 months of the Relocation Date). For purposes of this section, the term "Relocation Expenses" shall include but is not limited to (a) all direct expenses regarding your relocation incurred by the Company and (b) any expenses related to your relocation that are reimbursed by the Company. You agree to reimburse the Company for the applicable amount of Relocation Expenses owed pursuant to this section within thirty (30) days after the later of your separation date or the date you receive an itemization of Relocation Expenses incurred from the Company. In the event you fail to make timely reimbursement of Relocation Expenses, you agree to further reimburse the Company for any and all attorneys' fees and costs incurred by the Company in enforcing your repayment obligations. The Company will determine in its reasonable judgment what portion, if any, of the Relocation Expenses are nondeductible expenses in accordance with applicable tax law and will comply with all tax reporting obligations. Payment of the Relocation Expenses is contingent upon you first signing a Relocation Expense Repayment Agreement, which is enclosed with this offer letter.

Annual Performance Bonus Program: Employees at Moderna work hard and are well rewarded for their performance. To that end, you will be eligible to participate in the Company's annual performance bonus program, subject to its terms and conditions, with the potential to earn an annual performance bonus at an initial target level of 90% of your then annual base compensation. Performance bonuses

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under the Company's annual performance bonus program are subject to the Company's sole discretion based upon multiple factors, including but not limited to the Company's performance, overall business conditions, and your individual performance and likelihood of continued employment, which means that any annual performance bonus could be higher, lower, or equivalent to the target bonus amount. The components of the Company's annual incentive bonus program are subject to periodic review and adjustment. As your Start Date with the Company is between January 1 and the first Monday of October of this year, you will be eligible to earn an annual incentive bonus payment for this year prorated to your length of employment during this calendar year. You must be actively employed by the Company at the time annual performance bonus awards are distributed to employees in your role to be eligible to receive an annual performance bonus award. Annual performance bonus awards are typically paid on or before March 15 of the calendar year following the bonus eligibility year.

New Hire and Long-Term Incentive Equity Program: As an additional incentive for you to join the Company and to contribute to its long-term growth, you will be eligible to participate in both new hire and annual long-term equity incentive award programs. Subject to approval by the Company's Board of Directors (the "Board") and the Company's parent entity, within thirty (30) trading days of your Start Date you will be granted a new hire long term equity award equivalent to a total value of $5,000,000.00 (the "New Hire Equity Award") with the effective date of the New Hire Equity Award being the date the grant is approved by the Board (the "Grant Date"). Further, subject to the Board's approval, you also will be eligible to receive an annual long-term equity award related to your performance during the eligible performance period and potential for long-term impact (the "Annual Equity Award") provided your Start Date is on or before the first Monday in October of this year, which shall not be subject to proration in your first year of employment. The target grant value of an Annual Equity Award at your level is currently between $3,000,000.00 and $4,000,000.00. Annual Equity Awards typically will be issued in the first quarter of the year. The New Hire Equity and Annual Equity Award grants are conditioned upon, among other things, your execution of all incentive award program documentation required by the Company. At this time, the Board has approved that 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. As a condition to the vesting of each installment of the New Hire Equity Award, you must be actively employed by the Company as of the relevant vesting date without any prior interruption of service. All Equity Awards are subject to the terms and conditions of the Company's equity award plans and Board approvals, as they may be amended 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 to which you may be entitled under applicable law, Moderna's organizing documents, a vote of stockholders or a resolution of directors, or otherwise.

All compensation, payments, stock, stock options, and benefits referred to above are subject to withholdings, taxes and other deductions as required by applicable laws or regulations.

There are many additional benefits to joining Moderna and they are outlined in further detail at https://modernabenefits.com/fair/index and throughout the onboarding process.

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Preparing For Your Moderna Experience To Begin:

Protection of Moderna Innovation: In connection with your employment, you will be exposed to and provided with confidential and/or trade secret information about the Company and its present and future operations, products, and services ("Confidential Information"). In order to protect such Confidential Information and the Company's goodwill, this offer of employment is contingent upon you signing the Employee Confidentiality, Assignment, Nonsolicitation, and Noncompetition Agreement (the "Restrictive Covenant Agreement"), attached to this offer letter as Exhibit A, and your ongoing observance of its terms.

Protection Of Third-Party Innovation: You represent that your employment with the Company does not violate any pre-existing restriction, obligation, or contract, and that you are not subject to any agreements with non-competition, non-solicitation, invention assignment, proprietary information, confidentiality, or similar provisions that could prevent you from devoting your full business time, know- how, and attention to your work at the Company. You understand that your initial and continued employment with the Company is contingent upon the accuracy of this representation. If you are subject to any such restriction or agreement, please immediately provide me with a copy of the applicable agreement for review prior to accepting this offer. You also represent and agree that you will abide by the terms of any ongoing obligations to your present or prior employers or any other person, including but not limited to promises relating to the hiring or solicitation of employees, the solicitation of clients or customers, and maintaining the confidentiality of proprietary information or trade secrets. By accepting this offer, you agree that you will not, at any time, bring with you to the Company or use or disclose any confidential or proprietary information or trade secrets of any person, employer, or entity with whom or with which you have an agreement or obligation to keep in confidence that is not generally available to the public or has not been legally transferred to you or the Company.

Pre-Hire Requirements: This offer of employment is contingent upon the satisfactory completion of professional reference and background checks (which include verification of employment and education as well as a job-related criminal background screen) and a pre-employment drug test. We suggest that you do not resign from your current position and do not relocate until you have received confirmation from the Company that these pre-hire requirements have been successfully completed, as this offer will be rescinded if any of the above conditions are not satisfied. This offer is also contingent upon satisfactory proof of your right to work in the United States. Please expect to complete an I-9 Employment Verification Form with supporting documentation of eligibility to work in the United States on or immediately prior to your Start Date. By accepting this offer, you certify that you have not been debarred by the U.S. Food and Drug Administration or excluded from participation in federal health care programs by the Office of Inspector General, and further certify that in the event you are so debarred or excluded at any time during your employment, you will immediately report this to the Company's Compliance team. You understand that the Company and its agents may conduct ongoing checks of criminal history and other relevant government databases to confirm that your continued employment does not violate any of the Company's compliance obligations and authorize the Company and its agents to conduct such checks as needed.

PLEASE NOTE: *Moderna currently maintains a requirement that all US-based employees be fully vaccinated against COVID-19 prior to their employment start date unless a reasonable accommodation is*

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approved for those unable to be vaccinated where it is not an undue hardship to the Company to do so as provided under federal, state, and local law.

At-Will Employment: This offer letter does not constitute a contract of employment for any specific time period. You may terminate your employment with the Company at any time and for any reason simply by notifying the Company in writing. Likewise, the Company may terminate your employment at any time, with or without cause or advance notice, and as needed in a dynamic business, may change your job duties, title, reporting structure, and other terms and conditions of employment at any time, for any legal reason, 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. Your employment-at-will status can only be modified in a written agreement signed by you and the Chief Executive Officer of the Company or his designee.

Entire Agreement: This offer letter, together with the Restrictive Covenant Agreement, forms the complete employment arrangement with the Company and supersedes any other agreements or promises made to you by anyone regarding this offer, whether oral or written. Changes to your initial employment terms, require a written modification signed by you and the Company's Chief Executive Officer. The terms of this offer letter and the resolution of any disputes arising out of, related to, or in any way connected with this offer letter or your employment with the Company will be governed by the laws of the Commonwealth of Massachusetts, without giving effect to conflict of law provisions.

We look forward to your acceptance of this offer on or before Monday, April 25, 2022. You acknowledge and agree that electronic signatures, whether digital or encrypted, of you and the Company on this offer letter are intended to have the same force and effect as manual signatures.

We look forward to you joining the Moderna team and are pleased that you will be working with us to build a transformative company for patients.

On behalf of Moderna,

/s/ Tracey Franklin

Tracey Franklin
Chief Human Resources Officer

YOU ACKNOWLEDGE THAT YOU HAVE CAREFULLY READ THIS OFFER, INCLUDING ITS EXHIBIT A, AND UNDERSTAND AND AGREE TO ALL OF ITS PROVISIONS AND CONDITIONS AS DEMONSTRATED BY YOUR ELECTRONIC SIGNATURE. YOU FURTHER REPRESENT THAT YOU WERE GIVEN THIS OFFER, INCLUDING ITS EXHIBIT A, AT LEAST TEN DAYS PRIOR TO THE START DATE AND HAD THE OPPORTUNITY TO REVIEWIT WITH A REPRESENTATIVE OF YOUR CHOOSING.

Acknowledged:

/s/ Arpa Garay Date: 22 April 2022
Arpa Garay

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
Brizo Ltd.	Bermuda
Moderna Australia Pty Ltd	Australia
Moderna Austria GmbH	Austria
Moderna Belgium SRL	Belgium
Moderna Biopharma Canada Corporation	Canada
Moderna Biotech Distributor UK Ltd.	United Kingdom
Moderna Biotech Ireland Limited	Ireland
Moderna Biotech Kenya Manufacturing Ltd.	Kenya
Moderna Biotech Manufacturing UK Ltd.	United Kingdom
Moderna Biotech Securities, Inc.	Massachusetts
Moderna Biotech Singapore Pte. Ltd.	Singapore
Moderna Biotech Spain, S.L.U.	Spain
Moderna Biotech UK Limited	United Kingdom
Moderna Charitable Foundation, Inc.	Delaware
Moderna Denmark ApS	Denmark
Moderna Enzymatics Co. Ltd.	Japan
Moderna France	France
Moderna Germany GmbH	Germany
Moderna Hong Kong Limited	Hong Kong
Moderna Italy S.r.l.	Italy
Moderna Japan Co., Ltd.	Japan
Moderna Korea Limited	South Korea
Moderna Manufacturing Australia Pty Ltd	Australia
Moderna Manufacturing Canada Corp.	Canada
Moderna Malaysia Sdn. Bhd.	Malaysia
Moderna Netherlands B.V.	Netherlands
Moderna Norway AS	Norway
Moderna Poland sp. z o.o.	Poland
Moderna Portugal, Unipessoal LDA	Portugal
Moderna Services, Inc.	Delaware
Moderna Sweden AB	Sweden
Moderna Switzerland GmbH	Switzerland
ModernaTX, Inc.	Delaware
Moderna Taiwan Co., Ltd	Taiwan
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-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
(4) Registration Statement (Form S-3 No. 333-238467) of Moderna, Inc.;

of our reports dated February 24, 2023, 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, 2022.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 24, 2023

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 24, 2023

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, James M. Mock, 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 24, 2023

By: /s/ James M. Mock

James M. Mock
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, 2022 (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 24, 2023

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, James M. Mock, 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, 2022 (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 24, 2023

By: /s/ James M. Mock
James M. Mock
Chief Financial Officer
(Principal Financial Officer)