Overview

We are creating a new class of transformative medicines based on messenger RNA (“mRNA”) to improve the lives of patients. From the beginning, we designed our strategy and operations to realize the full potential value and impact of mRNA over a long time horizon across a broad array of human diseases. We built and continue to invest in a platform to advance the technological frontier of mRNA medicines. We made and continue to make forward investments in scalable infrastructure and capabilities to pursue a pipeline of potential medicines that reflect the breadth of the mRNA opportunity. Since we nominated our first program in late 2014, we and our strategic collaborators have advanced in parallel a diverse development pipeline, of which 18 have entered clinical studies and another has an open investigational new drug application (“IND”). Our current development pipeline consists of 24 development candidates across our 23 programs. Our therapeutic and vaccine development programs span infectious diseases, immunology, rare diseases, cardiovascular diseases and autoimmune diseases. We have assembled an exceptional team of approximately 830 employees and have established strategic alliances with leading biopharmaceutical companies, including AstraZeneca, Merck & Co., and Vertex Pharmaceuticals, as well as government-sponsored and private organizations focused on global health initiatives, including Biomedical Advanced Research and Development Authority (“BARDA”), Defense Advanced Research Projects Agency (“DARPA”), the Bill & Melinda Gates Foundation and the Coalition for Epidemic Preparedness Innovations (“CEPI”). As of March 2, 2020, we have raised over $3.7 billion in total funding from our strategic collaborators and investors and have up to $2 billion to invest and create value (includes cash and investments of $1.26 billion, net proceeds of approximately $550 million from our financing in February 2020 and up to $185 million in additional grant funding). As we unlock the inherent advantages of mRNA, we aim to address as many diseases and impact as many patients as our technology, talent, and capital permit.

mRNA, the software of life

mRNA transfers the instructions stored in DNA to make the proteins required in every living cell. Our approach is to use mRNA medicines to instruct a patient’s own cells to produce proteins that could prevent, treat, or cure disease. A schematic of the central role of mRNA in making proteins is shown in the figure below.

![Figure showing DNA, mRNA, and Protein]

We believe mRNA’s intrinsic properties could serve as a foundation for a new class of medicines for patients. Every cell in the human body utilizes mRNA in existing natural processes to produce all types of proteins, including secreted, membrane, and intracellular proteins, in varying quantities, in different locations, and in various combinations. mRNA has a pharmacological profile that we believe is consistent with the target profile of traditional therapeutics and has a
simple molecular structure that comprises a sequence of four chemically similar nucleotides. To change a protein encoded by an mRNA molecule, only a change to the sequence within the mRNA is required. As a result, each mRNA molecule is highly chemically similar, yet mRNAs can encode proteins with divergent chemical properties and functions.

mRNA medicines, we believe, represent an opportunity that could meaningfully exceed that of other classes of biopharmaceuticals. One such class, recombinant protein therapeutics, which focuses on secreted proteins, today generates over $200 billion in annual worldwide sales. Two other types of proteins, intracellular and membrane proteins, represent as much as two-thirds of all human proteins and are critical to human biology; however, delivery of these proteins is currently beyond the reach of recombinant protein technology. We believe that mRNA medicines could address all three protein types, including these areas untapped by recombinant protein therapeutics.

The breadth of biology addressable using mRNA technology is reflected in our current development pipeline of 24 development candidates across our 23 programs. These span 27 different proteins: eleven different antigens (including complexes and virus-like particles (“VLPs”) for infectious disease vaccines; two different types of neoantigen cancer vaccines; four different immuno-modulator targets (including membrane and systemically secreted proteins) for immuno-oncology programs; one secreted, local regenerative factor for a heart failure program; five secreted proteins of diverse biology (an antibody, an engineered protein hormone, a lysosomal enzyme, a cell surface ligand and an engineered cytokine); and four intracellular enzymes for rare disease programs. The diversity of proteins made from mRNA within our current development pipeline or that have been in clinical trials is shown in the figure below.

Our strategic principles and approach to managing risk

To guide our business, we established a set of strategic principles: discover and develop a large pipeline in parallel; undertake sustained and long-term investment in technology creation; accelerate learning; integrate across critical parts of the value chain; and forward invest in capabilities and infrastructure. We apply these principles to critical capital allocation decisions such as: how much capital we devote to technology, drug discovery, development, and
infrastructure; which development candidates to advance and how; whether to advance development candidates alone or in collaboration with strategic collaborators or other sources of funding; and which capabilities to build internally versus outsource. In addition, we see four key risks inherent to our business—technology risk, biology risk, execution risk, and financing risk. We seek to actively manage these risks as we apply our strategic principles in our decision making. There is no single strategic principle nor single category of risk that dominates our decision making.

We aim to compartmentalize risk in part by using modalities, each of which is a group of programs that share a combination of technologies to create a common set of product features. Each modality is designed to overcome the challenges of delivering the right amount of mRNA to the right tissue at the right times across a portfolio of applications.

We currently have six modalities: prophylactic vaccines; cancer vaccines; intratumoral immuno-oncology; localized regenerative therapeutics; systemic secreted & cell surface therapeutics; and systemic intracellular therapeutics. In January 2020, we announced that we believe the Phase 1 data from the CMV vaccine and chikungunya antibody programs have de-risked the prophylactic vaccines and systemic and cell surface therapeutics modalities. As such, we have moved these to Core modalities and intend to bring new development candidates forward within these two areas.

We announced two new development candidates in systemic surface and cell surface therapeutics in January 2020 and three new development candidates in prophylactic vaccines in February 2020.

**Our platform**

We have created a platform to improve the underlying pharmaceutical properties of our mRNA medicines. Our platform consists of three core areas: mRNA technologies, delivery technologies, and manufacturing processes. We pursue mRNA science to minimize the undesirable activation of the immune system by mRNA and to maximize the potency of mRNA once in the target cells. We pursue delivery science to protect mRNA from extracellular enzymes that would degrade it, to deliver mRNA to desired tissues, and to facilitate the transport of mRNA across cell membranes to the translational machinery inside the cell. Finally, we pursue manufacturing process science to optimize these features for our potential mRNA medicines and to develop the technical capability to scale our mRNA for clinical development. We believe that our science provides the foundation for technology advancement, with the ultimate goal of identifying new modalities and expanding the utility of our existing modalities.

**Executing at scale on a broad pipeline**

Executing rapidly on many pipeline programs in parallel requires investment in scalable capabilities across the entire drug development value chain. mRNA has common chemical features, design rules, and synthetic processes that permit us to invest in scalable infrastructure, built on a digital backbone and enabled by automation, that is designed to generate and advance a broad pipeline. We stage our scale efforts into three infrastructure groupings, or engines, to: (1) advance new product ideas to development candidates, (2) move development candidates into early clinical trials for human proof of concept, and (3) advance these candidates through late-stage development, approval, and eventual commercialization. These engines are supported and enabled by our integrated digital investments, our highly talented and motivated team members, and our deep capital base, which in total allow us to execute effectively.

Manufacturing is a strategically critical component of our infrastructure, and in July 2018, we opened our 200,000 square foot current good manufacturing practices (“cGMP”) manufacturing facility. This facility provides us with significant supply chain integration, while also providing flexible capacity that can produce up to 100 cGMP lots per year to support our current and future pipeline. In February 2019, based on our anticipated future growth, we entered into a lease agreement for additional office and laboratory space in Norwood, Massachusetts, totaling an additional approximately 200,000 square feet.
We believe that digital technologies, such as robotics, automation, artificial intelligence, and cloud computing are critical to operationalize our strategy, accelerate our pace of learning, and execute at high quality and scale. Cloud enablement is a critical component of our digital infrastructure as we generate complex data sets, and our scientists need computational power and agility to operate without being limited by traditional computing technology. The Internet of Things allows for smart, interconnected devices that provide real-time synchronization of operations and the data from equipment provides real-time guidance to our scientists and engineers. Automation allows us to scale our operations reliably and reproducibly, continue to increase our operating efficiency, reduce errors, and improve our quality and compliance. Advanced analytics and artificial intelligence (“AI”) enable us to draw insights from our data; we are constantly generating large data sets that can provide important insights if mined appropriately. A few examples below demonstrate the benefits of our strategy:

- One approach 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.

- 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.

- We analyze the mRNA sequences produced in our Research Engine as part of our quality control requirements. Analysis of sequencing data can be cumbersome and time consuming. We are developing Bayesian models to accelerate the assessment of sequencing data and more rapidly provide our scientists with high quality mRNA.

Our strategic collaborators and investors

We have established a wide range of strategic alliances with leading biopharmaceutical companies, including AstraZeneca, Merck & Co., and Vertex Pharmaceuticals, as well as government-sponsored and private organizations focused on global health initiatives, including BARDA, DARPA, the Bill & Melinda Gates Foundation and the Coalition for Epidemic Preparedness Innovations (“CEPI”). Our strategic collaborators contribute their therapeutic expertise, provide significant capital, and over time have helped to validate our platform. Each of AstraZeneca, Merck & Co., and DARPA has entered into multiple strategic alliances with us. We have also raised funding from a diverse group of investors, including well-established global institutional investors. As of March 2, 2020, we have raised over $3.7 billion in total funding from our strategic collaborators and investors, including $563.0 million of net proceeds from our initial public offering in December 2018. This funding has enabled us to create our mRNA platform, establish cGMP manufacturing, including the build-out of our Norwood, Massachusetts facility, progress our pipeline of 24 development candidates across our 23 programs, and provide operational enterprise support. We have up to $2 billion to invest and create value (includes cash and investments of $1.26 billion, net proceeds of approximately $550 million from our financing in February 2020 and up to $185 million in additional grant funding).

Our team

We have assembled a team with deep scientific, clinical, manufacturing, business, and leadership expertise in biotechnology, platform research, drug discovery, and development. Our founding Chief Executive Officer, Stéphane Bancel, was previously the CEO of bioMérieux and managing director of Eli Lilly & Company, Belgium, before joining Moderna in 2011. Our board of directors is chaired by our co-founder Noubar Afeyan, Ph.D., Founder and CEO of
Flagship Pioneering, who has co-founded and successfully launched over 30 life science startups. Our leadership team and board of directors contribute a diverse range of experiences from leading companies and academic institutions including bioMérieux, Brigham Health, Eli Lilly & Company, Flagship Pioneering, GlaxoSmithKline, Goldman Sachs, Massachusetts Institute of Technology, McKinsey & Company, Motorola, Novartis, and Sanofi. The Chief Scientific Officer of our research platform was elected to the National Academy of Sciences in 2017 for her work on RNA. Our research efforts are also guided by world-class scientists and physicians on our Scientific Advisory Board, including Dr. Jack Szostak, the 2009 Nobel Laureate in Physiology or Medicine, and five members of the National Academies of Sciences, Engineering, and Medicine. We have assembled an exceptional team of approximately 830 employees, 50% of whom hold Ph.D., M.D., J.D., or Master’s degrees.

Our beginnings—Moderna and Flagship Pioneering

Moderna was founded in 2010 by Flagship Pioneering to develop and commercialize a new category of medicines to treat human diseases. Our early platform technology was conceived and launched by Flagship Labs (“FL”), the institutional innovation foundry of Flagship Pioneering, by an innovation team led by Dr. Noubar Afeyan (Moderna’s founding and current Chairman) working together with academic co-founders Dr. Derrick Rossi (Harvard Medical School), Dr. Robert Langer (MIT), and Dr. Kenneth Chien (Harvard Medical School). Inspired by chemically-modified mRNA used in cell culture experiments, the FL innovation team, working with a team of scientists assembled to launch Moderna, identified chemical modifications of mRNA, engineered mRNA sequences for greater in vivo potency, and demonstrated our first instances of in vivo protein expression. Stéphane Bancel joined Moderna’s Board of Directors in March 2011. Upon resigning as CEO of bioMérieux (BIM:FP), Mr. Bancel became Executive Chairman of Moderna and a Senior Partner at Flagship Pioneering in July 2011. He was then named Moderna’s founding CEO in October 2011.

Our mission

To deliver on the promise of mRNA science to create a new generation of transformative medicines for patients.

Our values

We execute against our strategy while being guided by our values:

- Quality, Integrity, and Respect: We believe these serve as the foundation upon which everything else is built.

- Bold: We are wholly committed to realizing the enormous potential of mRNA technology to transform the lives of patients.

- Collaborative: We know that the way to accomplish our goals is by working together, supporting each other, and respecting one another’s viewpoints. We act as one team.

- Curious: We are intensely curious and are always seeking to challenge and improve upon the status quo. We believe curiosity is the heart of innovation.

- Relentless: We are tenacious in the pursuit of our mission to bring medicines to patients. We learn from challenges and build on successes.
Our pipeline and progress

Our diverse pipeline comprises programs across six modalities and a broad range of therapeutic areas. A modality is a group of potential mRNA medicines with shared product features, and the associated combination of mRNA technologies, delivery technologies, and manufacturing processes. The following chart shows our current pipeline of 24 development candidates across our 23 programs, grouped into modalities.

<table>
<thead>
<tr>
<th>Modality</th>
<th>ID #</th>
<th>Program indication</th>
<th>Preclinical development</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3 and commercial</th>
<th>Moderna rights</th>
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<tr>
<td>Core modalities</td>
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<td>mRNA-1647</td>
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<td>Cytomegalovirus (CMV) vaccine</td>
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<td>Zika vaccine</td>
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<td>Merck to pay milestones and royalties</td>
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<td>Phase 2 dosing</td>
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<td>50-50 U.S. profit sharing; A2 to pay royalties, on ex-U.S. sales</td>
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<td>mRNA-6231</td>
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<td>MEI0119</td>
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<td>Solid tumors</td>
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<td>50-50 U.S. profit sharing; A2 to pay royalties, on ex-U.S. sales</td>
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<td>VEGF-A Myocardial ischemia</td>
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Abbreviations: A2, AstraZeneca; α-GAL, alpha galactosidase; BARDA, Biomedical Advanced Research and Development Authority; CEPI, Coalition for Epidemic Preparedness Innovations; DARPA, Defense Advanced Research Projects Agency; G6Pase, glucose 6-phosphatase; IL-2, interleukin 2; IL-12, interleukin 12; IL-23, interleukin 23; IL-36γ, interleukin 36 gamma; MUT, methylmalonyl-CoA mutase; PAH, phenylalanine hydroxylase; PCCA/PCCB, propionyl-CoA carboxylase subunit A/B; PD-L1, programmed death-ligand 1; VEGF-A, vascular endothelial growth factor A.

Our 24 development candidates are summarized by modality as follows:

Core prophylactic vaccines

- Prophylactic vaccines includes nine development candidates across eight programs: RSV vaccine (mRNA-1777 and mRNA-1172 or V172), CMV vaccine (mRNA-1647), hMPV/PIV3 vaccine (mRNA-1653), H7N9 vaccine (mRNA-1851) Zika vaccine (mRNA-1893), pediatric RSV vaccine (mRNA-1345), EBV vaccine (mRNA-1189) and novel coronavirus vaccine (mRNA-1273). Six programs have either an ongoing or completed Phase 1 trial, six of which have observed positive Phase 1 data to warrant continued advancement within a trial or further development, including hMPV/PIV3 vaccine, which has advanced into a Phase 1b age de-escalation clinical trial and CMV vaccine, which has advanced into a Phase 2 dose-escalation trial. For our global health program, discussions on funding our H7N9 vaccine program through approval are ongoing.
Recent key highlights for the development candidates in our prophylactic vaccines modality include:

- **RSV vaccine (mRNA-1777 and mRNA-1172 or V172):** The phase 1 study of mRNA-1172 led by Merck is ongoing. mRNA-1172 has shown enhanced potency in preclinical studies compared with the companies’ first RSV candidate mRNA-1777. Further development of mRNA-1777 has been paused. RSV causes upper and lower respiratory tract illness worldwide. To date, no effective vaccine to prevent RSV has been approved, and the only approved prophylaxis treatment is limited to the monoclonal antibody palivizumab, marketed as Synagis in the United States for pediatric patients at high risk for RSV infection. We have licensed worldwide commercial rights for mRNA-1172 to Merck.

- **CMV vaccine (mRNA-1647):** In January 2020, we announced positive seven-month interim safety and immunogenicity data after the third and final vaccination in the Phase 1 study of mRNA-1647. mRNA-1647 successfully immunized seronegative participants and boosted baseline titers in seropositive participants. The vaccine was generally well-tolerated. There were no vaccine-related serious adverse events, and the most common solicited local adverse reaction (AR) across all vaccinations was injection site pain. The most common solicited systemic ARs reported overall were headache, fatigue, myalgia and chills. Enrollment has been completed in the randomized, observer-blind, placebo-controlled, dose-confirmation Phase 2 study. Manufacturing and planning are underway for the pivotal Phase 3 study, which is expected to start in 2021. We own worldwide commercial rights to mRNA-1647.

- **hMPV/PIV3 vaccine (mRNA-1653):** The first participant in the Phase 1b age de-escalation study of mRNA-1653 has been dosed. In February 2019, we announced topline data from a first interim analysis of an ongoing Phase 1 clinical trial that showed that vaccination with mRNA-1653 boosted antibody titers one month after vaccination at all dose levels and was generally well-tolerated. No serious adverse events, adverse events of special interest, or adverse events leading to withdrawal were reported. Injection site pain was the most commonly reported solicited local adverse event and the most common Grade 3 adverse event. Topline data from a second planned interim analysis showed that hMPV and PIV3 serum neutralizing antibody titers remained above baseline through seven months. There is no approved vaccine for hMPV although this RNA virus has been determined to be one of the more frequent causes of upper and lower respiratory tract infections. We own worldwide commercial rights to mRNA-1653.

- **Zika vaccine (mRNA-1893):** The 10 µg, 30 µg and 100 µg cohorts in the Phase 1 study of mRNA-1893, which recently received Fast Track designation from the U.S. Food and Drug Administration ("FDA"), have been fully enrolled. mRNA-1893 is being developed in collaboration with BARDA within the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. We own worldwide commercial rights to mRNA-1893.

- **EBV vaccine (mRNA-1189):** We designated mRNA-1189 a new development candidate in February 2020. mRNA-1189 is an mRNA vaccine against Epstein-Barr virus (EBV) containing five mRNAs that encode viral proteins in EBV, gp350, gB, gp42, gH and gL. Similar to our CMV vaccine (mRNA-1647), the viral proteins in mRNA-1189 are expressed in their native membrane-bound form for recognition by the immune system. There is no approved vaccine for EBV.

- **Pediatric RSV vaccine (mRNA-1345):** We designated mRNA-1345 a new development candidate in February 2020. mRNA-1345 is an mRNA vaccine against respiratory syncytial virus (RSV) in young children encoding for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state. We intend to combine mRNA-1345 with mRNA-1653, vaccine against hMPV and PIV3, to create a combination vaccine against RSV, hMPV and PIV3. There is no approved vaccine for RSV.
- **Novel coronavirus (SARS-CoV-2) vaccine (mRNA-1273):** We designated mRNA-1273 a new development candidate in February 2020. Vials of mRNA-1273 have been shipped to the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH), to be used in the planned Phase 1 study in the US. mRNA-1273 is an mRNA vaccine against the novel coronavirus encoding for a prefusion stabilized form of the Spike (S) protein, which was selected by Moderna in collaboration with investigators at the NIAID Vaccine Research Center (VRC). Manufacture of this batch was funded by the Coalition for Epidemic Preparedness Innovations (CEPI). Currently there are no approved vaccines specific to SARS-CoV-2.

- Anticipated next steps in our prophylactic vaccines modality are: Phase 2 interim analysis at three months (one month after the second vaccination) and Phase 3 start for CMV vaccine (mRNA-1647), Phase 1b seropositive age de-escalation immunogenicity data readout for mRNA-1653, Phase 1 safety and immunogenicity data for mRNA-1172 and mRNA-1893, start of Phase 1 by the National Institutes of Health (NIH) for mRNA-1273 and IND filings for mRNA-1189 and mRNA-1345.

**Core systemic secreted & cell surface therapeutics**

- Systemic secreted & cell surface therapeutics includes five development candidates: antibody against Chikungunya virus (mRNA-1944), Relaxin (AZD7970), Fabry disease (mRNA-3630), PD-L1 (mRNA-6231), and IL-2 (mRNA-6981). The antibody against Chikungunya virus development candidate is in collaboration with DARPA and the program is being evaluated in a Phase 1 clinical trial. The Relaxin program, which is in collaboration with AstraZeneca, the Fabry disease program, the PD-L1 program and the IL-2 program are in preclinical development. Recent key highlights for our development candidates in our systemic secreted & cell surface therapeutics modality include:

  - **Antibody against Chikungunya virus (mRNA-1944):** In September 2019, we announced positive data in the first analysis of safety and activity in a Phase 1 clinical trial evaluating escalating doses of mRNA-1944 in healthy adults. mRNA-1944 resulted in a dose-related increase in levels of protein expression and achieved expected therapeutic levels at a well-tolerated dose (0.3mg/kg). No significant adverse events were observed at the low (0.1 mg/kg) and middle (0.3 mg/kg) doses; infusion-related adverse events were observed at the high dose (0.6 mg/kg), which resolved spontaneously without treatment. mRNA to protein translation in humans for mRNA-1944 was predicted by preclinical data. Dosing of the cohort at 0.6 mg/kg with steroid premedication has been completed. Dosing of an additional cohort with two doses of 0.3 mg/kg (without steroid premedication) given one week apart is expected. We own worldwide commercial rights to mRNA-1944.

  - **Entering into autoimmune therapeutic area (mRNA-6981 and mRNA-6231):** In January 2020, we announced the entry into a fifth therapeutic area, autoimmune diseases, building on the clinical validation of the systemic delivery of mRNA provided by the clinical proof of concept of the chikungunya antibody. Autoimmune diseases are characterized by immune activation in response to antigens normally present in the body, reflecting a loss of tolerance. Within this therapeutic area, we are developing two potential medicines, mRNA-6231 and mRNA-6981, designed to engage peripheral tolerance pathways to dampen autoimmune activation and help restore immune homeostasis, thereby reducing autoimmune pathology. Based on the introduction of these new development candidates, we updated the name of this modality.
from systemic secreted therapeutics to systemic secreted & cell surface therapeutics. In this modality, mRNA is delivered systemically to create proteins that are either secreted or expressed on the cell surface.

- Anticipated next steps in our systemic secreted & cell surface therapeutics modality are: Further development of the 0.6 mg/kg dose of mRNA-1944 and IND filings for AZD7970, mRNA-3630, mRNA-6231 and mRNA-6981.

Cancer vaccines

- Cancer vaccines includes two development candidates: Personalized cancer vaccine (“PCV”) (mRNA-4157) and KRAS vaccine (mRNA-5671). We are collaborating with Merck on both programs. Recent key highlights for our development candidates in our cancer vaccines modality include:

  - **PCV (mRNA-4157):** Interim data from the Phase 1 clinical trial of PCV showed that it was well-tolerated at all dose levels studied, including up to 1 mg, elicited neoantigen-specific T-cell responses in one patient, and there were no dose-limiting toxicities or Grade 3/4 adverse events or serious adverse events reported when administered as a monotherapy or in combination with pembrolizumab. The most common Grade 2 adverse events were fatigue, soreness at the injection site, colitis, and myalgias. These safety, tolerability, and immunogenicity data and the initial clinical activity observed support our randomized Phase 2 clinical trial investigating a 1mg dose of mRNA-4157 in combination with Merck’s pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resectable melanoma. This trial is ongoing and as of February 12, 2020, 25 patients have been dosed with either mRNA-4157 in combination with pembrolizumab or pembrolizumab alone. The Phase 1, open-label, multi-center clinical trial is ongoing to evaluate mRNA-4157 in combination with Merck’s pembrolizumab in subjects with unresectable solid tumors. As of February 12, 2020, 15 patients with resected solid tumors (melanoma, colon and lung cancers) received mRNA-4157 as adjuvant monotherapy after resection of their primary tumor. An additional 56 patients with metastatic, unresected solid tumors (melanoma, bladder, lung, colon, prostate, head and neck and endometrial cancers) received at least one dose of mRNA-4157 in combination with pembrolizumab. We share worldwide commercial rights to mRNA-4157 with Merck.

  - **KRAS vaccine (mRNA-5671):** The Phase 1 open-label, multi-center study to evaluate the safety and tolerability of mRNA-5671 both as a monotherapy and in combination with pembrolizumab, led by Merck, is ongoing. The clinical trial enrolls patients with KRAS mutant advanced or metastatic non-small cell lung cancer, colorectal cancer, or pancreatic adenocarcinoma, and centrally confirmed Human Leukocyte Antigen (“HLA”) HLA-A*1101 and/or HLA-C*0802 allele expression. mRNA-5671 is designed to generate and present the four most prevalent KRAS mutations as neoantigens to the immune system. We share worldwide commercial rights to mRNA-5671 with Merck.

- Anticipated next steps in our cancer vaccines modality are: Additional Phase 1 data and initial Phase 2 data for mRNA-4157 and initial Phase 1 data for mRNA-5671.

Intratumoral immuno-oncology

- Intratumoral immuno-oncology includes three development candidates: OX40L (mRNA-2416), OX40L/IL-23/IL-36γ ("Triplet") (mRNA-2752), and IL-12 (MEDI1191). OX40L is currently being evaluated in a Phase 1/2 trial that
includes a Phase 2 expansion cohort in patients with advanced ovarian carcinoma. Triplet and IL-12 are currently in Phase 1 clinical trials. Recent key highlights for our development candidates in our intratumoral immuno-oncology modality include:

- **OX40L (mRNA-2416):** The Phase 1/2 trial for mRNA-2416 is an open-label, multicenter study of repeated intratumoral injections of mRNA-2416 in patients with advanced relapsed/refractory solid tumor malignancies and lymphoma. The monotherapy arm of the study has been completed and we are not planning an expansion cohort of mRNA-2416 as a monotherapy. We have initiated a dose finding cohort at 4 mg mRNA-2416 given in combination with durvalumab (IMFINZI®) followed by a Phase 2 expansion cohort in ovarian cancer. mRNA-2416 encodes for OX40L, which is a membrane protein, a class of proteins that we believe cannot be manufactured for administration to tumor cells by recombinant technologies. mRNA-2416 is being developed for the treatment of solid tumors following local intratumoral injection. We own worldwide commercial rights to mRNA-2416.

- **OX40L/IL-23/IL-36γ (Triplet) (mRNA-2752):** The Phase 1 trial evaluating mRNA-2752 as a single agent and in combination with durvalumab in patients with advanced solid tumor malignancies and lymphoma is ongoing. As of February 12, 2020, 26 patients have been dosed with mRNA-2752 including 16 patients in monotherapy and 10 patients in combination with durvalumab. mRNA-2752 is an investigational mRNA immuno-oncology therapy that encodes a novel combination of three immunomodulators designed to activate the immune system to recognize tumors that are resistant to checkpoint inhibitors. We own worldwide commercial rights to mRNA-2752.

- **IL-12 (MEDI1191):** The Phase 1 open-label, multi-center study of intratumoral injections of MEDI1191 alone and in combination with durvalumab in patients with advanced solid tumors, led by AstraZeneca, is ongoing. MEDI1191 is an mRNA encoding for IL-12, a potent immunomodulatory cytokine. We share worldwide commercial rights to MEDI1191 with AstraZeneca.

- Anticipated next steps in our intratumoral immuno-oncology modality are: Phase 2 expansion cohort start for mRNA-2416 in patients with advanced ovarian carcinoma, complete Phase 1 dosing for mRNA-2752, and Phase 1 data for MEDI1191.

**Localized regenerative therapeutics**

- Localized regenerative therapeutics includes one development candidate: VEGF-A (AZD8601). The Phase 2a study of AZD8601 for VEGF-A for ischemic heart disease in patients undergoing coronary artery bypass grafting (CABG) surgery with moderately impaired systolic function, led by AstraZeneca, is ongoing. We have licensed worldwide commercial rights to AZD8601 to AstraZeneca. The anticipated next step for AZD8601 is receiving Phase 2a data.

**Systemic intracellular therapeutics**

- Systemic intracellular therapeutics includes four development candidates: MMA (mRNA-3704), PA (mRNA-3927), PKU (mRNA-3283), and GSD1a (mRNA-3745). The MMA program has enrolled the first patient in the Phase 1/2 study, study start-up is ongoing for the Phase 1/2 study in PA and the PKU and GSD1a programs are in preclinical
development. Recent key highlights for our development candidates in our systemic intracellular therapeutics modality include:

- **Methymalonic acidemia ("MMA") (mRNA-3704):** The Phase 1/2 open-label, dose escalation study has enrolled its first patient for the first cohort following a protocol amendment expanding the eligibility criteria to patients 8 years and older for the first cohort. This study is evaluating mRNA-3704 for the treatment of MMA due to methylmalonyl-CoA mutase (MUT) deficiency. We plan to initiate several sites outside the U.S. and recently received Medicines and Healthcare products Regulatory Agency (MHRA) approval in the U.K. The objectives of this study are to evaluate safety and tolerability, assess the pharmacodynamic response and characterize the pharmacokinetic profile of mRNA-3704. This is our first rare disease program to advance into clinical testing. The mRNA-3704 program uses the same LNP formulation as mRNA-1944. We own worldwide commercial rights to mRNA-3704.

- **MMA and Propionic Acidemia ("PA") Natural History Study ("MaP"):** This is a global, multi-center, non-interventional study for patients with confirmed diagnosis of MMA due to methylmalonyl-CoA mutase ("MUT") deficiency or PA and is designed to identify and correlate clinical and biomarker endpoints for these disorders. Enrollment in the study has been completed.

- **Propionic Acidemia ("PA") (mRNA-3927):** Study start-up in the U.S. is ongoing for the open-label, multi-center Phase 1/2 study of multiple ascending doses of mRNA-3927 in primarily pediatric patients with PA. The objectives of this study are to evaluate the safety and tolerability of mRNA-3927 administered via IV infusion, assess the pharmacodynamic response as assessed by changes in plasma biomarkers and characterize the pharmacokinetic profile of mRNA-3927. The mRNA-3927 program uses the same LNP formulation as mRNA-1944. We own worldwide commercial rights to mRNA-3927.

- **GSD1a (mRNA-3745):** We designated mRNA-3745 as a new development candidate for the rare inherited metabolic disease glycogen storage disease type 1a.

- Anticipated next steps in our systemic intracellular therapeutics modality are: Phase 1 data for mRNA-3704 and mRNA-3927 and IND filings for mRNA-3283 and mRNA-3745.

**Overall progress**

We dosed our first subject in a clinical trial in December 2015, five years after our inception. Since then, more than 1,700 patients and healthy volunteers have enrolled in our clinical trials and we or our strategic collaborators have achieved first-in-human dosing for a total of 16 different mRNA investigational medicines. Phase 1 clinical trials were, or are, being conducted to assess safety and tolerability of these investigational medicines, which, for all investigational medicines with data readouts to date, have provided sufficient data to warrant continued advancement within a trial or further development. However, for certain programs we have elected to advance follow-on candidates over earlier generation candidates despite generating Phase 1 safety and tolerability data in such candidates that would support additional dose escalation or clinical advancement. We recently announced that enrollment has been completed in the Phase 2 dose-confirmation study of MRNA-1647 in both CMV-seronegative and CMV-seropositive participants.
We have also observed the following activity in Phase 1 clinical trials for the following programs, with additional programs yet to read out:

- **Prophylactic vaccines - Virus neutralizing antibody responses in healthy volunteers in these six viral vaccine programs**: CMV vaccine (mRNA-1647), hMPV/PIV3 vaccine (mRNA-1653), RSV vaccine (mRNA-1777), H7N9 vaccine (mRNA-1851), H10N8 vaccine (mRNA-1440), and Chikungunya vaccine (mRNA-1388).

- **Systemic secreted & cell surface therapeutics - Antibody against Chikungunya virus (mRNA-1944)**: Detectable levels of CHKV-24 antibody in all participants, marking the first systemic mRNA therapeutic to show production of a secreted protein in humans.

- **Cancer vaccines - PCV (mRNA-4157)**: Neoantigen-specific T-cell responses supporting the initiation of a randomized Phase 2 clinical trial in combination with pembrolizumab.

- **Intratumoral immuno-oncology - OX40L (mRNA-2416)**: Protein production in tumor tissue from patients after intratumoral administration of mRNA-2416, an immune co-stimulator.

- **Localized regenerative therapeutics - VEGF-A (AZD8601)**: Dose-dependent protein production in patients, along with pharmacologic activity in the form of changes in local blood flow, directly quantified after intradermal administration of AZD8601.

**Forward-Looking Statements**

This Moderna, Inc. Company Overview contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning potential development candidate applications, development candidate activities, clinical program next steps, preclinical and clinical studies, expected clinical progression, enrollment and conclusions; regulatory submissions and approvals, risk management; the Company’s cash, cash equivalents and investments and grant funding status and the Company’s future expected net cash used in operating activities and purchases of property, plant and equipment and estimates and forward-looking projections with respect to Moderna or its anticipated future performance or events. In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this Moderna, Inc. Company Overview are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors, many of which are beyond Moderna’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, among others: preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore Moderna’s preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no mRNA drug has been approved in this new potential class of medicines, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; and those described in Moderna’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC’s website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements in this Moderna, Inc. Company Overview in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna’s current expectations and speak only as of the date hereof.