Dutch statutory board report and financial statements of CureVac N.V.

for the fiscal year ended December 31, 2020

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Dutch Statutory Board Report

1. Introduction

In this report, unless otherwise indicated or the context otherwise requires, all references to "CureVac" or the "Company," "we," "our," "ours," "ourselves," "us" or similar terms refer to CureVac N.V. and, where appropriate, its subsidiaries, including CureVac AG.

We own or have rights to various trademarks and trade names, including CureVac® and the CureVac logo that we use in connection with the operation of our business. This report may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. We do not intend our use or display of other entities' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity. Solely for convenience, the trademarks, trade names and service marks in this report are referred to without the symbols ® and ™, or SM, but the omission of such references should not be construed as any indication that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

1.1 Preparation

This report has been prepared by CureVac's management and has been approved by CureVac's management board (the "**management board**") and CureVac's supervisory board (the "**supervisory board**") pursuant to Section 2:391 of the Dutch Civil Code ("**DCC**"). It also contains (i) CureVac's financial statements within the meaning of Section 2:361(1) DCC and (ii) to the extent applicable, the information to be added pursuant to Section 2:392 DCC. This report relates to the fiscal year ended December 31, 2020 and, unless explicitly stated otherwise, information presented in this annual report is as at December 31, 2020. The financial statements included in sections 9 and 10 of this report have been prepared in accordance with the International Financial Reporting Standards, as adopted by the European Commission ("**EU IFRS**") and Part 9 of Book 2 of the DCC. The report of CureVac's independent auditor, Ernst & Young Accountants LLP, is included in section 11. The Dutch Corporate Governance Code ("**DCGC**") recommends that the report includes separate reports from the management board and the supervisory board. The report does also include the information that is required to be included in a supervisory board report.

1.2 Forward-Looking Statements

This report contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this report can be identified by the use of forward-looking words such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate" and "potential," or other similar expressions.

Forward-looking statements appear in a number of places in this report and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to of various factors, including, but not limited to, those identified under the section entitled "Risk Factors" in this report. These risks and uncertainties include factors relating to:

- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing of and our ability to obtain and maintain regulatory approval for our product candidates;
- the ability and willingness of our third party collaborators to continue research and development activities relating to our product candidates;

- the exercise by the Bill & Melinda Gates Foundation of withdrawal rights;
- our and our collaborators' ability to obtain, maintain, defend and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection;
- the rate and degree of market acceptance of our products;
- our ability to commercialize our product candidates, if approved;
- our ability and the potential to successfully manufacture our drug substances and delivery vehicles for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- general economic, political, demographic and business conditions in the United States and Europe;
- fluctuations in inflation and exchange rates in Europe;
- our ability to implement our growth strategy;
- our ability to compete and conduct our business in the future;
- our ability to enroll patients for our clinical trials;
- the availability of qualified personnel and the ability to retain such personnel;
- regulatory developments and changes in the United States and foreign countries including tax matters;
- our ability to overcome the challenges posed by the COVID-19 pandemic to the conduct of our business;
- other factors that may affect our financial condition, liquidity and results of operations; and
- other risk factors discussed under section 4.

You should read this report carefully with the understanding that our actual future results may be materially different from and worse than what we expect. If our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Other sections of this report include additional factors which could adversely impact our business and financial performance. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. Moreover, we operate in an evolving environment. Thus, new risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements.

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events or otherwise, except as required by law.

2. Company and business overview

2.1 History and development of the Company

On April 7, 2020, CureVac B.V. was incorporated under the laws of the Netherlands and became the holding company of CureVac AG in connection with our initial public offering on August 14, 2020, pursuant to the corporate reorganization. As part of the corporate reorganization, the legal form of CureVac B.V. was converted from a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a Dutch public company (*naamloze vennootschap*), and the articles of association of CureVac N.V. became effective. Following the Corporate Reorganization, CureVac N.V. became the holding company of CureVac AG and the historical consolidated financial statements of CureVac AG included in this Annual Report became part of the historical consolidated financial statements of CureVac N.V. Our legal and commercial name is CureVac N.V.

Our principal executive offices are located at Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany and our telephone number at this address is +49 7071 9883 0. Our additional offices are in Frankfurt am Main (Germany) and Boston (Massachusetts, United States).

Since August 14, 2020, our common shares have traded on Nasdaq under the symbol "CVAC." Our agent for service of process in the United States is CureVac Inc., located at 250 Summer St. 3rd Fl., Boston, Massachusetts 02210.

Under US law we are an emerging growth company and as such, we are eligible to, and intend to, take advantage, for up to five years, of certain exemptions from various US reporting requirements (not from DCC reporting requierements) applicable to other public companies that are not Emerging Growth Companies, such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

We would cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer" with at least $700 million of equity securities; (iii) the issuance, in any three-year period, by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov. Our website can be found at www.curevac.com. The information on our website is not incorporated by reference into this Annual Report, and you should not consider information contained on our website or any websites mentioned in this Annual Report to be part of this Annual Report.

Our capital expenditures for 2020, 2019 and 2018 amounted to €39.6 million, €20.1 million and €14.7 million, these expenditures were primarily for research and development and general administration.

As the result of our organic growth, our workforce has increased over the last three years from an approximate average workforce of 381 in fiscal 2018 to 486 in fiscal 2020.

2.2 Business overview

Overview

We are a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid that has the potential to improve the lives of people. Our vision is to revolutionize medicine and open new avenues for developing therapies by enabling the body to make its own drugs. Messenger ribonucleic acid, or mRNA, plays a central role in cellular biology in the production of proteins in every living cell. We are the pioneers in successfully harnessing mRNAs designed to prevent infections and to treat diseases by mimicking human biology to synthesize the desired proteins. Our technology platform is based on a natural approach to optimize mRNA constructs that encode functional proteins that either induce a desired immune response or replace defective or missing proteins using the cell's intrinsic translation machinery. Our current product portfolio includes clinical and preclinical candidates across multiple disease indications in prophylactic vaccines, oncology and protein therapy.

In our clinical pipeline for prophylactic vaccines, we are rapidly advancing our mRNA vaccine candidate, CVnCoV, against coronavirus (SARS-CoV-2), for which we initiated a Phase 1 dose-escalation trial in healthy volunteers in June 2020, a Phase 2a clinical trial in older adults in September 2020 and a pivotal Phase 2b/3 clinical trial in December 2020. For the Phase 1 clinical trial, we reported positive interim results on November 10, 2020, enabling us to select a recommended dose of 12µg to advance in the Phase 2a as well as in the pivotal Phase 2b/3 clinical trial. The Phase 2a clinical trial is a partially observer-blind, multi-centered, controlled, dose-confirmation trial, and is fully enrolled with 674 participants. Based on the detection of a relevant number of COVID-19 infections in the Phase 2a clinical trial, on March 31, 2021, we submitted a protocol amendment to include a secondary endpoint for vaccine efficacy. The secondary endpoint is expected to allow for the collection of relevant efficacy data in the total population of the trial with a focus on the subgroup of approximately 270 participants above the age of 60. We currently expect to report a first data readout for the Phase 2a clinical trial in the second quarter of 2021. Furthermore, on March 27, 2021, we filed a protocol amendment for the Phase 2a clinical trial to enroll approximately 40 adolescent participants between the ages of 12 and 17 in Panama and Peru, which is expected to start in the 2nd quarter 2021, and will form the first part of a broader study of this age group. Contingent on a successful safety review, it is planned to recruit a larger number of adolescent participants and allow for geographical reach into other Latin American countries and Europe. Further, age-related data is expected to be generated in an upcoming new Phase 2 clinical trial, focusing on immunogenicity, including a deep characterization of the immune response in older adults. In view of the current roll-out of authorised vaccination in this older target population, boosting of previous vaccination will be assessed in this Phase 2 clinical trial which will be performed at sites in France, and is expected to start in the second half of 2021. Our pivotal Phase 2b/3 trial is a randomized, observer-blind, placebo-controlled, multicentered study to evaluate efficacy and safety of CVnCoV, which has successfully completed recruitment, with approximately 40,000 participants. We currently expect to conduct a first case-driven interim analysis in the second quarter of 2021, depending on the infection rate of SARS-CoV-2 in clinical trial participants. An additional Phase 3 trial to evaluate the safety, reactogenicity and immunogenicity of CVnCoV in adults with an elevated risk of severe COVID-19 infection due to comorbidities was recently started. Selected comorbidities include obesity, chronic cardiovascular disease, chronic kidney disease, chronic obstructive pulmonary disease (COPD), HIV, type 2 diabetes mellitus and post-renal transplantation. This additional Phase 3 clinical trial is expected to enroll approximately 1,200 participants at multiple sites in Belgium. Furthermore, we plan to initiate a Phase 3 flu-co-administration study with our partner Bayer to assess compatibility of CVnCoV with established seasonal vaccines. The co-administered Phase 3 clinical trial is expected to enroll 1,000 participants in Argentina, Colombia and Peru. It will evaluate the safety, reactogenicity and immunogenicity of CVnCoV co-administered with a licensed quadrivalent influenza vaccine versus separate administration of the two vaccines in adults 60 years and older. In February 2021, we initiated a rolling submission with the EMA, which will allow the EMA to assess CVnCoV's compliance with standards for vaccine efficacy, safety and pharmaceutical quality as a prerequisite for a formal market authorization application. The rolling submission process with the EMA was started with the submission of a first preclinical data package and was recently advanced with two additional packages, including CMC data as well as first clinical data from our dose-escalation Phase 1 trial. Subject to the clinical trial results of CVnCoV, we expect to apply for conditional regulatory approval in the second quarter of 2021. On May 28, 2021, the independent Data Safety Monitoring Board (DSMB) confirmed that the pivotal Phase 2b/3 study (HERALD) for CureVac's first-generation COVID-19 vaccine candidate, CVnCoV, has completed a first interim analysis at 59 adjudicated COVID-19 cases. The DSMB confirmed that there were no safety concerns for CVnCoV. As a standard procedure within a blinded trial, CureVac has no access to trial data. The trial will continue to collect sufficient data in order to conduct statistically significant efficacy analysis. In addition, in April 2021, we initiated a rolling submission with Swissmedic, Switzerland's authority responsible for the authorization and supervision of therapeutic products, which will also allow Swissmedic to review the safety, effectiveness and pharmaceutical quality as a prerequisite for a formal market authorization application. We have already provided the first data package on CVnCoV to Swissmedic. In prophylactic vaccines, we are also engaged in a clinical program, CV7202, which we are currently investigating in a Phase 1 clinical trial for potential vaccination against rabies. In our clinical pipeline for oncology, we are investigating our lead oncology program, CV8102, in a Phase 1 clinical trial for the treatment of four types of solid tumors and an expansion cohort in advanced melanoma.

mRNA-based medicines represent a novel class of medicine that have the potential to address limitations of conventional treatment modalities. We believe the modular nature of mRNA has the potential for higher efficacy, greater speed and lower cost of production as compared to conventional treatment modalities. mRNA delivery enables direct production of any protein (secreted, membrane and intracellular) in the body and has shown a wide range of activity. The flexible chemical structure of mRNA, utilizing only four nucleotide buildings blocks, allows us to encode for a broad range of proteins with simple sequence changes, offering design versatility, specificity and limited off-target effects. Transient expression of mRNA limits the risk of irreversible changes to the cells' DNA and allows for modified dosing based on a patient's needs as well as opportunity for repeat dosing. We believe the modular nature of mRNA has the potential for higher efficacy, greater speed and lower cost of production as compared to conventional treatment modalities. We are leveraging these inherent advantages of mRNA-based medicines in the development of our mRNA technology platform.

We have built an extensive expertise in the fields of mRNA biology, optimization and production. We have continued to invest in developing our proprietary technology platform, which we refer to as the RNAoptimizer, over the past 20 years. We optimize mRNAs to preserve critical protein-RNA interactions as these are an inherent feature of the natural building blocks we employ. Our differentiated technology platform is designed to optimize each component of the mRNA-based medicine. Our RNAoptimizer platform is built on three core pillars:

- ***Protein design:*** optimizing the specific properties of encoded protein;
- ***mRNA optimization:*** optimizing characteristics such as half-life and translation efficacy of the mRNA molecule; and
- ***mRNA delivery:*** selecting the best-suited delivery system from our diverse portfolio of proprietary and third party delivery systems.

By leveraging each of these pillars, we have observed improved required protein expression levels while modulating the interaction with the immune system in preclinical and clinical trials. We continue to invest in all levels of optimization to improve the methods we currently employ and to further advance our mRNA-based medicines.

We consider our manufacturing process an important part of our strategy that allows us to match our flexible and versatile technology platform with equally flexible and versatile manufacturing setups to supply clinical developments as well as potential commercial demand. In the context of COVID-19, we are currently producing material for our vaccine candidate, CVnCoV, in our GMP III facility and building a broad and integrated European vaccine manufacturing network with highly experienced Contract Development and Manufacturing Organization partners for each of the key manufacturing steps for CVnCoV. Partners strengthening our European manufacturing network include Bayer AG, Celonic Group, Fareva, GSK, Novartis AG, Rentschler Biopharma SE and Wacker Chemie AG, among others, and we may enter into additional agreements in the future. With this network strategy, which includes our current partners but is set to further expand with additional partners, we are expecting to significantly increase our existing manufacturing capacities for CVnCoV to an overall annual output of up to 300 million doses in 2021 and approximately one billion doses in 2022, while managing potential supply chain risks. As part of the multistage manufacturing process, all manufactured doses are expected to go through extensive quality control protocols, which adds approximately up to three months before manufactured doses can be released for distribution. In house, we currently operate three GMP-certified suites, with the capacity to supply our clinical programs and support potential early commercialization activities. We are in the process of building a fourth GMP large-scale production facility at CureVac's headquarters in Tübingen, which is being designed to cover all manufacturing steps from starting material to formulation, and which could potentially supply materials for hundreds of millions of doses of our vaccine product candidates to support our future commercial launches. The GMP IV large-scale production facility is supported by the European Investment Bank. In addition to our GMP manufacturing facilities, we are developing a novel downsized, mobile and automated process for manufacturing of mRNA therapeutics, which we refer to as The RNA Printer®. With its modular design and decentralized concept, we believe that it could be used for a rapid response in outbreak scenarios or be placed as a stand-alone device in front lines of epidemic areas.

Our approach seeks to mitigate clinical and developmental risk across multiple levels to advance and expand our broad product portfolio. We have made advances in utilizing the potential of our technology platform through rational disease selection. We consider a number of factors in our

disease selection process, including unmet medical need, immune response, duration of expression, dosing requirements, delivery and targeted tissue types, among other factors. Our programs target the underlying modes of action of the disease that play a critical role in the pathology of the disease. We are initially targeting diseases that require an active immune response (such as prophylactic vaccines and oncology) and require transient expression of mRNA in tissue types that are more easily accessible. We believe these initial indications are amenable to localized delivery using a lipid nanoparticle, or LNP, delivery system. Following the encouraging results from our initial prophylactic vaccines program in clinical studies and based on our advanced understanding of mRNA biology and immune stimulation control, we have expanded our product portfolio to also target indications that require an immune silent approach (such as protein delivery), given the need for higher doses, repeated dosing and longer expression of the protein. These initial indications are using LNP delivery systems, or our proprietary polymer-based delivery system, which we refer to as the CureVac Carrier Molecule, or CVCM. Our access to a broad range of delivery systems allows us to target multiple tissue types.

In response to the global pandemic due to novel coronavirus 2019 disease, or COVID-19, we have rapidly advanced our mRNA vaccine program against the novel coronavirus, or SARS-CoV-2. Upon publication of the sequence of SARS-CoV-2 at the end of January 2020, we designed and optimized a variety of potential antigenic constructs based on the spike (S) protein to elicit high immunogenicity. Early exploratory data on these constructs indicated high immunogenicity and titers of S-specific binding and neutralizing antibodies in mice after a single vaccination. The results of our preclinical studies suggested that our vaccine candidate against SARS-CoV-2 was active at low dose and triggered fast induction of a balanced immune response with high levels of virus-neutralizing antibodies, or VNTs, and T-cell responses.

Based on the preclinical results, we initiated a Phase 1 dose-escalation trial in healthy volunteers in June 2020, a Phase 2a clinical trial in older adults above 60 years old in September 2020 and a pivotal Phase 2b/3 clinical trial in December 2020. We currently expect to report a first data readout for the Phase 2a clinical trial in the second quarter of 2021. On November 10, 2020, we reported positive interim Phase 1 data, which showed that our vaccine candidate induced relevant antibody titers as of the cutoff date of October 31, 2020. The quality of the immune responses observed in vaccinated healthy volunteers was found to be comparable to the immune response identified or detected in convalescent sera taken from recovered COVID-19 patients, thereby mimicking the immune response observed after a natural COVID-19 infection. We believe these interim data supported our decision to advance a 12µg dose in the pivotal clinical trial. Our pivotal Phase 2b/3 trial, called HERALD, has completed recruitment, with approximately 40,000 participants, above the age of 18. Of those participants, approximately 75% were enrolled in sites in Latin America and 25% were enrolled in sites in Europe. The study is randomized, observer blind, placebo-controlled, on a two-dose schedule and was started with an initial Phase 2b safety, reactogenicity and immunogenicity part, which was stratified according to age (participants between 18 and 60 years old and participants above 60 years old), and was completed in February 2021. Subsequently, the Phase 2 study merged into the current Phase 3 safety and efficacy trial. The Phase 2b/3 trial has a primary safety objective and two primary efficacy objectives: the demonstration of the efficacy of preventing first episodes of confirmed cases of COVID-19 of any severity in participants who have never been infected with SARS-CoV-2. Depending on the infection rate of SARS-CoV-2 in clinical trial participants, we currently expect to conduct a first case-driven interim analysis in the second quarter of 2021, depending on the infection rate of SARS-CoV-2 in clinical trial participants. Additionally, the rapid spread of new variants of SARS-CoV-2 across the world has supported the need to identify variants causing COVID-19 infections in the countries where our Phase 2b/3 study is being conducted. On March 30, 2021, we submitted a trial protocol amendment to the regulatory authorities to address presently circulating SARS-CoV-2 variants via the implementation of a corresponding secondary endpoint. We are working closely with many organizations on the development of this vaccine candidate. We are also producing material for our vaccine candidate in our GMP III facility and are building up a broad and integrated European vaccine manufacturing network with highly experienced Contract Development and Manufacturing Organization partners for each of the key manufacturing steps for CVnCoV. With this network strategy, which includes our current partners but is set to further expand with additional partners, we are expecting to significantly increase our existing manufacturing capacities for CVnCoV to an overall annual output of up to 300 million doses in 2021 and approximately one billion doses in 2022, while managing potential supply chain risks. As part of the multistage manufacturing process, all manufactured doses are expected to go through extensive quality control protocols, which adds approximately up to three months before manufactured doses can be released for distribution. The additional GMP IV large-scale production facility supported by the European Investment Bank at CureVac´s headquarters in Tübingen is currently in development.

In February 2021, we announced a new collaboration with GSK for our COVID-19 vaccine program, which went into effect in April 2021. With GSK, we will jointly advance so called second- or next-generation COVID-19 vaccine candidates, which will be based on new mRNA backbone concepts, encoding either for the original S protein or S protein mutations. Subject to regulatory approval, we are targeting to introduce new second-generation COVID-19 vaccine candidates in 2022. Additionally, we are currently negotiating the details of a collaboration with the United Kingdom government. The collaboration with the United Kingdom government is expected to include joint developments of vaccine concepts to address emerging COVID-19 variants through the government's Vaccine Taskforce, which is at the forefront of virus variant surveillance and expertise. Our potential collaboration with the United Kingdom government would grant us high-quality scientific input to select the most relevant mutations for new vaccine candidates against SARS-CoV-2 variants. Furthermore, the collaboration with the United Kingdom government is expected to be designed to fast-track the regulatory pathway of variant-optimized vaccines. Subject to regulatory approval, we are targeting to introduce variant-optimized first-generation COVID-19 vaccine candidates in early 2022.

Our next advanced prophlactic vaccine program, CV7202, is being developed for prophylactic vaccination against rabies. CV7202 is an mRNA that encodes the rabies virus glycoprotein, RABV-G, formulated with LNPs. We are currently investigating CV7202 in a Phase 1 clinical trial, evaluating safety, including reactogenicity, and immunogenicity. In January 2021, we published data from our Phase 1 trial of CV7202 in rabies. CV7202 induced adaptive immune response as shown by rabies-specific VNTs above the World Health Organization, or WHO, thresholds considered to be protective, after the second dose in all subjects, at the lowest 1µg and 2µg dose levels. We also showed that the lowest dose levels (1µg and 2µg mRNA) were generally well tolerated. We are currently assessing the timeline for advancing CV7202 into a Phase 2 clinical trial.

In oncology, we are exploring a range of potential approaches, including intratumoral therapy and novel cancer vaccines targeting neoepitopes and tumor associated antigens. Our lead oncology candidate, CV8102, is a complex of single-stranded non-coding RNA which has been optimized to maximize activation of cellular receptors that normally detect viral pathogens entering the cells (such as toll-like receptor 7, or TLR7, TLR8, and retinoic acid inducible gene I, or RIG-I pathways), mimicking a viral infection of the tumor. CV8102 is designed to recruit and activate antigen-presenting cells at the site of injection to present tumor antigens released from tumor cells to T cells in the draining lymph node. This potentially leads to activation of tumor-specific T cells, which can kill tumor cells at the injected site, but also at distant non-injected tumor lesions or metastases. CV8102 is currently being evaluated in a Phase 1 clinical trial for the treatment of four types of solid tumors — cutaneous melanoma, or cMEL, adenoidcystic carcinoma, or ACC, squamous cell carcinoma of skin, or SCC, and squamous cell carcinoma of head and neck, or HNSCC. As of October 5, 2020, we have enrolled 50 patients (29 in the single-agent cohort and 21 in the combination cohort with anti-PD-1) in the Phase 1 dose-escalation portion of the study. As of the cutoff date of October 5, 2020, in the single-agent CV8102 cohort, we observed one patient with a complete response and two patients with a partial response according to RECIST 1.1. In addition, nine patients experienced a best response of stable disease after eight-weeks of treatment (associated with shrinkage of non-injected lesions in one patient, shrinkage of injected lesion in one patient and shrinkage of both the non-injected and injected lesions in one patient). Of the 29 patients treated with single-agent CV8102, nine (31%) remained free of progression for ≥ six months as of the cutoff date. In the PD-1 combination cohort, one PD1 refractory melanoma patient experienced a partial response according to RECIST 1.1. As of the cutoff date, one PD-1 pretreated patient with HNSCC and one PD-1 refractory melanoma patient experienced stable disease after the eight-week treatment period and the melanoma patient showed regression of the injected and some non-injected lesions, while other non-injected lesions showed progression. In February 2021, we initiated the expansion of our Phase 1 study to confirm the safety, tolerability and efficacy of CV8102 at a 600µg dose, the selected dose to be advanced in a Phase 2 clinical trial. The expansion part of the Phase 1 trial will enroll 30 patients with PD-1 refractory melanoma, who will receive intratumoral injections of CV8102 in combination with PD-1 antibodies, as well as 10 patients who will be treated with CV8102 only.

Our development efforts for protein therapy are based on delivering optimized mRNAs to trigger production of antibodies or therapeutic proteins. Using our technology, we can instruct human cells to produce specific proteins in the nucleus, cytoplasm, cellular organelles, cell membrane, or get them secreted. Based on this "healthy" information delivered by mRNA, our cells can produce proteins, which are required to treat the disease caused by missing or inactive proteins. Protein therapy spans broad therapeutic areas and has the potential to be used as a treatment against infectious diseases in passive immunization (protection against an infectious disease with the encoding of the adequate protective antibody) and toxins (protection against a toxin with the encoding of the adequate protective antibody) and to be applied in many disease indications including

cancer (mRNA encoded cancer antibodies), cardiovascular diseases, and autoimmune diseases. Our mRNA optimization process, which is a core pillar of our RNAoptimizer platform, is designed to increase protein expression with the aim to reach therapeutic levels. In preclinical studies in non-human primates, we have demonstrated that antibodies encoded by mRNA can be produced in hepatocytes very rapidly and can reach therapeutic levels in the blood stream. We are also currently advancing multiple undisclosed programs in preclinical studies across eye disorders and lung diseases as well as delivering therapeutic antibodies.

To date, our revenues have consisted of upfront licensing payments, product sales and compensation for research and development services, all of which relate to our license and collaboration agreements. For the years ended December 31, 2018, 2019 and 2020, €12.9 million, €17.4 million and €48.9 million, respectively, or 100%, of our total revenue, in each respective year, was derived from our license and collaboration agreements.

The following is a summary of revenue by geographic area. Revenue is attributed to geographic region based on the location of our license and collaboration partner:

	2018	**2019**	**2020**
North America	69.4%	82.2%	71.3%
Europe	30.6%	17.8%	28.7%
Rest of the World	-%	-%	-%

We have built an intellectual property portfolio in the United States, Europe and other major geographies. As of January 15, 2021, we owned approximately 882 issued patents worldwide, including 63 issued U.S. patents, 57 issued European patents (which have been validated in various European countries resulting in a total of approximately 608 national patents in European countries), and 154 issued patents in other foreign countries, 125 pending U.S. patent applications, 73 pending European patent applications and 317 pending patent applications in other foreign countries. Our patent portfolio includes claims relating to our RNA technology platform, our CVCM delivery system and our CV8102, CV7202, CV-SSIV and CVnCoV product candidates.

We are led by a team of veterans with extensive experience in the biopharmaceutical industry, including experience in nucleic acid therapy, oncology, rare and infectious diseases and antibodies. Our management team as well as our supervisory board members have broad expertise in the clinical, regulatory and commercialization aspects of oncology, prophylactic vaccines and protein therapy as well as in drug development, process development and manufacturing for mRNA therapies. As of December 31, 2020, we had over 500 employees, including 154 employees with advanced scientific degrees. Since our founding in 2000, we have raised €1.66 billion in gross proceeds from a combination of equity and debt financings with an additional €50 million of external committed financing outstanding.

Our Product Portfolio

Our differentiated mRNA technology platform is designed to address a broad range of diseases across multiple therapeutic areas. Given the strengths of our platform, the broad potential of mRNA-based medicines and our rational approach to disease selection, we have chosen to leverage our platform to initially focus on advancing our product candidates in the areas of prophylactic vaccines, oncology and protein therapy.

A disease indication may require an approach that triggers an immune response (immune active) or that does not require immune activation (immune silent). Each of the disease indications that we are targeting require different levels of immune activation for the mRNA-based medicines to be effective. For the immune active side of our technology, we focus on RNA or mRNA-based medicines in prophylactic vaccines and oncology. For the immune silent side of our technology, we have expanded our preclinical product portfolio to include mRNA therapies based on the expression of therapeutic proteins (including ocular and lung applications).

** Unidentified indication.

Our lead proprietary programs include:

- Our lead vaccine candidate CVnCoV against SARS-CoV-2, which we have rapidly advanced in response to the global pandemic due to COVID-19. Based on the results of preclinical studies, we initiated a Phase 1 clinical trial in June 2020 and a Phase 2a clinical trial in September 2020. On November 10, 2020, we reported positive interim Phase 1 data and selected a recommended dose of 12µg for further clinical testing. In December 2020, we initiated a pivotal Phase 2b/3 trial.

- Our vaccine program, CV7202, is currently in a Phase 1 clinical trial as a vaccine candidate against rabies. In January 2021, Phase 1 data was published in a scientific journal. We are currently assessing the timeline for advancing CV7202 into a Phase 2 clinical trial.

- Our lead oncology program, CV8102, is currently in a Phase 1 dose escalating clinical trial for four types of cancers as a monotherapy and in combination with anti-PD-1. In February 2021, we initiated the expansion of our Phase 1 study to confirm the safety, tolerability and efficacy of CV8102 in patients with advanced melanoma at 600µg, the selected dose to be advanced in a Phase 2 clinical trial.

Our key partnered programs include:

- We have partnered with Boehringer Ingelheim for the development of BI1361849 (previously CV9202) which is a therapeutic vaccine candidate designed to elicit antigen-specific immune responses against tumor-associated antigens frequently overexpressed in patients with non-small cell lung cancer, or NSCLC. BI1361849 is currently being studied by the Ludwig Institute for Cancer Research in a Phase 1/2 clinical trial in NSCLC, in combination with durvalumab, a PD-L1 inhibitor, and tremelimumab, an anti CTLA-4 antibody.

- We have partnered with CRISPR Therapeutics for the development of novel Cas9 mRNA constructs for use in gene editing therapeutics, with improved properties such as increased potency, decreased duration of expression and reduced potential for immunogenicity. CRISPR Therapeutics has an exclusive license to the improved constructs in three of their *in vivo* gene editing programs.

- We have a broad strategic partnership with Genmab to leverage our mRNA technology platform to develop up to four mRNA-based novel therapeutic antibodies. This represents the first publicly announced strategic partnership focused on differentiated mRNA-based antibodies.

- We have received grants from the Bill & Melinda Gates Foundation to develop prophylactic vaccines designed to prevent picornaviruses, influenza, malaria and rotavirus.

- We are collaborating with CEPI on several vaccine projects including our first generation COVID-19 vaccine candidate, CVnCoV, and the development of programs against Lassa virus

and yellow fever. Further, we are collaborating with CEPI on the development of our RNA Printer. We also have several academic collaborations, including with SERI for target discovery research in mRNA-based eye therapy, and Yale University for target discovery research in mRNA-based pulmonary therapy.

* For further details on our collaboration agreements, see "section 2 — Business Overview — Collaborations."

** Unidentified indication.

(1) We have initiated a combined Phase 2b/3 clinical trial, called HERALD, for our COVID-19 vaccine candidate, CVnCoV, see "— RNA-Based Prophylactic Vaccines — COVID-19 Vaccines Program — CVnCoV Phase 2b/3 Clinical Trial."

(2) CEPI provided funding, which was used for our Phase 1 clinical trial, which has completed dosing and recruitment, but we are still monitoring patients. See "—Collaborations — Coalition for Epidemic Preparedness Innovations Framework Partnering Agreement."

Our Strengths

We are developing a broad portfolio of product candidates currently in preclinical or clinical development stages that we believe position us at the forefront of targeted immune active and immune silent mRNA medicines. Our key strengths include:

- ***We have a differentiated mRNA technology platform that has the potential to address a wide range of diseases.*** As the pioneers in the field of mRNA-based medicines, we have a deep understanding of mRNA biology, its interaction with the cellular translation machinery as well as the immune system. We have built our differentiated RNAoptimizer platform to incorporate these insights over the past 20 years. We optimize mRNA to preserve critical protein-RNA interactions as these are an inherent feature of the natural building blocks we employ. Given the potential advantages of the mRNA-based medicines over existing treatment modalities, such as potential for broad application, natural biology, wide range of activity, flexibility, design versatility, transient expression and a single manufacturing process, we believe that we have the potential to address a broad range of diseases across multiple therapeutic areas. Our technology platform has been validated in clinical and preclinical studies in selected disease indications.

- We have a broad portfolio of mRNA-based medicines in preclinical and clinical development stages being designed for efficacy, safety and protein expression at relatively low doses. The potential of our technology optimized for immune activation has been observed in multiple early-stage clinical studies. We are developing our product candidates and have conducted preclinical studies and initiated Phase 1 trials of several of our product candidates as well as

Phase 2a and Phase 2b/3 clinical trials for our COVID-19 vaccine candidate, CVnCoV. Additionally, CV7202, our prophylactic vaccine candidate trial against rabies, induced protective antibody titers above the WHO threshold in a Phase 1 study, following two doses as low as 1µg of mRNA. Our lead oncology product candidate, CV8102, for the treatment of four types of solid tumors through intratumoral treatment, has shown evidence of single-agent therapeutic activity with shrinkage of non-treated lesions, with limited treatment emergent adverse events. Our most clinically advanced vaccine product candidate, CVnCoV, is our mRNA vaccine program against coronavirus (SARS-CoV-2), for which we initiated a Phase 1 clinical trial in healthy volunteers in June 2020 and reported positive interim results on November 10, 2020. As of the cutoff date of October 31, 2020, the interim results showed that CVnCoV induced relevant antibody titers. The quality of the immune responses observed in vaccinated and healthy volunteers was found to be comparable to the immune response identified or detected in convalescent sera taken from recovered COVID-19 patients, thereby mimicking the immune response observed after a natural COVID-19 infection. We believe these interim data supported our decision to advance a 12µg dose in the pivotal clinical trial. A Phase 2a clinical trial evaluating CVnCoV in older adults was initiated in September 2020. The Phase 2a clinical trial is a partially observer-blind, multi-centered, controlled, dose-confirm trial, and is fully enrolled with 674 participants in Peru and Panama. Based on the detection of a relevant number of COVID-19 infections in the Phase 2a clinical trial, on March 31, 2021, we submitted a protocol amendment to include a secondary endpoint for vaccine efficacy. The secondary endpoint is expected to allow for the collection of relevant efficacy data in the total population of the trial with a focus on the subgroup of approximately 270 participants above the age of 60. We currently expect to report a first data readout for the Phase 2a clinical trial in the second quarter of 2021. Furthermore, on March 27, 2021, we filed a protocol amendment for the Phase 2a clinical trial to enroll approximately 40 adolescent participants between the ages of 12 and 17 in Panama and Peru, which is expected to start in the 2nd quarter 2021, and will form the first part of a broader study of this age group. Contingent on a successful safety review, it is planned to recruit a larger number of adolescent participants and allow for geographical reach into other Latin American countries and Europe. Further, age-related data is expected to be generated in an upcoming new Phase 2 clinical trial, focusing on immunogenicity, including a deep characterization of the immune response in older adults. In view of the current roll-out of authorised vaccination in this older target population, boosting of previous vaccination will be assessed in this Phase 2 clinical trial which will be performed at sites in France, and is expected to start in the second half of 2021.Our pivotal Phase 2b/3 trial was initiated in December 2020, and is fully enrolled with approximately 40,000 participants. The Phase 2b/3 trial is randomized, observer blind, placebo-controlled, on a two-dose schedule and was started with an initial Phase 2b safety, reactogenicity and immunogenicity part, which was stratified according to age (participants between 18 and 60 years old and participants above 60 years old), and was completed in February 2021. Subsequently, the Phase 2 study merged into the current Phase 3 safety and efficacy trial. We currently expect to conduct a first case-driven interim analysis of the pivotal Phase 2b/3 trial in the second quarter of 2021, depending on the infection rate of SARS-CoV-2 in clinical trial participants. Additionally, the rapid spread of new variants of SARS-CoV-2 across the world has supported the need to identify variants causing COVID-19 infections in the countries where our Phase 2b/3 study is being conducted. On March 30, 2021, we submitted a trial protocol amendment to the regulatory authorities to address presently circulating SARS-CoV-2 variants via the implementation of a corresponding secondary endpoint. An additional Phase 3 trial to evaluate the safety, reactogenicity and immunogenicity of CVnCoV in adults with an elevated risk of severe COVID-19 infection due to comorbidities recently started. Selected comorbidities include obesity, chronic cardiovascular disease, chronic kidney disease, chronic obstructive pulmonary disease (COPD), HIV, type 2 diabetes mellitus and post-renal transplantation. This additional Phase 3 clinical trial is expected to enroll approximately 1,200 participants at multiple sites in Belgium. Furthermore, in early May, we plan to initiate a Phase 3 flu-co-administration study with our partner Bayer to assess compatibility of CVnCoV with established seasonal vaccines. The co-administered Phase 3 clinical trial is expected to enroll 1,000 participants in Argentina, Columbia and Peru. It will evaluate the safety, reactogenicity and immunogenicity of CVnCoV co-administered with a licensed quadrivalent influenza vaccine versus separate administration of the two vaccines in adults 60 years and older. We are working closely with many organizations on the development of our CVnCoV vaccine.

In the immune silent area, our approaches optimized for protein therapies have been evaluated in multiple preclinical disease models.

- ***We have the ability to target different tissue types based on our delivery systems.*** We have access to a number of mRNA delivery systems, including third party and our proprietary systems, which allow us to target distinct tissues in an optimal way. Our initial clinical programs are based on localized delivery or using the LNP delivery system. Our prophylactic vaccine programs rely on LNP-based delivery systems administered intramuscularly and provide access to the immune cells. Moreover, LNP-based systems deliver mRNA efficiently to the hepatocytes in the liver, if administered intravenously. Protein expressed in the liver may either restore a specific function in the liver itself or produce secreted proteins for release into circulation. We rely on third party state-of-the-art LNP delivery systems for our initial clinical programs but we are developing our own proprietary LNP delivery system. In addition to LNPs, we have developed our proprietary polymer-based delivery system called CVCM, which allows us to further expand into other indications. CVCMs offer the ability to target indications that require localized, long-term dosing and create formulations that are appropriate for certain tissue types (such as lung, eye and mucosal).

- ***We have invested in building our in-house manufacturing infrastructure, capabilities and expertise to rapidly, efficiently and cost-effectively produce mRNA-based medicines at commercial-scale.*** We have continued to invest in our manufacturing platform since 2000 and have manufactured thousands of mRNA constructs and obtained manufacturing authorization for over 80 products. We consider our manufacturing process an important part of our strategy that allows us to continuously improve our technology platform and maintain flexibility in clinical development. In the context of COVID-19, we are currently producing material for our vaccine candidate in our GMP III facility and are building a broad and integrated European vaccine manufacturing network with highly experienced Contract Development and Manufacturing Organization partners for each of the key manufacturing steps for CVnCoV. With this network strategy, which includes our current partners but is set to further expand with additional partners, we are expecting to significantly increase our existing manufacturing capacities for CVnCoV to an overall annual output of up to 300 million doses in 2021 and approximately one billion doses in 2022, while managing potential supply chain risks. As part of the multistage manufacturing process, all manufactured doses are expected to go through extensive quality control protocols, which adds approximately up to three months before manufactured doses can be released for distribution. In house, we currently operate three GMP-certified suites, with the capacity to supply our clinical programs and support potential early commercialization activities. We are in the process of building a fourth GMP large-scale production facility at CureVac's headquarters in Tübingen, which is being designed to cover all manufacturing steps from starting material to formulation, and which could potentially supply for hundreds of millions of doses of our vaccine product candidates to support our future commercial launches. The GMP IV large-scale production facility is supported by the European Investment Bank. All of our mRNA-based active ingredients for various fields of application originate from a common technology platform and are based on identical source materials, which enables us to produce mRNA-based medicines using a substantially similar platform process concept.

- ***We have entered into strategic partnerships with leading biopharmaceutical companies and research and non-profit institutions to expand the applications of our technology platform.*** We have a history of partnering with leading biopharmaceutical companies such as Bayer AG, Boehringer Ingelheim, CRISPR Therapeutics, Genmab and GSK. We also have received research grants from the Bill & Melinda Gates Foundation and CEPI for the development of several prophylactic vaccines. Our academic collaborations are focused on identifying and evaluating novel targets in selected therapeutics areas. We have collaborations with SERI, and Yale University for eye disorder and pulmonary diseases, respectively. These partnerships and collaborations allow us to expand the application of our platform and bring in external expertise and capabilities.

- ***We have built an intellectual property portfolio in a variety of markets for our platform and product candidates.*** As pioneers in the field of mRNA therapies, we have built an intellectual property portfolio in the United States and other major geographies. As of January 15, 2021, we owned approximately 882 issued patents worldwide, including 63 issued U.S. patents, 57 issued European patents (which have been validated in various European countries resulting in a total of approximately 608 national patents in European countries), and 154 issued patents in other foreign countries, 125 pending U.S. patent applications, 73 pending European patent applications and 317 pending patent applications in other foreign countries. These patents include claims relating to our mRNA technology platform, our CVCM delivery system, CV8102, CV7202, and other product candidates. We

believe our patent applications and other patents are the most cited among mRNA companies' intellectual property.

- ***We have a long history of mRNA research and development and are led by an experienced management team.*** We are led by veterans of the biopharmaceutical industry with extensive experience in nucleic acid therapy, oncology, rare and infectious diseases, and antibodies. Our management team as well as our supervisory board members have broad expertise in the clinical, regulatory, and commercialization aspects of oncology, prophylactic vaccines and rare diseases as well as in drug development, process development, and manufacturing for mRNA-based medicines. Members of our management team have held senior positions at Bristol-Myers Squibb, GSK, Ipsen, LION Bioscience, McKinsey&Company, Pharmacia (Pfizer), Pixium Vision, Sirona Dental Systems, Sygnis Pharma AG, and other companies. Our broader team includes 164 individuals with advanced scientific degrees working on advancing our mRNA platform.

Our Strategy

Our goal is to build a leading, fully integrated mRNA-based medicines company that can transform the lives of people. The key components of our strategy include:

- ***Continue to invest in our proprietary technology platform to be the leading mRNA platform company.*** We intend to invest in our proprietary technology platform to broaden its potential across therapeutic areas, in addition to broadening our pipeline in existing therapeutic areas. We believe our continued investment will enable us to further optimize the three core pillars of our technology platform — protein design, mRNA optimization and mRNA delivery — and to further enhance our treatment approaches by offering higher selectivity, greater protein expression, potential combination therapies and reduced or flexible dosing. We are continuing to build on our deep expertise in mRNA-based medicines based on what we have learned from our current programs to apply to our future programs.

- ***Utilize a rational disease selection approach to minimize clinical and commercial risk for our programs and broader platform.*** Our strategy is to maximize the potential of our technology platform through our rational disease selection approach to clinical development. We are initially targeting diseases that require an active immune response (such as prophylactic vaccines and oncology) and require transient expression of mRNA in tissue types that are more easily accessible. Based on the proof of concept achieved in our clinical trials for these initial indications, we have expanded our product portfolio to target diseases that require an immune silent approach (such as protein therapy).

- ***Rapidly advance our lead product candidates through clinical development and regulatory approval.*** Our product candidates are currently in preclinical or clinical development stages. We have rapidly advanced our lead mRNA vaccine, CVnCoV against SARS-CoV-2 through preclinical studies. Based on the results from our preclinical studies, we initiated a Phase 1 study in healthy volunteers in June 2020 and a Phase 2a clinical trial in September 2020. On November 10, 2020, we reported positive interim Phase 1 data. In December 2020, we initiated a pivotal Phase 2b/3 trial. Given the urgency of the need for additional effective vaccines for COVID-19, we have initiated a rolling submission with the EMA and Swissmedic as an accelerated regulatory pathway. Our vaccine candidate, CV7202, is currently in development for the prophylactic vaccination of rabies. In January 2021, Phase 1 data was published in a scientific journal. We are currently assessing the timeline for advancing CV7202 into a Phase 2 clinical trial. Similarly, our lead oncology candidate, CV8102, is currently being evaluated in a Phase 1 clinical trial for the treatment of four types of solid tumors — cMEL, ACC, SCC and HNSCC. In February 2021, we initiated the expansion of our Phase 1 study to confirm the safety, tolerability and efficacy of CV8102 at 600µg, the selected dose to be advanced in a Phase 2 clinical trial, in an expansion cohort of patients with advanced melanoma.

  We believe that by initially targeting diseases with high unmet medical need, we will be able to rapidly advance our programs through clinical development. We intend to pursue the appropriate regulatory pathways available to further accelerate our development efforts.

- ***Continue to invest in our manufacturing capabilities across all manufacturing steps from starting material to formulation to further add scale and flexibility for potential commercialization.*** We believe that our manufacturing capabilities are a key strategic advantage that offer us flexibility, scalability, versatility and reliability in discovery

and development. Beyond the integrated European network of CMOs needed for the short term capacity increase for COVID-19, we are currently building our GMP IV facility, which is being designed to cover all manufacturing steps from starting material to formulation and would allow us to further scale up, reduce manufacturing time and reduce production costs. In addition, we are developing a new automated and mobile production concept, The RNA Printer®, which would enable downscaling of the production of mRNA material, allowing us to be more flexible and respond rapidly to manufacturing needs. We have successfully manufactured RNA batches with the first RNA Printer prototype and are currently establishing a first version of The RNA Printer® under cleanroom conditions to provide clinical trial material. In parallel, we are already developing a new version to further improve The RNA Printer® concept.

- ***Selectively seek strategic partners to develop and commercialize product candidates in certain therapeutic areas and geographies.*** We plan to continue to seek additional partnerships with other leading biopharmaceutical companies with specialized capabilities, including development and commercialization expertise in selected therapeutic areas and geographies. We may pursue partnerships that allow us to expedite the discovery and development of product candidates, complement our internal development expertise, broaden the breadth of our technology platform, and provide us with non-dilutive financing, while allowing us to retain economic rights to our product candidates that we view as strategically important. Our approach of partnering with a number of biopharmaceutical companies allows us to execute on a broad range of programs simultaneously, while mitigating our drug development risk.

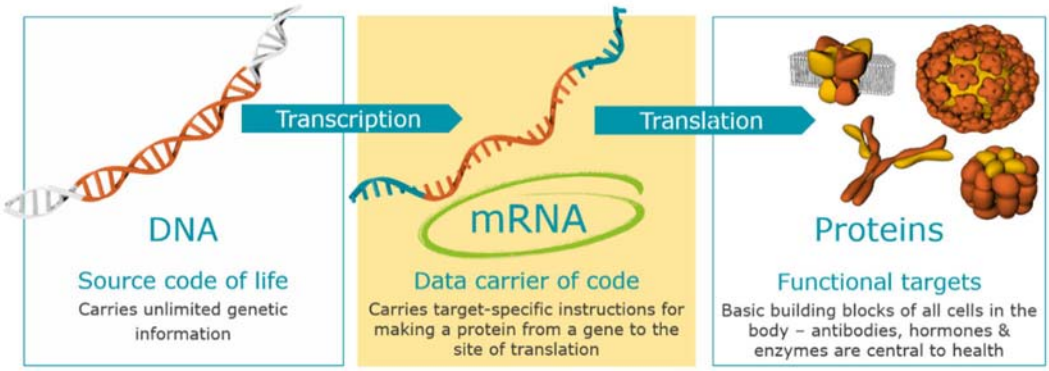
- ***Seek strategic acquisitions or in-licenses of technology or assets that are complementary to our programs and technology platform.*** mRNA-based medicines is an emerging field with ongoing advancements and discoveries. As the pioneers in the field, we have made significant strides in advancing and optimizing our technology platform over the past 20 years. We may seek acquisitions and in-licensing opportunities that can augment our internal expertise, expand our competitive differentiation and further enhance our mRNA technology platform.

- ***Strengthen and expand our intellectual property portfolio to protect our scientific and technical know-how.*** We intend to continue to strengthen and expand our intellectual property to protect our advances in scientific and technical know-how. Our intellectual property strategy is focused on covering advancements in our technology platform, manufacturing processes, and product candidates. In addition to patent protection, we also rely on trade secrets and confidentiality agreements to protect other proprietary information that is not patentable or that we elect not to patent.

Overview of mRNA Therapeutics

The Role of mRNA

mRNA is a molecule instructing the translation of genetic information encoded in DNA by cells into proteins, which carry out essential cellular functions. As depicted in the figure below, genetic information stored in DNA is transferred to mRNA in a process called transcription in the cell nucleus. In transcription, double-stranded DNA is temporarily unwound and copied into single-stranded mRNA by the enzyme RNA polymerase. mRNA is then transported to the cytoplasm where it instructs synthesis of proteins through a process called translation. In translation, cellular structures called ribosomes decode mRNA bases in groups of three (called codons) as amino acids. Each codon specifies a particular amino acid which are the building blocks of protein molecules which perform distinct functions within the body.



Limitations of Existing Treatment Modalities

There are several existing treatment modalities that seek to address the underlying cause of absent or defective proteins associated with diseases, including protein replacement therapy, gene therapy, gene editing, RNA interference and small molecule therapies. Other treatment modalities seek to harness the immune system, including antibody therapies and traditional prophylactic vaccines. Each of these treatment modalities have certain limitations as discussed below:

- *Protein Replacement Therapy:* While this approach has been successfully used to treat a subset of protein-based disorders, it is mostly limited to proteins that function outside of the cell.

- *Antibody Therapy:* Antibody therapeutics are largely administered intravenously and, being proteins themselves, have applications largely limited to surface molecules. In addition, antibodies have historically faced challenges due to their relatively large size, inadequate pharmacokinetics and tissue accessibility as well as unwanted interactions with the immune system.

- *Gene Therapy:* Gene therapy is usually a one-time intervention meant to provide lasting levels of therapeutic protein. While expected to be a one-time treatment, the duration of treatment efficacy is still largely unknown and it may not be amenable to repeat dosing due to neutralizing antibodies against the gene therapy vehicle. In addition, large-scale manufacturing is costly, time consuming and complex.

- *Gene Editing:* Despite its promise, gene editing is still in the early stages of development and has potential risks related to unwanted on and off-target DNA modifications, incomplete targeting or mosaicism that hinder intended modifications. Similar to gene therapies, manufacturing complexities and costs for gene editing are also challenging.

- *RNA Interference:* RNA interference has potential in silencing certain genes but has limitations in replacing defective or missing proteins, as well as highly expressed proteins. Most of the current efforts in this treatment modality are focused on genes expressed in the liver, with limited evidence of applications in extra-hepatic tissues.

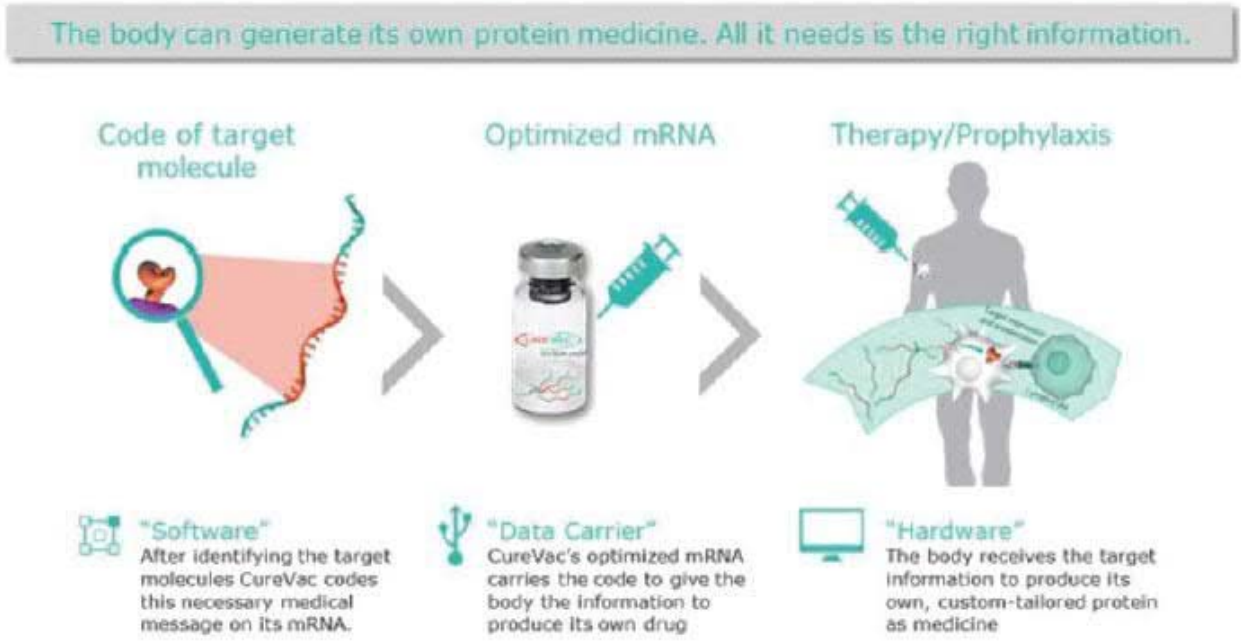
- *Small Molecule:* While small molecules offer advantages over other treatment modalities in terms of biodistribution, tolerability, and delivery, they do not directly address specific gene defects and have a high potential to cause off-target toxicities.

- *Traditional Prophylactic Vaccines:* While traditional prophylactic vaccines are one of the most successful and cost-effective global health interventions, their complex development and costly production processes create a high barrier to entry, long development cycle and limitation in developing vaccines with high serotype coverage.

mRNA as a Novel Treatment Modality

mRNA, as the universal template for protein synthesis, can direct the synthesis of any protein in the body. To treat a medical condition, we identify a target protein and encode the information required to synthesize this protein on the mRNA. The mRNA, optimized using our platform, carries this code to give a patient's body the information to produce its own, custom-tailored protein as medicine.

mRNAs are typically characterized by their rate of translation into protein and their short and predictable, yet steerable half-life. We optimize these mRNA properties for specific therapeutic needs to provide the most efficacious mRNA-based medicine. mRNAs provide the flexibility to deliver medicines that are required for a limited time as well as the opportunity to deliver repeated doses that can be adjusted to patient needs. The development and manufacturing of mRNA-based medicines can also proceed much more quickly than traditional protein-based therapies, including antibodies.



Key potential advantages of mRNA therapies that could position it as a novel treatment modality include:

- *Broad application:* mRNA has the ability to produce all types of proteins, including secreted, membrane and intracellular proteins. This enables broad applicability across a variety of diseases.
- *Natural biology:* mRNAs mimic human biology to produce proteins in the body in contrast to recombinant proteins that are manufactured using processes that are foreign to the body.
- *Wide range of activity:* mRNAs can be used to create therapies that can be applied as an agonist, an antagonist or for vaccines.
- *Flexibility:* A large number of alternative mRNA candidates can be generated in short time and tested to optimize both the mRNA and protein format.
- *Design versatility:* Therapeutic protein expressed from mRNA *in situ* can be designed for efficacy without being limited by the constraints which recombinant proteins are subject to.
- *Specificity:* mRNA-based medicines encode proteins which offer much higher specificity of interactions compared to small molecule drugs, which limits any potential off-target effects.
- *Repeat dosing:* mRNA-based medicines can be dosed repeatedly given their low immunogenicity.
- *Transient expression:* Short-lived expression of mRNA limits the risk of unforeseen adverse effects of lasting protein expression (as seen in gene therapy and gene editing) and allows for modified dosing schedules adjusted based on patient's needs.
- *Manufacturing:* mRNA production process is independent of the encoded protein as changes to the mRNA sequence do not affect its chemical and physical properties, allowing for higher efficiency, greater speed and lower cost of production.

Historical Challenges with Developing mRNA Treatments

Using mRNA as a treatment has long been of interest given its potential to address limitations of existing treatment modalities. However, mRNA has historically been limited by the following theoretical and practical hurdles:

- *Stability:* Naked mRNA is rapidly degraded by RNase enzymes present throughout the body which limits the duration of its therapeutic effect. An effective mRNA would need to be masked from these enzymes.

- *Uptake by cells:* Uptake of naked mRNA into cells is relatively inefficient. A more effective mRNA-based medicine would need a delivery system that delivers mRNA efficiently into cells.

- *Expression level:* Protein expression levels from synthetic mRNA obtained by *in vitro* production have been considered too low historically for therapeutic purposes, which underlines the need for an optimized mRNA construct.

- *Immunogenicity:* Non-optimized mRNA in the body rapidly activates receptors on immune cells which triggers the innate immune response and can lead to shut down of protein translation in cells. An effective mRNA-based medicine needs to modulate the immune system according to the disease indication being targeted.

- *Tissue targeting:* Each indication requires delivery to a specific tissue. An effective mRNA-based medicine would need a delivery system that efficiently delivers mRNA to a specific target tissue with low off-target delivery and toxicity.

- *Manufacturing:* mRNA manufacturing technology must be scalable and cost-effective to enable large production for multiple clinical trials and commercialization.

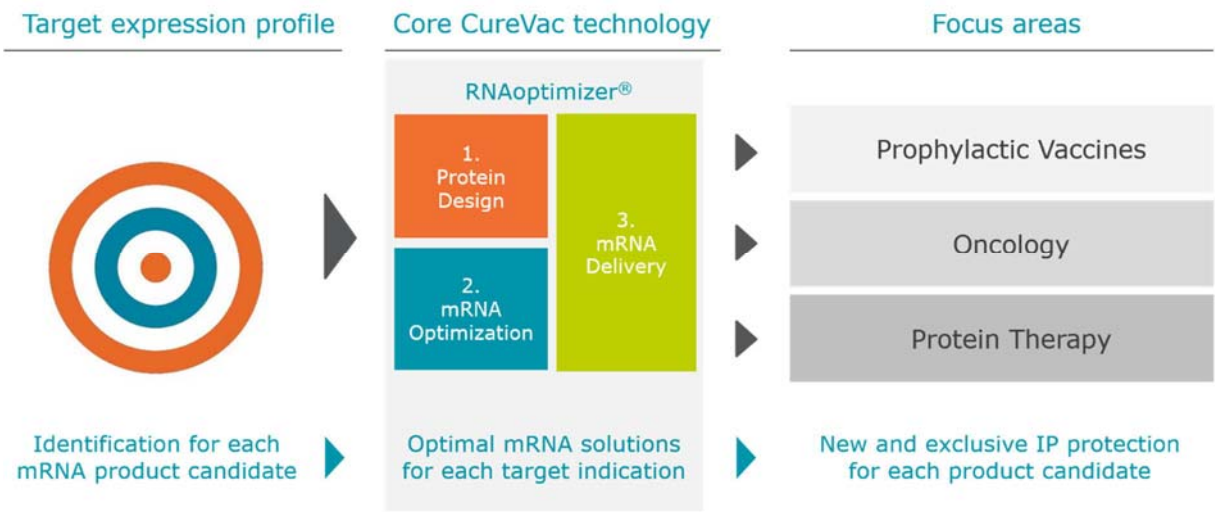
Our Proprietary Technology Platform

The therapeutic potential of mRNAs was discovered by our co-founders in 2000. As the pioneers in the field of mRNA, we have built extensive expertise in mRNA biology, optimization and production. We have developed our proprietary technology platform, called RNAoptimizer, through continued investments over the past 20 years. We believe that we have created the broadest and most versatile platform to develop optimized mRNA-based medicines that has potential to offer differentiated profile in terms of safety, stability and expression.

Our optimization approach covers three pillars: protein design, mRNA optimization and mRNA delivery. Our approach is based on the extensive data libraries we have generated to date. To improve protein expression from *in vitro* produced mRNA, we isolated high numbers of human natural mRNAs from different cells and identified elements which stabilize mRNA in a natural way and improve their interaction with the cellular translation machinery. We continue to invest in all levels of optimization to improve the methods we currently employ and continue advancing mRNA-based medicines.

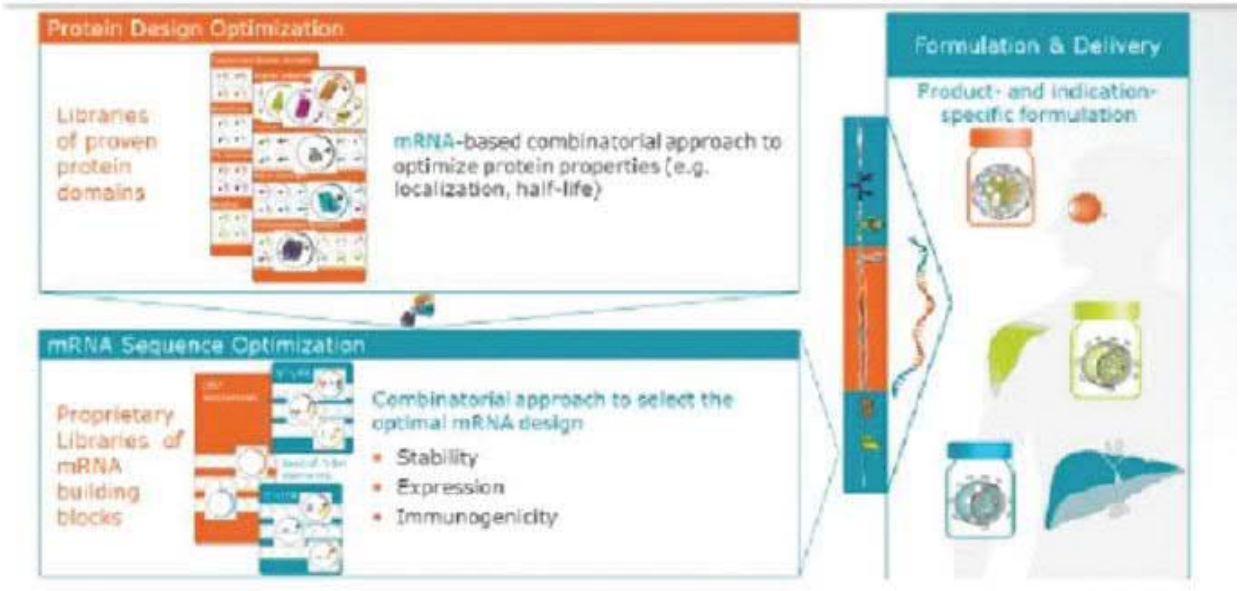
We have a long track record of performing clinical trials with multiple product candidates since 2008. The data generated in these clinical trials has allowed us to better understand the biology of mRNA and to further accelerate development in new therapeutic areas and approaches. We were the first company to demonstrate that mRNA vaccines can induce protective antibody titers in a naïve human subjects with a previous version of our current rabies vaccine product candidate.

Our product candidates consist of two major components: the protein-coding mRNA and a delivery vehicle. Once we have established delivery capability to a target tissue, we can design new product candidates that vary only in the mRNA component, which we expect will allow for rapid target and development candidate identification. We believe that this will enable our platform to be flexible and scalable as we develop additional product candidates.



Our process for creating novel mRNA therapies comprises the following three pillars:

- ***Protein Design:*** Our goal is to define the amino acid sequence to optimize specific properties of the encoded protein.
- ***mRNA Optimization:*** Our goal is to define the nucleotide sequence of the mRNA encoding the optimized protein to improve the properties of the mRNA molecule.
- ***mRNA Delivery:*** Our goal is to define mRNA encapsulation and delivery to select the optimal formulation for each specific indication and tissue.



First Pillar: Protein Design

Proteins play a central role in biology, including formation of the structural framework of the body, aiding in intra- and extracellular transport, biological catalysts (such as enzymes), controlling the activity of cells, and enabling signal transduction throughout the body. Accordingly, mutations that alter the function of a protein that plays a critical role inside the body can disrupt normal development and cause disease. Diseases could be caused by low expression, over expression, or abnormal structures for specific proteins.

We target diseases that are caused by these abnormal or missing proteins. Once our team identifies the protein of interest for a specific vaccine or therapeutic target with a defined target product profile, protein design further improves the potential efficacy by adaptation of the amino acid sequence. Protein design is based on modulation of beneficial protein characteristics that are

not present in the naturally occurring protein. We have a library of validated protein domains that can be leveraged using a combinatorial approach to optimize the properties of the target protein.

Our protein design process considers multiple factors before the protein is encoded in the mRNA, including half-life, stabilization of tertiary structure, oligomerization, secretion, and immunogenicity. We have the ability to modify each of these parameters while ensuring that these modifications work in harmony with the required function of the target protein.

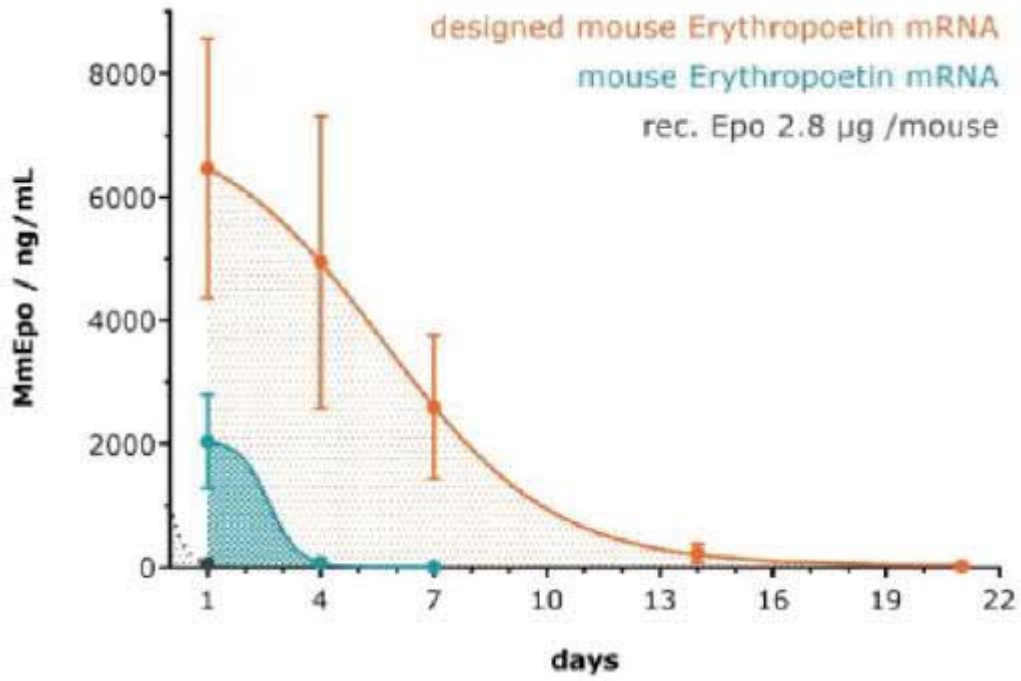
Protein design always depends on the function of the individual protein of interest. The protein can serve as a therapeutic protein without any activation of the immune system or the protein can serve as an antigen with the goal of inducing strong immune responses against it. We employ different optimization strategies to support these distinct functions and requirements. For example, we can enhance certain parameters to extend the half-life or localization of a protein in the case of therapeutic proteins while making sure that RNA sensors remain muted to avoid activation of the immune system. For vaccines, our goal is to induce an optimal immune response mimicking response induced by bacterial or viral infections. Therefore, protein design is always bespoke and multi-factorial to support distinct functions and requirements of the specific target protein.

Below are several specific examples of protein modifications by which we designed a protein's properties relative to the wild-type protein:

Extended Half-Life of Secreted Protein

This approach relies on the addition of supplementary short domains to the coding sequence of the protein of interest. Although this fusion increases protein size, the additional domains recruit binding proteins already present in blood which promote stabilization of the target protein by preventing proteolytic degradation. To support the efficient persistence of a secreted protein in the bloodstream, we can improve the half-life of this protein by adding specific, endogenous domains. By tailoring the pharmacokinetic profile of secreted proteins, we have the ability to reduce the frequency of dosing, generating a better therapeutic window, and using less material.

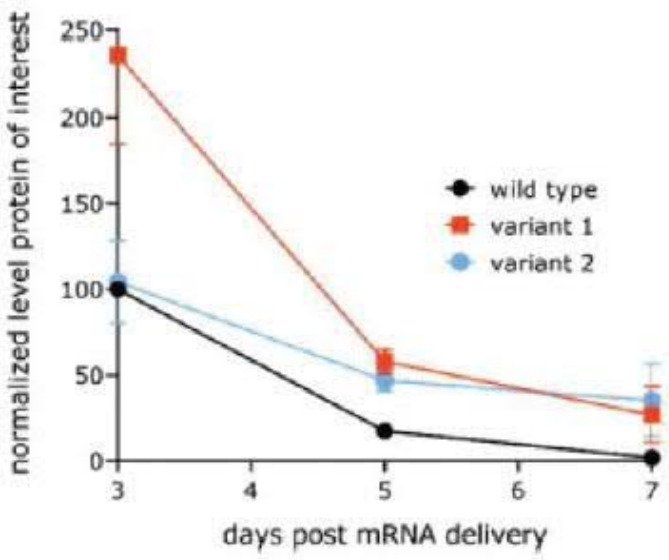
For example, wild-type erythropoietin (Epo) is a protein that has a very short half-life of three to four hours in the bloodstream. In a preclinical model, mice were dosed with mouse Epo and protein engineered mouse Epo, both encoded with our optimized mRNA. Dosing with the engineered mouse Epo protein showed an increase in serum titers and pharmacokinetic profile. We were able to increase the half-life and availability of functional Epo in blood from four days to two weeks by fusing endogenous Epo to a selected domain. Notably, both mRNA-encoded Epo proteins showed significantly higher protein expression levels than the injected recombinant Epo, which was cleared from the bloodstream after a single day.



Mice received a single injection in the tail vein of recombinant protein (control) or mRNA encoding proteins. Mice received 2.8 µg of recombinant mouse Epo protein. Wild-type Epo encoded by our optimized mRNA and engineered Epo protein encoded by our optimized mRNA were administered at a dose of 0.4 mg/kg giving rise to relevant serum titers of functional Epo and different pharmacokinetic profiles.

Extended Half-Life of Intracellular Protein

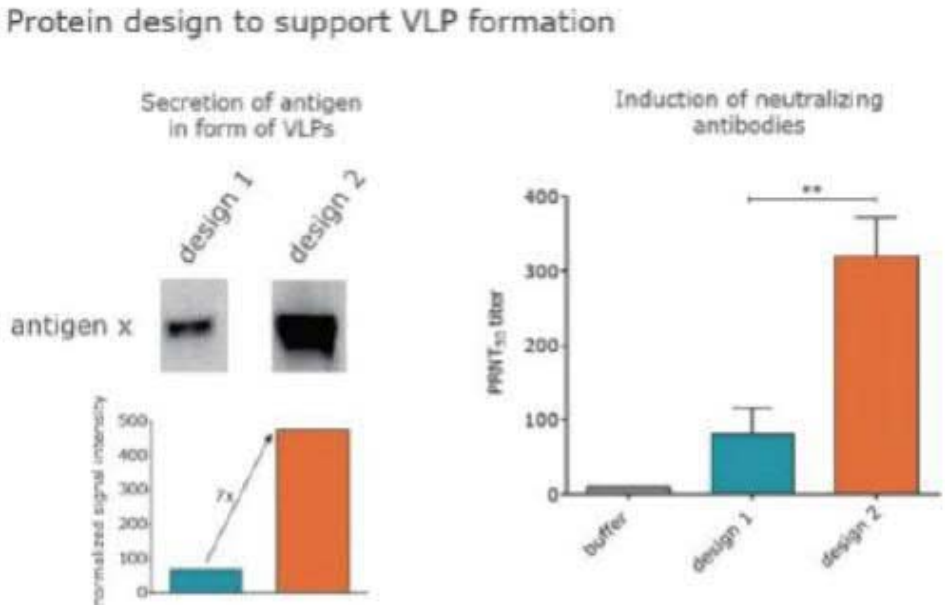
Similar approaches can also be applied to intracellular proteins, promoting the half-life of functional target proteins. In the example below, protein variant 1 represents the fusion of a protein of interest with a selected protein domain, while variant 2 represents a construct with a single point mutation within the protein of interest. In contrast to the wild-type protein, both engineered protein variants enabled the detection of protein even one week after mRNA delivery to hepatocyte cells in culture.



Intracellular abundance of engineered protein variants in comparison to unmodified wild-type protein. Protein levels were determined by whole cell Western Blot analysis in human hepatocytes, followed by normalization to signals from a cytosolic loading control and relative to the wild-type protein. Same doses used in wild-type and engineered protein variants.

Increased Oligomerization

Protein oligomerization is a process that converts monomers to macromolecular complexes through polymerization. We can engineer protein oligomerization by adding domains capable to perform this process to the target protein. As antigens need to be secreted and build clusters to form virus-like particles, or VLPs, this oligomerization process is beneficial in boosting the immune response.

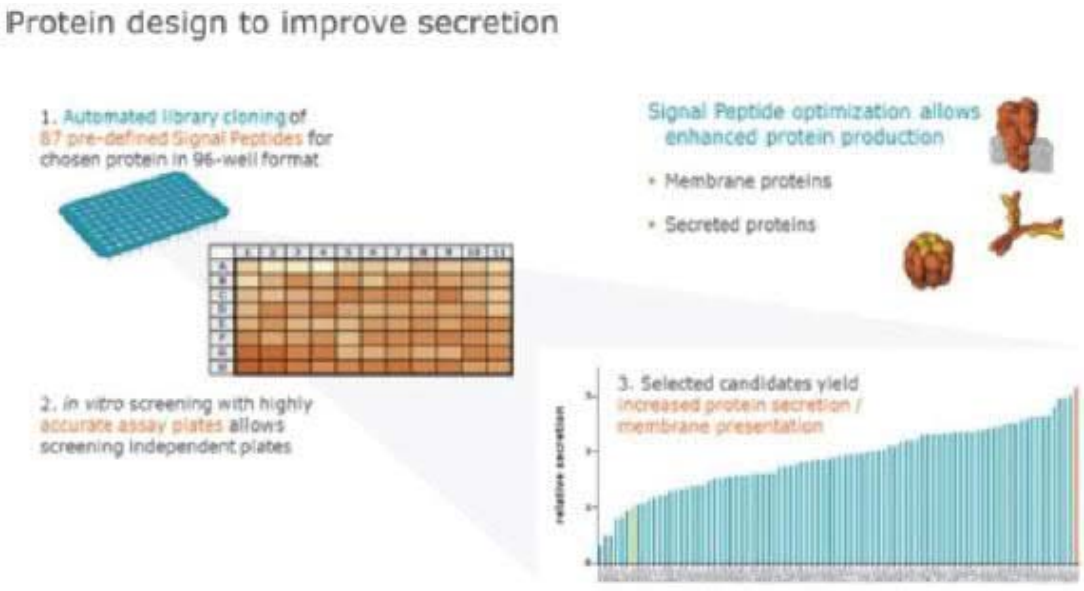


Protein sequence of viral antigen was optimized (design 2) by adding an element promoting secretion and clustering of antigen. In the left-hand side of the graphic, secretion of antigen in form of clusters was confirmed by Western Blot analysis of supernatants from transfected human cells. In the right-hand side of the graphic, vaccination of mice with an mRNA vaccine based on this improved protein design resulted in higher immunogenicity, measured by induction of virus neutralizing antibodies.

Improved Secretion

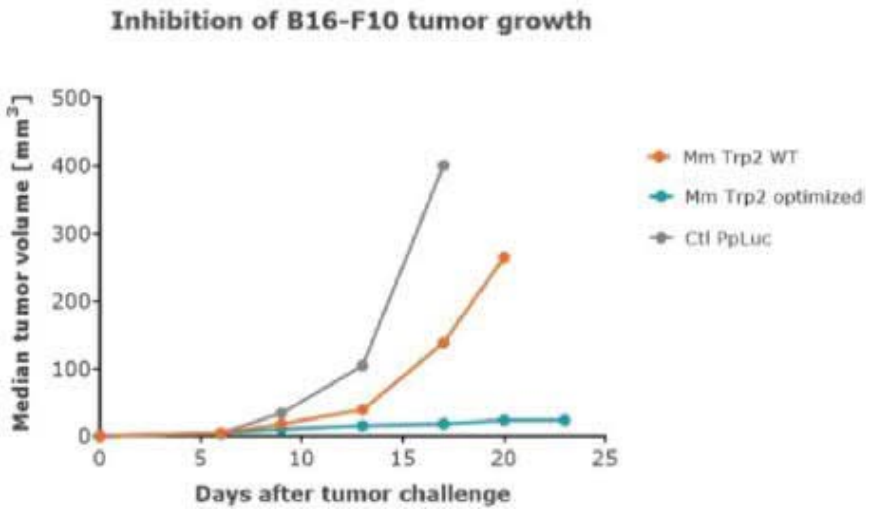
The potency of secreted target proteins can be improved by using alternative, more powerful signal peptides. These signal peptides are responsible for transporting the target protein from the cytoplasm to the outside of the cell, where the secreted protein fulfills its primary function. We screen large libraries of signal peptides to optimize secretion of any given target protein and in any cell type of choice.

For example, we selected a set of 87 verified signal peptides to maximize secretion. These were combined with the novel target protein via automated cloning to enable facile screening and selection of the most potent product candidate. In the figure below, the top hit from this screen increased the secreted protein levels in primary human muscle cells by three-fold relative to the native signal peptide.



Modified Immunogenicity

If the target protein serves as a therapeutic agent, it is important to curb the protein's natural immunogenicity. Our protein design process analyzes and replaces immunogenic epitopes, masking immunogenic epitopes and thereby rendering the target protein more immunosilent. In contrast, we also have the ability to improve immunogenicity for certain applications (for example in a cancer vaccine) by protein design. These protein sequence adaptations promote immunogenicity and suppress tumor growth in mouse models, as shown in the below example.

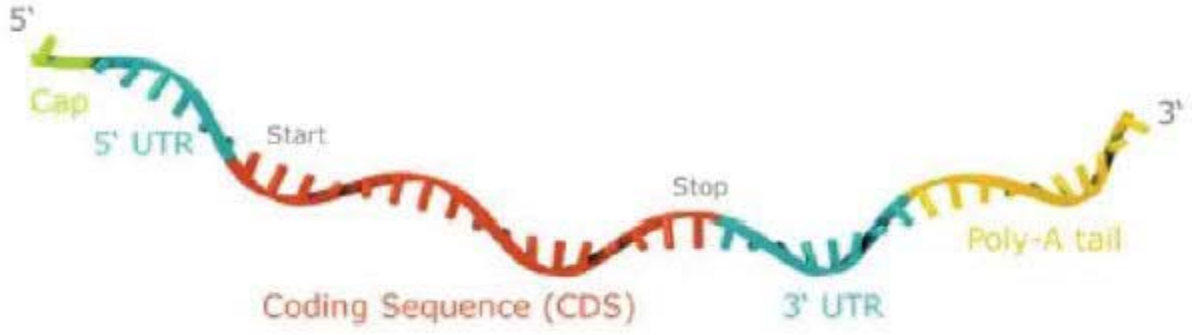


Therapeutic vaccination with mRNA vaccine encoding optimized Trp2 cell antigen inhibited tumor growth in murine melanoma model. Syngeneic mice were challenged subcutaneously with melanoma cells. When tumors were palpable, mice were vaccinated intradermally twice a week with LNP-formulated mRNA encoding either wild-type murine antigen Trp2 or Trp2 designed to improve antigen presentation. Mice vaccinated with LNP-formulated irrelevant mRNA (PpLuc) served as control.

Second Pillar: mRNA Optimization

Overview of mRNA Biology

mRNA is a linear polymer comprised of four monomers called nucleotides: adenosine (A), guanosine (G), cytidine (C), and uridine (U). The sequence at any mRNA's center instructing the synthesis of the protein encoded by it is the open reading frame (ORF, also known as coding sequence). The ORF is a continuous stretch of groups of three nucleotides (called codons) that is decoded and translated into protein by the ribosome. The process of translation begins at the first codon of the ORF, always an AUG (the start codon). The start codon signals to the ribosome where to start protein synthesis. The ribosome then progresses along the ORF one codon at a time, adding the amino acid to the protein chain fitting to the codon. A stop codon at the end of the ORF (UAA, UAG, or UGA) signals to the ribosome to terminate protein synthesis. In every cell, hundreds of thousands of mRNAs are translated into 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 sequence, mRNAs contain the following elements:

- Untranslated regions, or UTRs — UTRs are sequences that are not translated into protein. The 5′ UTR precedes the start codon, the 3′ UTR follows the stop codon. These regions play important roles in gene expression including mRNA stability, mRNA localization and translational efficiency via protein-RNA interactions. Some of the elements in the UTRs form characteristic secondary structures that are involved in mRNA regulation.

- 5′ cap — The cap structure is required to recruit ribosomes and additional proteins involved in translation to the mRNA.

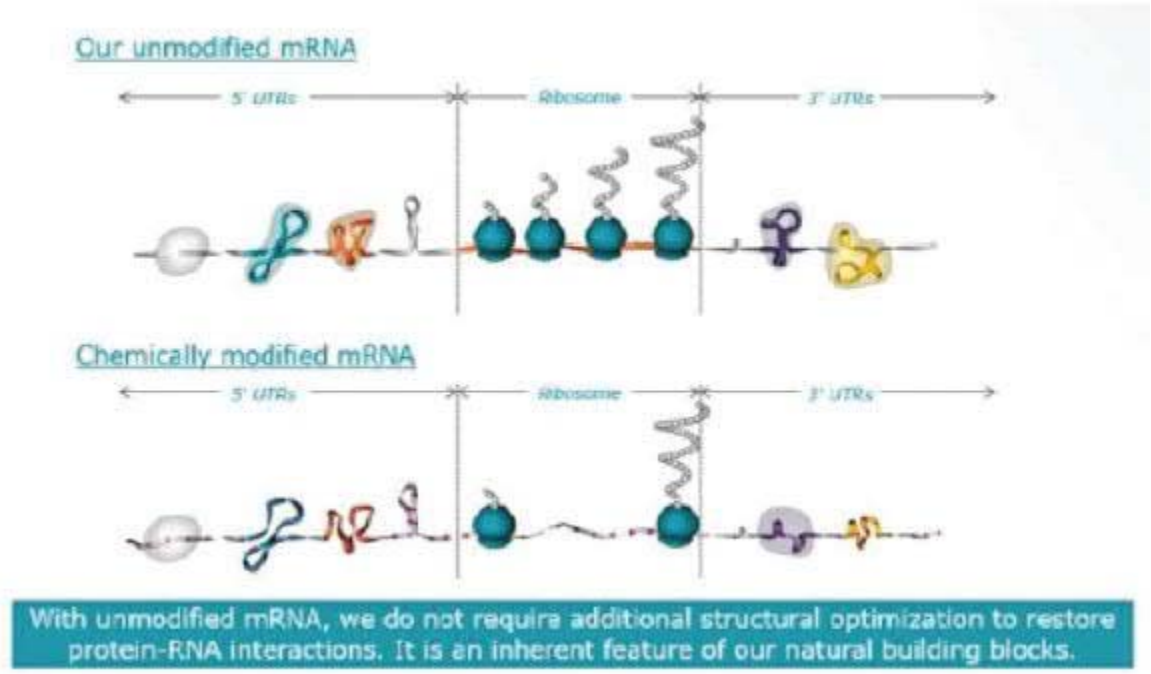
- 3′ polyadenosine, or poly-A, tail — The 3′ poly-A tail is a long sequence of adenosine nucleotides (often several hundred) at the 3′ end of mRNA. This tail promotes mRNA export from the nucleus and translation, and protects mRNA from degradation. In addition, the 3′ end of the mRNA can include a stretch or sequence of nucleotides following the 3′ poly-A tail.

Our Approach

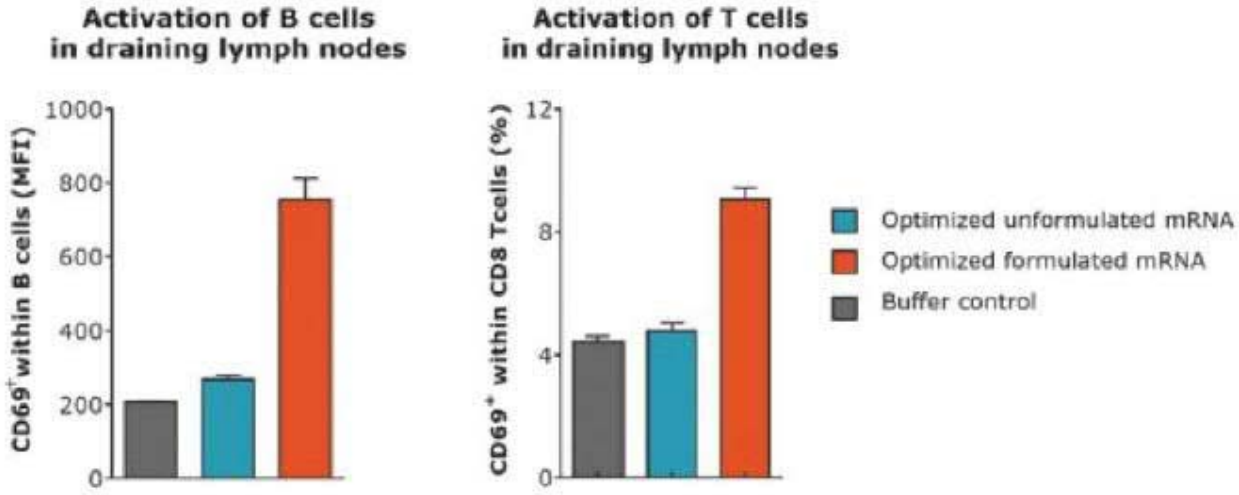
Our mRNA optimization process is designed to generate the most efficacious mRNA for any particular target and indication by optimizing translation, stability and immunogenicity. Each of these parameters can be modified by changing individual mRNA elements and their interplay guided by the envisaged application. Our mRNA molecule contains six elements that can be optimized to improve the potential efficacy of the mRNA construct. These elements include 5′ cap, 5′ UTR, ORF, 3′ UTR, and 3′ poly-A tail and 3′ end.

Depending on the target and indication, the required pharmacokinetics of protein expression might be different. Some applications may require the highest possible protein expression but only for a limited time, as is the case for gene editing approaches. For other applications, for example some protein replacement therapies, long-lasting protein expression might be key. Peak level and duration of protein expression can be adjusted by the choice or design of enhancer and stabilizing elements in untranslated regions of mRNA. Each of the mRNA elements together in combination with the overall sequence influence the degree of activation of the immune system by any particular mRNA. Therefore, our approach to RNA optimization always considers multiple factors as well as the whole construct to generate the optimal mRNA.

UTRs contribute decisively to the potential efficacy of therapeutic mRNAs. Natural mRNAs contain several different 5′ and 3′ UTRs, setting the individual level of translation and stability for each message. We have tapped this natural wealth of regulatory sequences and identified a large set of UTRs that confer translation or mRNA stability via diverse protein-RNA interactions. Producing mRNA *in vitro* using the four natural building blocks of mRNA (adenosine (A), guanosine (G), cytidine (C), and uridine (U)), we find that many of these UTRs retain their favorable properties also in combination with a heterologous ORF, for example in coding for a therapeutic protein of interest. Specifically, with our unmodified mRNA, no additional structural optimization to preserve or restore these critical protein-RNA interactions is required as these are an inherent feature of the natural building blocks we employ.



Historically, one factor limiting the use of mRNA as a treatment has been the observation that *in vitro* produced synthetic mRNA activated the innate immune system, resulting in a fast shutdown of protein translation in cells. An effective mRNA therapy would need to evade recognition by the immune system to avoid shut down of protein translation. We have accumulated significant knowledge about the signatures recognized by the innate immune system over the past few years. With the insights we have gained, we are able to avoid signatures activating the immune system in elements at our disposal or eliminate them from mRNA constructs. This is demonstrated by the following example where formulated mRNA was injected intradermally in mice and both B cells and T cells were activated in the draining lymph node. In contrast, unformulated mRNA injected intradermally had limited immunostimulatory capacity.



10 µg of mRNA, either free or formulated, was administered intradermally to the back of mice. 24 hours post treatment, draining lymph nodes were isolated and the activation status of immune cells was analyzed by flow cytometry. A higher CD69 signal indicates activation of the respective immune cells.

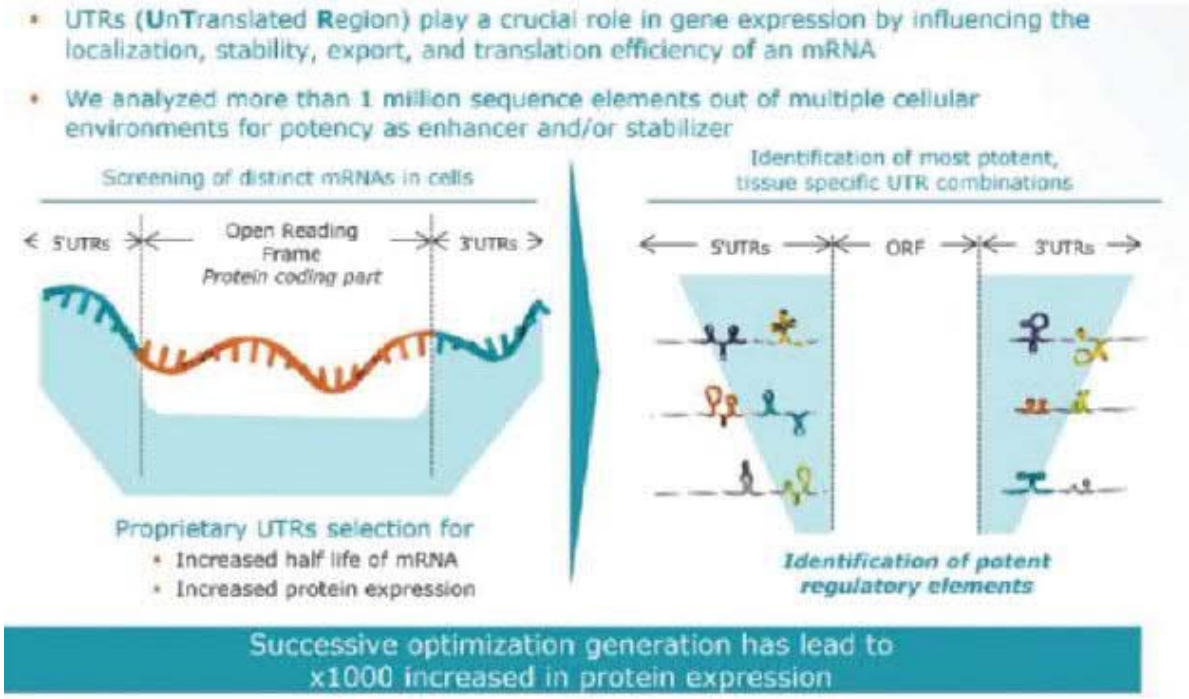
Cap Structure

The cap structure influences translation as it recruits the translational machinery including initiation factors and the ribosome. The cap structure also affects mRNA stability due to its influence on the various proteins recruited to mRNA. Further, the cap structure is a determinant of activation

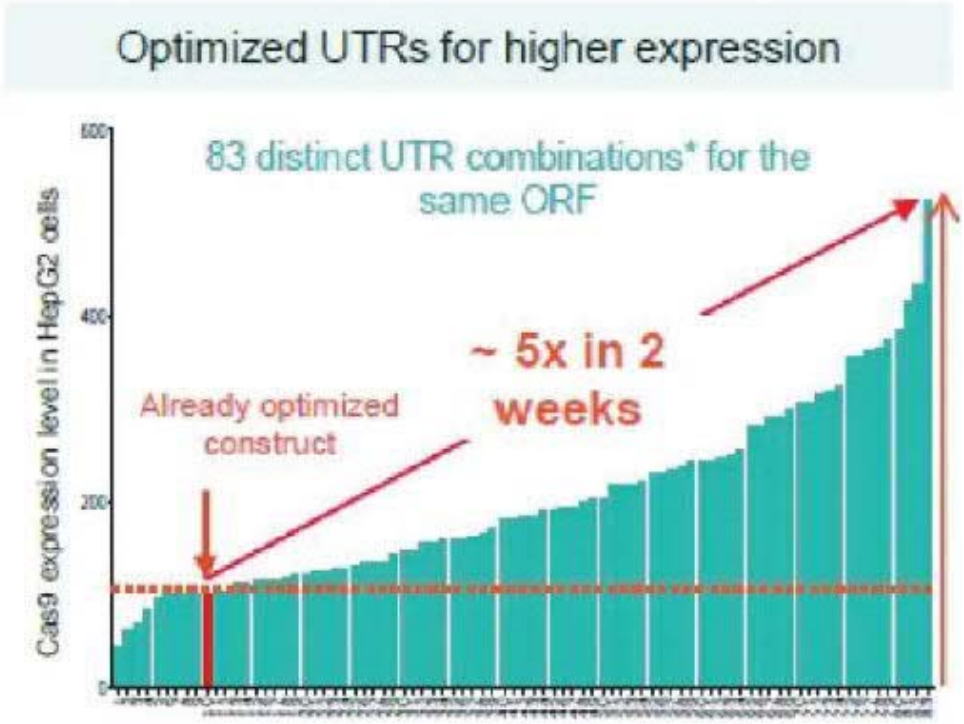
of the innate immune system as different cap structures are differentially recognized by several innate immune sensors. In addition, different cap structures are incorporated during *in vitro* production of mRNA with different capping efficiency, resulting in varying proportion of mRNA lacking a cap, which is an mRNA species which is recognized by yet other sensors of the innate immune system. Accordingly, there is great potential to improve protein expression and immunosilence in mRNA by optimizing the cap structure. We have access to several cap structures, including those we have developed and commercially available ones.

5′ and 3′ UTRs

We have identified high numbers of naturally occurring 5′ and 3′ UTRs. Using bioinformatics analysis to identify patterns of increased expression, duration of expression, and reduced immunogenicity, we have catalogued more than one million 5′ and 3′ UTRs. From these, we selected a large set of potential enhancer elements (improving the rate of protein expression) and stabilizer elements (improving half-life of protein expression). By running a high throughput combinatorial approach, we identify and create optimized UTR combinations for a specific construct. Further, we have created UTR sub-libraries because we discovered that different UTRs perform differently in various tissue types.



Below is an example of the effectiveness of our UTR library to optimize protein expression as part of our collaboration with CRISPR Therapeutics. An open reading frame coding for an optimized Cas9 protein was combined with 83 UTR combinations via automated cloning. This target-specific UTR screening increased Cas9 protein levels in HepG2 cells five-fold compared to an already optimized construct.

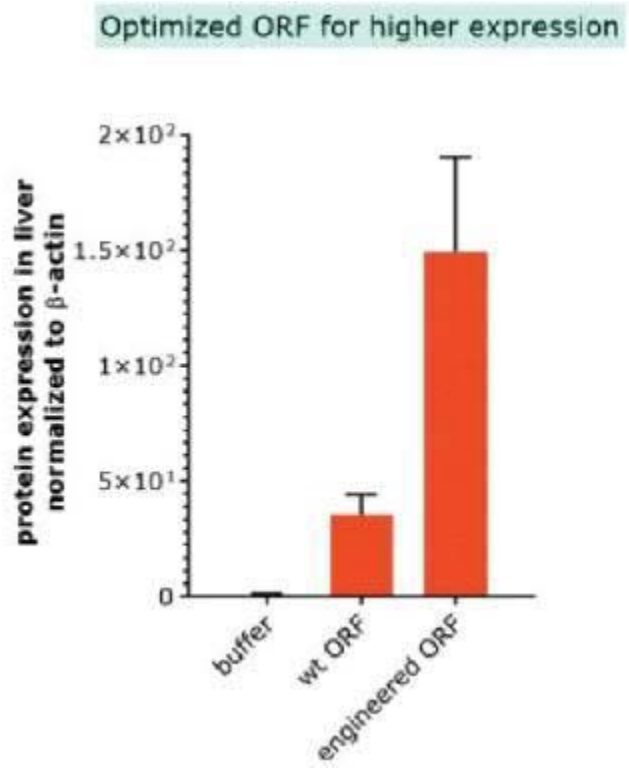


To maximize expression of the target protein a set of 83 combinations of untranslated regions (UTR) was selected from screens identifying stable or highly translated endogenous transcripts. These UTR combinations were combined with the target open reading frame (ORF) via automated cloning to enable facile screening and selection of the most potent product candidates. Target-specific UTR screening led to a five-fold increase in protein levels in HepG2 cells compared to an already optimized construct.

Open reading frame (ORF)

The ORF instructs the synthesis of the protein it encodes by the ribosome. The ORF is a continuous stretch of groups of three nucleotides called codons. Ribosomes decode each codon as an amino acid to be added to the nascent protein. Each codon specifies a particular amino acid, however, many amino acids are specified by more than one codon. Due to this multiplicity of codons that specify an amino acid, any protein can be encoded by a myriad of coding sequences differing in their codon composition. These various ORFs differ largely in their properties and for any particular protein a top-performing ORF needs to be identified or designed to make an efficacious mRNA-based medicine. We currently optimize the ORF in a broad, holistic approach that includes multiple parameters taking into account codon optimality. Our algorithms also take into account that, similar to UTRs, different codons are optimal for different tissues. Furthermore, these algorithms also analyze and consider secondary structure. For example, as certain elements are known to drive immune stimulation by secondary structure, our algorithms avoid generation of sequences that may give rise to such immune stimulations.

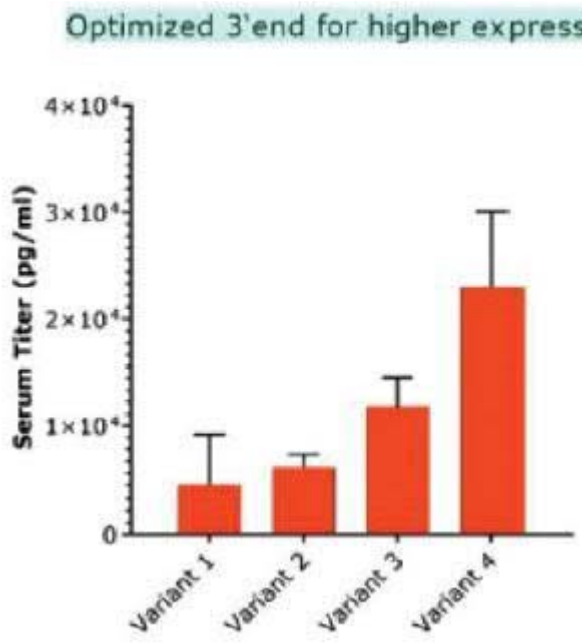
In the following example, protein expressed from our mRNA containing a wild-type coding sequence was abundant in the livers of mice injected intravenously with LNP-encapsulated mRNA. However, protein levels were higher from our mRNA containing a coding sequence engineered for maximal protein expression.



Abundance of a therapeutic protein in mouse liver expressed from an engineered open reading frame (ORF) in comparison to the wild ORF. mRNAs containing ORF variants were formulated in LNPs and injected intravenously into mice (called engineered ORF). Protein levels were determined by Western Blot analysis of liver lysates, followed by normalization to the signal from a loading control.

Poly(A) tail and 3' end

The 3' end of the mRNA molecule, prone to degradation by nucleases, is another form of optimization. The 3' end can be sealed using different stabilizing elements, including secondary structure or specific nucleotide sequences, to inhibit RNA nucleases degrading RNA from the 3' end.



Impact of different mRNA 3' end on serum levels of a therapeutic protein. mRNAs containing different vector-encoded 3' end variants were formulated in LNPs and injected intravenously at a dose of 20 µg into female Balb/c mice. Six hours after injection, serum levels of secreted protein were determined by an enzyme-linked immunosorbent assay test, also referred to as ELISA, to measure antibodies in blood.

Finally, we analyze the structure of the optimized mRNA as a whole including ORF and UTRs to predict its recognition by RNA sensors and immune activating potential and modify any inappropriate elements.

Third Pillar: mRNA Delivery

The potency of the administered mRNA drug product is the combination of the potential efficacy of the mRNA that encodes the protein and the delivery system that transports the mRNA to the cells. Protein levels are highly correlated with the number of transfected cells which requires optimized delivery systems. While it is possible to deliver mRNA directly into the target tissue without delivery systems in certain cases, the presence of RNA degrading enzymes in blood and interstitial fluids rapidly regrade any extracellular mRNA. Additionally, cell membranes act as a significant barrier to entry of large molecules such as mRNA. These delivery technologies enable us to deliver large quantities of mRNA to the target cells.

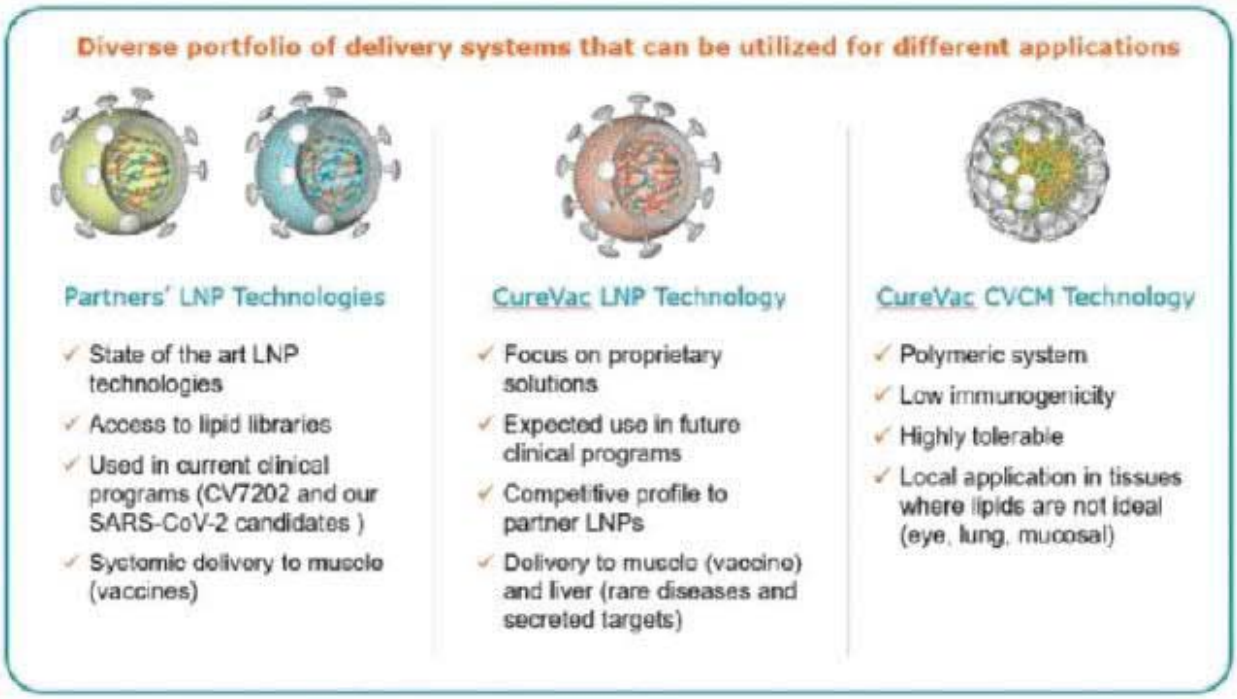
We have access to a diverse portfolio of third party and proprietary delivery systems that allow us to target a range of diseases. Access to this broad range of delivery technologies allows us to select the best-suited technology for development of each of our product candidates. We choose the most suited delivery system based on a number of factors including immunogenicity, duration of treatment, dose levels, mode of administration and targeted tissue type.

The key delivery systems that we currently employ include:

- Lipid-based delivery systems — We employ lipid nanoparticles, or LNPs, to deliver our mRNA-based prophylactic and cancer vaccines locally. For protein and antibody therapeutic candidates, we apply LNP-formulated mRNA systemically. We have relied on third party state-of-the-art LNP delivery systems for our initial clinical programs, and we are developing our proprietary LNP delivery systems for our future clinical programs.

- Polymer-based delivery systems — We employ our novel, proprietary PEGylated polymer system, the CureVac Carrier Molecule, or CVCM, to administer therapeutic candidates to such organs as eye and lung. CVCMs are designed to be delivered locally and their administration method may vary (injection, nebulization, among others) due to the robustness of the formulation.

LNPs and CVCM delivery technologies complement each other in their applicability and enable us to cover a greater number of modalities within the mRNA space. With these delivery modalities at hand, we are currently expanding our development pipeline and plan to bring new mRNA therapies to different organs and applications.



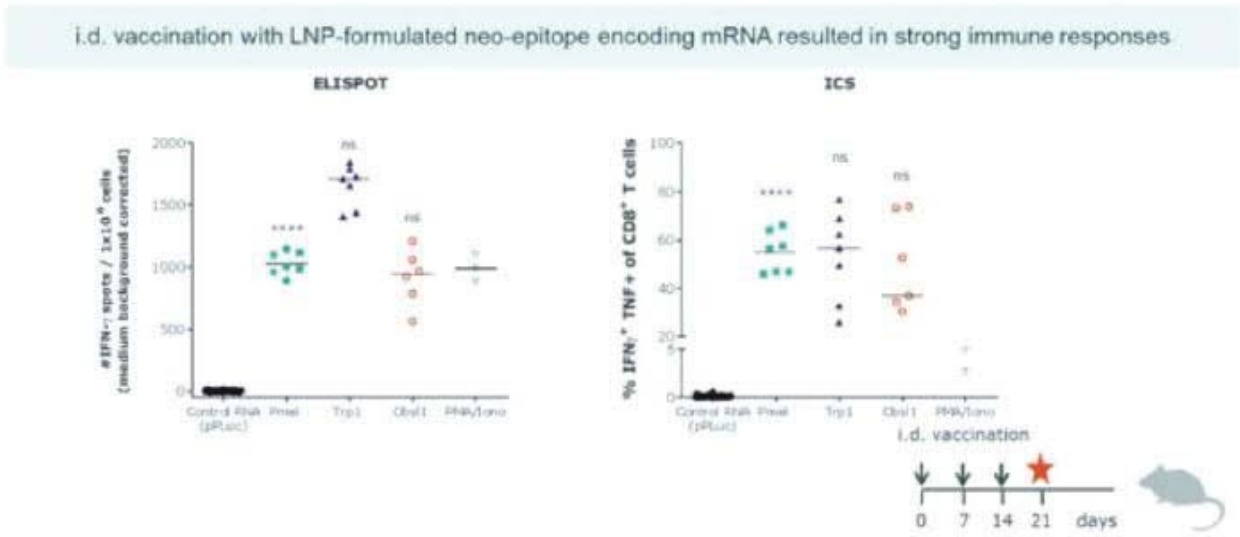
Lipid Nanoparticles (LNPs)

A variety of nanoparticles have been developed over the years for use in drug delivery. LNPs represent the most clinically advanced non-viral delivery systems. Encapsulation of the mRNA within LNPs enables delivery to the site of action within the cell. LNPs protect the mRNA from degradation, rapid excretion and liver clearance, enabling higher bioavailability and longer half-life.

LNPs consist of different lipids that form together a lipid nanoparticle with a solid core. The four primary LNP components include cationic lipids, pegylated lipids, phospholipids, and cholesterols. LNPs mimic low-density lipoproteins, which allows them to be taken up by an endogenous cellular transport pathway to deliver the mRNA cargo to cells. When LNPs are injected into biological systems, they attach to natural transport proteins, apolipoproteins, to facilitate the transport of lipids within the bloodstream and throughout the body. Following intravenous administration, the apolipoprotein binding enables efficient transport of the mRNA cargo to the liver. Once internalized in endosomes within cells, the LNPs are designed to escape the endosome and release their mRNA cargo into the cytoplasm, where the mRNA can be translated. 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.

The properties of each LNP system can be customized based on altering each component or overall composition. All of the LNPs we employ in our projects are designed to be biodegradable. We have extensively tested over 40 different delivery solutions and have selected the ones we use based on comparative data for the most efficient LNPs available from third parties for licensure. Having access to these technologies enables us to develop fast powerful solutions for vaccines and protein therapy.

Besides the licensed LNP technology from our partners, we are also developing our own LNP technology. We have established two ionizable lipid families and are developing those LNPs for application in local vaccination and systemic delivery to the liver. For local vaccination in skin and muscle, we are currently conducting a systematic screening of LNP components and compositions, optimized exactly for this route. Those adjusted LNP formulations incorporating our own lipids helped to raise significant levels of immune response in epitope based vaccinations.



The graphs above demonstrate the induction of antigen-specific T cell responses after intradermal vaccination of mice with LNP-formulated mRNA encoding for selected neoepitopes. Animals vaccinated with LNP-formulated mRNA encoding reporter protein served as negative controls. Stimulation of splenocytes harvested 7 days post last vaccination with respective peptides demonstrated strong induction of antigen-specific T cells in enzyme-linked immune absorbent spot, or Elispot, (depicted in the left-hand graph) and Fluorescence-activated cell sorting, or FACs analysis (depicted in the right-hand graph).

CureVac Carrier Molecule or CVCM Delivery Technology

Our proprietary CVCM delivery technology is a polymer-based approach for local delivery of mRNA medicines to selected tissues. CVCMs are uptaken via endocytosis and at lower pH during the trafficking, the core peptide and the lipids get protonated. The lipids are then released from the CVCM particles and are inserted into the endosomal membrane, thereby disrupting the membrane. Within the reducing environment of the cytosol, the CVCMs get destabilized and broken down into its components, resulting in mRNA being efficiently released.

We believe the CVCM delivery technology offers the following key advantages:

- *Stability:* CVCM formulation confers physicochemical stability by design and generates very stable complexes that can survive physical stress. CVCMs can be effectively spray dried, lyophilized, or nebulized, enabling formulation methods that are difficult to achieve with LNPs.

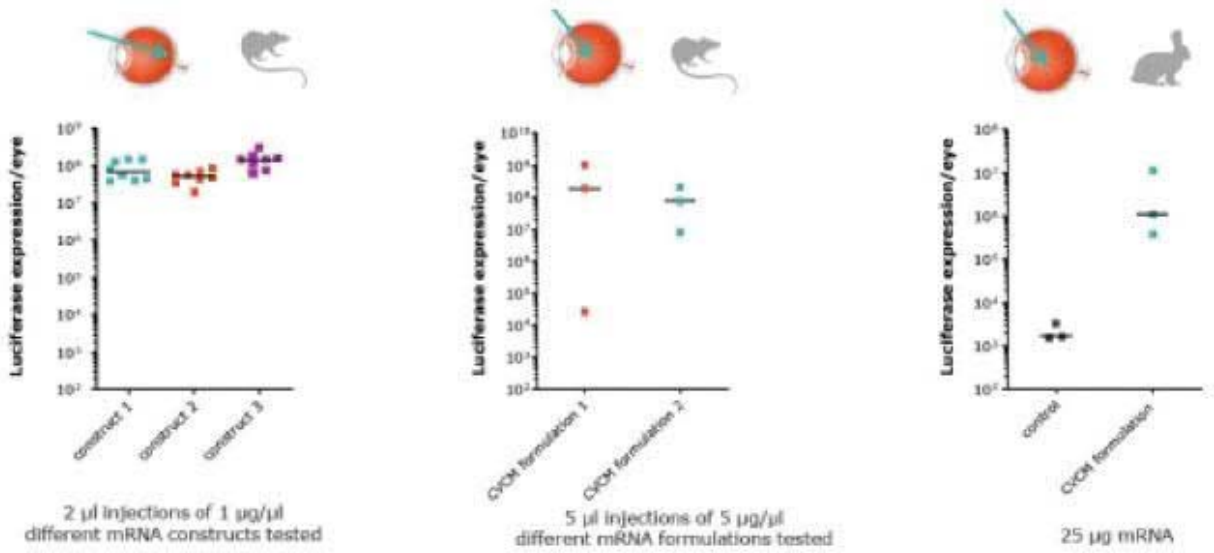
- *Degradation and Excretion:* The human body handles the degradation and excretion of hydrophilic materials very well, without any accumulation in lipid membranes. CVCM polymer is designed and equipped with intrinsic degradation mechanism that enables fast decomposition in the cytosol of cells.

- *Tolerability:* The human body tolerates polymers very well due to the fact that polymers do not disturb the lipid membrane. We have extensively optimized and adapted our CVCM system for mRNA to enable efficient complexation and protection of the mRNA in hostile environments. The excipient to cargo ratio is an important metric that influences the tolerability of delivery systems. For our CVCMs, this excipient to cargo ratio is very low, allowing us to deliver higher amounts of mRNA.

- *Immunogenicity:* Polymeric systems are immunosilent as they do not mimic virus-like particles and do not interact with RNA or lipid sensors.

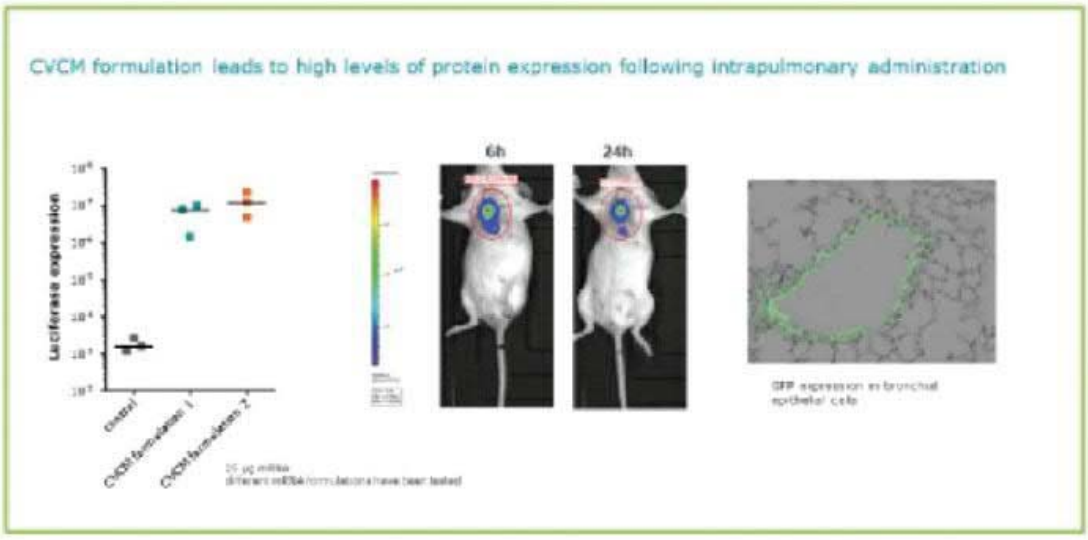
- *Production of mRNA Therapies:* Polymeric systems tend to be water soluble and enable a homogeneous mixing with the mRNA, thus allowing for less complicated production methods.

The combination of low immune stimulatory capacity and high tolerability makes CVCM formulation highly suitable for sensitive tissues like eye (nerve tissue) and lung (immune sensitive). In preclinical models, CVCM technology enabled high protein in eye (nerve tissue) after intravitreal or sub-retinal administration.



CVCM nanoparticles mediated protein expression in eye in rats (left panel subretinal injection; middle panel intravitreal injection) and rabbits (right panel intravitreal injection)

The high physicochemical stability during physical stress is also well suited for the administration of CVCM formulation to the lung via the airway. Enabling an administration as an aerosol or as a dry powder formulation.



CVCM formulated mRNA, encoding Luciferase was delivered, intratracheal using penncentury device.

Our Approach to Disease Selection

Our approach seeks to mitigate risk across multiple levels to advance and expand our broad product portfolio. While mRNA is still an emerging treatment modality, we believe that we have made advances towards utilizing the potential of our technology platform through rational disease selection. Our approach for selecting new programs is based on the following key factors:

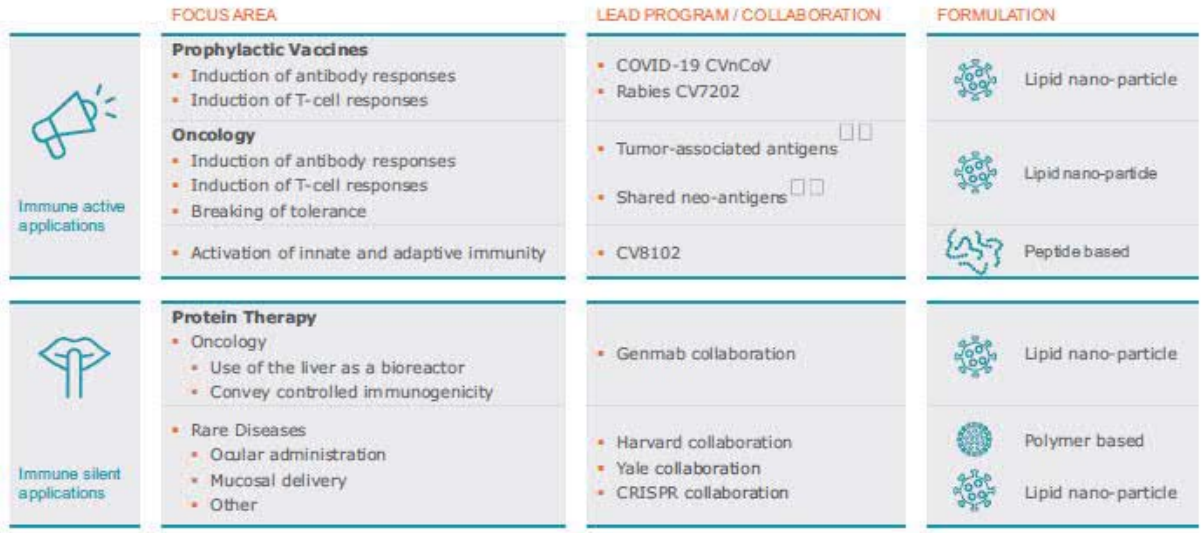
- Target diseases with high unmet medical needs that are not effectively addressed using the current standard of care.
- Target areas where the underlying mode of action of the disease is understood or hypothesized which allows us to identify the required protein(s) or antigen(s).

- Identify areas where mRNA therapies have potential to have differentiated profile compared to the conventional treatment modalities.

- Assess the likelihood of being able to address the disease using our technology platform and seek to continuously improve and expand the capabilities of our platform to address an even broader range of diseases.

- Seek to build on our deep understanding of mRNA biology, data derived from our technology platform and previous clinical and preclinical studies to apply to new indications.

In building our product portfolio, we have considered a number of factors including immune response, duration of expression, dosing requirements, delivery technology, target tissue type, potential for responsiveness to mRNA-based medicine, and target disease profile, among other factors. A disease indication may require an mRNA-based medicine that triggers an immune response, or that is immune active, or an mRNA-based medicine that requires no immune activation, or that is immune silent. Each of the disease indications that we are targeting require different levels of immune activation for the mRNA-based medicine to be effective. Our approach is to initially target indications that require an immune active approach (such as prophylactic vaccines), given the need for lower doses and transient expression of the antigen. These initial indications are amenable to localized delivery using an LNP delivery system. Following the proof of concept observed in preclinical studies from our prophylactic vaccines program and our advanced understanding of mRNA biology and immune stimulation modulation, we have expanded our product portfolio to target indications that require an immune silent approach (such as protein delivery). Targeting diseases amenable to the immune silent approach requires higher doses and longer expression of the protein, with potential for long-term repeat dosing for chronic diseases. By using both LNP and our proprietary CVCM delivery systems, we are able to address a broad range of target tissue types.



We are able to explore the full potential of mRNA product candidates via two main approaches:

- ***Immune active.*** For indications that require immune stimulation such as prophylactic and therapeutic vaccines, our technology optimizes the combination of mRNA molecules encoding specific antigens and selected delivery modalities to provide the desired immunostimulatory capacity. This allows us to design vaccines with high immunogenic effect. The goal is to induce an immune response against the encoded antigen. The mRNA is taken up by cells, including dendritic cells, at the injection site. Expressed antigens are then presented to the adaptive immune system leading to selective activation of T cells and B cells that recognize these antigens. These activated adaptive immune cells can then recognize and attack similar antigens that are found on tumors or pathogens.

- ***Immune silent.*** For indications that require no immune stimulation such as protein delivery, our technology can also design product candidates to be immunosilent and to express encoded proteins over an extended period of time. These product candidates can be expressed either locally (eye or lung) or systemically, using the liver as a bioreactor for production of the therapeutic proteins (enzymes and antibodies).

Oncology

mRNA is a versatile platform for cancer vaccine development allowing to encode a wide range of antigens from full length tumor associated antigens to neoepitopes. We are taking multiple approaches in oncology to induce tumor-specific immune responses in patients:

- ***Intratumoral therapy:*** Intratumoral injection of immunostimulating agents into tumors is an alternative to classic vaccination to induce a therapeutic immune response. High concentration of such agents can be achieved by local administration in the tumor tissue with little systemic side effects. Intratumoral immunotherapy activates antigen-presenting cells in the tumor environment and draining lymph nodes to present a broad panel of antigens expressed by the tumor to T and B cells and induce a systemic immune response against the injected tumor as well as non-injected metastatic lesions (abscopal effect).

  Our lead oncology product candidate, CV8102, is based on a complex of single stranded non-coding RNA with a polymeric peptide carrier which has been shown to activate the TLR7, TLR8 and RIG-I pathways. These pathways activate the innate immune system upon detection of RNA molecule. We are currently evaluating CV8102 in a Phase 1 clinical trial for the treatment of four types of solid tumors. We are also investigating mRNAs encoding immunostimulating proteins for intratumoral therapy. We have shown in several animal models that intratumoral injection of mRNA encoding immunostimulating proteins, such as cytokines, can induce regression of the injected tumors and prolong survival of the animals. We are testing different mRNA constructs and formulations in preclinical studies to achieve optimal expression of proteins in the tumor. We are also exploring combinations of mRNA encoding different immunostimulating proteins in order to demonstrate optimal therapeutic level in tumor models that are refractory to immunotherapies like anti-PD-1 agents.

- ***Novel cancer vaccines:*** We are also working on discovery of novel vaccines against tumor-associated antigens, which are antigens that are overexpressed in tumor tissues with no or little expression on healthy tissues, using our LNP formulations. It is known that these antigens are often less immunogenic than neoantigens and require optimized design to improve their presentation to immune cells as well as vaccine formulation with strong immunostimulating properties (vaccine adjuvant effect) to enable the induction of relevant immune responses.

  We have demonstrated in a preclinical model that an optimized LNP formulated mRNA vaccine, encoding a TAA, that is also a self-antigen, can induce cellular and anti-tumoral immune responses and single-agent therapeutic activity. These immune responses led to single-agent therapeutic effect in the B16F10 tumor model that does not respond to anti-PD-1 antibodies alone. The therapeutic effect of the vaccine was further enhanced by concomitant systemic anti-PD-1 antibody treatment. Based on these encouraging data, we are developing vaccine candidates targeting tumor associated antigens for different indications. We aim to focus on indications and settings with a high medical need showing a low response rate to anti-PD-1 antibodies alone or indications with minimal residual disease after standard of care surgery (adjuvant setting) and aim to use the vaccines to prevent cancer relapse.

  We are also developing novel vaccine targeting a number of neoantigens. We have demonstrated that LNP formulated mRNA vaccines encoding are also able to induce T cell responses against model neoantigens.

Prophylactic Vaccines

Similar to the proteins expressed on cancer cells, infectious disease-related proteins, such as viral surface proteins, specific target for the body's immune defense system can be expressed by injected mRNA and then presented to B and differentiated T cells, activating a specific immune response. We believe that our mRNA technology offers a platform for the development and production of prophylactic vaccines against infectious diseases. We believe our mRNA vaccines offer many potential advantages over existing vaccine technologies, including:

- mRNA vaccines mimic several aspects of a natural viral infection and has the potential to offer improved and balanced immune response.

- mRNAs allow us to encode for specific protein antigens of choice, offering potential for the development against known and yet unidentified pathogenic threats.

- mRNAs allow production of multivalent vaccines with the potential to either demonstrate a broader efficacy by including additional target pathogens, or to strengthen potential efficacy by better targeting a specific pathogen, for example by adding of immunogenic epitopes, or both.

- mRNA vaccines are generally expected to be safer than live or attenuated vaccines since no living virus is injected. As they do not interact with the host-cell DNA, they avoid the potential risk of genomic integration posed by DNA-based vaccines.

- mRNA binds to pattern recognition receptors and mRNA vaccines are thereby self-adjuvanting, a property which peptide- and protein-based vaccines lack.

- Rapid speed of development from knowing the sequence of the virus to progressing programs in clinical development given our ability to produce antigens without dedicated cell cultures and fermentation-based manufacturing processes.

- Commercial-scale production of mRNA is fast, cost-effective and, in contrast to traditional vaccine approaches, does not require cell culture or the use of live pathogens and as a result, multiple vaccines can be produced in the same plant.

Our current approach to the development of potential prophylactic vaccines is focused on:

- ***CVnCoV for SARS-CoV-2:*** Our most advanced mRNA vaccine program against SARS-CoV-2 is currently being evaluated in Phase 1, Phase 2a and Phase 2b/3 clinical studies. Positive interim data reported for our Phase 1 clinical trial showed that, as of the cutoff date of October 31, 2020, our vaccine candidate induced relevant antibody titers. The quality of the immune responses observed in vaccinated and healthy volunteers was found to be comparable to the immune response identified or detected in convalescent sera taken from recovered COVID-19 patients, thereby closely mimicking the immune response observed after a natural COVID-19 infection.

- ***CV7202 for rabies:*** Our most advanced program, CV7202, is a rabies vaccine candidate currently in a Phase 1 clinical trial. CV7202 induced adaptive immune response as shown by rabies-specific VNTs above the WHO thresholds considered to be protective, 28 days after the second dose in all subjects, at the lowest 1µg and 2µg dose levels.

- ***CV-SSIV for influenza:*** As part of our influenza program, we have evaluated mRNA-based influenza vaccines starting with a monovalent influenza vaccine followed by seasonal cocktails based on influenza hemagglutinin, or influenza HA. In preclinical studies, we demonstrated that the multivalent mRNA vaccines induced hemagglutination inhibition, or HI, titers above the accepted threshold for protective immunity in ferrets and non-human primates, or NHPs.

- ***Respiratory Syncytial Virus, or RSV vaccine:*** Our approach for the RSV program is based on delivering mRNAs encoding for the RSV F (fusion) protein. Based on *in vivo* challenge studies in cotton rat, we have demonstrated that our mRNA vaccines induce high levels of virus neutralizing antibodies, protect animals against RSV infection, without any signs of lung pathology.

- ***Other prophylactic vaccines:*** In partnership with the Bill & Melinda Gates Foundation, we are developing prophylactic vaccines for prevention of other infectious diseases associated with high mortality in the developing world including malaria and rotavirus.

Protein Therapy: Deliver mRNA to express the right protein wherever needed

We are seeking to optimize mRNA molecules to trigger production of antibodies. Our antibody work has potential to protect against viruses and toxins and can be applied in many disease indications including cancer, cardiovascular diseases, infectious diseases and autoimmune diseases. In preclinical studies in non-human primates, we have demonstrated that antibodies encoded by mRNA can be produced in hepatocytes very rapidly and can reach in the blood stream at relevant therapeutic levels.

With our technology, we can instruct human cells to produce specific proteins in the nucleus, cytoplasm, cellular organelles, cell membrane, or get them secreted. Based on this "healthy" information delivered by mRNA, our cells are designed to produce proteins, which are required to treat the disease caused by missing or inactive proteins.

We believe there are several advantages of our technology applied to development of protein therapy, including:

- mRNA encoded proteins can function within or outside of cells as well as inside cell membranes, allowing us to address intracellular protein deficiencies that are not addressed by recombinant proteins.

- mRNAs can enable production of complex proteins that are challenging to make using recombinant technologies due to their folding requirements and complexity.

- Administered mRNAs encode proteins using natural pathways allowing for post-translational modifications such as glycosylation whereas recombinant proteins use non-human post-translational modifications which may lead to lower effectiveness and increased immunogenicity.

- mRNA constructs can be optimized to produce proteins that offer desirable pharmacology relative to the wild-type protein, such as increased half-life.

- mRNA allows for dosing flexibility to meet patient needs without causing irreversible changes to the genome.

- mRNA can be delivered repeatedly, creating the opportunity to provide long-term benefit for treatment of chronic diseases.

We currently have collaborations focused on:

- ***Therapeutic antibodies:*** We are also developing mRNAs therapies to produce antibodies systemically using the liver as a bioreactor for subsequent secretion and systemic distribution of the antibodies to primary organs affected by a disease. Our collaboration with Genmab, a global leader in antibody discovery and design, will allow us to work with novel antibodies produced using our mRNA technology. This partnership represents the first-ever publicly disclosed mRNA antibody focused deal and will allow us to optimize and manufacture mRNA encoded antibodies for Genmab.

- ***Eye diseases:*** Using our CVCM delivery system that enables different routes of delivery to the eye, we are investigating development of mRNA-based treatments for undisclosed ophthalmic indications. We have a collaboration with SERI for our discovery efforts.

- ***Lung diseases:*** The CVCM delivery system is also well suited for delivery of mRNA to the lung, administered as either an aerosol or a dry powder formulation. Proof of concept *in vivo* animal studies showed that CVCM mRNA formulations, administered using the intrapulmonary route, were able to transfect airway epithelial cells and produce functional therapeutic proteins in the lung. We have a collaboration with Yale University focused on discovery of novel molecular targets in pulmonary diseases.

Our Key Pipeline Candidates

RNA-Based Therapeutics in Oncology

CV8102

CV8102 is the first compound we are developing for treatment of various solid tumors using an intratumoral approach. CV8102 is based on a complex of single stranded non-coding RNA with a polymeric peptide that binds and coats the RNA, protecting it from rapid degradation while also helping to stimulate the immune system.

CV8102 was shown to activate cellular receptors that normally detect viral pathogens entering the cells (such as TLR7, TLR8 and RIG-I pathways). By mimicking a viral infection at the injection site, CV8102 is designed to induce an inflammation that can activate the immune system to reject the tumor. CV8102 was initially developed as a vaccine adjuvant and was shown to enhance the induction of multifunctional CD8 T cell responses and therapeutic activity of peptide vaccines against cancer in preclinical models.

CV8102 is currently in a Phase 1 clinical trial for the intratumoral treatment of four types of solid tumors — cutaneous melanoma, or cMEL, adenoidcystic carcinoma, or ACC, and squamous cell carcinoma of skin, or SCC, as well as squamous cell carcinoma of head and neck, or HNSCC.

As of October 5, 2020, we have enrolled 50 patients (29 in the single-agent cohort and 21 in the combination cohort) in the Phase 1 dose-escalation portion of the study. Intratumoral CV8102 was observed to be tolerated without dose limiting toxicities, or DLTs, at dose levels up to 600 µg (single-agent and combination).

As of October 5, 2020, in the 900 µg single-agent cohort, one out of six patients experienced a DLT of Grade 3 increase in the liver enzymes ALT and AST, observed in the context of a Grade 2 cytokine release syndrome. Another patient in this cohort experienced a potentially related Grade 3 immune-mediated pneumonitis that occurred after DLT evaluation period set forth in the protocol.

In the 900 µg combination cohort, 2 patients have been treated without DLTs as of the cutoff date and enrollment in this cohort continues.

As of the cutoff date, we have observed preliminary evidence of single-agent activity with objective tumor responses according to RECIST 1.1:

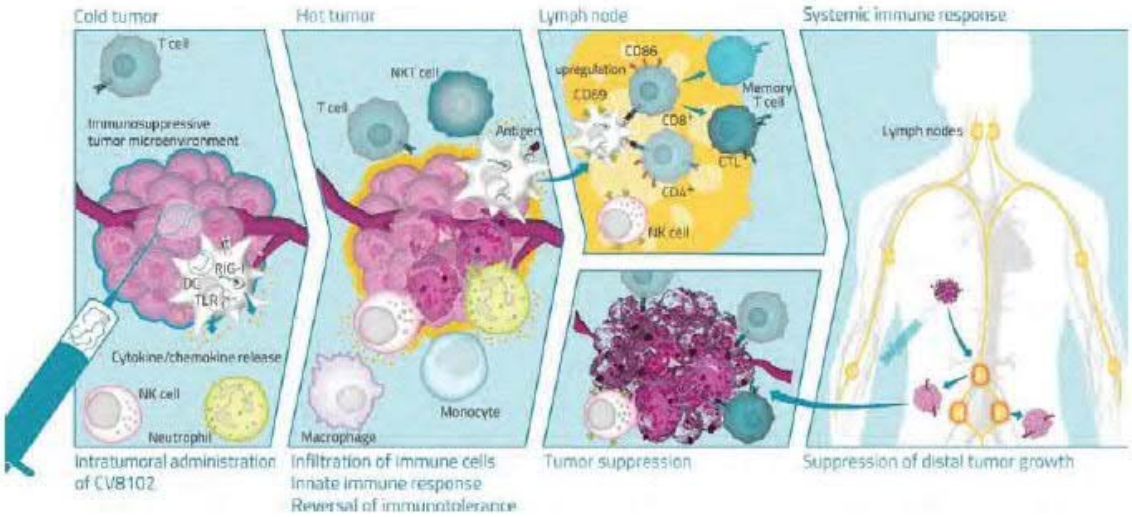
- 1 complete response (CR) in a melanoma patient
- 2 partial responses (PR) in a melanoma patient and a patient with squamous cell cancer of the skin (cSCC)

As of the cutoff date, October 5, 2020, three additional patients showed a stabilization of their disease with lesion regression: two patients with shrinkage of non-injected lesions (1 HNSCC and 1 melanoma patient) and one cSCC patient with shrinkage of the injected lesion.

In February 2021, we initiated the expansion of our Phase 1 study to confirm the safety, tolerability and efficacy of CV8102 at a 600µg dose, the selected dose to be advanced in a Phase 2 clinical trial. The expansion part of the Phase 1 trial will enroll 30 patients with PD-1 refractory melanoma, who will receive intratumoral injections of CV8102 in combination with PD-1 antibodies, as well as 10 patients who will be treated with CV8102 only. Initially, CV8102, with or without co-administration of anti-PD-1 treatment, will be injected weekly for five weeks, followed by three injections at two- or three-week intervals depending on the anti-PD-1 antibody schedule. Patients showing evidence of clinical benefit are eligible for further injections for up to 12 months.

Mechanism of Action

CV8102 is designed to activate cellular receptors that normally detect viral pathogens entering the cells (such as TLR7, TLR8 and RIG-I pathways) mimicking a viral infection of the tumor. CV8102 is designed to recruit and activate antigen-presenting cells at the site of injection to present tumor antigens released from tumor cells to T cells in the draining lymph node. This potentially leads to activation of tumor-specific T cells, which can kill tumor cells at the injected site, but also at distant non-injected tumor lesions or metastases. Activation of other immune cells like natural killer, or NK, cells at the site of injection may also contribute to the antitumor effect. This mechanism of action is illustrated in the figure below.



In preclinical models, CV8102 was shown to initially activate the innate immune system at the site of injection and the draining lymph node based on increase in number or activation of NK cells, monocytes and plasmacytoid dendritic cells. There was also an increased expression of genes associated with T-cell mediated cytotoxicity. These effects were enhanced by concomitant treatment with anti-PD-1 antibodies which also led to increased tumor infiltration by CD8+-T cells.

Market Opportunity

CV8102 is currently being developed against four types of cancers, each frequently exhibiting easily accessible superficial tumor lesions:

- cMEL is an aggressive form of cancer that starts in the pigment-producing cells of the skin and can spread widely to other parts of the body. Cutaneous melanoma accounts for the majority of skin cancer-related deaths in the United States. In 2018, there were approximately 300,000 new cases of cutaneous melanoma and approximately 60,000 deaths worldwide. In the United States, the National Institute of Health, or NIH, estimates approximately 100,000 new diagnoses of cutaneous melanoma, and approximately 7,000 deaths in 2020. According to the National Comprehensive Cancer Network, or NCCN, guidelines, while surgical removal of the tumor is the primary treatment for localized melanoma, for patients with metastatic disease, chemotherapy and targeted therapies including the BRAF inhibitors are also recommended. Based on published literature, the majority of patients treated with BRAF inhibitors develop secondary resistance within a relatively short amount of time. Checkpoint inhibitors are recommended as the first-line treatment for advanced / unresectable metastatic melanoma, but their side effects are severe and a significant subset of patients (approximately 40% to 45%) do not respond to these drugs and many of those who do respond (approximately 30% to 40%), develop secondary resistance. There are very limited therapeutic options for patients who have failed anti-PD-1 and targeted therapy (if eligible). Intralesional oncolytic virus therapy, or Tvec, is considered for selected cases, but its use is mostly limited to metastatic stage IIIc or M1A disease.

- HNSCC occurs in the outermost surface of the skin or certain tissues within the head and neck region including the throat, mouth, sinuses and nose. Squamous cell carcinoma makes up about 90% of all head and neck cancers. Consumption of tobacco products and alcohol and having a poor diet are important risk factors. HNSCC is the seventh leading cause of cancer-related mortality: in 2018, an estimated approximately 700,000 people were diagnosed with HNSCC worldwide, with approximately 350,000 deaths. In the United States, according to American Society of Clinical Oncology, or ASCO, approximately 65,000 new cases are diagnosed annually and more than 14,500 deaths are reported every year. Published literature indicates that more than two-thirds of patients with HNSCC initially present with locoregionally advanced disease (stage III-IV). HNSCC treatment typically involves a combination of chemotherapy, radiation and surgery. According to the Cancer Network and published literature, for patients with early-stage disease, these treatment approaches lead to approximately 60% to 80% response rate. The 5-year progression-free survival, or PFS, rate of advanced HNSCC has continued to remain at 40% to 50% and the average time to relapse is less than 2 years regardless of the combination of various treatment modalities. In patients with advanced disease, more than 50% develop local or

regional recurrence and nearly 30% develop distant metastases. Based on the NCCN, the recommended first line treatment for recurrent/metastatic HNSCC include chemotherapy combinations with Cetuximab and anti-PD-1 antibody treatment with or without platinum based chemotherapy. We believe, based on publications and our analysis, that the typical response rate to anti-PD-1 antibodies in patients with HNSCC is below 20%, and that there is still a significant unmet need.

- ACC is an uncommon form of malignant neoplasm that arises within secretory glands, most commonly the major and minor salivary glands of the head and neck. Other sites of origin include the trachea, lacrimal gland, breast, skin and vulva. ACC accounts for around 10% of all salivary gland neoplasms, 22% of all salivary gland malignancies and about 1% of all head and neck malignancies. The National Cancer Institute, or NCI, estimates that 1,200 patients are diagnosed annually in the United States with ACC and 15,000 patients are affected. Globally, ACC incidence rate is estimated between 0.4 to 13.5 cases per 100,000 annually. The primary treatment of ACC is surgery, which is usually followed by post-operative radiotherapy. According to the American Society of Clinical Oncology, or ASCO, while the 5-year survival of ACC is 89%, 15-year survival is only approximately 40%. For patients with recurrent or advanced/ metastatic disease not amenable to curative intent surgery there is no approved systemic standard treatment. There are minimal options for treatment of advanced ACC, traditional chemotherapy has been proven to be of minimal benefit, so patients often seek clinical trials as a second line option, leading to a high unmet medical need.

- SCC is the second most common form of skin cancer that develops in the squamous cells that make up the middle and outer layers of the skin. While not life-threatening, it can be aggressive and can spread to the other parts of the body, causing serious complications. According to ASCO, in the United States, out of 5.4 million skin cancer cases, 20% are SCC. According to published literature, global incidence varies widely with highest incidence reported in Australia and lowest rates reported in Africa. Given most countries do not have cancer registries for skin cancer, figures reported are likely underestimated. Although most SCC are localized and easily treated, approximately 5% of patients experience local recurrence, approximately 4% develop nodal metastases and approximately 2% die of the disease. According to NCCN, most SCC are managed through different surgical methods, along with topical therapy, cryotherapy and photodynamic therapy. Surgical methods usually lead to good prognosis and cure rates greater than 90%. In the rare case of metastases, radiation therapy, immunotherapy and/or chemotherapy are deployed. Despite the available treatments, 10-year survival rate is less than 20% in patients with locoregional lymph node metastases and less than 10% in the presence of distance metastases, leading to a significant clinical unmet need.

Phase 1 Clinical Trial of Intratumoral CV8102

We initiated a Phase 1 clinical trial of CV8102 for the treatment of various solid tumors in 2017. The Phase 1 clinical trial is evaluating intratumoral administration of CV8102 in patients with advanced melanoma, squamous cell carcinoma of the skin, squamous cell carcinoma of the head and neck, or adenoid cystic carcinoma. Patients receive CV8102 as single-agent or in combination with anti-PD-1 therapy. Patients with advanced inoperable melanoma, cutaneous or head and neck squamous cell or adenoid cystic carcinoma are eligible for single-agent CV8102, and patients with advanced inoperable melanoma and head and neck squamous cell carcinoma indicated for anti-PD-1 therapy or who did not respond or slowly progressed on anti-PD-1 therapy are eligible for the combination. CV8102 is administered for up to eight intratumoral injections into a single accessible tumor lesion over a 12-week period.

The objectives of this clinical trial include to define the maximum tolerated dose and recommended dose for CV8102 alone and in combination with an anti-PD-1 therapy, and to evaluate safety and tolerability of CV8102 administered alone and in combination with an anti-PD-1 therapy. Secondary endpoints include anti-tumor activity analyses and tumor response assessment.

Key Inclusion Criteria:

- Patients enrolled into single-agent CV8102 dose escalation cohorts must have:
    - histologically confirmed advanced cMEL, SCC, HNSCC or ACC with documented disease progression;
    - not amenable to resection or locoregional radiation therapy with curative intent; and
    - at least 1 line of anti-cancer therapy for advanced disease (except adenoid cystic carcinoma).
- Patients enrolled into CV8102 anti-PD-1 combination cohort must have:
    - histologically confirmed advanced cMEL or HNSCC; and
    - indication for anti-PD-1 therapy or currently receiving anti-PD-1 therapy with stable of slowly progressing disease after at last eight-weeks (HNSCC) or 12 weeks (cMEL) of anti-PD-1.
- Presence of at least one injectable lesion that is measurable according to RECIST 1.1 criteria.
- Recovered from prior relevant toxicities to grade ≤ 1.
- ECOG PS 0 or 1, 18 years of age or older.

Key Exclusion Criteria:

- Rapidly progressing multifocal metastatic or acutely life-threatening disease;
- Prior use of topical/local TLR-7/8 agonists within the past 6 months;
- Prior anti-cancer therapy administered 2-4 weeks prior to the first dose of the study drug depending on the indication;
- Lesions that are to be injected in previously irradiated areas unless progressive tumor growth has been demonstrated (no prior irradiation of injected lesions on patients with melanoma); or
- Treatment with any investigational anticancer agent within 4 weeks prior to the first dose of the study drug.

Primary Endpoints:

- Determine maximum tolerated dose, or MTD, based on occurrence of DLTs within 2 weeks after the first dose and recommended dose, or RD, respectively, for CV8102 alone and with anti-PD-1 therapy.
- Tolerability and safety of CV8102 alone and in combination with anti-PD-1 therapy.

Secondary Endpoints:

- Evaluate anti-tumor activity of CV8102 alone and in combination with anti PD-1 antibodies per RECIST 1.1 and irRECIST criteria.
- Evaluate duration of response, progression-free survival and disease control rate at 6 months.
- Evaluate tumor response of injected and non-injected lesions.
- Evaluate survival time.

Exploratory Endpoints:

- Evaluate effects on immune parameters and other biomarkers of interest in the peripheral blood.

- Evaluate effects on immune cell infiltration and other biomarkers of interest in tumor biopsy specimen (in selected cohorts during the expansion phase).

Preliminary Patient Demographics

As of October 5, 2020, 50 patients were enrolled in the clinical trial: 29 in the single-agent cohort and 21 in the combination cohort with anti-PD-1 antibodies. In the single-agent cohort, 41% of patients had melanoma, 14% HNSCC, 14% SCC and 31% ACC. 55% of patients were pretreated with anti-PD-1 antibodies and 7% with anti CTLA-4 antibodies.

In the combination cohort, 86% of patients had cMEL and 14% had HNSCC. 86% were pretreated with anti-PD-1 antibodies and 48% with anti CTLA-4 antibodies.

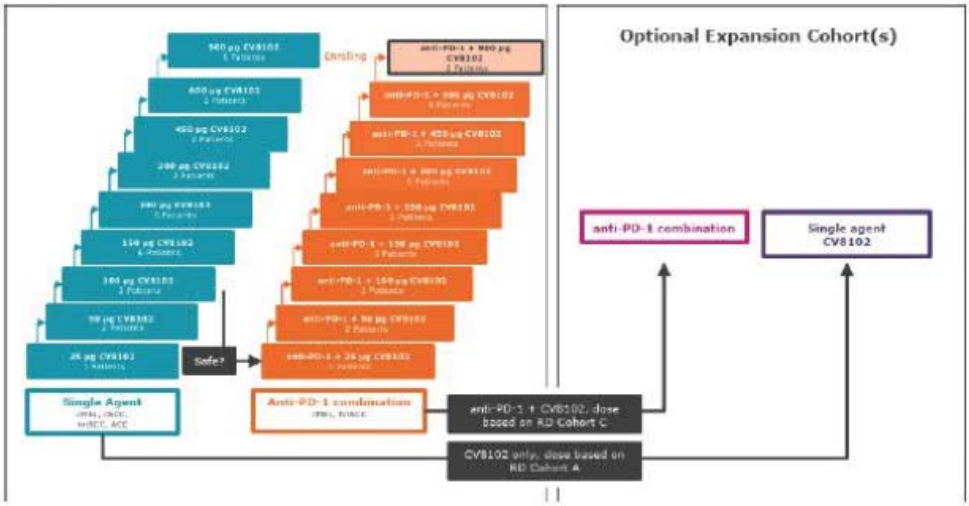
Characteristics	Number of patients (%)		
	Single agent (n=29)	anti-PD-1 combination (n=21)	All (n=50)
Age			
range (yrs)	35-91	36-90	35-91
median (yrs)	68	70	68.5
Gender			
Male	12 (41)	10 (48)	22 (44)
Female	17 (59)	11 (52)	28 (56)
cMEL			
Stage IIIB	1 (3)	-	1 (2)
Stage IIIC	4 (14)	5 (24)	9 (18)
Stage IV	7 (24)	13 (62)	20 (40)
HNSCC			
Stage IV	4 (14)	3 (14)	7 (14)
cSCC			
Stage III	1 (3)	N/A	1 (2)
Stage IV	3 (10)		3 (6)
ACC			
Stage IV	9 (31)	N/A	9 (18)
ECOG PS			
0	16 (55)	15 (71)	31 (62)
1	13 (45)	6 (29)	19 (38)
Pre-treatment anti-PD-1	16 (55)	18 (86)	34 (68)
Pre-treatment with anti-CTLA4	2 (7)	10 (48)	12 (24)

Percentages presented above have been rounded to the nearest whole number.

CV8102 is administered weekly for the first five cycles and then every two to three weeks for the subsequent cycles for a total of eight injections or until disease progression or death of the patient. In the single-agent cohorts, more than eight injections may be administered should the patient experience a clinical benefit.

Dose escalation of single-agent CV8102 and the combination with anti-PD-1 are running in parallel, with the single-agent cohort being more advanced due to an earlier start of enrollment. We consider a dose level to be safe once it is cleared with monotherapy. This CV8102 dose level is then combined with an anti-PD-1. In parallel, the study continues with the next cohort of the dose escalation monotherapy. Once that higher monotherapy dose is considered safe, combination follows.

Phase 1 Dose Cohorts and Enrollment Status as of April 2020



As of October 5, 2020, the clinical trial's 900 µg cohorts had not yet encountered an MTD and has involved one DLT in the single-agent cohort. We presented a Phase 1 trial update at the virtual SITC Conference in November 2020.

Preliminary Safety Data

Preliminary safety data:
Treatment emergent AEs occurring in ≥ 10% of patients as of October 5, 2020

AE preferred term	Number of patients with ≥1 TEAE (%)*			
	Single agent (n= 29) DL 25-900 µg	anti-PD-1 combination (n= 21) DL 25-900 µg	All (n= 50)	
			G1/G2	≥ G3
Any Adverse Event	29 (100)	21 (100)	50 (100)	18 (36)
Pyrexia	15 (52)	10 (48)	25 (50)	-
Fatigue	12 (41)	6 (29)	18 (36)	-
Chills	6 (21)	9 (43)	15 (30)	-
Headache	9 (31)	3 (14)	12 (24)	-
Injection site pain	8 (28)	4 (19)	12 (24)	-
Nausea	8 (28)	3 (14)	11 (22)	-
Influenza like illness	7 (24)	2 (10)	9 (18)	-
Pain in extremity	4 (14)	4 (19)	8 (16)	-
Urinary tract infection	3 (10)	5 (24)	8 (16)	-
C-reactive protein increased	5 (17)	2 (10)	7 (14)	-
Anaemia	5 (17)	1 (5)	5 (10)	2 (4)§
Arthralgia	4 (14)	2 (10)	6 (12)	-
Decreased appetite	3 (10)	3 (14)	6 (12)	-
Injection site erythema	2 (7)	4 (19)	6 (12)	-
Asthenia	3 (10)	2 (10)	5 (10)	-
Tumor hemorrhage	2 (7)	3 (14)	3 (6)	2 (4) §

§ AEs were assessed as unrelated to CV8102 by the investigators

There was one DLT (Grade 3 elevation of liver enzymes in context of a Grade 2 cytokine release syndrome) observed in the 900 µg single-agent dose cohort. No Grade 4 or 5 AEs related to CV8102 were reported. As of October 2020, the clinical trial has not yet encountered an MTD and has involved one DLT in the 900 µg single-agent cohort. Adverse events were graded according to the NCI-

Common Terminology Criteria for Adverse Events. Grades refer to the severity of the adverse events with unique clinical descriptions of the severity of each AE based on the following general guideline:

Grade 1: Mild; asymptomatic or mild symptoms or clinical or diagnostic observations only or intervention not indicated.

Grade 2: Moderate; minimal, local or non-invasive intervention indicated or limiting age appropriate instrumental activities of daily living.

Grade 3: Severe or medically significant but not immediately life-threatening or hospitalization or prolongation of hospitalization indicated or disabling or limiting self-care activities of daily life.

Grade 4: Life-threatening consequences or urgent intervention indicated.

Grade 5: Death related to adverse event.

As of October 5, 2020:

- The most frequently reported adverse events occurring in more than 20% of patients were mild to moderate pyrexia, fatigue, chills, headache, injection site pain and nausea.
- 18 (36%) patients experienced treatment emergent ≥ Grade 3 AEs and 7 (14%) patients experienced Grade 3 AEs considered treatment related per investigator's judgment (one of the events fulfilled criteria for dose limiting toxicities per protocol). There were no Grade 4 or 5 AEs considered related to study treatment.
- In the single-agent CV8102 cohort, four patients experienced transient Grade 3 elevations of liver enzymes (1 at 150 µg dose level, 2 at 200 µg dose level and one at the 900 µg dose level, the latter fulfilled DLT criteria per protocol, because it occurred within one week after the second injection). One patient in the 900 µg cohort experienced an immune mediated Grade 3 pneumonitis and was recovering on steroid treatment approximately one week later. The patient had already experienced a previous episode of Grade 1 pneumonitis that may have been related to previous treatment with anti PD-1 antibodies prior to study enrollment.
- In the combination cohort of CV8102 with anti-PD-1 antibodies, one patient (100 µg dose level) experienced Grade 3 hypertension, mild chills, fever and tachycardia on day of administration of CV8102 and anti-PD-1 requiring inpatient observation (SAE) and transient asymptomatic Grade 3 elevation of serum lipase. One patient (100 µg dose level) experienced transient asymptomatic Grade 3 elevation of serum amylase.

Treatment Related Serious Adverse Effects (SAEs)

As of October 5, 2020:

- In the combination cohort of CV8102 with anti-PD-1 antibodies, one patient required inpatient observation after Grade 3 hypertension, mild chills, fever and tachycardia (100 µg dose level), one patient experienced Grade 2 cytokine release syndrome (300 µg dose level) and one patient Grade 1 cytokine release syndrome (600 µg dose level).

Preliminary Efficacy Data

Tumor responses were assessed according to Response Evaluation Criteria in Solid Tumors, or RECIST 1.1. The overall response evaluation according to RECIST 1.1 integrates changes in both measurable and non-measurable tumor lesions that can be assessed by radiographic imagining (CT or MRI) or clinical examination (documented by photographs). Assessment was performed by the investigators at baseline and at defined time points during the study period. Responses per RECIST 1.1 criteria are defined as follows:

A CR is the disappearance of all tumor lesions that were present before start of treatment without appearance of new lesions.

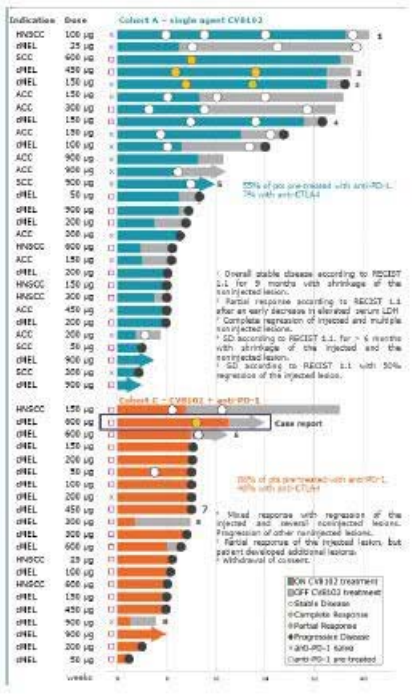
A PR is a ≥ 30% decrease in the sum of diameters of specified tumor lesions (called target lesions) taking as reference the baseline sum diameters without progression or disappearance of the other lesions and without appearance of new lesions or CR of target lesions without disappearance of other lesions but without progression or appearance of new lesions.

Progressive disease, or PD, indicates a ≥ 20% increase in the sum of diameters of specified tumor lesions (called target lesions) (taking as reference the smallest sum of diameters while on study) and at least a 5 mm increase and/or an unequivocal progression of existing further lesions (called nontarget lesions) or appearance of new lesions.

Stable disease indicates there is neither sufficient shrinkage nor increase in size of tumor lesions to declare PR or PD and no appearance of new lesions.

The tables below show duration of treatment, response and time to progression of individual patients enrolled in the trial.

Preliminary data on overall tumor response and duration according to RECIST 1.1 as of October 5, 2020



Preliminary efficacy data for single-agent CV8102

As of October 5, 2020, one patient showed a CR and two patients showed a PR according to RECIST 1.1 after single-agent CV8102. In addition, nine patients experienced a best response of stable disease after eight-weeks of treatment (associated with shrinkage of non-injected lesion in one patient, shrinkage of injected lesion in one patient and shrinkage of both the non-injected and injected lesions in one patient). Nine of the 29 (31%) patients treated with single-agent CV8102 remained free of progression for more than six months.

Preliminary efficacy data in combination with PD-1 antibodies

As of October 5, 2020, one patient with PD-1 refractory melanoma showed a partial response according to RECIST 1.1 in the combination cohort.

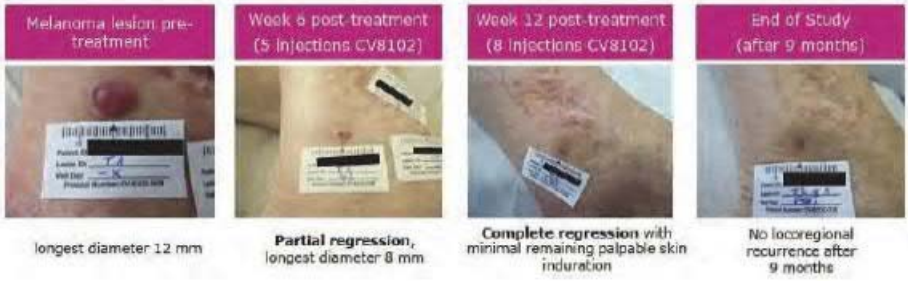
One PD-1 refractory melanoma patient experienced stable disease after the eight-week treatment period with regression of the injected and some non-injected lesions, while other non-injected lesions showed progression. One PD-1 pretreated patient with HNSCC experienced stable disease after the 16-week treatment period.

The number of treated patients and follow-up time in this cohort were more limited as compared to the single-agent cohort. The patient population was also more heavily pretreated compared to the patients enrolled in the single-agent cohort (86% vs. 55% were pretreated with anti-PD-1 antibodies and 48% vs. 7% with anti-CTLA-4 antibodies).

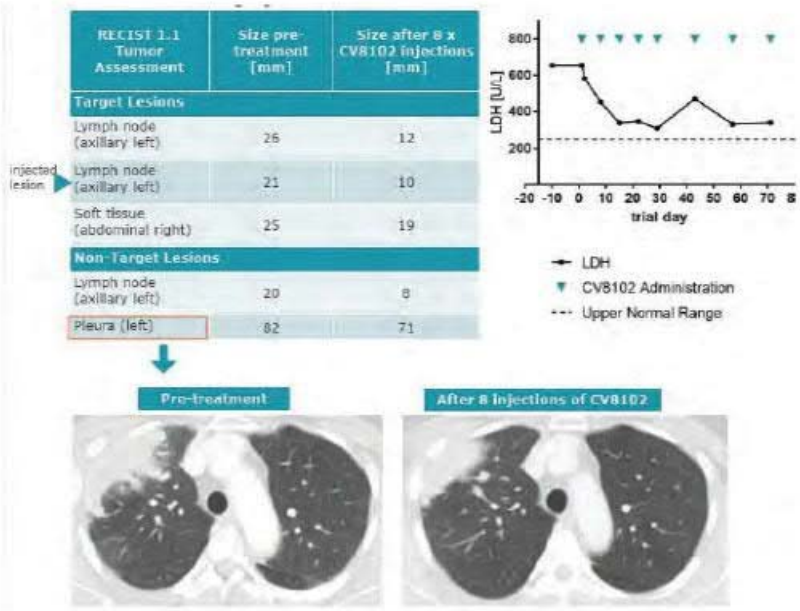
Single-agent Response Data

Case reports of patients with observed tumor shrinkage after single-agent CV8102:

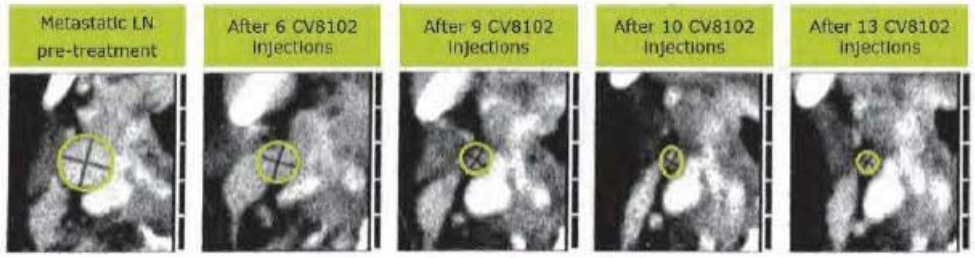
- A 74-year-old female patient with Stage IIIc melanoma and multifocal in-transit metastases was treated with single-agent CV8102 (150 µg). The pictures below show the injected primary tumor before treatment, after first five weekly injections, and after eight injections at 12 weeks. After the first five injections, a partial regression of the injected lesion became apparent, which turned into a complete regression after eight injections (12 weeks). An MRI scan showed a complete regression of all noninjected in transit metastases. The response data together represent a confirmed complete response based on RECIST 1.1 criteria. The patient continued to receive injections at monthly intervals for up to nine months without locoregional recurrence but there was occurrence of a new intraabdominal soft tissue lesion.



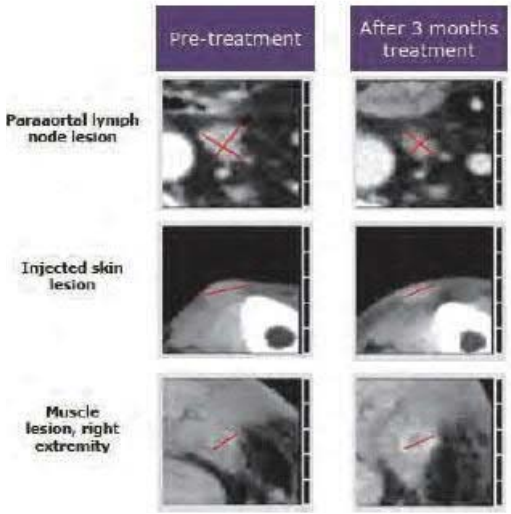
- A 50-year-old female patient with Stage IV melanoma, metastases in ipsilateral supraclavicular lymph nodes and distant detectable metastases at study entry was treated with single-agent CV8102 (450 µg). The patient previously experienced early tumor progression on adjuvant treatment with Nivolumab and subsequently underwent multiple resections of cutaneous and lymph node metastases and radiation prior to study entry. The patient received eight intratumoral injections of CV8102 into an axillary lymph node metastasis. After an early decrease in serum LDH she developed a partial response. Treatment with CV8102 was ongoing as of April 2020. The table below shows the decrease in the size of measurable tumor lesions after eight intratumoral injections of CV8102. The CT scan shows the decrease in size of the noninjected metastatic pleural lesion. The graph shows the decrease in serum LDH over time during the treatment period.



- A 91-year-old male patient with Stage IV HNSCC with large buccal and small lip lesion and a contralateral metastatic cervical lymph node was treated with single-agent CV8102 (100 µg) after pretreatments with cetuximab, external beam radiation, and multiple surgeries. The patient experienced prolonged stable disease according to RECIST 1.1 until the end of study, after nine months. Whereas the injected buccal lesion remained stable in size, the noninjected contralateral metastatic lymph node showed ongoing regression.



- A 64-year-old male patient with Stage IV melanoma (150 µg dose level, single-agent CV8102) who had progressed on previous anti-PD-1 antibody treatment experienced stable disease according to RECIST 1.1 for six months, with shrinkage of the injected lesion in the skin, and shrinkage of a noninjected contralateral paraaortic lymph node lesion.



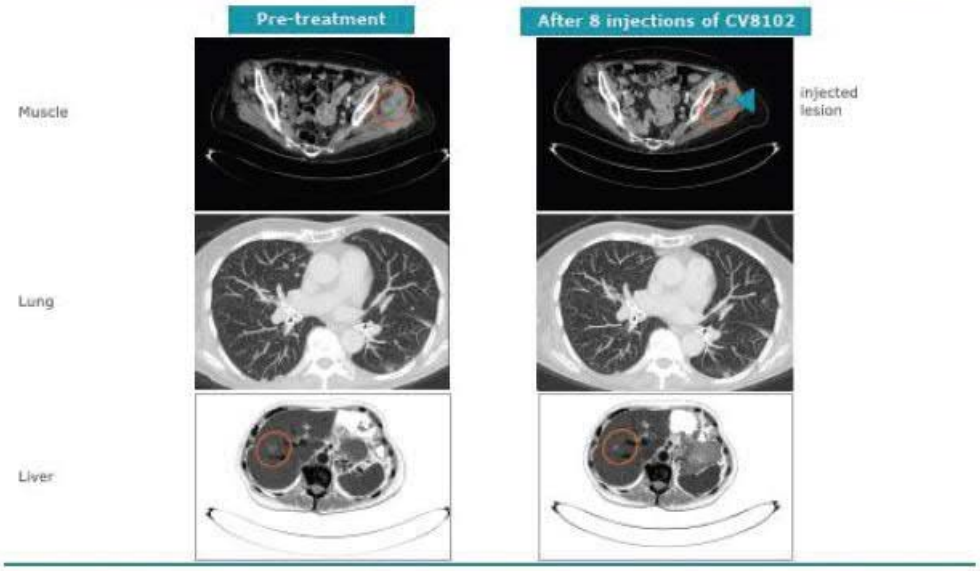
Combination response data:

A 90-year-old female patient with Stage IVc melanoma and metastatic lesions in the lung and liver was treated with eight intratumoral injections of CV8102 (600 µg) in combination with the anti-PD-1 antibody Pembrolizumab.

The patient was pretreated with Nivolumab in combination with Ipilimumab followed by Nivolumab monotherapy that resulted in progressive disease four months prior to study entry.

After eight injections, the patient showed a partial response according to RECIST 1.1 with regression of the injected lesion in a muscle and multiple non-injected lung and liver lesions as of October 5, 2020.

RECIST 1.1 Tumor Assessment	Size pre-treatment [mm]	Size after 8 x CV8102 injections [mm]
Target Lesions		
Muscle	31.4	19.8
Lung	6.4	4
Lung	6.8	0
Liver	18.4	10.1



Expanded Phase 1 Clinical Trial of Intratumoral CV8102

In February 2021, we initiated the expansion of our Phase 1 study to confirm the safety, tolerability and efficacy of CV8102 at a 600µg dose, the selected dose to be advanced in a Phase 2 clinical trial. Furthermore, the expansion part of the Phase 1 trial will evaluate the effects of CV8102 on systemic and intratumoral immune markers, which will provide additional clinical insights on CV8102's mode of action.

The expansion part of the Phase 1 trial will enroll 30 patients with PD-1 refractory melanoma, who will receive intratumoral injections of CV8102 in combination with PD-1 antibodies, as well as 10 patients who will be treated with CV8102 only. Initially, CV8102, with or without co-administration of anti-PD-1 treatment, will be injected weekly for five weeks, followed by three injections at two- or three-week intervals depending on the anti-PD-1 antibody schedule. Patients showing evidence of clinical benefit are eligible for further injections for up to 12 months.

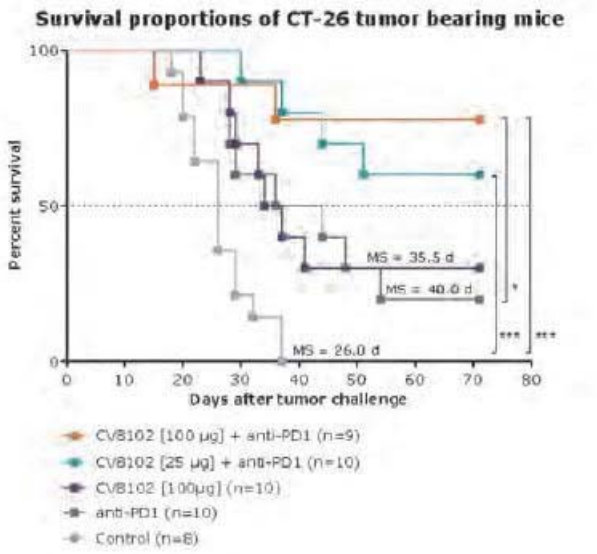
CV8102 with Rabies Vaccine

We completed a Phase 1 clinical trial to investigate the safety and tolerability of intramuscular administered CV8102 and an intramuscular administered combination of CV8102 and rabies vaccine in humans. CV8102 was injected intramuscularly on days 0 and 21, either alone or mixed with fractional doses of the licensed rabies vaccine (Rabipur) as model antigen. The primary endpoint was to assess the safety and reactogenicity of various dose levels of CV8102 alone or combined with a licensed rabies vaccine in healthy 18 to 40 year-old male volunteers. A secondary endpoint was to assess the immune-enhancing potential of bedside-mixes of CV8102 with fractional doses of the licensed rabies vaccine by measuring induction of rabies virus neutralizing titers. Fifty-six volunteers received 50 to 100 µg CV8102 alone, bedside-mixed CV8102 and rabies vaccines, or the rabies vaccine alone. When given alone or mixed with the rabies vaccine, CV8102 caused mostly Grade 1 or 2 local or systemic reactogenicity, but no related SAEs. Given 100 µg CV8102 was associated with marked C-reactive protein, or CRP increases, further dose escalation was stopped. Combining 25 to 50 µg of CV8102 with fractional doses of the rabies vaccine significantly improved the kinetics of virus neutralizing titer responses, and 50 µg CV8102 also improved the magnitude of virus neutralizing titer responses to 1/10 of the rabies vaccine but caused severe but self-limiting influenza-like symptoms in two of 14 subjects. In conclusion, two intramuscular doses of 25-50 µg CV8102 appeared well tolerated with an acceptable reactogenicity profile while significantly enhancing the immunogenicity of fractional doses of the licensed rabies vaccine.

CV8102 Key Preclinical Data

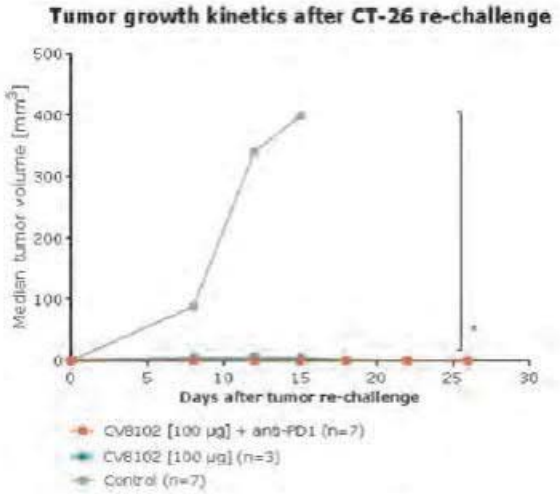
In preclinical tumor models, CV8102 showed dose-dependent antitumor activity as single-agent and synergistic activity in combination with systemic anti-PD-1 antibodies, including therapeutic activity in the A20 tumor model that did not respond to systemic anti-PD-1 antibody therapy alone.

Synergistic activity observed in CV8102 and anti-PD-1 combination therapy



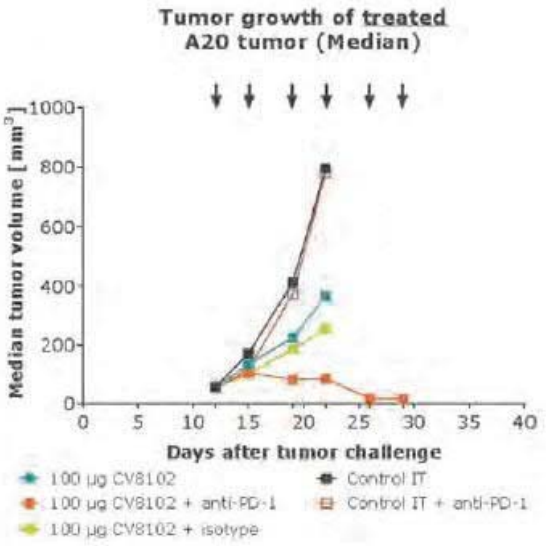
In a Kaplan-Meier curve, the graph above demonstrates the effect of monotherapy CV8102 treatment and combination of CV8102 with anti-PD-1 treatment. In the murine CT26 tumor model, an established colon carcinoma model, treatment led to an increased survival time, an increased proportion of animals surviving, and a memory effect (protective immunity of animals who achieved a complete remission after tumor re-challenge). In this model, the anti-PD-1 monotherapy as well as the CV8102 show limited improvement in survival times, whereas the combination of CV8102 and anti PD-1 resulted in a significant prolongation of survival times.

CV8102 ± anti-PD-1 treatment conferred protective immunity against tumor re-challenge in CT26 model



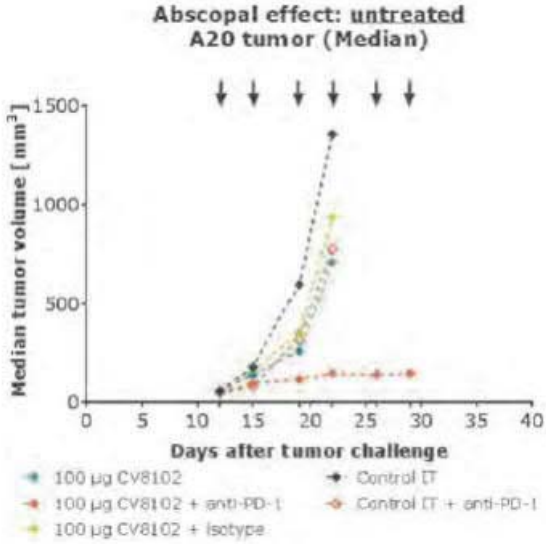
The graph above takes those animals from the previously described experiment that survived and were cured either with CV8102 alone or with combination therapy. The control arm represents animals that did not have any pretreatment. Animals treated with prior CV8102 and CV8102 treatment in combination with anti-PD-1 that were tumor-free following the prior experiment were re-challenged with the same tumor and showed no observed regrowth of the tumor. Those animals that survived and were cured and then re-challenged had a protective immunity against the tumor, which is an effect of the original treatment with CV8102 alone or in combination with anti-PD-1.

CV8102 ± anti-PD-1 treatment led to complete tumor remission in anti-PD-1 resistant A20 tumor model



The graph above represents a study performed in the A20 tumor model, which is non-responsive to anti-PD-1 therapy. The anti-PD-1 monotherapy did not result in any inhibition of tumor growth. Treatment with CV8102 monotherapy showed some inhibition of tumor growth and combination therapy of CV8102 and anti-PD-1 demonstrated synergistic anti-tumor activity.

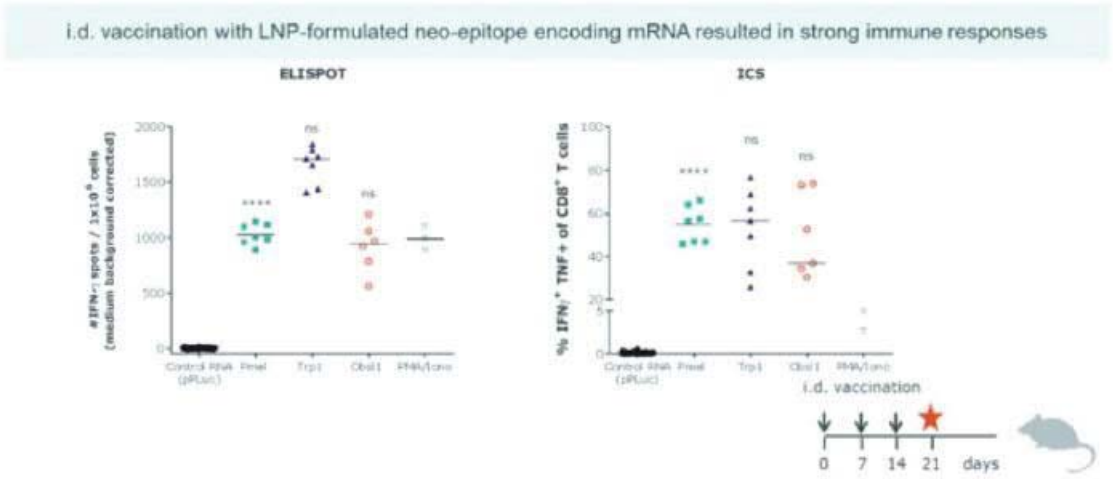
CV8102 ± anti-PD-1 treatment led to complete remission of abscopal untreated tumors in A20 model



The graph above depicts an experiment that was conducted simultaneously to the prior A20 model experiment in such a way that the animals received tumor injections in both flanks (left and right), but intratumoral treatment occurred only in the left flank. This graph shows data from the untreated flanks and demonstrates the abscopal effect which mirrors that observed in the prior experiment, whereby anti-PD-1 monotherapy has no effect, CV8102 alone exhibits limited improvement in survival times, and the combination of CV8102 and anti-PD-1 results in complete remission in four out of 10 animals.

Discovery of new therapeutic cancer vaccine candidates

Our discovery efforts in oncology are also focusing on novel therapeutic cancer vaccines candidates. In preclinical studies, we have demonstrated that LNP formulated mRNA vaccines encoding are able to induce T cell responses against model neoantigens as well as tumor associated self-antigens.



The graphs above demonstrate the induction of antigen-specific T cell responses after intradermal vaccination of mice with LNP-formulated mRNA encoding for selected neoepitopes. Animals vaccinated with LNP-formulated mRNA encoding reporter protein served as negative controls. Stimulation of splenocytes harvested 7 days post last vaccination with respective peptides demonstrated strong induction of antigen-specific T cells in Elispot (depicted in the left-hand graph) and FACs analysis (depicted in the right-hand graph).

BI1361849 (formerly CV9202) for the treatment of Non-Small Cell Lung Cancer, or NSCLC

BI1361849 is a product candidate for a therapeutic vaccine designed to elicit antigen-specific immune responses against tumor-associated antigens frequently overexpressed in patients with NSCLC (namely NY-ESO1, Mage C1, Mage C2, Survivin, 5 T4 and Muc1). We have partnered BI1361849 with Boehringer Ingelheim, who is advancing the product candidate through clinic development. BI1361849 is currently being evaluated in a Phase 1/2 clinical trial in NSCLC in combination with durvalumab, a PD-L1 inhibitor, and tremelimumab, an anti CTLA-4 antibody. The clinical trial is being conducted by the Ludwig Institute for Cancer Research, or LICR.

Mechanism of action of BI1361849

BI1361849 acts through two synergistic pathways. Free mRNA molecules encode the protein sequence of the six antigens which are translated into proteins, and protamine-coated mRNA molecules act as a vaccine adjuvant to activate the innate immune system which recruits and activates antigen-presenting cells. The antigen-presenting cells display the translated antigens to T cells and B cells to elicit an adaptive immune response against such antigens, including activation of cytotoxic T cells and antibody-producing B cells. The mRNAs in BI1361849 encode the NSCLC-associated antigens NY-ESO-1, MAGE-C1, MAGE-C2, survivin, 5T4, and MUC-1.

Market Opportunity

Lung cancer is the most common form of cancer worldwide and the most common cause of cancer-related deaths in both men and women. According to ACS, in 2018, there were approximately 2 million new cases of lung cancer worldwide and approximately 1.7 million related deaths. According to ASCO, in the United States, there were approximately 230,000 new cases of lung cancer and an estimated 154,000 deaths from the disease. The deaths from lung cancer account for approximately 25% of all cancer deaths in the United States. NSCLC accounts for approximately 80% to 85% of lung cancer cases.

Surgery is the recommended treatment for early-stage NSCLC patients, but 75% of lung cancers are diagnosed at stage III or IV when resection is no longer possible. Targeted therapies are used for metastatic NSCLC with Estimated Glomerular Filtration Rate, or EGFR, c-ros oncogene 1, or ROS1, BRAF and Anaplastic lymphoma kinase, or ALK mutations. However, in up to 50% of advanced NSCLC patients, who are ineligible or resistant to treatment with EGFR or ALK inhibitors, the treatment of choice is a PD-1/PD-L1 checkpoint inhibitor, because of elevated levels of PD-L1. Despite the availability of multiple therapies, the prognosis remains poor, with overall five-year survival for all patients diagnosed with NSCLC as low as 18%, based on data from the American Lung Association.

Phase 1/2 clinical trial of BI1361849 in combination with durvalumab and tremelimumab

The Ludwig Institute for Cancer Research has initiated a Phase 1/2 clinical trial investigating BI1361849 (formerly CV9202) in combination with the PD-L1 inhibitor durvalumab and anti-CTLA-4 antibody tremelimumab in patients with advanced NSCLC. The primary endpoint of this trial is safety, with secondary endpoints of objective response rate, progression-free survival, duration of response, and overall survival.

This open-label multicenter two-arm study is to evaluate the safety and preliminary efficacy of the addition of a vaccine therapy to 1 or 2 checkpoint inhibitors for NSCLC. The first arm evaluates BI1361849 in combination with durvalumab (anti-PD-1), and the second arm evaluates BI1361849 in combination with both durvalumab (anti-PD-1) and tremelimumab (anti-CTLA4). For each arm of the study, there is a dose evaluation phase in which the recommended combination dose, or RCD, is determined according to a standard 3+3 design. The dose evaluation phase is followed by an expansion phase, in which the cohort at the RCD is expanded to 20 subjects (inclusive of the subjects from the dose evaluation cohort).

Clinical Data

BI1361849 (former CV9202) was investigated in an exploratory, open-label, multicenter Phase 1b trial. The Phase 1b trial evaluated treatment with BI1361849 combined with local radiation in 26 Stage IV NSCLC patients with PR stable disease (SD) after first-line standard therapy. The study was conducted across 13 centers in Germany, Austria and Switzerland. Eligible patients were 18 years old or older with histologically or cytologically confirmed Stage IV NSCLC and for those with non-squamous cell histology, a confirmed EGFR mutation status. Patients were stratified into three strata:

- Non-squamous NSCLC, EGFR mutation, PR/SD after ≥ 4 cycles of platinum-and pemetrexed-based treatment (n= 16);
- Squamous NSCLC, PR/SD after ≥ 4 cycles of platinum-based and non-platinum compound treatment (n= 8); and
- Non-squamous NSCLC, EGFR mutation, PR/SD after ≥ 3 and ≤ 6 months EGFR-tyrosine kinase inhibitor (TKI) treatment (n= 2).

Patients received intradermal BI1361849, local radiation (4 × 5 Gy), then BI1361849 until disease progression requiring the start of systemic second-line treatment or patients experiencing unacceptable toxicity. Strata 1 and 3 also had maintenance pemetrexed or continued EGFR-TKI therapy, respectively. The primary endpoint was evaluation of safety and secondary endpoints included assessment of clinical efficacy (every 6 weeks during treatment) and of immune response on Days 1 (baseline), 19 and 61.

The mean number of successful BI1361849 administrations, defined as successful administration of at least 10 of the 12 injections per treatment, was 8.4 (range 2 to 25) with median duration of treatment of 81 days. Study treatment appeared well tolerated with injection site reactions and flu-like symptoms were the most common BI1361849-related adverse events. For the primary endpoint, BI1361849- and/or radiation-related AEs of >= grade 3 were reported in four (15.6%) of the 26 patients: two patients (12.5%) in stratum 1 (one event each of dyphagia and fatigue), one patient (12.5%) in stratum 2 (fatigue), and one patient (50%) in stratum 3 (pyrexia). Three out of 4 events were related to BI1361849 and one event (dysphagia) was related to study radiation. There were no serious treatment emergent adverse event, or TEAEs related to BI1361849 and no TEAEs leading to death. The following table provides an overview of the TEAEs by stratum.

Overview of treatment emergent adverse events (safety analysis set)

Patients with a least one event, n (%)	**Stratum 1 (n=16)**	**Stratum 2 (n=8)**	**Stratum 3 (n=2)**	**Overall (n=26)**
TEAE	16(100.0)	8(100.0)	2(100.0)	26(100.0)
BI1361849- and/or radiation-related AE	16(100.0)	8(100.0)	2(100.0)	26(100.0)
TEAE related to BI1361849	15(93.8)	8(100.0)	2(100.0)	26(96.2)
TEAE related to radiation	4(25.0)	1(12.5)	0(50.0)	5(19.2)
Serious TEAE	7(43.8)	3(37.5)	1(50.0)	11(42.3)
Serious BI1361849- and/or radiation-related AE	1(6.3)	0	0	1(3.8)
Related to BI1361849	0	0	0	0

Patients with a least one event, n (%)	Stratum 1 (n=16)	Stratum 2 (n=8)	Stratum 3 (n=2)	Overall (n=26)
Related to radiation	1(6.3)	0	0	1(3.8)
TEAE toxicity grade ≥ 3(a)	9(56.3)	4(50.0)	2(100.0)	15(57.7)
BI1361849- and/or radiation-related AE toxicity grade ≥ 3(a)	2(12.5)	1(12.5)	1(50.0)	4(15.4)
Related to BI1361849	1(6.3)	1(12.5)	1(50.0)	3(11.5)
Related to radiation	1(6.3)	0	0	1(3.8)
Serious BI1361849- and/or radiation-related AE toxicity grade ≥ 3(a)	1(6.3)	0	0	1(3.8)
Related to BI1361849	0	0	0	0
Related to radiation	1(6.3)	0	0	1(3.8)
TEAE leading to discontinuation	4(25.0)	0	0	4(15.4)
TEAE toxicity grade ≥ 3 leading to discontinuation	2(12.5)	0	0	2(7.7)
TEAE leading to interruption/dose modification	4(25.0)	0	0	4(15.4)
TEAE leading to death	0	0	0	0

Abbreviations: AE adverse event, TEAE treatment-emergent adverse event

(a) National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) toxicity grading

In comparison to baseline, 25 patients evaluable for immunomonitoring revealed increased BI1361849 antigen-specific immune responses in the majority of patients (84%), whereby antigen-specific antibody levels were increased in 80% and functional T cells in 40% of patients, and involvement of multiple antigen specificities was evident in 52% of patients. Additional exploratory, post hoc analysis demonstrated detectable increase of functional CD4+ and CD8+ T cells to BI1361849 over time. Broadening of the antibody repertoire against antigens not covered by BI1361849 was also observed in 50% of all evaluable patients and in eight of the 14 (57%) analyzable pemetrexed treated patients in stratum 1. This demonstrated that the combination of radiotherapy with active tumor immunotherapeutic BI1361849 can initiate an antigen cascade to broaden the anti-tumor immune response.

Of the 26 patients in the safety set evaluated for efficacy, overall 46% (12 of 26) demonstrated stable disease as best overall response. One patient treated in combination with pemetrexed chemotherapy achieved a confirmed partial response with decreasing measurable tumor size up to the last follow-up visit. Another patient exhibited decreasing target lesion sizes not formally qualifying as PR. Shrinkage of non-irradiated lesions greater than 15% occurred in six patients, five in stratum 1 and one in stratum 2. Median progression-free survival was 2.87 months (95% CI; range 1.43-4.27) and median overall survival time from first treatment was 13.95 months (95% CI; range 8.93-20.87).

Best overall response (safety analysis set)

	Patients with response, n (%) [95% confidence interval]			
Parameter	Stratum 1 (n=16)	Stratum 2 (n=8)	Stratum 3 (n=2)	Overall (n=26)
Response (CR + PR) rate	1 (6.3) [0.2-30.2]	0 [0.0-36.9]	0 [0.0-84.2]	1 (3.8) [0.1-19.6]
Best overall response				
CR	0 [0.0-20.6]	0 [0.0-36.9]	0 [0.0-84.2]	0 [0.0-13.2]
PR	1 (6.3) [0.2-30.2]	0 [0.0-36.9]	0 [0.0-84.2]	1 (3.8) [0.1-19.6]
SD	8 (50.0) [24.7-75.3]	3 (37.5) [8.5-75.5]	1(50.0) [1.3-98.7]	12 (46.2) [26.6-66.6]
PD	7 (43.8) [19.8-70.1]	4 (50.0) [15.7-84.3]	1(50.0) [1.3-98.7]	12 (46.2) [26.6-66.6]
NE	0 [0.0-20.6]	1 (12.5) [0.3-52.7]	0 [0.0-84.2]	1 (3.8) [0.1-19.6]

Confirmed response according to Response Evaluation Criteria for Solid Tumors (RECIST) version 1.1

Abbreviations: CR complete response, NE not evaluable, PD progressive disease, PR partial response, SD stable disease

In these initial trials, BI1361849 was administered via conventional needle-based intradermal injection, later shown to be a suboptimal mode of injection for the protamine formulated rabies vaccine. Our preclinical data demonstrated improved antigen expression at the site of injection if the protamine formulated vaccine was injected via a needle-free jet device. Based on that data, BI and LICR decided to use needle-free injection technique in the LICR trial. Additionally, based on preclinical data showing a synergism of mRNA vaccines and systemic immune checkpoint blockade along with widespread use of PD-L1 inhibitors in advanced NSCLC, BI decided to continue the further development of BI1361849 in combination with immune checkpoint blockade.

RNA-Based Prophylactic Vaccines

COVID-19 Vaccines Program

Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome, or MERS-CoV, and Severe Acute Respiratory Syndrome, or SARS-CoV. Coronaviruses are transmitted between animals and people and can evolve into strains not previously identified in humans. On January 7, 2020, a novel coronavirus (2019-nCoV) was identified as the cause of pneumonia cases and deaths in Wuhan, China, and an exponentially increasing number of cases have since then been found in a growing number of countries worldwide. On March 11, 2020, the World Health Organization designated COVID-19, the disease caused by the novel coronavirus SARS-CoV-2, an international pandemic. The disease has infected over 147 million people around the world. Over 3.1 million have died to date.

Upon publication of the sequence of the novel Coronavirus (SARS-CoV-2), we designed and optimized potential antigenic constructs based on the spike (S) protein to elicit high immunogenicity. Our approach is based on encoding a stabilized S-protein and we successfully conducted several preclinical studies that we started in January 2020. The results of our preclinical studies suggested that our vaccine candidate against SARS-CoV-2 was active at low dose (2 µg) and induced high levels of virus-neutralizing antibodies. Based on the preclinical results, we initiated a Phase 1 clinical trial in healthy volunteers in June 2020, a Phase 2a clinical trial in older adults above 60 years old in September 2020 and a pivotal Phase 2b/3 clinical trial in December 2020. For the Phase 2a clinical trial, we currently expect to report a first data readout in the second quarter of 2021. On November 10, 2020, we reported positive interim Phase 1 data, showing that our vaccine candidate induced relevant antibody titers. The quality of the immune responses observed in vaccinated and healthy volunteers was found to be comparable to the recovered immune response identified or detected in convalescent sera taken from recovered COVID-19 patients, thereby mimicking the immune response observed after a natural COVID-19 infection. We believe these interim data supported our decision to advance a 12µg dose in the pivotal clinical trial. Our pivotal Phase 2b/3 trial, called HERALD, is randomized, observer blind, placebo-controlled, on a two-dose schedule, and is fully enrolled with approximately 40,000 participants, above the age of 18. Of those participants, approximately 75% were enrolled in sites in Latin America and 25% were enrolled in sites in Europe. The study was started with an initial Phase 2b safety, reactogenicity and immunogenicity part, which was stratified according to age (participants between 18 and 60 years old and participants above 60 years old), and was completed in February 2021. Subsequently, the Phase 2 study merged into the current Phase 3 safety and efficacy trial. We currently expect to conduct a first interim analysis of the pivotal Phase 2b/3 trial in the second quarter of 2021, depending on the infection rate of SARS-CoV-2 in clinical trial participants. Additionally, the rapid spread of new variants of SARS-CoV-2 across the world has supported the need to identify variants causing COVID-19 infections in the countries where our Phase 2b/3 study is being conducted. On March 30, 2021, we submitted a trial protocol amendment to the regulatory authorities to address presently circulating SARS-CoV-2 variants via the implementation of a corresponding secondary endpoint.

In February 2021, we announced a new collaboration with GSK for our COVID-19 vaccine program, which went into effect in April 2021. With GSK, we will jointly advance so called second- or next-generation COVID-19 vaccine candidates, which will be based on new mRNA backbone concepts, encoding either for the original S protein or S protein mutations. Subject to regulatory approval, we are targeting to introduce new second-generation COVID-19 vaccine candidates in 2022. Additionally, we are currently negotiating the details of a collaboration with the United Kingdom government. The collaboration with the United Kingdom government is expected to include joint developments of vaccine concepts to address emerging COVID-19 variants through the government's

Vaccine Taskforce, which is at the forefront of virus variant surveillance and expertise. Our potential collaboration with the United Kingdom government would grant us high-quality scientific input to select the most relevant mutations for new vaccine candidates against SARS-CoV-2 variants. Furthermore, the collaboration with the United Kingdom government is expected to be designed to fast-track the regulatory pathway of variant-optimized vaccines. Subject to regulatory approval, we are targeting to introduce variant-optimized first-generation COVID-19 vaccine candidates in early 2022.

CVnCoV Phase 1 Clinical Trial

We initiated a Phase 1 clinical trial for CVnCoV in June 2020. This is a partially blinded, placebo-controlled, dose-escalation, first in human, clinical trial to evaluate the safety, reactogenicity and immunogenicity after 1 and 2 doses of the investigational SARS-CoV-2 mRNA vaccine, CVnCoV administered intramuscularly in healthy adults 18 to 60 years of age. The primary objective is the assessment of safety and the key secondary endpoint assesses the proportion of subjects seroconverting for SARS-CoV-2-neutralizing antibodies, as measured by an activity assay. The Phase 1 trial is being conducted at three active clinical sites in Germany and one active clinical site in Belgium. The Phase 1 trial is fully enrolled, with 280 adults assigned to seven dose groups between 2µg and 20µg of CVnCoV. The dose groups included 2µg (n=56), 4µg (n=56), 6µg (n=56), 8µg (n=56), 12µ (n=28), 16µg (n=16), and 20µg (n=12). In addition, the 2µg, 4µg, 6µg and 8µg cohorts include up to 10 placebo patients. The majority of the participants recruited in each dose group were seronegative, with several seropositive participants (i.e., participants that were previously infected with SARS-CoV-2). All of the subjects received two doses of CVnCoV on days 1 and 29.

Subjects must satisfy the following criteria at trial entry:

Key inclusion criteria:

- Healthy male and female participants ages 18 to 60 years old;
- Physical examination and laboratory results without clinically significant findings according to the Investigator's assessment; and
- Body Mass Index (BMI) ≥18.0 and ≤30.0kg/m^2 (≥18.0 and ≤32.0kg/m2 for subjects with SARS-CoV-2 positive serology).

Key exclusion criteria:

- Use of any investigational or non-registered product (drug or vaccine) other than the trial vaccine within 28 days preceding the administration of the trial vaccine, or planned use during the trial period.
- Receipt of any other vaccines within 14 days (for inactivated vaccines) or 28 days (for live vaccines) prior to enrollment in this trial or planned receipt of any vaccine within 28 days of trial vaccine administration.
- Receipt of any investigational SARS-CoV-2 or other CoV vaccine prior to the administration of the trial vaccine.
- Any known allergy, including allergy to any component of CVnCoV or aminoglycoside antibiotics.
- Active or currently active SARS-CoV-2 infection as confirmed by reactive PCR within three days of first trial vaccine administration.
- History of confirmed SARS or MERS.
- Administration of immunoglobulins, or Igs, and/or any blood products within the three months preceding the administration of any dose of the trial vaccine.
- Presence or evidence of significant acute or chronic, medical or psychiatric illness.

Positive interim Phase 1 data was reported on November 10, 2020, and showed that, as of the cutoff date of October 31, 2020, CVnCoV induced relevant antibody titers. The quality of the immune response observed in vaccinated and healthy volunteers was found to be comparable to the immune response identified in convalescent sera taken from recovered COVID-19 patients, thereby mimicking

the immune response observed after a natural COVID-19 infection. We believe these interim data supported our decision to advance a 12µg dose in the pivotal Phase 2b/3 trial, which we initiated in December 2020 and, which is investigating the efficacy, safety and immunogenicity of CVnCoV.

As the primary objective of the Phase 1 study, safety and reactogenicity were assessed based on one or two doses of CVnCoV, ranging from 2 µg to 12 µg per dose, administered 28 days apart. As of the cutoff date, all doses were generally well tolerated as illustrated in the figure below. No treatment-related serious adverse events were reported.

Local solicited adverse events, or AEs, showed a dose-dependent increase in incidence and severity. The vast majority of these reports were of Grade 1 and 2 injection site pain. The majority of cases of severe pain showed had onset within 24 hours of vaccination, decreased in severity and resolved within 48 hours. The incidence of reactions was similar after the second dose, but lower in severity.

Systemic solicited AEs also increased with dose level in terms of incidence and severity. Similar rates of systemic AEs were observed after the first and second vaccinations, but the severity of these systemic AEs increased following the second dose in the groups receiving the 4 µg to 12 µg doses. The majority of systemic AEs consisted of transient mild or moderate headache and fatigue, and to a lesser extent myalgia and chills. Overall, fever was observed less frequently than other systemic AEs. The majority of severe solicited AEs decreased or disappeared within 24-48 hours of onset. We believe these interim reactogenicity results, which showed limited presence of fever but symptoms including fatigue, headache and chills, were probably associated with the potential mechanism of action and induction of an innate immune response mediated by interferon and other immune-stimulatory cytokines.

Interim results from the subset of subjects that were SARS-CoV-2 seropositive at baseline show that CVnCoV was well tolerated in this population. Seropositive subjects showed less overall reactogenicity after administration of either 2µg or 4µg of CVnCoV than seronegative subjects.

SARS-CoV-2 mRNA vaccine candidate, CVnCoV, was generally well tolerated

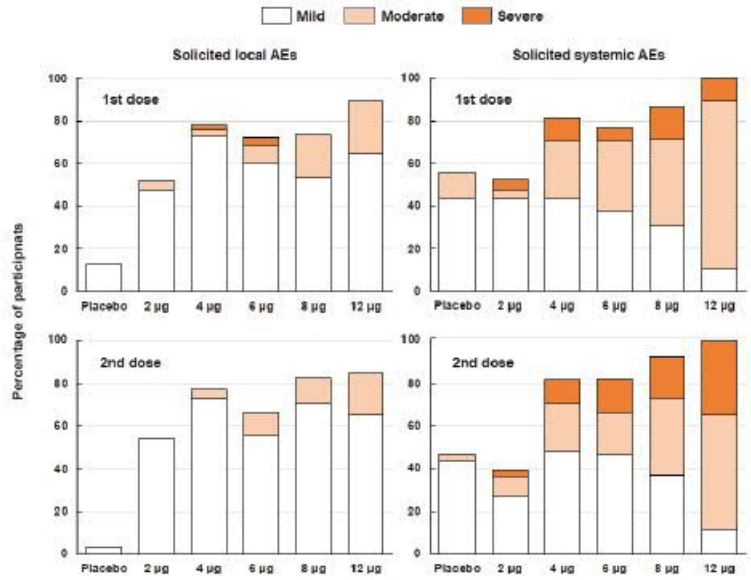


Figure. Overall incidence rates (%) of solicited local and systemic adverse events (AEs) per dose group after the first and second doses with severity classified as mild (Grade 1, white columns), moderate (Grade 2, light orange columns) or severe (Grade 3, orange columns). Data cutoff for reactogenicity was November 9, 2020.

The main secondary endpoint is the evaluation of the humoral immune response. This is measured by SARS-CoV-2 Spike protein-specific and receptor-binding domain, or RBD, specific IgG antibodies (measured by ELISA), as well as by SARS-CoV-2 virus-neutralizing antibodies (measured by micro-neutralization assay). Strong immune responses were observed in all vaccine groups using all three assays. No responses were observed in placebo recipients. As of the cutoff date, median titers measured in these assays two weeks after the second 12 µg dose were comparable to the

median titers observed in a panel of convalescent sera from recovered COVID-19 patients. Seroconversion (defined as a 4-fold increase over baseline titer) of virus-neutralizing antibodies two weeks after the second vaccination occurred in all participants who received 12 µg doses.

The applied human convalescent patient sera panel consisted of 67 convalescent patients, who exhibited multiple symptoms and of which 16 patients (24%) were hospitalized. Binding and neutralizing antibody titers of these convalescent patients are based on blood samples collected mainly at the peak time of humoral response, between four to eight-weeks after diagnostic confirmation of a SARS-CoV-2 infection.

Immune response shown as ELISA IgG antibodies against the Spike protein exhibited low but variable median titers in the baseline samples. At day 29, four weeks after the first dose, there were small dose-dependent increases with seroconversion rates of 6-28% across vaccine groups. On day 36, seven days after the second dose, there was a more marked increase in all groups with 49-82% seroconverting. This rate continued to increase to 79-91% at day 43 when median titers were 1712 (25th — 75th percentile: 789-3132), 2205 (1493-3183), 2839 (1232-7002), 3287 (1470-5770), and 5463 (2675-7132), in 2, 4, 6, 8 and 12 µg groups, respectively. Samples in the 8 µg group from day 57, four weeks after the second dose, showed a small decline in IgG median titers to 1825 (879-2834), but overall these titers persisted above baseline and the day 29 (pre-second dose) values. Notably, the value at day 43 in the 12 µg group was comparable to the median titer of 6381 (5400-12432) in the group of convalescent sera.

When IgG antibody titers against RBD were assessed, a response in the 8 µg group data was observed at day 29 after one dose. The marked increases in titers seven days (day 36) after the second dose were also observed when seroconversion rates were 17-66%. A further increase was observed on day 43 when the seroconversion rates were 83% and 91% in the 8 and 12 µg groups with median titers of 1240 (349-2952) and 1007 (678-3141), respectively, which were comparable to the median of 1448 (726-5391) observed in convalescent sera.

SARS-CoV-2 mRNA vaccine candidate, CVnCoV, elicited humoral immune responses

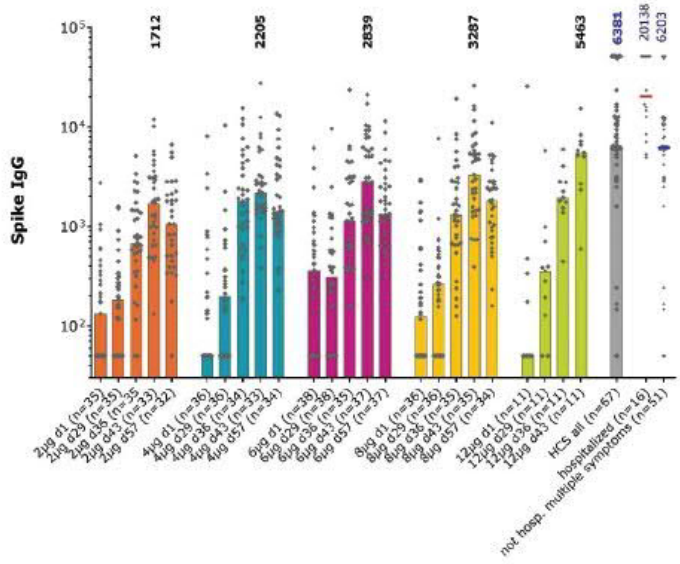


Figure. Anti-Spike protein IgGs in the different study groups and convalescent sera measured by ELISA. Bars show median values per group at each study time point, individual GMT values for each sample are shown as diamonds. Numbers show median values at day 43, two weeks after the second vaccination, for each group and the convalescent sera panel. Data cutoff for immunogenicity was October 31, 2020.

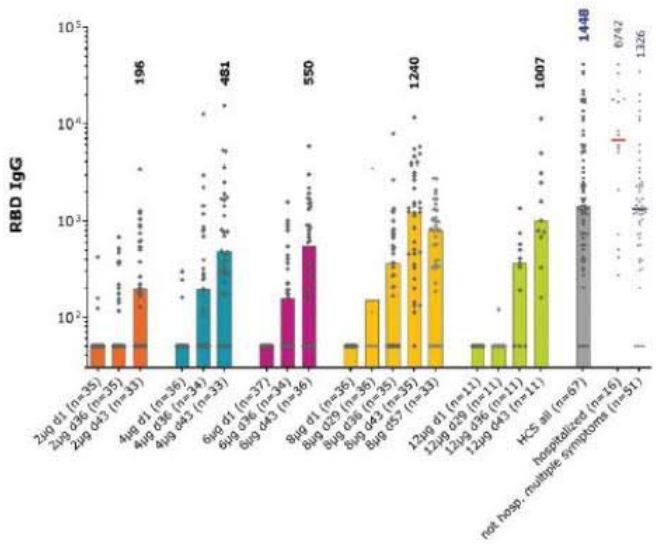


Figure. Anti-RBD IgGs in the different study groups and convalescent sera measured by ELISA. Bars show median values per group at each study time point, individual GMT values for each sample are shown as diamonds. Numbers show median values at day 43, two weeks after the second vaccination, for each group and the convalescent sera panel. Data cutoff for immunogenicity was October 31, 2020.

The observation of IgG antibody responses to the Spike protein and RBD translated into SARS-CoV-2 virus-neutralizing activity, as shown in the figure below. This response was less obviously dose-dependent from the available samples. More importantly, seroconversion reached 100% by day 43 for the 12 µg group (n = 11). The median neutralizing titer in this group on day 43 was comparable to that observed in convalescent sera. In contrast to Spike protein IgG levels, the 8 µg group median neutralizing titers observed at day 43 were generally maintained to day 57.

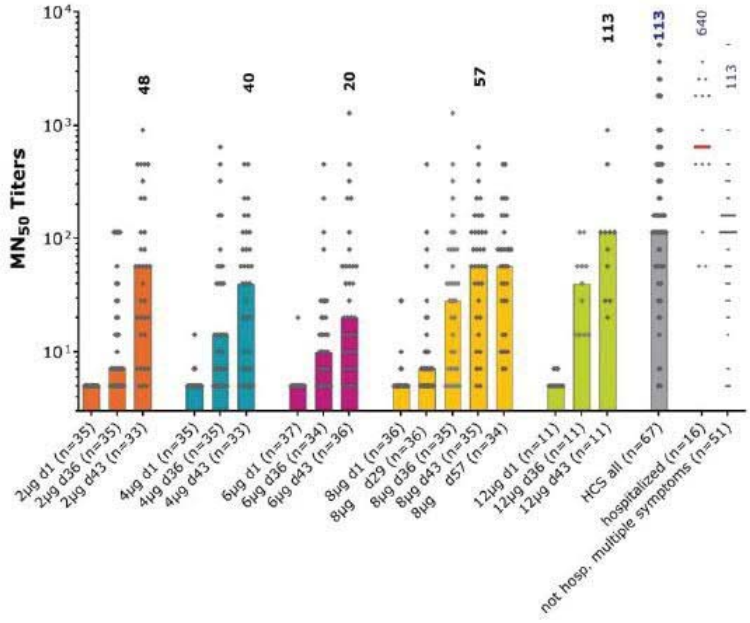


Figure. Anti-SARS-CoV-2 virus-neutralizing titers in the different study groups and convalescent sera measured by micro-neutralization. Bars show median values per group at each study time point, individual GMT values for each sample are shown as diamonds. Numbers show median MN50 values at day 43, two weeks after the second vaccination, for each group and in the convalescent sera panel. Data cutoff for immunogenicity was October 31, 2020.

Since an imbalance between binding versus neutralizing antibodies could hypothetically lead to immune-mediated disease enhancement, we further investigated the ratio of neutralizing to binding antibodies both for the Spike protein and for RBD. We calculated such ratios on an individual basis for vaccinated study participants for the recommended Phase 2b/3 dose of 12 µg as well as for convalescent patients. At day 43, after administration of two doses of CVnCoV, we observed that the ratios were comparable to the ratios measured in the sera from convalescent patients following a natural infection. This observation was also in line with the potential mechanism of action of CVnCoV, which is designed to mimic natural immune response to RNA viruses.

Immunogenicity of CVnCoV in subjects known to be SARS-CoV-2 seropositive at baseline is presented in the figure below. After vaccination with either 2µg or 4µg of CVnCoV, a rapid increase in antibody titers of more than a factor 10 was observed within one week post first vaccination even in subjects that showed with low antibody titers at baseline. These results were observed for both binding and neutralizing antibodies. The change in antibody titers following a second dose were less pronounced. Antibody titers remained stable in these patients up to day 57. We believe these results suggest a proper development of cellular memory in response to natural infection in seropositive subjects and supports the potential role of memory cells in providing long-term protection to SARS-CoV-2. As of the time of the interim data (data cutoff was October 31, 2020 for immunogenicity and November 9, 2020 for reactogenicity), CVnCoV was generally well tolerated in this population, and boosted the preexisting immune response already at low dose levels.

SARS-CoV-2 mRNA vaccine candidate, CVnCoV, boosted preexisting immune response

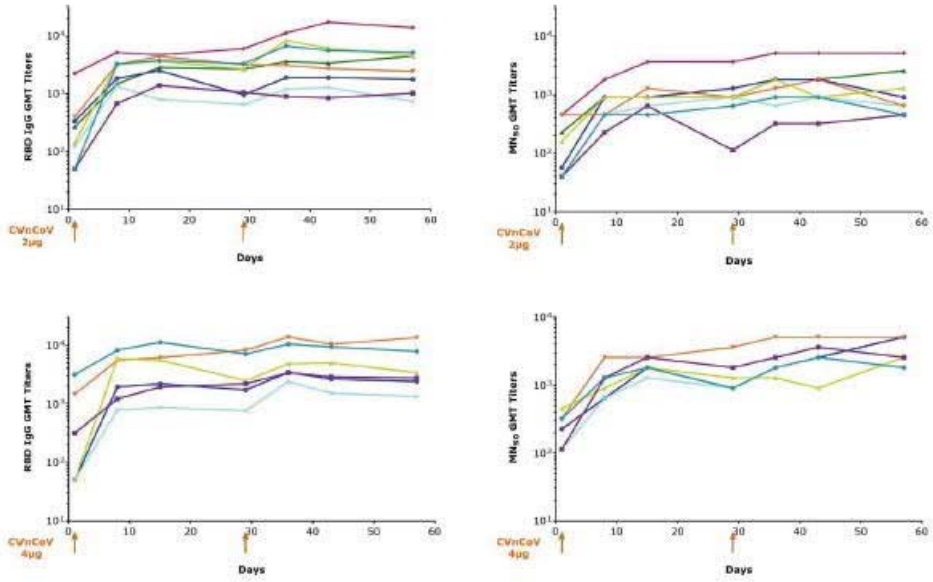


Figure. Boosting of antibody responses in seropositive subjects. Seropositive subjects were vaccinated either with 2µg (upper panel) or 4µg (lower panel) of CVnCoV on day 1 and 29. RBD binding antibodies as well as SARS-CoV-2 neutralizing antibodies were analyzed at multiple time points. Lines show individual subjects in both dose groups. Data cutoff for immunogenicity was October 31, 2020.

In summary, CVnCoV elicited a strong immune response against SARS-CoV-2 at all investigated doses as of the cutoff date. Induction of an adaptive humoral immune response was demonstrated by the observed increase in neutralizing antibodies, with 100% of participants seroconverting two weeks after two 12 µg injections. The neutralizing activity was associated with marked Spike protein-specific and RBD-specific IgG antibody responses. In the most comprehensive data set available for Spike IgGs, we observed markedly increased titers within seven days of the second vaccination, suggesting efficient priming by the first dose. In the 8 µg group, the VNT response remained stable at least up to day 57, the latest time-point with data currently available. Data in SARS-CoV-2 seropositive subjects showed that the doses of CVnCoV tested in this population were well tolerated, supporting its evaluation in a broader population without the need for previous testing for serostatus. Furthermore, interim data from seropositive subjects showed that memory responses were induced by the natural infection, since even in subjects with low antibody titers at baseline, low doses of CVnCoV were able to expand antibody titers within one week after the first vaccination. As shown in

the graph above, for some subjects, the expansion of antibody titers were above tenfold within one week after the first vaccination. We believe these results support the role of memory cells in providing long term protection to SARS-CoV-2. This is in line with our recently shared preclinical data in a hamster model, which also indicated induction of memory cells, priming after vaccination with a low dose of CVnCoV and a rapid boosting of neutralizing antibodies following virus challenge.

Overall, the available preclinical and clinical data are suggestive of a potential immune response mimicking the natural responses to infection, including a potent induction of an immune memory. More analyses on T and B cell memory responses are currently ongoing in this clinical study, as well as in preclinical studies and will further inform the unique mechanism of action of this mRNA vaccine candidate.

Based on the interim clinical results, the 12 µg dose was selected as the recommended dose for further clinical investigation, including a pivotal Phase 2b/3 trial, which was initiated in December 2020 and is fully enrolled with approximately 40,000 participants, and is investigating the efficacy, safety, and immunogenicity of our candidate vaccine, CVnCoV.

Furthermore, as part of the Phase 1 study, we administered higher doses of 16 µg and 20 µg to investigate the boundaries of the safety window and for completion of the assessments of the present groups. Subjects of all study groups are being followed up with until one year post-vaccination.

Preclinical Data

The preclinical evaluation of the immunogenicity, reactogenicity and protection efficiency of our lead vaccine candidate, CVnCoV, against SARS-CoV-2 was carried out in a BALB/c mouse and Syrian gold hamster models as well as in non-human primates (rhesus macaques) and a human ACE2 transgenic mouse model.

BALB/c Mouse and Syrian Gold Hamster Challenge Studies

The preclinical evaluation of our lead vaccine candidate, CVnCoV, against SARS-CoV-2 in mouse and hamster animal models showed that the vaccine candidate induced strong humoral and cellular immune responses with high titers of IgG binding and virus-neutralizing titers (VNTs) in mice and hamsters and robust CD4+ and CD8+ T cell responses in mice. In addition, administration of CVnCoV protected hamster lungs from challenge with the wild-type SARS-CoV-2 virus. To gain further insights in the risk of vaccine-enhanced disease, hamsters were also vaccinated with what we believe was a suboptimal dose of CVnCoV, which led to breakthrough viral replication, and were analyzed for any signs of vaccine-enhanced disease. No evidence of increased viral replication or exacerbated inflammation and damage to virus target organs was detectable, even for a suboptimal vaccine dose, providing evidence supporting the potential immunogenicity and safety of CVnCoV. The impact of different immunization schedules was investigated and is shown in the figures below for two intramuscular injections of 2µg of CVnCoV four, three, two or one week apart, i.e., on d0/d28, d7/d28, d14/d28 or d21/d28. Robust IgG1 and IgG2a titers were present seven days after a single vaccination and increased over time. A second injection with CVnCoV led to an increase in IgG1 and IgG2a binding antibodies. A trend towards lower immune responses following shorter intervals between the first and second vaccination remained detectable until termination of the experiment. High IgG titers are the basis for the development of VNTs, which are suggestive of a successful neutralization of the virus. IgG1 and IgG2a have been used in many third party studies as surrogate markers of TH1 and TH2 responses. It is known that interferon-γ (as a TH1 cytokine) and IL-4 (as a TH2 cytokine) induce isotype switching to IgG2a and IgG1, respectively. A balanced TH1 and TH2 response provides best grounds for a protective vaccine. The equivalent levels of IgG1 and IgG2a antibodies observed for CVnCoV were suggestive of a balanced TH1/TH2 profile, which gave no indication of a TH2 bias. As expected, the Alum-adjuvanted SECD protein domain, employed as a control for TH2 biased responses, induced high titers of IgG1 but comparatively low levels of IgG2a.

Induction of VNTs in mouse sera was assessed in a cytopathic effect, or CPE, based assay with the wild-type SARS-CoV-2 virus. Detectable levels of VNTs started to develop 4 weeks after a single injection, while a second injection led to a significant VNT increase in all groups. Analyses one and three weeks after the second vaccination, on day 35 and day 49, showed that responses rose over time. On day 49, all sera derived from animals vaccinated based on a day 0 / day 28 schedule showed neutralization of 50% of infecting virus in cell culture at a dilution of 1:5120.

SARS-CoV-2 mRNA vaccine candidate, CVnCoV, elicited high levels of humoral immune responses, which depended on the vaccination schedule and the dose

Impact of immunization schedule on binding and neutralizing antibody titers observed in mouse model

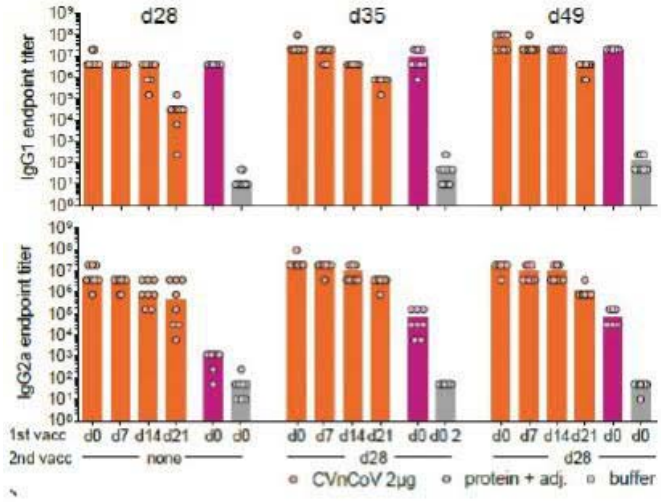


Figure. Mice (n=8) were vaccinated with 2µg CVnCoV via 2 intramuscular injections four, three, two or one week apart, i.e., d0/d28, d7/d28 d14/d28 or d21/d28 (orange columns). Alum-adjuvanted recombinant full-length Spike protein (extracellular domain) served as a control (purple columns). On day 28, day 35 and day 49 IgG titers were measured by ELISA. Values from individual animals (dots) and the median (bars) are reported for each group (buffer control grey column)

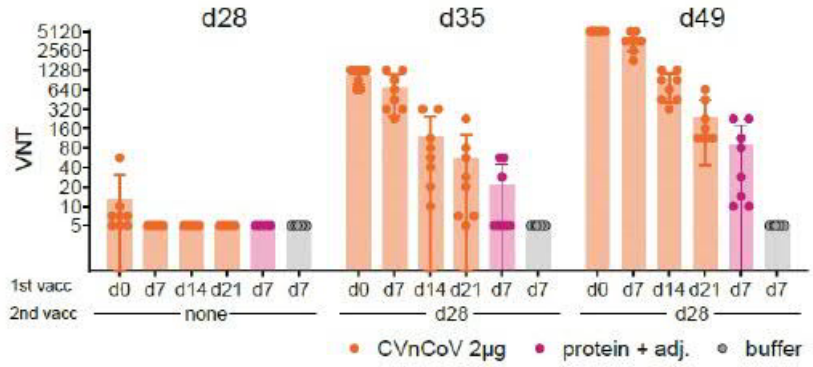


Figure. Mice (n=8) were vaccinated with 2µg CVnCoV via 2 intramuscular injections four, three, two or one week apart, i.e., d0/d28, d7/d28 d14/d28 or d21/d28 (orange columns). Alum-adjuvanted recombinant full-length Spike protein (extracellular domain) served as a control (purple columns). On day 28, day 35 and day 49 virus neutralizing titers (VNTs) based on cytopathic effect (CPE) were measured by micro-neutralization assay. Values from individual animals (dots) and the median (bars) are reported for each group (buffer control grey column).

Mice vaccinated with escalating doses of CVnCoV of 0.25 µg, 1 µg or 4 µg elicited dose-dependent humoral responses. IgG1 and IgG2a antibodies interacted with SECD, the isolated S receptor binding domain (RBD), the trimeric form of the S-protein (S trimer), and with the isolated N-terminal domain, or NTD, of the Spike protein. CVnCoV induced comparable levels of SECD, RBD and trimeric S reactive antibodies, with the exception of the lowest 0.25µg dose, which generated lower RBD responses. As observed previously, VNTs started to develop three weeks after a single vaccination and robust levels were detectable after a second vaccination for the 1 µg and 4 µg dose groups, respectively. Even the lowest dose of 0.25µg induced detectable levels of VNTs.

Impact of dose escalation on binding and neutralizing antibody titers observed in mouse model

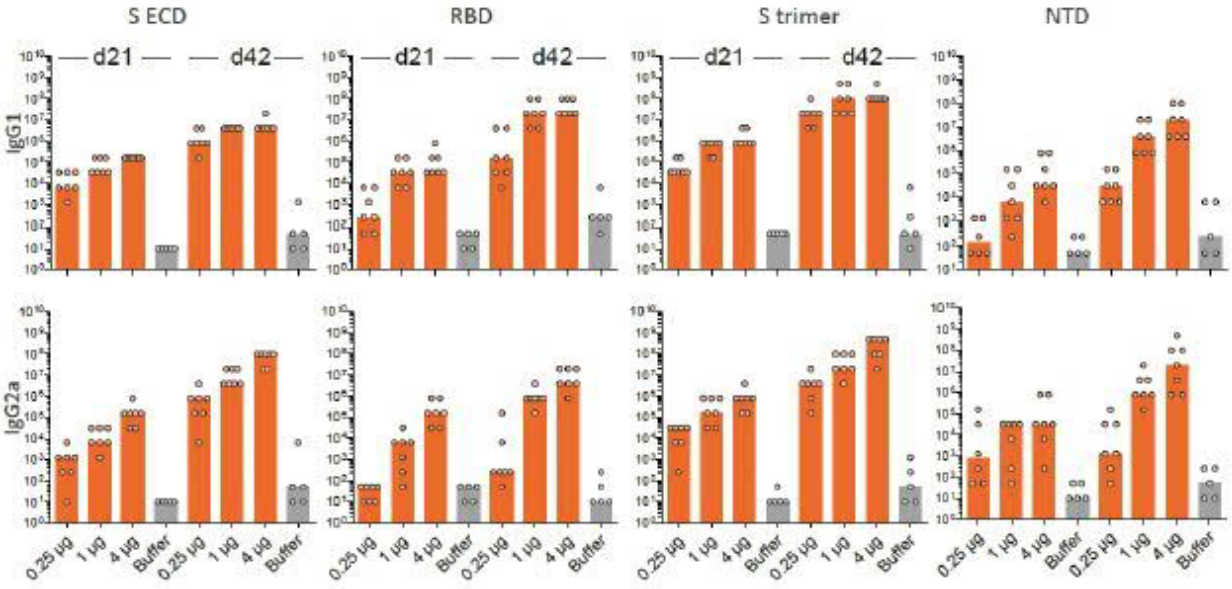


Figure. Mice (n=7) were vaccinated with 0.25µg, 1µg and 4µg of CVnCoV on day 0 and day 21 (orange columns). On day 21 and day 42 IgGs binding to S ectodomain (S ECD), receptor binding domain (RBD), S trimer and N-terminal domain (NTD) were measured by ELISA. Values from individual animals (dots) and the median (bars) are reported for each group (buffer control grey column).

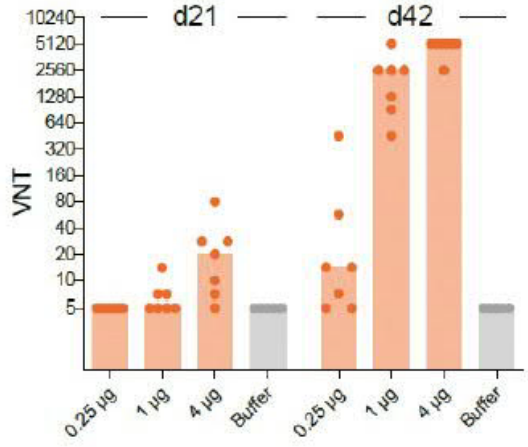
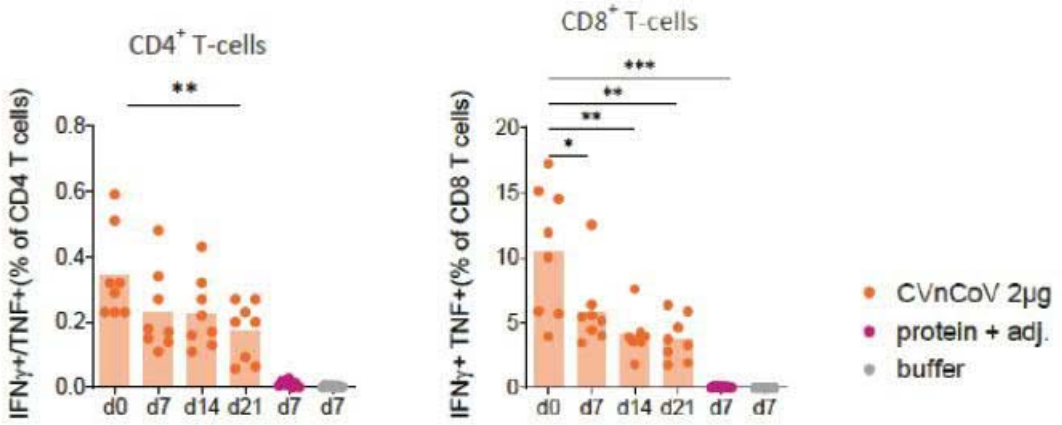


Figure. Mice (n=7) were vaccinated with 0.25µg, 1µg and 4µg of CVnCoV on day 0 and day 21 (orange columns). On day 21 and day 42 virus neutralizing titers (VNTs) based on cytopathic effect (CPE) were measured by micro-neutralization assay. Values from individual animals (dots) and the median (bars) are reported for each group (buffer control grey column).

Strong induction of IFNγ/TNF double positive T cells in CVnCoV-vaccinated mice was demonstrated by T cell analyses via intracellular staining of cells isolated three weeks after the second vaccination, on day 49. T cell responses were also shown to benefit from longer intervals between the first and second vaccination. Higher responses were detected in animals vaccinated according to a day 0/day 28 schedule with median values of IFNγ+/TNF+ CD4+ and CD8+ T cell of 0.34% and 10.5%, respectively. In contrast, IFNγ+/TNF+ CD4+ and CD8+ T cells remained undetectable in the protein control group.

SARS-CoV-2 mRNA vaccine induced multifunctional (IFNγ+ and TNFα+) CD4 and CD8 T cell responses



Mice (n=8) were vaccinated with 2µg CVnCoV via 2 intramuscular injections four, three, two or one week apart, i.e., d0/d28, d7/d28 d14/d28 or d21/d28 (orange columns). Alum-adjuvanted recombinant full-length Spike protein (extracellular domain) served as a control (purple columns). Multifunctional CD4+ and CD8+ T cells analysis was performed using FACS from cells isolated on day 49. Double positive IFNy and TNF CD4 and CD8 cells were quantified as percentage of total CD4 or CD8 cell counts, respectively.

Next, we sought to evaluate the protective efficacy of CVnCoV in Syrian hamsters. This model represents mild to moderate human lung disease pathology, and is one of the recognized and accepted models for investigating human-relevant immunogenicity and pathogenesis. Hamsters are believed to be susceptible to a wild-type SARS-CoV-2 virus infection, resulting in high levels of virus replication and histopathological changes in virus target organs such as the lungs. Animals vaccinated with two CVnCoV doses of 2 µg or 10 µg in a four-week interval developed dose-dependent binding IgG antibodies after the first vaccination that increased upon the second vaccination.

CPE-based VNT analysis showed that two vaccinations with 10 µg of CVnCoV induced robust levels of neutralizing titers in hamsters. Of note, a control group that received Alum-adjuvanted SECD protein developed IgG antibodies but no detectable VNT levels.

Four weeks after the second vaccination, all hamsters were challenged with the wild-type SARS-CoV-2 virus. Buffer control animal throat swabs, taken daily, showed peak replication-competent viral titers of two days post-challenge. Animals previously infected with SARS-CoV-2 remained negative throughout the experiment. Viral levels were significantly reduced in throat swabs of both CVnCoV-vaccinated groups. Vaccination with 10 µg of CVnCoV resulted in significantly diminished and delayed viral peaks three days post-challenge. At least two out of five animals in this group remained negative throughout the testing period. Viral levels in nasal turbinates revealed less pronounced, but detectable dose-dependent reduction of viral replication. Importantly, animals vaccinated with 10 µg of CVnCoV exhibited no detectable viral levels in the lungs, proving the ability of CVnCoV to protect animals from viral replication in the lower respiratory tract.

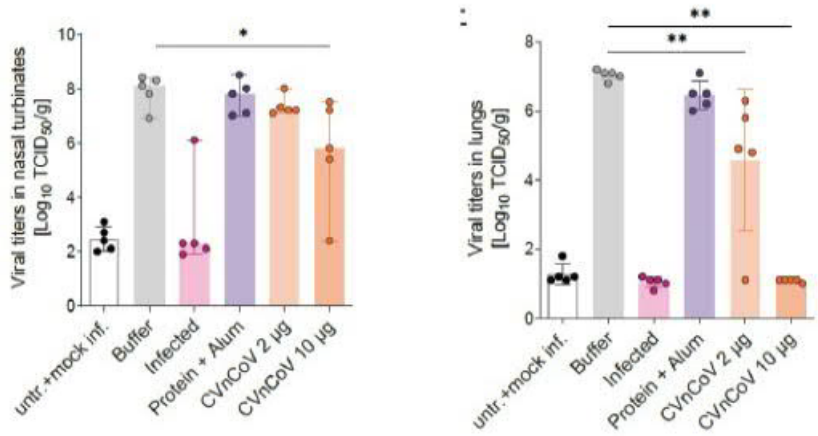


Figure based on unpublished preclinical data. Hamsters (n=5) were vaccinated with 2µg or 10µg of CVnCoV on day 0 and day 28 (orange columns). Alum-adjuvanted recombinant full-length Spike protein (extracellular domain) served as a control (purple columns). As additional controls, animals were either left untreated or infected intra-nasally with 102 TCID50/dose of SARS CoV-2 virus on day 0. Left, analysis of nasal turbinate on day 60. Right, analysis of lung tissues on day 60. Values from individual animals (dots) and the median (bars) are reported for each group (buffer control grey column).

Hamsters were vaccinated with different CVnCoV doses on day 0 and day 28. One group received only a single vaccination of the 8 µg dose. Animals were challenged on day 56 with SARS-CoV-2 virus and virus neutralizing titers were measured on days 56 (before) and day 63 (post-challenge). In contrast to buffer control, animals treated with a single dose vaccine, or with low dose of 0.4µg, developed VNT titers comparable to the hamsters vaccinated with two 8µg doses. This data indicates a good priming even with a low dose vaccine and induction of memory B cells, which produced high antibody amounts in response to virus challenge.

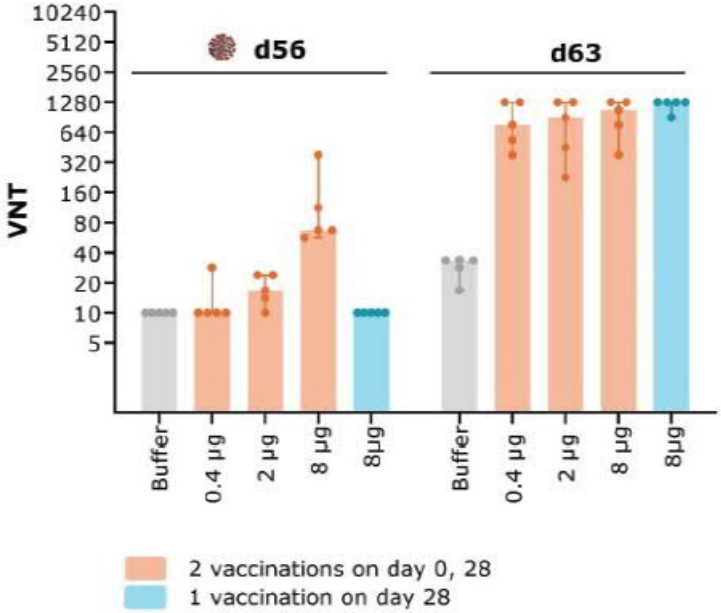


Figure based on unpublished preclinical data. Hamsters (n=5) were vaccinated with 0.4µg, 2µg or 8µg of CVnCoV on day 0 and day 28 (orange columns). One group received 8µg only on day 28 (blue column). Control group was treated with NaCl buffer (grey column). On day 56 all animals were infected intra-nasally with 102 TCID50/dose of SARS-CoV-2 virus. Virus neutralizing titers were measured on days 56 and 63 with microneutralization assay based on Cytopathic effect (CPE) at Viroclinics. Bars represent median VNT with range per group.

In summary, we believe the preclinical data collected for CVnCoV in mice and hamsters support the favorable safety profile of CVnCoV and showed fast induction of a balanced immune response with robust humoral responses featuring high levels of virus neutralizing titers in mice and hamsters that were dose-and dosing schedule-dependent. T cell analysis in mice showed high levels of cellular immune responses demonstrated by the induction of high S-specific CD4+ and CD8+ T cell levels, which are known to contribute to protection in respiratory infections. Consistent with robust immune responses, CVnCoV protected hamsters against SARS-CoV-2 viral challenge. These experiments showed significant reduction in virus levels in the upper respiratory tract and the absence of detectable live virus in the lungs of animals upon two vaccinations with 10 µg of CVnCoV. In addition, challenge infection in hamsters did not reveal evidence of disease enhancement, neither by enhanced viral levels in the respiratory tract, nor inflammation of lung tissue.

Non-Human Primate (Rhesus Macaques) Challenge Studies

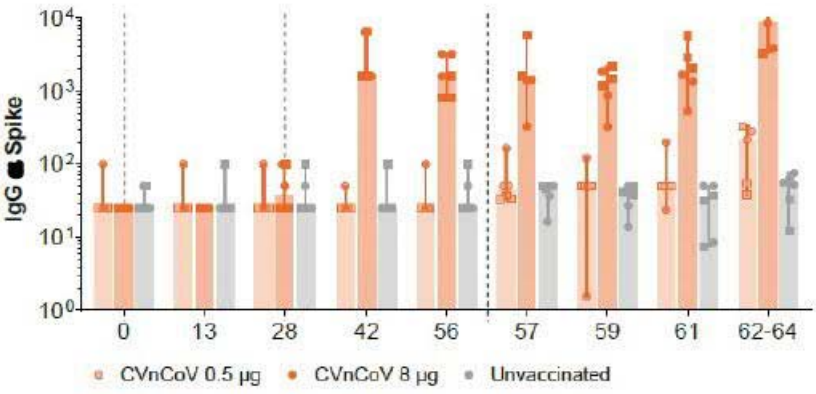
On December 23, 2020, we published preclinical data demonstrating the efficient protection of non-human primates vaccinated with CVnCoV from SARS-CoV-2. Rhesus macaques vaccinated with 8µg of CVnCoV showed robust humoral and cellular immune responses, including high levels of Spike protein and receptor binding domain (RBD) specific binding antibodies and virus neutralizing antibodies. Animals were shown to be protected from challenge infection with SARS-CoV-2 following vaccination with 8µg of CVnCoV. Comprehensive analyses gave no indication of enhanced disease upon CVnCoV vaccination. The data provide important evidence on the safety, immunogenicity and protective efficacy of CVnCoV at low doses in NHPs that extend our previously published preclinical data in mice and hamsters and further support the ongoing international clinical Phase 2b/3 efficacy study applying a 12µg dose.

Analysis of binding antibody titers to either the Spike protein or the isolated RBD showed a significant increase in IgG titers after the second vaccination on day 42, with animals exhibiting median endpoint titers of 1.6 x 103 and 3.2 x 103 for Spike protein and RBD antibodies, respectively.

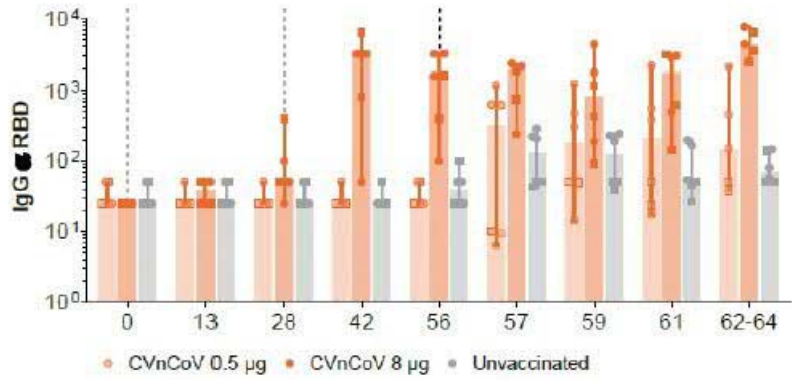
In agreement with the induction of binding antibodies, robust levels of virus neutralizing titers (VNTs) were detectable after the second vaccination in the 8µg group. VNTs peaked on day 42 at median titers of 2.7 x 104. Neutralizing antibody titers remained relatively unchanged upon challenge (day 56) until day 62, 63 and 64 of the experiment.

SARS-CoV-2 mRNA vaccine candidate, CVnCoV, elicited high levels of humoral immune responses

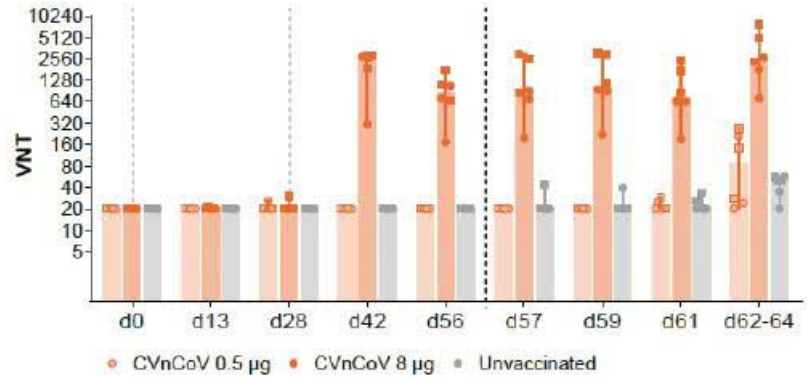
Spike protein specific binding IgG antibodies determined via ELISA and displayed as endpoint titers at different time points



RBD specific binding IgG antibodies determined via ELISA and displayed as endpoint titers at different time points



Virus neutralizing antibodies determined via focus reduction neutralization test at different time points

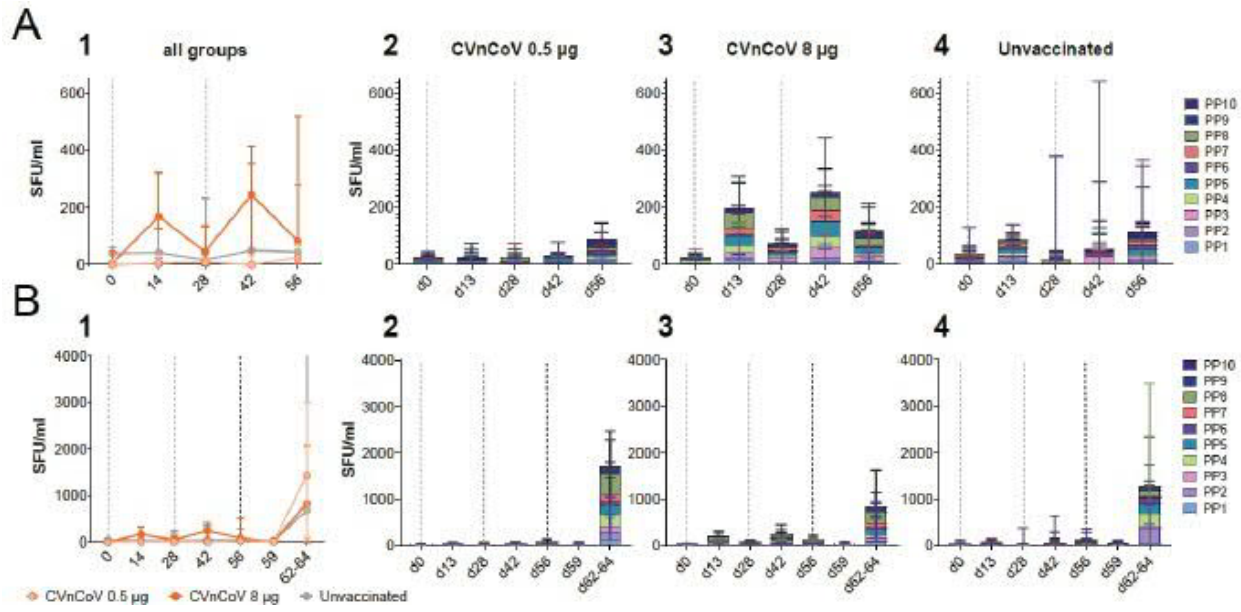


Figures. Rhesus macaques (n=18) were divided into three groups of six, each comprising three females and three males. Animals were vaccinated intramuscularly on day 0 and day 28 with 0.5µg (light orange columns) or 8µg (orange columns) of CVnCoV or remained unvaccinated (grey columns). All animals were challenged with 5.0 x 106 PFU of wild-type SARS-CoV-2 on day 56. All values are displayed as median with range. Square symbols represent male, round symbols represent female animals. Dotted lines represent vaccinations and challenge infection, respectively.

In order to assess CVnCoV induced cellular responses, peripheral blood mononuclear cells were isolated at different time points after vaccination and challenge infection and subsequently stimulated with pools of peptides spanning the whole SARS-CoV-2 Spike protein. IFNγ release of stimulated cells was measured by ELISpot. Analysis of summed responses to the peptide pools in the vaccination phase showed increases in Spike-specific IFNγ secreting cells in 8µg CVnCoV vaccinated animals, two weeks after the first and, more pronounced, two weeks after the second vaccination (Figure below, A1). Stimulation with ten individual pools, each covering approximately 140 amino acids of the Spike protein, demonstrated the induction of cells reactive to peptides across the whole length of the Spike protein upon vaccination with 8µg of CVnCoV (Figure below, A3).

Increased Spike-specific IFNγ responses were detectable in all animals post-challenge on day 62-64 (Figure below, B1-4). Of note, increases of cellular responses in animals vaccinated with 8µg of CVnCoV (Figure below, B3) were less pronounced than in the other groups, likely indicative of lower levels of viral replication in these animals.

SARS-CoV-2 mRNA vaccine candidate, CVnCoV, induced cellular responses



Figures. Peripheral blood mononuclear cells from animals either unvaccinated (grey line) or vaccinated with 0.5µg (light orange line) or 8µg (orange line) of CVnCoV were isolated at different time points and re-stimulated with Spike-specific peptide pools followed by IFNγ ELISpot analysis. (A) IFNγELISpot before challenge infection on day 56. Panel A1 shows the summed response covering the whole Spike protein; panels A2-4 depict stimulation results of ten individual pools covering the entire Spike protein in each group. (B) IFNγ ELISpot until termination of the experiment on day 62-64. Panel B1 shows the summed response covering the whole Spike protein; panels B2-4 depict stimulation results of ten individual pools covering the entire S protein in each group. SFU: spot forming unit; PP: peptide pool

Presence of SARS-CoV-2 RNA in the upper and lower respiratory tract following challenge infection (day 56) was monitored via reverse transcription quantitative polymerase chain reaction (RT-qPCR). Viral replication in the upper respiratory tract peaked on day 59 in unvaccinated animals, which reached median values of 2.7 107 cp/ml in nasal swabs, and remained detectable until termination on day 62-64 (Figure below, A). No significant difference between viral replication in animals vaccinated with 0.5 µg CVnCoV and unvaccinated control animals was measured in nose swabs.

Overall, 8µg CVnCoV vaccination induced the lowest number of viral RNA copies in the upper respiratory tract, where median values of 2.9 x 106 cp/ml in nasal swabs, respectively, were detectable on day 59. However, the difference between the study groups was not statistically significant. Parallel analyses of the lower respiratory tract of in-life (day 59) and post-mortem (day 62-64) bronchoalveolar lavage samples (BAL) showed significantly reduced levels of total viral RNA upon 8µg CVnCoV vaccination (Figure below, B). RNA levels in BAL were below the lower limit of quantification for all but one animal in the 8µg CVnCoV group on day 59, which featured low RNA counts. Total viral RNA levels in 0.5µg CVnCoV vaccinated animals were comparable to the control group.

Additional analyses assessing sub-genomic RNA via RT-qPCR indicative of viral replication yielded overall low sub-genomic RNA levels in the upper respiratory tract. Values peaked on day 59 and returned to baseline on day 62 in all animals (Figure below, D). In nasal swabs, sub-genomic RNA levels were lowest in CVnCoV vaccinated animals. Sub-genomic viral RNA analysis in BAL samples yielded comparable results: RNA indicative of replicating virus was detectable in BAL samples of unvaccinated and 0.5µg CVnCoV vaccinated animals on day 59 and day 62-64, respectively. All animals in the 8µg CVnCoV group were negative in these analyses (Figure below, E).

SARS-CoV-2 mRNA vaccine candidate, CVnCoV, protects non-human primates from challenge infection

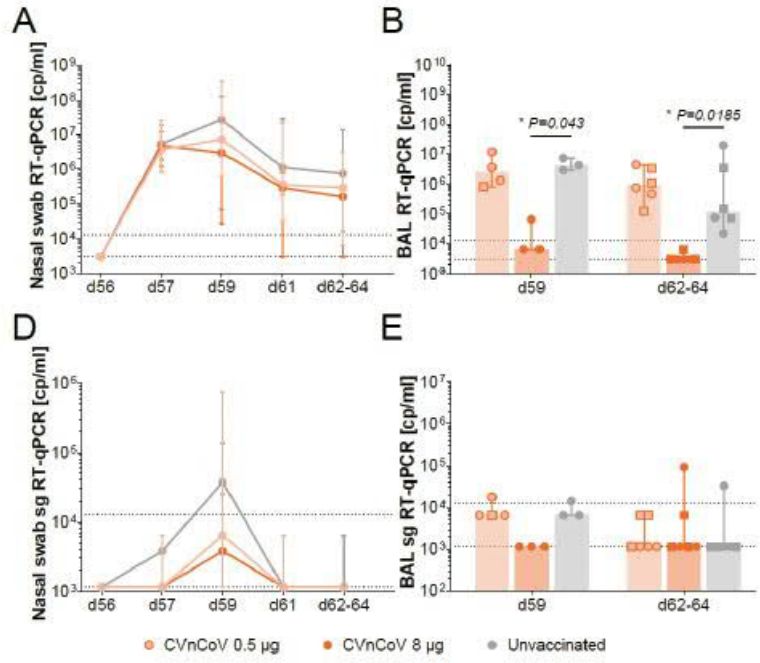


Figure: (A) Nasal swabs taken at different time points following challenge infection and (B) bronchoalveolar lavage (BAL) samples taken on day 59 and at termination on day 62-64 were analyzed for viral RNA via RT-qPCR. (D) Nasal swabs taken at different time points following challenge infection and (E) BAL samples taken on day 59 and at termination on day 62-64 were analyzed for sub-genomic RNA via RT-qPCR. Values are depicted as medians with range. Square symbols represent male, round symbols represent female animals. Lower and upper dotted lines represent lower limit of detection and lower limit of quantification, respectively. RT-qPCR Reverse transcription quantitative polymerase chain reaction

In summary, we believe the preclinical data collected for CVnCoV in rhesus macaques complement our preclinical data in mice and hamsters and further support the favorable safety profile of CVnCoV. As for the mice and hamster data, it showed induction of a balanced immune response with robust humoral responses featuring high levels of binding and neutralizing antibody titers and cellular responses. Consistent with robust immune responses, CVnCoV protected lungs of rhesus macaques against SARS-CoV-2 infection. The experiments showed reduction in virus levels in the upper respiratory tract and the absence of detectable live virus in the lungs of animals upon two vaccinations with a dose of 8µg of CVnCoV. In addition, challenge infection did not reveal evidence of disease enhancement in vaccinated animals.

Human ACE2 Transgenic Mice Challenge Studies with SARS-CoV-2 B.1.351 Variant (South African Variant)

On March 23, 2021, we published preclinical data demonstrating the protection efficiency of CVnCoV from the SARS-CoV-2 ancestral strain BavPat1 and the novel Variant of Concern B.1.351 (also referred to as the "South African" variant). The study was carried out in a transgenic mouse model, expressing the human ACE2 receptor, the receptor through which SARS-CoV-2 enters human cells. For immunization of the mice, 8µg of the CVnCoV vaccine candidate was administered following a two-dose schedule on days 0 and 28. Mice were challenged 4 weeks after the second vaccination with more than 10^5 $TCID_{50}$ of SARS-CoV-2 BavPat1 or B.1.351. Overall, CVnCoV vaccination was shown to induce robust antibody titers with variant neutralizing capacity and to provide full protection against infection and mortality during challenge infection.

For the analysis of antibody titers, sera from CVnCoV-vaccinated mice were collected on days 28 and 55. Analysis showed strong induction of RBD binding antibodies with a significant increase on day 55 (4 weeks after second vaccination) compared to day 28 (4 weeks after first vaccination). Robust RBD binding antibody titers were reflected by high virus neutralization titers (VNT). However,

consistent with other available variant studies, neutralization capacity of VNT titers was significantly lower for Variant of Concern B.1.351 (mean titer = 525) compared to BavPat1 (mean titer = 10,151).

To analyze the potential of CVnCoV to protect from SARS-CoV-2 challenge infection despite impacted VNT titers, immunized K18-hACE2 mice were studied applying a high-dose challenge model, which induces severe clinical disease resembling COVID-19 in humans. On day 4 following the challenge infection, non-vaccinated control animals (sham group) started succumbing to the BavPat1 infection. B.1.351 infection led to a delayed onset of severe disease compared to BavPat1, with 20% survival on day 10 after inoculation. By contrast, vaccination with CVnCoV resulted in complete protection (100% survival) against the lethal challenge infection with BavPat1 and B.1.351, with no significant weight loss or disease symptoms throughout the course of the challenge infection.

CVnCoV protects K18-hACE2 mice against SARS-CoV-2 variants BavPat1 and B1.351

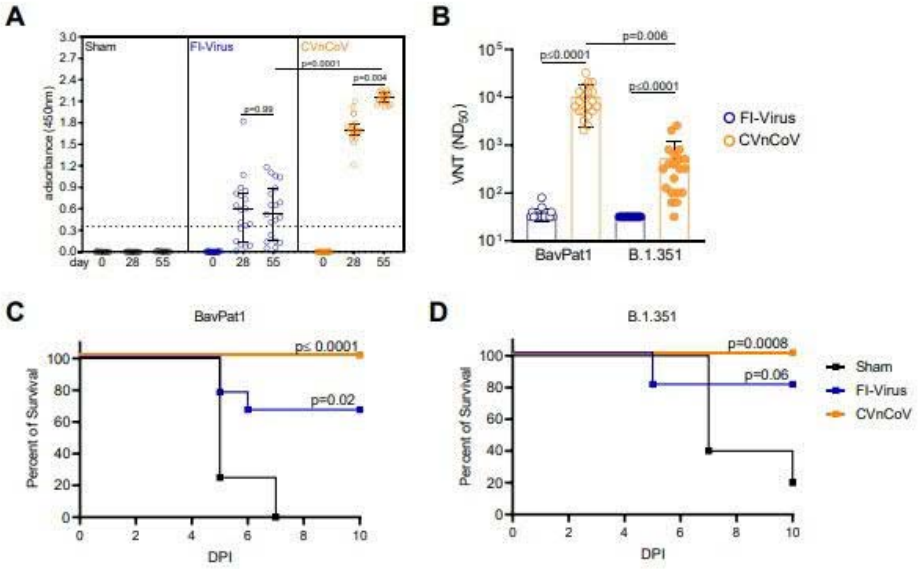


Figure: K18-hACE2 mice were vaccinated with 8µg CVnCoV or received 10^6 FI-Virus (formalin-inactivated and adjuvanted SARS-CoV-2-preparation) or NaCl (SHAM group) on day 0 and day 28 followed by i.n. challenge with $10^{5,875}$ $TCID_{50}$ of SARS-CoV-2 variants BavPat1 or $10^{5,5}$ $TCID_{50}$ B1.351. (A) RBD-Elisa with sera from K18-hACE2 mice on day 0, 28 and 55 of respective groups: median and interquartile range are presented. Dashed line indicates threshold for positive anti-RBD antibody level. (B) Virus neutralization assay using day 55 sera from all three groups. Bars indicate mean with SD. (C and D) Survival curves (Kaplan-Meyer) for K18-hACE2 mice from all three groups challenged either with BavPat1 (C) or B.1.351 (D) and followed up for 10 days post-infection (DPI). P-values were determined by nonparametric one-way ANOVA and Dunn's multiple comparisons test (A and B) or log-rank (Mantel-Cox) test (C and D).

Viral replication and hence viral RNA load following challenge infection was determined via RT-qPCR in saliva, the upper respiratory tract (URT) (conchae), the lower respiratory tract (LRT) (trachea, caudal lung and cranial lung) and the central nervous system (brain, cerebellum/cerebrum). In saliva, non-vaccinated control animals showed 4/4 and 4/5 positive samples after infection with BavPat1 or B.1.351, respectively. In contrast, after CVnCoV vaccination, no viral genomes were detected in the saliva of either challenge group. Similarly, the URT provided a niche for viral replication in non-CVnCoV treated animals. In the CVnCoV-vaccinated group challenged with BavPat1, only 3/10 animals showed low genome copy numbers in the conchae. No animal was positive in the LRT or the brain, indicating complete protection from infection by BavPat1. For B.1.351, 6/10 CVnCoV-vaccinated animals exhibited residual viral replication in the conchae, but viral levels were reduced without reaching statistical significance. In contrast, CVnCoV vaccination prevented any detectable replication of this variant in the LRT and the brain, with low viral copy numbers close to the limit of detection in the lung of only 2/10 animals, and in the cerebrum for only 1/10 animals.

CVnCoV prevents replication of SARS-CoV-2 variants BavPat1 and B.1.351 in K18-hACE2 mice

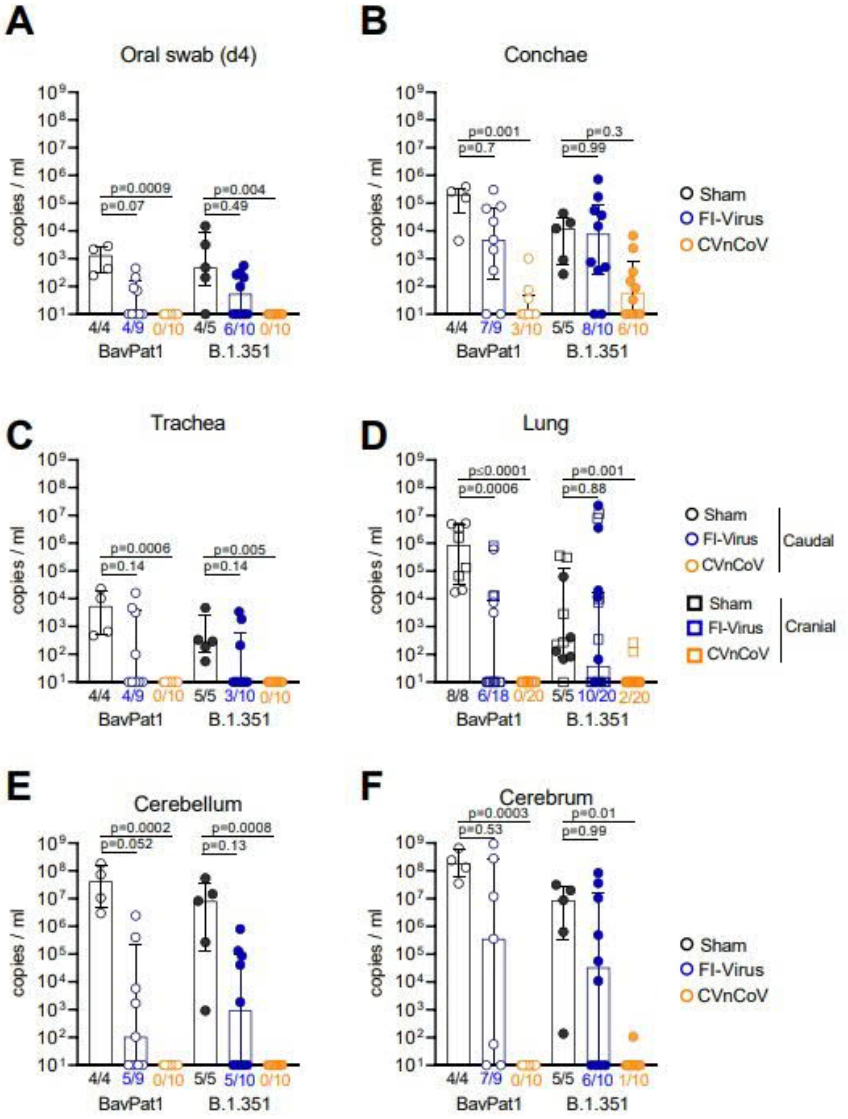


Figure: K18-hACE2 mice were vaccinated with 8µg CVnCoV or received 10^6 FI-Virus (formalin-inactivated and adjuvanted SARS-CoV-2-preparation) or NaCl (SHAM group) on day 0 and day 28 followed by i.n. challenge with $10^{5,875}$ $TCID_{50}$ of SARS-CoV-2 variants BavPat1 or $10^{5,5}$ $TCID_{50}$ B1.351. RT-qPCR for genomic RNA of SARS-CoV-2 was performed with either (A) oral swab samples at day 4 or (B) from organ samples of the upper respiratory tract, (C - E) the lower respiratory tract, and (F and G) the brain at day 10 or at the humane endpoint. P-values were determined by nonparametric one-way ANOVA and Dunn's multiple comparisons test. Scatter plots are labeled with median (height of the bar) and interquartile range.

In summary, we believe the preclinical data collected for CVnCoV in human transgenic ACE2 mice is important complementary data to existing studies investgating the impact of currently spreading Variants of Concern. The emergence of new strains with immune escape potential, such as variants of the B.1.351 lineage, pose a threat to global vaccination efforts, since all available COVID-19 vaccines were developed based on the ancestral SARS-CoV-2 strains. The B.1.351 variant is of particular interest due to the observed immune-escape features with a reduced neutralization efficacy. The described challenge study in a human transgenic mouse model complements our preclinical studies with SARS-CoV-2 variants specific data and provides further evidence on the protection efficiency of CVnCoV. Our data demonstrate that CVnCoV fully protects mice from lethal infection caused by BavPat1 and B.1.351. CVnCoV immunization resulted in abundant RBD binding and virus neutralizing antibodies, and conferred a complete and robust protection from viral

replication in the lung and the brain. Only very limited viral replication was observed in the URT of mRNA-vaccinated animals challenged with B.1.351. The reduced neutralizing capacity of sera from CVnCoV-vaccinated transgenic mice against B.1.351, and the insufficient prevention of replication in the conchae, might reflect the currently detected transmission rates of this variant in human populations previously exposed to the ancestral strain. Nevertheless, our study provides the first evidence for the efficacy of a vaccine to prevent disease and viral dissemination from the site of infection against an emerging SARS-CoV-2 variant in a sensitive, well-established and accepted *in vivo* model.

CVnCoV Phase 2b/3 Clinical Trial (Pivotal Trial for CVnCoV Safety and Efficacy)

We initiated our Phase 2b/3 trial, called HERALD, in December 2020, and has successfully completed recruitment, with approximately 40,000 participants, above the age of 18. Of those participants, approximately 75% were enrolled in sites in Latin America and 25% were enrolled in sites in Europe. The study is randomized, observer blind, placebo-controlled, on a two-dose schedule and was started with an initial Phase 2b safety, reactogenicity and immunogenicity part, which was stratified according to age (participants between 18 and 60 years old and participants older than 60 years old), and was completed in February 2021. Subsequently, the Phase 2 study merged into the current Phase 3 safety and efficacy trial. The Phase 2b/3 trial has a primary safety objective and two primary efficacy objectives: the demonstration of the efficacy of preventing first episodes of confirmed cases of COVID-19 of any severity and preventing moderate to severe confirmed cases of COVID-19 in participants who have never been infected with SARS-CoV-2. We currently expect to conduct a first interim analysis of the pivotal Phase 2b/3 trial in the second quarter of 2021, depending on the infection rate of SARS-CoV-2 in clinical trial participants. Additionally, the rapid spread of new variants of SARS-CoV-2 across the world has supported the need to identify variants causing COVID-19 infections in the countries where our Phase 2b/3 study is being conducted. On March 30, 2021, we submitted a trial protocol amendment to the regulatory authorities to address presently circulating SARS-CoV-2 variants via the implementation of a corresponding secondary endpoint.

CVnCoV Temperature Stability Studies

Temperature stability studies of CVnCoV are being carried out in parallel with the clinical development. A first study readout announced on November 12, 2020, showed stability of the COVID-19 vaccine candidate for at least three months at standard fridge temperature (2-8 °C/36-46 °F) and up to 24 hours of the ready-to-use vaccine candidate when stored at room temperature.

Storage of sample material, as well as analytical testing of CVnCoV, was performed under standard conditions defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, or ICH. ICH guidelines include standards for drug development including methodologies to ensure efficacy, safety and quality of active drug substance and dosage forms over time and to establish shelf life or expiration period and to support label claims.

Stability of the liquid drug product of CVnCoV was tested at the anticipated storage concentration and stored at +5°C (+41°F) as well as below -60°C (-76°F). CVnCoV fulfilled all set release specifications at both temperatures after three months. The stability study is ongoing with the goal to further evaluate the potential for a longer commercial product shelf-life.

We believe the reported stability results from testing of our COVID-19 vaccine candidate show the potential to be compatible with existing vaccine cold-chain infrastructures, which we believe could enable decentralized vaccine storage and significantly facilitate large-scale vaccination efforts during the current pandemic.

CVnCoV Phase 3 Clinical Trial

On December 21, 2020, we announced initiation of a clinical Phase 3 study to evaluate the safety and immunogenicity of CVnCoV in healthcare workers at the University Medical Center Mainz in the Rhine-Main Region of Germany. The Phase 3 study is a randomized, observer-blind and placebo-controlled clinical study and will enroll more than 2,500 healthy participants, above the age of 18. The Phase 3 study follows an epidemiological, non-interventional study conducted with healthcare workers from the University Medical Center Mainz which focuses on the rate at which SARS-CoV-2-specific antibodies arise and can be detected in hospital employees as well as the frequency of virologically confirmed COVID-19 cases in this cohort of hospital employees.

CV7202: Rabies Vaccine

CV7202 is our next-generation rabies vaccine encoding the rabies virus glycoprotein, RABV-G protein formulated with LNPs, which have shown to increase immunogenicity in animal models. RABV-G is one of only five proteins encoded by the rabies virus. As a dominant part of the virus surface and its role in virus entry into the host cell, RABV-G is the only target of virus-neutralizing antibodies conferring protection against challenge.

We initiated a Phase 1 clinical trial for CV7202 in the fourth quarter of 2018, which is fully enrolled. Follow-up in this clinical trial is ongoing and data will be collected along the different time points during the study. We will follow all study participants for up to two years after their last vaccination to collect safety data and to monitor persistence of VNT and other immune parameters.

Rabies Disease Background

Rabies is an infectious viral disease that is almost always fatal following the onset of clinical symptoms. In up to 99% of cases, domestic dogs are responsible for rabies virus transmission to humans.

Rabies can affect both domestic and wild animals. It is spread to people through bites or scratches, usually via saliva. According to the World Health Organization, rabies remains an important disease, leading to 60,000 human deaths every year worldwide, primarily in Asia and Africa, where dog rabies is endemic.

There are commercially available rabies vaccines that are both safe and effective. They can be used to prevent rabies before and for a period of time after exposure to the virus (such as by a dog or bat bite). However, these vaccines require multiple vaccinations both before and after virus exposure. Additional major limitations for the commercially available rabies vaccines are cost and access, particularly in the developing world, as well as supply shortages.

CV7202 Phase 1 Clinical Trial

We initiated a Phase 1 clinical trial for CV7202 in the fourth quarter of 2018. This ongoing non-randomized, open label Phase 1 clinical trial evaluates safety, including reactogenicity, and immunogenicity after one and two doses of investigational Rabies vaccine CV7202, administered intramuscularly in healthy adults 18 to 40 years of age, at different doses. A control group received Rabipur according to the standard schedule. The primary endpoint is the assessment of safety and the key secondary endpoint assesses the proportion of subjects with a protective immune response as defined by WHO as rabies-specific serum VNTs ≥0.5 IU/ml.

Key inclusion criteria:

Subjects must satisfy the following criteria at trial entry:

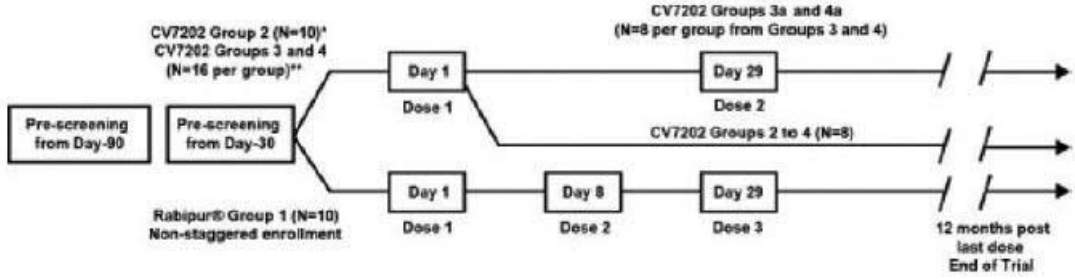
- healthy male and female subjects ages 18 to 40 years old; and
- physical examination and laboratory results without clinically significant findings and Body Mass Index, or BMI, ≥18.0 and ≤32.0 kg/m.2.

Key exclusion criteria:

Any trial subject who meets any of the following criteria will not qualify for entry into the trial:

- use of any investigational or non-registered product (drug or vaccine) other than the trial vaccine within four weeks preceding the administration of the trial vaccine, or planned use during the trial period;
- receipt of any other vaccines within 14 days (for inactivated vaccines) or 28 days (for live vaccines) prior to enrollment in this trial or planned receipt of any vaccine within 28 days of any trial vaccine administration;
- receipt of any licensed or investigational rabies vaccine prior to the administration of the trial vaccine;
- administration of immunoglobulins (Igs) and/or any blood products within the three months preceding the administration of any dose of the trial vaccine; or

- known allergy to any component of CV7202 such as type I allergy to beta-lactam antibiotics or Rabipur.



Patient demographics:

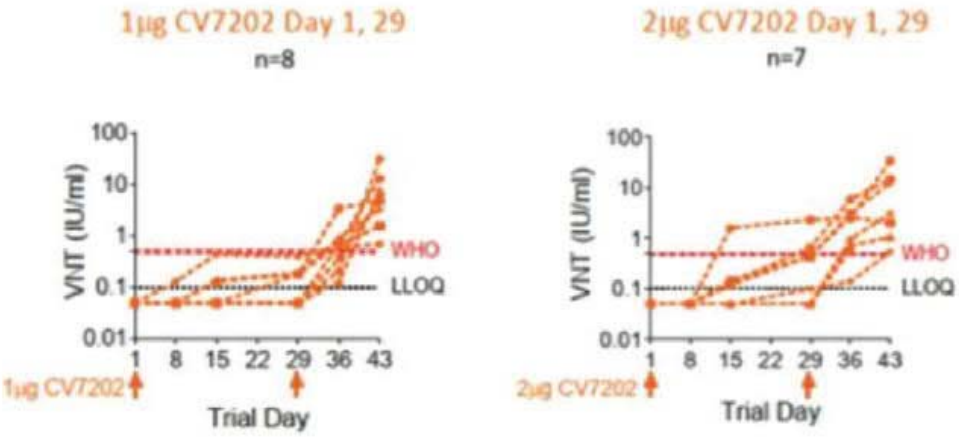
As of March 16, 2020, we enrolled a total of 53 subjects in three CV7202 groups, 1μg (n=16), 2μg (n=16) and 5μg (n=10), and one Rabipur group (n=11) as control. In both the CV7202 1μg and 2μg groups, subjects received a single dose of CV7202 on Day 1 (n=8), or two doses of CV7202 on Days 1 and 29 (n=8). In the CV7202 5μg group, the 10 subjects received a single dose of CV7202 on Day 1. Of the 11 subjects enrolled in the Rabipur group received, 10 subjects received the licensed three-dose primary vaccination schedule on Days 1, 8 and 29, respectively.

Preliminary safety results:

Based on our preliminary data as of March 2020, a dose-dependent reactogenicity was observed in the trial. Local and systemic events were solicited for seven days after each vaccination, unsolicited events for 28 days after each vaccination and serious adverse events throughout the entire study. While all subjects in the vaccine and control groups reported at least one solicited AE, the vast majority of solicited AEs were Grade 1 or 2 in intensity and transient in nature. Grade 3 solicited AEs were experienced by none of the subjects in the CV7202 1μg and the Rabipur groups, 3/16 (19%) subjects in the CV7202 2μg group, and 7/10 (70%) subjects in the CV7202 5μg group. Grade 3 solicited local AEs were reported for 1/16 (6%) subjects in the CV7202 2μg and 1/10 (10%) subjects in the CV7202 5μg group. Grade 3 solicited systemic AEs were reported for 3/16 (19%) subjects in the CV7202 2μg group and 6/10 (60%) subjects in the CV7202 5μg group. Unsolicited AE considered as related to the vaccination increased with increasing mRNA content: from 1/8 (13%) subject after each dose in the CV7202 1μg group to 7/10 (70%) subjects in the CV7202 5μg group.

Preliminary immunogenicity results:

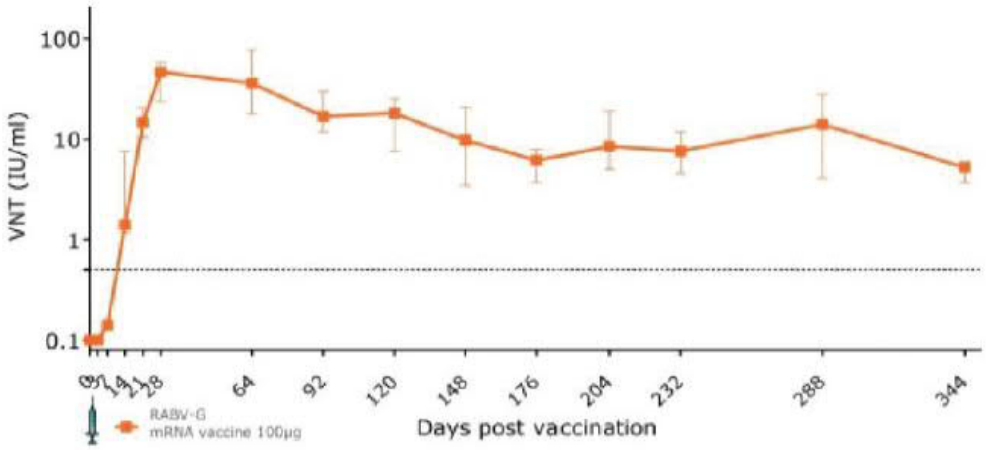
Based on our preliminary data as of January 2020, after two doses of 1μg or 2μg CV7202, 28 days apart, all evaluable subjects had virus neutralizing titers, or VNTs, above the ≥0.5IU/mL level considered protective 14 days after Dose 2 (Day 43). Subjects in the CV7202 5 μg group did not receive a second dose of CV7202. Between the CV7202 1μg and 2μg groups, geometric mean titers, or GMTs, of rabies-specific VNTs after the first dose administration showed a dose-dependent increase but, in the majority of subjects, remained below the antibody level recommended by the WHO as an adequate response to vaccination (≥0.5IU/mL), considered to be protective. No further dose-dependent increase was observed in the rabies-specific-VNTs following a single dose of 5μg CV7202, potentially confirming the hypothesis that they were partially suppressed by the higher than expected innate immune response. Values less than the lower limit of quantification, or LLOQ, are shown as half LLOQ in the figure below.



CV7202 Preclinical Data

In preclinical studies, we have shown that optimized formulation leads to more robust immune responses to multiple antigens and higher VNTs. CV7202 was found to be highly potent in multiple animal studies, and protected against the rabies virus infection in non-human primates. CV7202 leads to rapid generation of neutralizing antibodies that exceed the threshold agreed upon by the WHO for rabies protection. These results, obtained after a single administration in non-human primates, were sustained at high levels through at least 344 days post-vaccination.

CV7202 Induces Rabies-Neutralizing Antibodies After Single Administration in Non-Human Primates



CV-SSIV: Influenza Vaccine

Disease Overview

Influenza is a highly contagious virus that causes mild to severe respiratory virus that can lead to death. According to the CDC, the burden of illness during the 2018-2019 season was estimated to include approximately 35.5 million people getting sick with influenza, 16.5 million people going to a healthcare provider for their illness, 490,600 hospitalizations, and 34,200 deaths from influenza in the United States. The WHO reports that globally there are as many as five million severe influenza cases annually, leading to as many as 650,000 deaths.

Limitations of Current Influenza Vaccines

Influenza viral infections can be prevented by vaccination although there are several limitations associated with current flu vaccines. Flu vaccines are not always effective, primarily because the influenza virus and its associated antigens undergo mutations or changes in its sequence over short periods of time, which is called antigenic drift. Vaccines that are developed for the predominant strain infecting people can be rendered ineffective as the virus mutates as it passes from person to person. The process of developing a standard traditional vaccine typically takes approximately eight months from strain identification to doctor's office availability, increasing the likelihood that a significant pool

of viruses circulating will be poorly recognized by antibodies in vaccinated individuals. Additionally, vaccine efficacy tends to wane over time. For these reasons, vaccination of the target population needs to be repeated every year before the start of the next influenza season, putting a significant burden on the health system. Furthermore, only a part of the population targeted to get the yearly shot is vaccinated each year, leaving many individuals unprotected.

Our Approach to Influenza Vaccine

We believe that there is a significant market for a more and broader effective vaccine for influenza that protects over several seasons and that, in case of exceptional changes in the circulating strains, could also be customized to include specific and multiple new strains. We believe that our platform offers the potential for the rapid development of safe and effective vaccines. We believe that the mRNA-based vaccines allows us to address several of the limitations of the currently available seasonal vaccines.

We believe key potential advantages of our approach to traditional seasonal vaccines include:

- Commercial seasonal vaccines usually contain three to four strains of the virus and may offer limited protection as the virus mutates. Adding more strains or further antigens, which can increase or broaden the level of protection conferred by the vaccine, might be an advantage of an mRNA-based vaccine.

- mRNA-based vaccines offer greater production flexibility to adapt to circulating seasonal strains. An mRNA influenza vaccine can be generally produced in under three months from strain identification to a finished GMP product. This rapid vaccine development process would allow treatment of a larger fraction of patients before too many changes are introduced by viral mutations.

- Traditional egg-produced vaccines rely upon high-yielding production strains and often have to contend with egg-adaptation during passage, neither aspects are an issue for mRNA-based vaccination.

We are also developing a Supra Seasonal Influenza Vaccine, or SSIV. We believe that the initial step towards the development of an SSIV is the development of a multivalent, improved seasonal influenza vaccine. Based on performance of our mRNA next-generation influenza vaccine in preclinical studies, including broadening and persistence of immunity, this multivalent formulation could be considered a first-generation multi-year, supra-seasonal influenza vaccine. The characteristics for the mRNA-based seasonal influenza vaccines are a building block in the development of an SSIV where the induction of long-lasting, potent antibody responses, and the possibility to combine several antigens in one vaccine formulation in the absence of antigenic interference are key prerequisites.

CV-SSIV Overview

Our CV-SSIV contains a mixture of antigens derived from hemagglutinin, or HA, and neuraminidase, or NA, constructs, all from seasonal strains recommended by the WHO, targeting both Influenza A and B strains. The inclusion of NA supports a vaccine with extended breadth, given that NA is more conserved compared to HA, and has the potential to confer protection against drifted seasonal but also pandemic strains in upcoming seasons.

Preclinical Data for CV-SSIV

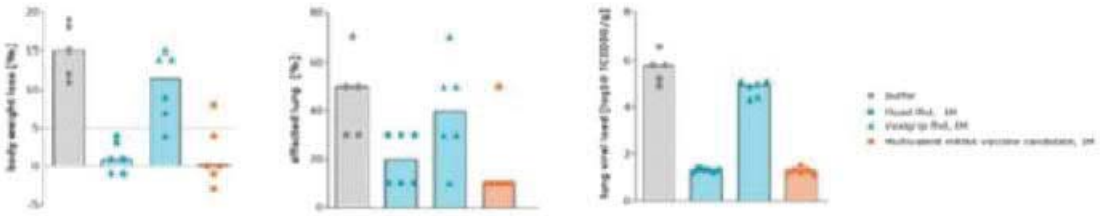
As part of our influenza program, we have evaluated mRNA-based influenza vaccines starting with a monovalent influenza vaccine followed by several seasonal multivalent influenza vaccines. Our preclinical experiments have shown that we can encode for multiple targets in our cocktail mRNA vaccines without experiencing immuno-dominance.

In these preclinical studies, it was demonstrated that our vaccines induced hemagglutinin-inhibition, or HI, titers above the accepted threshold for protective immunity in ferrets. The immunogenicity of the seasonal influenza vaccine was further evaluated in ferrets testing the breadth of antibody response against historic seasonal viral strains. The HI titer induced by mRNA vaccination against specific isolates were comparable to Fluad produced for the same season. Fluad is the only licensed adjuvanted seasonal influenza vaccine and has been shown to outperform standard of care split vaccine in older adults and very young children. Retrospective studies of the past season could not show a difference between both types of vaccine.

In immunogenicity studies in ferrets, our multivalent influenza vaccine candidate 2, showed no antigenic interference as judged by HI titer due to the addition of more antigens to multivalent influenza vaccine candidate 1. HI titer against influenza A virus strains were over 1:40 and neutralizing antibody against influenza B virus were detected using a microneutralization assay. Additionally, functional anti-NA antibodies were induced against influenza A strains analyzed using an assay and titers were comparable to Fluad. Overall, the immune response to influenza A virus were comparable to Fluad, whereas the responses to influenza B virus were lower for our multivalent vaccine candidate 2 than for Fluad. We anticipate that this response will be significantly enhanced in humans who are influenza pre-immune.

As shown in the figure below, the seasonal multivalent vaccine candidate 2 was tested in a ferret challenge infection model. Ferrets were vaccinated with influenza mRNA vaccine candidate two delivered using LNPs or the licensed vaccine Vaxigrip (left light-blue column) and adjuvanted vaccine Fluad (right light-blue column) via needle-based injection on day 0 and 21 (2-dose regimen). Values from individual animals (dots) and the median (bars) are reported for each group (buffer control grey column). Four weeks after the last vaccination, animals were challenged with influenza A via intratracheal route. Four days after infection, animals were euthanized and virology and pathology was investigated in respiratory tissues. Multivalent vaccine candidate 2 induced better protection in the ferret model than the licensed non-adjuvanted split vaccine (Vaxigrip) and showed comparable activity to the adjuvanted vaccine Fluad.

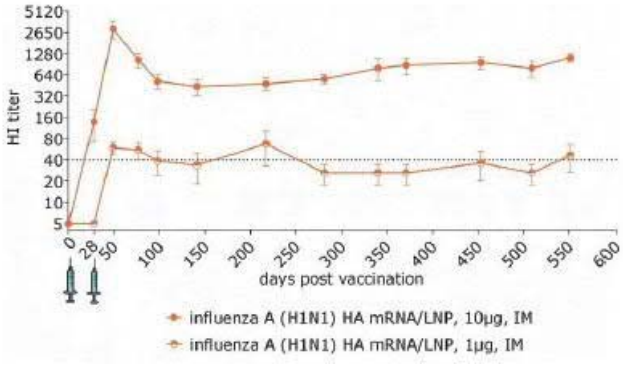
mRNA Vaccination Candidate Protected from Weight Loss and Viral Replication Comparable to the Adjuvanted Influenza Vaccine Fluad in Ferrets



Ferrets (n=6, female) were vaccinated with a multivalent influenza LNP/mRNA vaccine or the licensed vaccine Vaxigrip and adjuvanted vaccine Fluad®2017/2018 via i.m. needle-based injection on days 0 and 28. Four weeks post last vaccination animals were challenged with 106 TCID50 of influenza A/Netherlands/602/2009 H1N1 via intratracheal route. Four days after infection, animals were euthanized and virology and pathology was investigated: in body weight (A), affected lung tissues (B) and viral titers in the lung (C). Values from individual animals (dots) and the median (bars) are reported for each group.

As shown in the figure below, the longevity of antibody response was evaluated in NHP immunized with a monovalent HA vaccine, Cynomolgus monkeys were vaccinated with 1 or 10 µg LNP-formulated mRNA encoding HA of influenza A via intramuscular needle-based injection on days 0 and 28. Functional antibodies were determined in the serum of the immunized animals at the indicated time points using the HI assay. Our vaccine showed HI titers above the protective threshold (>1:40) for at least 1.5 years following a two-dose primary immunization series.

LNP-Formulated Influenza A H1N1 HA mRNA Vaccine Induce High and Long Lasting Functional Antibody Titers in NHP



Respiratory Syncytial Virus (RSV) Program

Disease Overview

RSV is a leading cause of respiratory disease globally. The virus causes infections at all ages but young infants have the highest incidence of severe disease. The National Institute of Allergy and Infectious Diseases estimates that by the age of two years, almost all children will have been infected with RSV in the United States. Globally, RSV has been estimated to cause approximately 33 million cases of RSV-related acute lower respiratory tract infections, or LRTI, annually in children less than five years of age, with approximately three million cases requiring hospitalization, and approximately 60,000 dying from complications associated with the infection. In addition, RSV infections can be a significant problem for certain immunocompromised adults and high-risk older adults. Adults at highest risk for severe RSV infection include older adults, especially those 65 years and older, adults with chronic heart or lung disease and adults with weakened immune systems. According to the CDC, RSV is responsible for approximately 177,000 hospitalizations and 14,000 deaths annually in people over 65 years of age within the United States. Market research by GlobalData indicates that the RSV market is expected to grow from $418.6 million in 2018 to $5.39 billion by 2028 in the United States, the United Kingdom, France, Germany, Italy, Spain and Japan.

There are no effective RSV vaccines approved to date and the only approved prophylactic treatment is palivizumab, marketed as Synagis in the United States. Synagis is a monoclonal antibody for the prevention of RSV in premature babies or babies with underlying medical conditions of bronchopulmonary dysplasia or congenital heart disease. Synagis's highly restrictive label, combined with the high cost of prophylactic therapy, has limited wider uptake.

Historical Approaches to RSV Vaccines

In 1968, a formalin-inactivated whole RSV vaccine was tested for newly infected and immunized children but was not effective and resulted in vaccine-induced amplification of disease. Since the most severe cases of RSV occur in the first months of life, past approaches have focused on increasing the maternal immune response by developing maternal anti-RSV antibodies. To date, the efforts to develop maternal anti-RSV antibodies through administration of a vaccine have been unsuccessful.

While the reasons for the failure of RSV vaccines to protect against infection remain unclear, the lack of understanding regarding the identity of the natural protective immune response in subjects has challenged the development of an effective RSV vaccine. In certain previous clinical studies, an increase in the immune response has been detected but has not resulted in any further protection against the progression of the RSV infection. Currently, there are several vaccines for RSV in development, including subunit vaccines, attenuated vaccines, and those delivering RSV antigens by recombinant vectors such as vaccinia virus or bovine-based systems.

Our Approach

The surface of RSV contains two glycoproteins: the attachment glycoprotein, or G, and the fusion glycoprotein, or F. Deletion of RSV G leads to a viable but attenuated virus, indicating that RSV G is not essential for viral entry. In contrast, the RSV F protein is essential to the viral replication process, as it facilitates pH-independent fusion of the viral membrane with the host-cell plasma membrane, leading to infection of the host cell. Expression of RSV F on the surface of cells can also cause fusion with neighboring cells, leading to the formation of multinucleated syncytia. The F protein is expected to induce virus neutralization titer against both subtypes of RSV A and B.

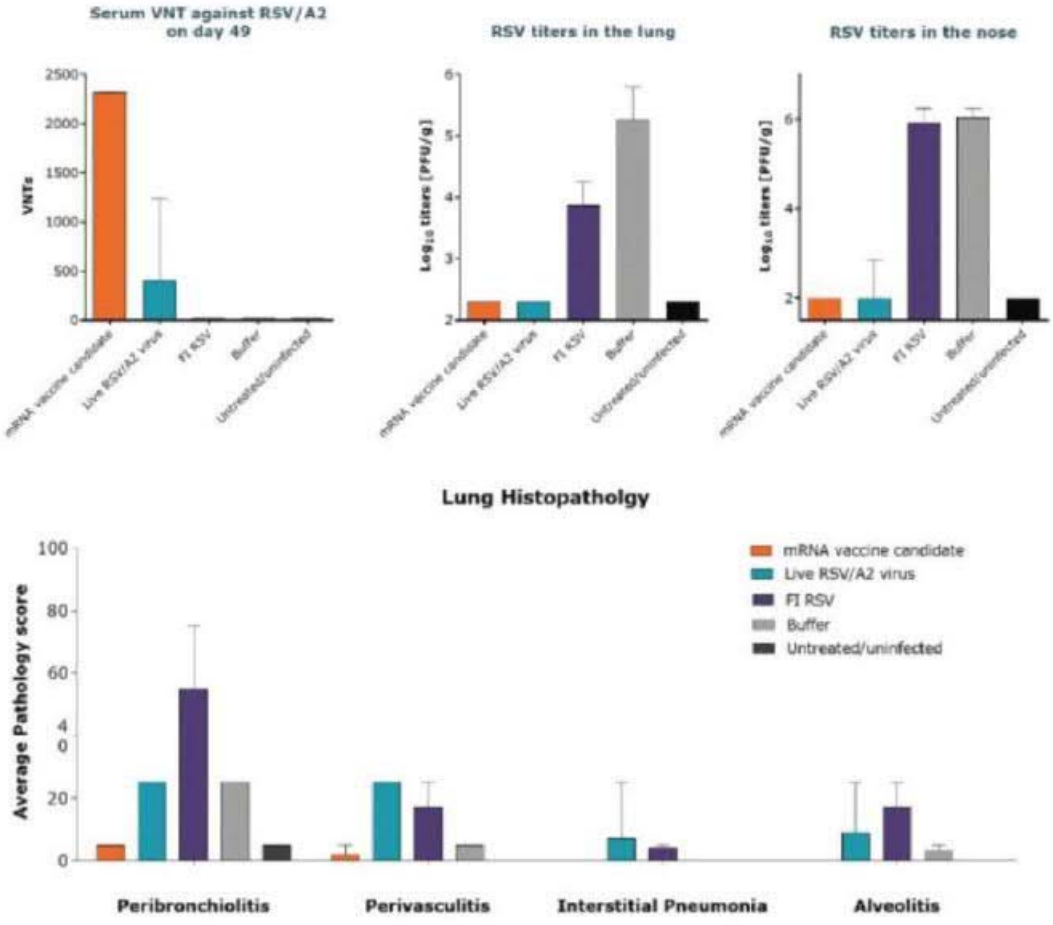
Our approach for the RSV program is based on delivering mRNAs encoding for the RSV F (fusion) protein. This is considered as an advantage over vaccines consisting of the glycoprotein G. Glycoprotein G determines the RSV subtypes and hence, vaccines that aim to protect against all RSV subtypes would need to include a glycoprotein from both RSV A and B each. Therefore, an approach targeting the RSV F as protective antigen has an advantage to target both RSV A and B. Consequently, we have been able to show that our vaccines encoding for RSV F induce high levels of virus neutralizing antibodies, a likely correlate of protection against RSV.

Preclinical Data

In preclinical studies, we showed that the delivery of our mRNA-based vaccines leads to the stimulation of TLR7, thus supporting affinity maturation of antibodies. In addition, we showed that antigen delivery via mRNA mediates correct protein folding and localization. For our RSV vaccine, we also analyzed the potential to minimize worsening immunopathology, a phenomenon also known as

vaccine-dependent disease enhancement, or VDE, that may also be relevant for other respiratory viral infections such as for the novel SARS-CoV-2. Our RSV vaccine induces a balanced immune response, thus avoiding the Th2-biased response associated with enhanced respiratory disease or VDE.

In preclinical studies, we have demonstrated that our vaccines encoding for RSV F induce high levels of virus neutralizing antibodies, a likely correlate of protection against RSV. In a cotton rat challenge model, our RSV vaccine was compared to formalin-inactivated virus for evaluating enhanced respiratory disease and live RSV. Cotton rats vaccinated twice at day 0 and day 28 showed high RSV neutralizing antibody titers in the serum 28, 49 or 63 days post-vaccination. Animals were challenged with RSV at day 63 and subjected to histopathologic analysis at day 68. The study showed that our RSV vaccine was able to protect lungs from viral replication and significantly reduced viral titers in the nose, when measured using plaque assay five days post-RSV challenge. Evaluation of signs of VDE were analyzed by lung histopathology FI virus induced peribronchiolitis in cotton rats, which was not detectable in animals vaccinated with our RSV vaccine.



Cotton rats (n= 5 per group) were vaccinated twice (d0 and d28) as indicated. RSV neutralizing antibody titers in the serum were analyzed 28, 49 or 63 days post-vaccination (top panel). Protection was assessed by measuring viral load in lung and nose at day 5 post-RSV challenge (top right panel). Lung histopathology was analyzed at day 68 after animals were challenged with RSV at day 63 (lower panel). Upper graphs show titers measured on day 63.

In this study RSV F encoding vaccine induced high levels of virus neutralizing antibodies, a likely correlate of protection. Functional antibody responses for mRNA vaccinated groups were higher than live virus vaccinated groups. Protection in lungs and nose are shown in the top right panel (viral titers via plaque assay five days post-RSV challenge). FI virus induces peribronchiolitis in cotton rats, which is not detectable in animals vaccinated with mRNA.

Other Prophylactic Vaccines for Infectious Diseases

In partnership with the Bill & Melinda Gates Foundation, we are developing prophylactic vaccines for prevention of other infectious diseases associated with high mortality in the developing world including malaria and rotavirus. Preclinical studies are ongoing, with encouraging results, which could lead to the decision for further clinical development of the candidate vaccines.

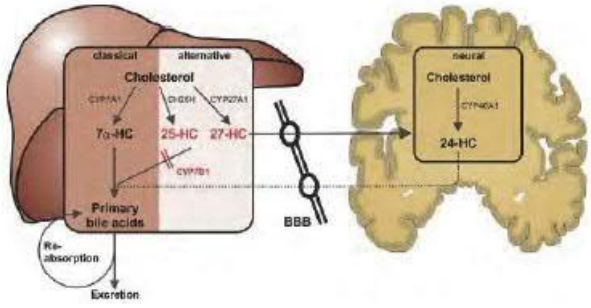
Furthermore, we are collaborating on several vaccine projects with CEPI, a public-private initiative to strengthen the vaccine research. This focuses on the development of the mRNA Printer, a mobile, automated production unit for rapid mRNA supply. This innovative platform is being designed to provide a rapid supply of LNP-formulated mRNA vaccine candidates that can target known pathogens (including Lassa fever, yellow fever and SARS-CoV-2) and prepare for rapid response to new and previously unknown pathogens.

RNA-Based Therapeutics in Protein Therapies

mRNA-based protein supplementation offers a therapeutic approach to compensate for lack of proteins in monogenetic diseases caused by loss-of-function mutations. It offers a potentially curative treatment option, especially in diseases in which the protein is expressed predominantly in organs that can be reached by intravenous delivery (such as the liver). Despite the success of classical enzyme-replacement therapy in several metabolic disorders, this therapeutic approach is not well suited for treatment of diseases caused by the lack of functional intracellular proteins, especially if the proteins are located in or on intracellular compartments. Additionally, as therapeutic proteins are conventionally manufactured by using human, animal, or even plant cells, the pharmacological and biochemical properties of such recombinant proteins may differ from endogenously expressed enzymes. Cellular localization, folding, and post-translational modifications can especially be critical for the correct function of a therapeutic protein. Delivery of mRNA can overcome these limitations and is likely to result in expression of a functional protein at a physiological cellular location. An example of our rare disease approach is for the potential treatment of hereditary spastic paraplegia, or HSP.

Hereditary Spastic Paraplegia

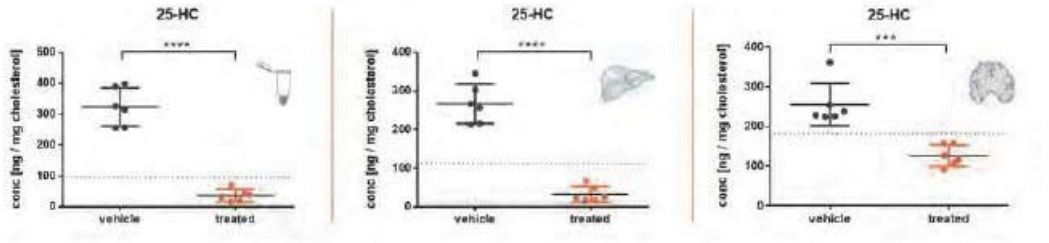
HSP is a group of inherited disorders that are characterized by progressive weakness and spasticity of the legs due to axonal degeneration of the corticospinal tract. Hereditary spastic paraplegia type 5, or SPG5, is caused by autosomal recessive loss-of-function mutations in CYP7B1, a gene encoding for the cytochrome P-450 oxysterol 7-α-hydroxylase, essential for the alternative pathway of bile acid synthesis in the liver. Mutations causing SPG5 lead to decreased enzyme activity of CYP7B1 and accumulation of oxysterols in the serum, the liver, and then the central nervous system. The accumulation of hydroxyl cholesterol, or HC, in the brain is what is believed to be the pathologic correlate of this particular disease, which leads to spasms and paraplegia as symptoms. To date, no curative treatment for SPG5 is available. Current clinical treatment strategies for SPG5 are based on the reduction of cholesterol by applying cholesterol-lowering drugs (statins), which consequently lead to a reduction of oxysterols.



Our approach is based on replacement of CYP7B1 by administration of mRNA. We have studied the intravenous application of formulated CYP7B1 mRNA in mice lacking the endogenous *Cyp7b1* gene. Comparable to the human situation in SPG5 patients, a drastic increase of these oxysterols was detected in all three compartments (serum, liver and brain) of knockout mice. Using this *in vivo* model, we were able to demonstrate that a therapeutic approach with mRNA can restore human CYP7B1 protein that exhibits physiological function and eliminates abnormal cholesterol metabolites.

As shown below, we investigated the safety and efficiency of repeated dosing with four consecutive doses of 40 µg LNP-encoded mRNA of CYP7B1 administered intravenously every five days. LNP loaded with a non-translating mRNA were applied as control (vehicle). Prior to the administration, serum samples were taken to determine basal oxysterol levels. Two days after the last injection (17 days of treatment), animals were sacrificed, and serum, liver, and brain samples were analyzed. Oxysterol analysis of these samples demonstrated a significant decrease of 25 hydroxy cholesterol, or 25 HC, in the serum and liver. mRNA expression of the human CYP7B1 in the liver led to a reduction of 25 HC in the liver by 8-fold and in serum by approximately 88%. These effects are accompanied by a reduction of the accumulation of 25 HC in the brain by more than 50%. Additionally, repetitive treatment resulted in a significant decrease of 27-HC and 3β-HCA in livers of treated compared to vehicle animals.

In addition, repeat intravenous delivery of CYP7B1 mRNA was found to be well tolerated in this study. Neither the CYP7B1 mRNA nor the restored protein nor the LNP induced liver toxicity. None of the treated animals presented signs of toxic or adverse effects. LNP particles encapsulating non-coding mRNA led to a temporary increase in oxysterol levels (25-HC and 27-HC) in liver and serum in the vehicle group, which is expected given cholesterol is an essential component of LNPs.

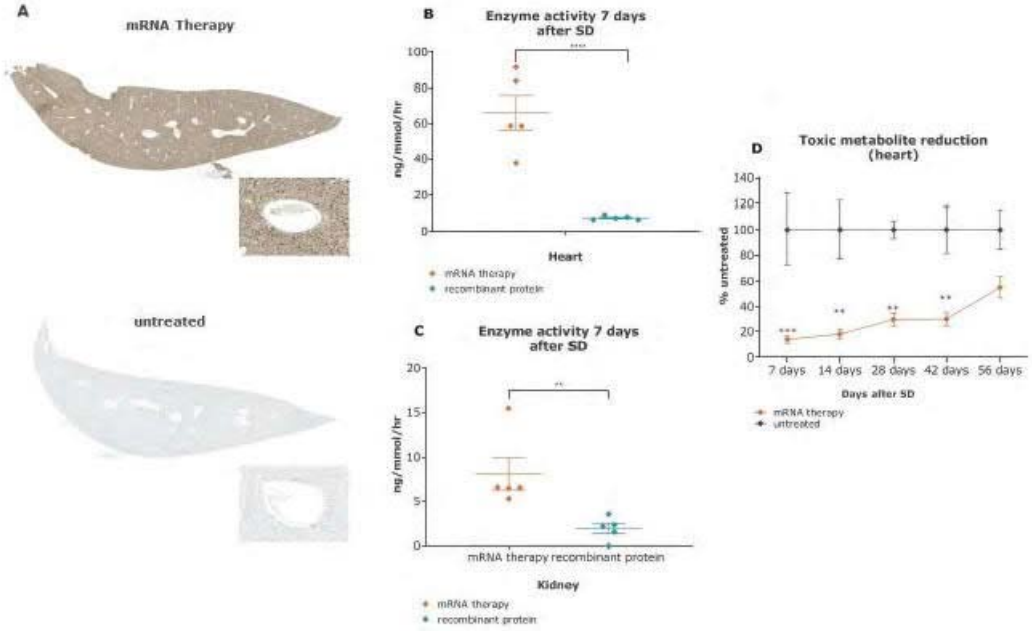


Lysosomal Storage Disorders

Lysosomal storage diseases are well-defined, single-gene disorders that are amenable to correction by systemic mRNA therapy.

We have conducted preclinical studies in an undisclosed lysosomal storage disease, or LSD, to evaluate LNP delivery of mRNA encoding the deficient enzyme to the liver, production of the enzyme by the liver, and subsequent secretion and systemic distribution of the enzyme to the primary organs affected by the disease. In this specific LSD, the enzyme deficiency results in a progressive accumulation of lipid in cellular lysosomes, which ultimately affect the functioning of the heart and kidneys. Enzyme replacement therapy, or ERT, which involves intravenous administration of recombinant enzyme, has been the standard of care for this specific LSD. In contrast to ERTs, our LNP mRNA technology specifically and efficiently targets the liver to naturally produce the missing enzyme, which is subsequently secreted into the bloodstream and distributed to the affected organs. In this specific LSD, the liver is not the target organ, but is used to produce the endogenous native enzyme.

As shown below, LNP delivered mRNA therapy produces a high and homogenous expression of the missing enzyme in the livers of knockout mice (Figure A, brownish stain). The endogenously produced enzyme is then secreted into the bloodstream with a better pharmacokinetic profile than the injected recombinant protein. The enzyme is then taken up by the target organs to be treated. In this example, the enzyme is taken up by the heart (Figure B) and kidney (Figure C) and localized into the lysosomes. Our mRNA therapy, through prolonged synthesis and secretion by the liver, led to higher enzyme activity in the organs compared to the infused recombinant enzyme (Figures B and C). This higher enzyme activity leads to a significant and prolonged reduction of accumulated lipids in the organs of mRNA-treated animals (Figure D).



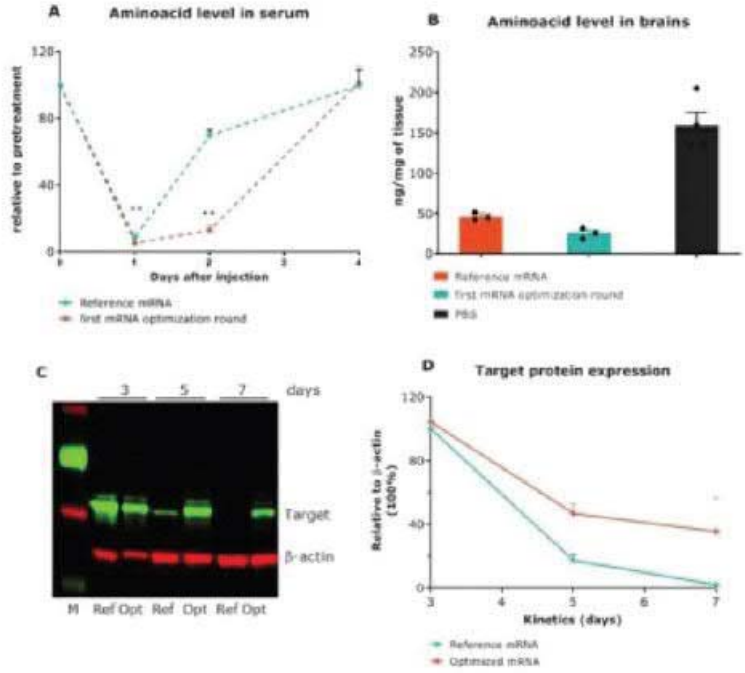
Liver-Specific Metabolic Diseases

We are applying a similar approach to inherited liver-specific metabolic disorders of amino acids, nitrogen, and essential nutrients. The goal of these studies is to restore the specific enzyme or protein that is deficient in the liver by LNP-mediated delivery of mRNA to the liver. As such, the target organ for correction is the liver, and secretion and systemic distribution of the enzyme or protein to other organs is not required for a therapeutic effect.

Our ability to optimize mRNA stability and translation, in combination with optimization of the expressed protein, is an important part of our technical expertise. Using a process of mRNA and protein optimization, we believe that we are able to extend the duration of protein expression to meet a defined target product profile.

One example of this technology is the mRNA that we are developing for a metabolic amino acid disorder. In this inherited disorder, a liver-specific intracellular enzyme is deficient resulting in decreased metabolism of the amino acid. As a result, there is a toxic build-up of the amino acid in the blood, which leads to severe consequences for the central nervous system.

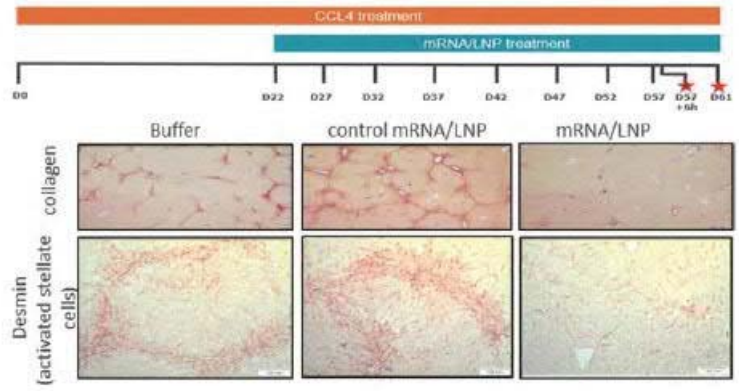
A single intravenous injection of a liver-targeted LNP formulation containing the therapeutic mRNA leads to a marked decrease in the level of the amino acid in the sera of knockdown animals (Figure A), but also in the brain (Figure B). Several rounds of mRNA and protein optimization were subsequently performed. Improving the mRNA molecular structure during the first round of optimization prolonged the protein and its therapeutic effect (Figure A) compared to the reference mRNA. Protein optimization (Figures C and D) of the expressed target enzyme increased its expression/stability and/or activity *in vitro*. The combination of both optimization programs resulted in a candidate with improved characteristics.



Fibrotic Liver Diseases

According to published literature, chronic liver diseases cause two million deaths a year worldwide. We have shown that the delivery of liver-specific protein factors, which are down regulated in fibrosis, can resolve liver fibrosis, a key pathological feature of NAFLD, NASH, cirrhosis and hepatocellular carcinoma. Protein factor treatment of liver diseases is uniquely suited to mRNA medicines enabling the expression of intracellular proteins. Moreover, we believe that in this particular case, the LNP technology allows us to deliver mRNA almost exclusively to the target cells, hepatocytes.

In a CCL4 chemically induced mouse model of liver fibrosis, we delivered eight doses of LNP-mRNA at an interval of five days at 2 mg/kg. The figure below illustrates the ability of an mRNA-delivered protein factor to reduce collagen, the main fibrotic material deposited in fibrosis, and eliminate activated stellate cells, the source of collagen (stained red). To confirm the potential activity of this mRNA therapy, we obtained similar data in two other unrelated murine models: a diet-induced model and a knockout mouse model of liver fibrosis. These findings offer preclinical proof of concept for this therapeutic concept to treat acute and chronic liver diseases, as well as diseases of other organs.

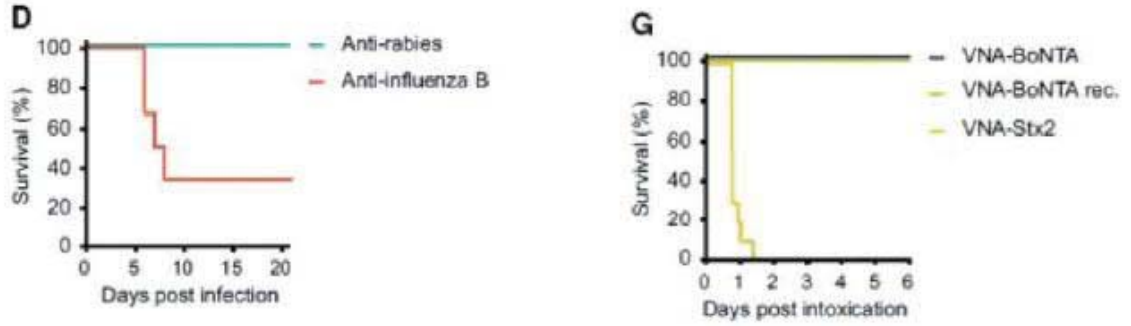


Therapeutic Antibodies

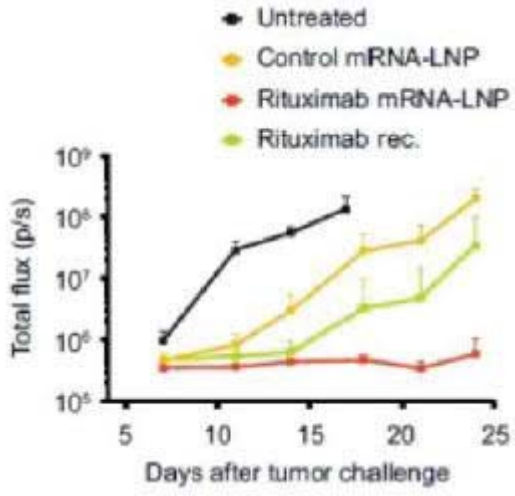
mRNA has the potential to promote expression without inducing an adverse immune response against the encoded protein. We have tested various antibodies using different designs to evaluate our platform's potential for prophylactic and therapeutic antibodies.

We evaluated the use of mRNA for passive immunization in two indications, rabies and botulism, that can be considered prototypes for anti-pathogen and anti-toxin therapies, respectively. Single injections of mRNA-LNPs were sufficient to establish rapid, strong, and long-lasting serum antibody titers *in vivo*, thereby enabling both prophylactic and therapeutic protection against lethal rabies infection or botulinum intoxication. In both models, the high levels of *in vivo* serum expression conferred full protection in pre- and post-exposure scenarios.

The left side of the below graphic shows that mice expressing the anti-rabies mAb survived, whereas the majority of control animals which received anti-influenza mAb mRNA succumbed. The right side of the below graphic shows that mice treated post-intoxication with VNA-BoNTA mRNA or recombinant VNA-BoNTA also survived.



We have also demonstrated that mRNA-mediated antibody expression may be effective in the field of cancer immunotherapy, where mAbs are widely used in medical practice. In a preclinical study conducted in mice, we compared the efficacy of rituximab-encoding mRNAs to recombinant rituximab. We inoculated mice intravenously with luciferase expressing Raji lymphoma cells and started treatment with 50 µg of mRNA-LNP encoding rituximab and 200 µg of recombinant rituximab at various time points. mRNA-LNPs coding for an irrelevant antibody were used as further control. Control animals revealed strong tumor cell proliferation and had to be euthanized 17 days after inoculation due to severe symptoms. As shown in the picture below, repeated administration of mRNA-LNP for rituximab strongly decelerated or even abolished tumor cell growth compared to continued tumor growth for recombinant rituximab.



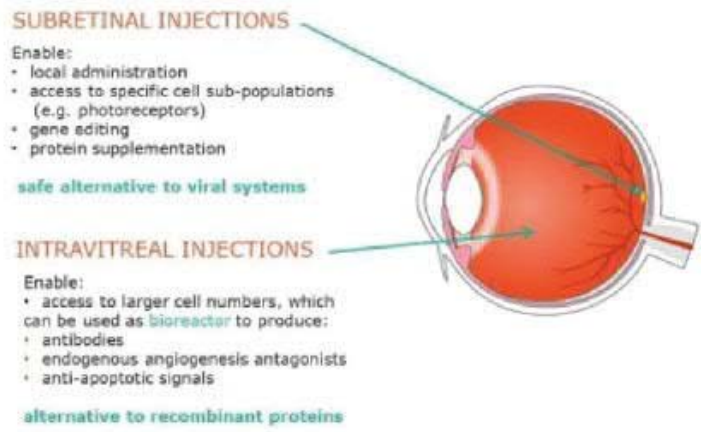
Eye Diseases

With the development of the CVCM delivery system, we were able to begin exploring the treatment of eye and lung diseases with mRNA therapy. We have strategic collaborations with SERI for the development of mRNA-based treatments for currently undisclosed eye indications. We believe that the treatment of eye diseases with mRNA therapy represents an excellent opportunity for the mRNA approach for the following reasons:

- Therapeutic protein can be produced directly and locally within the target tissue;
- Local treatment in the eye requires lower mRNA doses, thereby minimizing systemic exposure;

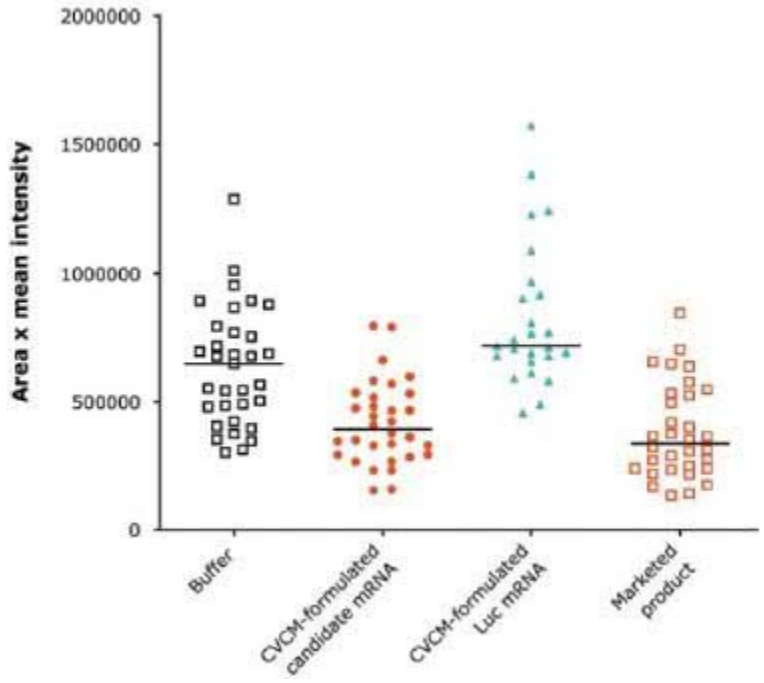
- Enables production of endogenous proteins to stop or prevent pathological processes locally in the eye, such as neo-vascularization or apoptosis;
- Enables expression of multi-domain intracellular or transmembrane proteins in key cells within the eye overcoming limitations of recombinant proteins;
- No concern with potential side effects typical for viral gene vector;
- No mRNA construct size restrictions as with viral gene vectors; and
- The eye is an immune-privileged organ.

Our proprietary CVCM delivery system allows for different routes of delivery, including subretinal and intravitreal injections, of our mRNA-based medicines for the treatment of different eye diseases. The subretinal route provides access to specific cell subpopulations such as photoreceptors, while the intravitreal route allows access to larger cell populations which can be used as a local bioreactor to produce therapeutic proteins in the eye.



In vivo studies showed that intravitreal injection of CVCM-based mRNA formulations expressed high levels of fluorescent protein in both rat and rabbit eyes. This route of administration might potentially allow the expression of secreted therapeutic proteins within the eye. Similar expression of fluorescent protein was achieved following intraretinal injection of CVCM-formulated mRNA in rats.

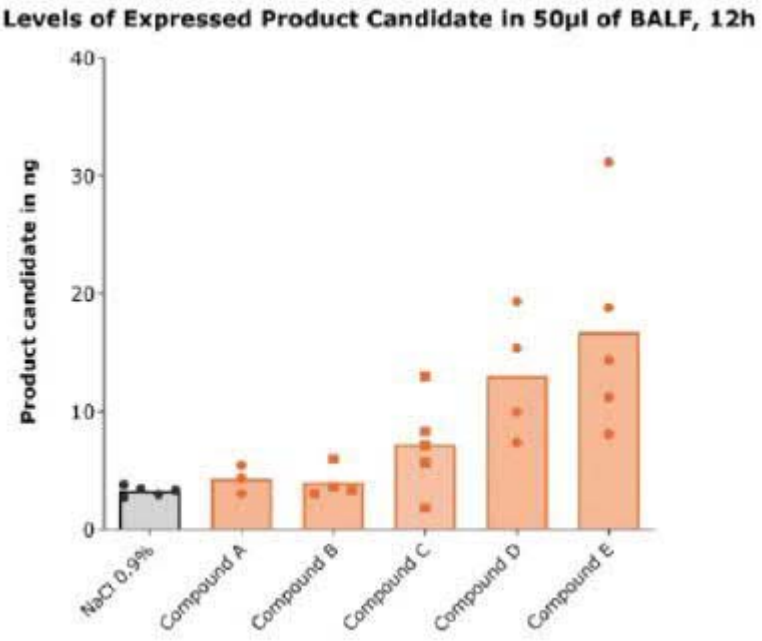
To further optimize the CVCM delivery system for ocular administration, formulations containing mRNA encoding product candidates were tested in a rat model. The animal model has been used in the development of therapeutics to treat retinal diseases. Multiple intravitreal injections of the CVCM-based mRNA formulations were well tolerated. As shown below, administration of CVCM formulated with mRNA encoding for product candidates at a 5 µg dose showed comparable inhibitory activity to currently marketed products at the applicable labeled dose.



Based on the positive preclinical data demonstrating efficient delivery of mRNA to the eye using the CVCM delivery system, the agreement and collaboration with SERI moved ahead. We believe that the clinical and research expertise in eye diseases at SERI would allow us to fully leverage our mRNA and CVCM delivery technology in the discovery and validation of eye disease targets amenable to mRNA treatment. In collaboration with SERI, a high-priority rare eye condition has been identified for development. Multiple therapeutic targets have been identified for this condition and mRNAs have been generated and are currently being tested in preclinical studies.

Lung Diseases

The CVCM delivery system is also well suited for the delivery of mRNA to the lung administered as either an aerosol or a dry powder formulation. Proof-of-concept *in vivo* animal studies showed that CVCM mRNA formulations, administrated using the intrapulmonary route, were able to transfect airway epithelial cells and produce functional therapeutic proteins in the lung. Levels of product candidate were determined in broncho-alveolar lavage fluid, or BALF, collected 12 hours after instilling different CVCM-based mRNA formulations encoding for the target protein. As shown in the below graphic, Compounds A through E showed increased levels of expressed product candidates in the murine lung compared to a control (NaCl).



Our agreement with Yale University leverages Yale's leadership in lung discovery research with our technical capability to deliver mRNA to the lung, where it would express therapeutic proteins. The goal is to discover novel molecular targets in pulmonary diseases that could potentially be treated with mRNA therapy. With the Yale investigators, we have identified a high-priority pulmonary disease indication to pursue together with a novel therapeutic target for the treatment of the disease. Additional studies will explore new mRNA therapeutic targets to treat the disease.

Significant Agreements

Collaborations

We have entered into various licensing and commercialization agreements, including the following agreements with respect to product candidates:

Collaboration and License Agreements

2020 GlaxoSmithKline Collaboration and License Agreement

In July 2020, we entered into a Collaboration and License Agreement with GSK, which we refer to as the 2020 GSK Agreement, pursuant to which we are collaborating with GSK to research, develop and commercialize prophylactic and therapeutic non-replicating mRNA-based vaccines and antibodies targeting infectious disease pathogens. Under the terms of the 2020 GSK Agreement, we granted GSK a worldwide exclusive, sublicensable (subject to certain conditions) license under certain of our intellectual property relating to vaccines and antibodies encoded by our proprietary mRNA targeting certain selected pathogens, or GSK Program Products, and a non-exclusive license under certain LNP technology to develop, manufacture and commercialize a certain number of such GSK Program Products for use in connection with the infectious diseases targeted under the 2020 GSK Agreement. We additionally granted GSK an exclusive option for a certain period to add additional products in the field of infectious diseases as GSK Program Products. If such additional product targets a coronavirus other than SARS-CoV-2 or a pandemic pathogen as listed on the WHO or CEPI list of priority diseases, at our election such product will be developed and commercialized on a cost and profit split basis under the GSK COVID Agreement, discussed below, or on a milestone and royalty basis under the 2020 GSK Agreement. GSK is permitted for a certain period to replace any of the GSK Program Products with an alternative product, up to a certain number of times, and to exchange any antigen or antibody for which we have granted GSK a license under LNP technology for an alternative antigen or antibody, up to a certain number of times. In the event we obtain rights to any intellectual property controlled by a third party that is useful but not necessary for the development, manufacture or commercialization of the GSK Program Products, we must, at GSK's election, use commercially reasonable efforts to obtain a sublicense to such rights on behalf of GSK. Under the terms of the 2020 GSK Agreement, GSK granted us a royalty-free, non-exclusive license under certain GSK-controlled technology to perform certain development and manufacturing

activities under the 2020 GSK Agreement. The 2020 GSK Agreement was amended and restated in April 2021.

For a certain period after the effective date, GSK has the right to reserve up to a certain number of antigens and we and our affiliates will be prohibited from granting any rights to a third party with respect to any such antigen for use in connection with infectious diseases. Under the terms of the 2020 GSK Agreement, GSK and its affiliates and sublicensees and we and our affiliates are additionally prohibited from developing, manufacturing or commercializing, directly or indirectly, any prophylactic or therapeutic mRNA-based vaccine or mRNA-based antibody targeting a pathogen targeted by a GSK Program Product, other than as contemplated under the 2020 GSK Agreement. Such exclusivity obligation will continue on a pathogen-by-pathogen basis for the duration of the 2020 GSK Agreement, so long as such pathogen is targeted by a GSK Program Product. We are additionally prohibited from granting any third party any license under the licensed LNP technology, or using such LNP technology ourselves, in connection with any GSK Program Product for so long as such GSK Program Product is being developed or commercialized under the 2020 GSK Agreement, except as contemplated under the 2020 GSK Agreement. We are additionally prohibited, for the period during which GSK's option to license additional GSK Program Products remains outstanding, from commercializing or granting any third party the right to develop or commercialize any prophylactic or therapeutic mRNA-based vaccine or mRNA-based antibody targeting certain pathogens for use in connection with infectious diseases.

We and GSK are required to complete certain development activities with respect to the GSK Program Products set forth in various development plans. Among other development responsibilities, we are required to provide clinical supply and will in principle be responsible for sponsoring Phase 1 clinical trials for the GSK Program Products. We will be required to make certain manufacturing facility enhancements and, at the request of GSK, we must negotiate and agree in good faith on a commercial supply agreement pursuant to which we will reserve certain manufacturing capacity for GSK. At GSK's request, we are required to transfer to GSK all know-how necessary for GSK's development activities under the 2020 GSK Agreement and all know-how necessary for the manufacture of the GSK Program Products. GSK is generally responsible for development activities following completion of Phase 1 clinical trials and is required to use diligent efforts to secure marketing authorization following completion of all necessary clinical trials. GSK is responsible for the commercialization of approved GSK Program Products in all countries other than Austria, Germany and Switzerland and is required to use diligent efforts to commercialize approved GSK Program Products in certain major market countries. At our request, we and GSK will negotiate and agree in good faith to a distribution agreement pursuant to which we will have the exclusive right to commercialize GSK Program Products in Austria, Germany and Switzerland, and we will pay GSK royalties at the rate set out below. We and GSK are required to provide development data to the other party thorough a joint steering committee.

GSK paid us an upfront payment of €120 million and is required to pay us a manufacturing capacity reservation fee of €30 million following a certain regulatory milestone event, which is creditable against future milestone payments. We are eligible to receive up to between €28 million to €45 million in development milestone payments, €32 million to €35 million in regulatory milestone payments and €70 to €100 million in commercial milestone payments, depending on the GSK Program Product. Upon each exercise of its option to add additional products as GSK Program Products, GSK is required to compensate us for certain development costs and pay any accrued milestone payments. If GSK exercises its right to replace a GSK Program Product and if the replacement product was already under development by us, GSK must compensate us for certain development costs and pay any accrued milestone payments. We are eligible to receive tiered royalty payments ranging from a single-digit percentage to a low teens percentage on net sales, subject to certain customary reductions. GSK's royalty obligations continue on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire valid claim covering such product in such country, (ii) the earlier of expiration of regulatory exclusivity for such product in such country or 12 years following the first commercial sale of such product in such country, or (iii) ten years following the first commercial sale of such product in such country provided our proprietary know-how is required for such product. In any event, GSK's royalty obligations with respect to a product will expire in all countries no later than 20 years following the first commercial sale of such product in any country in which GSK is responsible for the commercialization of approved GSK Program Products. GSK is required to compensate us for certain development and regulatory costs we may incur in connection with our performance of our obligations under the 2020 GSK Agreement and we are eligible to receive up to €20,000 in reimbursements for expenses incurred recording or registering the licenses granted under the 2020 GSK Agreement. Under any distribution agreement entered into between us and GSK in connection with our distribution of a GSK Program Product in Austria, Germany and Switzerland, we will be required to purchase supply from GSK and

pay GSK a low thirties percentage royalty on net sales. As of December 31, 2020, we have received the upfront payment amounting to €120 million and approximately €0.9 million in development cost reimbursements.

The term of the 2020 GSK Agreement will continue until the expiration of the last-to-expire royalty term, unless terminated earlier by either party. GSK has the right to terminate the 2020 GSK Agreement in its entirety or on a program-by-program basis for convenience following a certain notice period. We and GSK both have the right to terminate the 2020 GSK Agreement on a program-by-program basis before the first commercial sale of a GSK Program Product under such program in the event of the other party's material breach following a cure period or after the first commercial sale of a GSK Program Product under such program if the other party fails to make any payments due, commits any willful and material breach of the restrictions on any license granted to such party, commits a material breach of its non-compete obligations or commits a persistent and material breach of its confidentiality obligations following a cure period. We additionally have the right to terminate on a program-by-program basis after the first commercial sale of a GSK Program Product under such program if GSK commits a material breach of its commercialization diligence obligations following a cure period.

Upon expiration, the licenses granted to GSK under the 2020 GSK Agreement will become fully paid-up, perpetual and non-exclusive. In the event GSK terminates the 2020 GSK Agreement or a program under the 2020 GSK Agreement for convenience or we terminate a program under the 2020 GSK Agreement for cause, we will have the right to elect to continue with the development and commercialization of such program ourselves. If we decline to continue with the development and commercialization of a terminated program, all licenses granted under the 2020 GSK Agreement will terminate. If we elect to continue with the development and commercialization of a terminated program, all licenses granted by us to GSK will terminate and GSK must grant us an exclusive license under any intellectual property developed under the 2020 GSK Agreement and, at our election, a non-exclusive license under technology which was used by GSK for the development, manufacture or commercialization of such terminated product. In the case of termination for GSK's convenience and if we elect to obtain such non-exclusive license, we will be required to pay GSK a single-digit percentage royalty on net sales. In the case of our termination for cause, the grant of rights and transition of the assets from GSK will be subject to a payment to GSK to be mutually agreed by the parties. In the event GSK terminates a program under the 2020 GSK Agreement for cause, GSK will have the right to elect to continue the development and commercialization of such program. If GSK declines to continue with the development and commercialization of a terminated program, all licenses granted under the 2020 GSK Agreement will terminate. If GSK elects to continue development and commercialization, all licenses granted to GSK under the 2020 GSK Agreement will survive termination and all payment obligations will remain in effect except that GSK will have the right to suspend payments until the amount of damages suffered by GSK has been agreed and set off against such payments.

GlaxoSmithKline COVID Collaboration and License Agreement

In April 2021, we entered into a new collaboration agreement with GSK, which we refer to as the GSK COVID Agreement, pursuant to which we are collaborating with GSK to research, develop and manufacture next-generation mRNA vaccines targeting the original SARS-CoV-2 strain as well as emerging variants, including multivalent and monovalent approaches. These vaccine candidates may either be used to protect unvaccinated individuals or to serve as boosters in the event that SARS-CoV-2 immunity gained from an initial vaccination reduces over time.

Under the terms of the GSK COVID Agreement, we granted GSK a worldwide, exclusive, sublicensable (subject to certain conditions) license under certain of our intellectual property relating to mRNA-based vaccines targeting SARS-CoV-2 and a non-exclusive license under certain LNP technology to develop, manufacture and commercialize certain SARS-CoV-2 pathogen vaccine products, or the GSK COVID Products, for use in connection with the prevention or treatment of diseases caused by the SARS-CoV-2 pathogen. The GSK COVID Products consist of (i) next-generation SARS-CoV-2 pathogen vaccine products (other than CVnCoV), (ii) vaccine products targeting coronaviruses other than SARS-CoV-2 for which GSK exercises its exclusive option pursuant to the 2020 GSK Agreement and where we elect to develop and commercialize such product on a cost and profit split basis under the GSK COVID Agreement and (iii) next-generation SARS-CoV-2 pathogen vaccine products (other than CVnCoV) that also target one or more pathogens that the parties are targeting under the 2020 GSK Agreement, which we refer to as Combination Products. We additionally granted GSK an exclusive option to obtain exclusive licenses under our intellectual property relating to certain mRNA-based vaccines targeting SARS-CoV-2 to develop, manufacture and commercialize CVnCoV and boosters for such vaccine, starting on a certain date and in

recognition of certain preexisting agreements regarding such vaccine. Upon exercise of such option, CVnCoV and related boosters will be considered GSK COVID Products. Prior to the exercise of GSK's option, we are free to amend or enter into further government and non-profit contracts with respect to CVnCoV but are prohibited from entering into further government and non-profit contracts with respect to GSK COVID Products, other than certain specifically contemplated future agreements. In the event we obtain rights to any intellectual property controlled by a third party that is useful but not necessary for the development, manufacture or commercialization of the GSK COVID Products, we must, at GSK's election, use commercially reasonable efforts to obtain a sublicense to such rights on behalf of GSK. Under the terms of the GSK COVID Agreement, GSK granted us a royalty-free, non-exclusive license under certain GSK-controlled technology to perform certain development and manufacturing activities under the GSK COVID Agreement.

GSK and its affiliates and sublicensees and we and our affiliates are prohibited from, subject to certain exceptions, developing, manufacturing or commercializing, directly or indirectly, any mRNA-based vaccine or mRNA-based antibody products targeting the SARS-CoV-2 pathogen, other than a GSK COVID Product as contemplated under the GSK COVID Agreement or CVnCoV and variants thereto. The exclusivity obligations remain in effect until the expiration or termination of the GSK COVID Agreement.

We and GSK are required to complete certain development activities with respect to the GSK COVID Products set forth in various development plans. Among other development responsibilities, we are required to provide clinical supply. Once a manufacturing and supply strategy for a given GSK COVID Product has been agreed upon between the parties, we must negotiate and agree in good faith on a commercial supply agreement pursuant to which we may be required to reserve certain manufacturing capacity for GSK. At GSK's request but not before a certain agreed upon date, we are required to transfer to GSK all know-how necessary for GSK's development activities under the GSK COVID Agreement and all know-how necessary for the manufacture of the GSK COVID Products. GSK is responsible for the commercialization of GSK COVID Products in all countries other than Austria, Germany and Switzerland and is required to use diligent efforts to commercialize approved GSK COVID Products in certain major market countries. At our request, we and GSK will negotiate and agree in good faith to a distribution agreement pursuant to which we will have the exclusive right to commercialize GSK COVID Products in Austria, Germany and Switzerland. We and GSK are required to provide development data to the other party thorough a joint steering committee.

Under the GSK COVID Agreement, GSK will pay us an upfront payment of €75 million. Upon GSK's exercise of its option to add CVnCoV and boosters for such vaccine as GSK COVID Products, GSK is required to compensate us for certain development costs. We and GSK agreed to equally share all development costs for GSK COVID Products, subject to certain exceptions. We and GSK will share all net profits generated from sales of GSK COVID Products, other than Combination Products, under profit sharing arrangements that in certain cases vary depending upon the GSK COVID Product in question, the time of sale, the number of doses sold and the party to whom the sale is made. We are eligible to receive tiered royalty payments ranging from a sub-teen percentage to a mid-teens percentage on net sales of Combination Products, subject to certain customary reductions. We will pay GSK a high-teen percentage royalty on net sales of all Combination Products in Austria, Germany and Switzerland. All royalty obligations continue on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire valid claim covering such product in such country, (ii) the earlier of expiration of regulatory exclusivity for such product in such country or 12 years following the first commercial sale of such product in such country, or (iii) ten years following the first commercial sale of such product in such country provided our proprietary know-how is required for such product. In any event, GSK's royalty obligations with respect to a product will expire in all countries no later than 20 years following the first commercial sale of such product in the respective party's territory.

The term of the GSK COVID Agreement will continue until the expiration of all applicable payment obligations, unless terminated earlier by either party. GSK has the right to terminate the GSK COVID Agreement in its entirety for convenience following a certain notice period and we have the right to opt out of the funding of the development, manufacture and commercialization of a GSK COVID Products on a product-by-product basis. In the event we opt out of funding the development of a GSK COVID Product, GSK can elect to cease the development and commercialization of the relevant product, or to continue it on the terms of the 2020 GSK Agreement. If GSK declines to continue with the development and commercialization, the agreement terminates in connection with that GSK COVID Product and all licenses granted under the GSK COVID Agreement will terminate. We and GSK both have the right to terminate the GSK COVID Agreement before the first commercial sale of a GSK COVID Product in the event of the other party's material breach following a cure period or after the first commercial sale of a GSK COVID Product if the other party fails to make any payments

due, commits any willful and material breach of the restrictions on any license granted to such party, commits a material breach of its non-compete obligations or commits a persistent and material breach of its confidentiality obligations following a cure period. We additionally have the right to terminate after the first commercial sale of a GSK COVID Product if GSK commits a material breach of its commercialization diligence obligations following a cure period.

Upon expiration, the licenses granted to GSK under the GSK COVID Agreement will become fully paid-up, perpetual and non-exclusive. In the event GSK terminates the GSK COVID Agreement for convenience or we terminate the GSK COVID Agreement for cause, all licenses granted to GSK under the GSK COVID Agreement will terminate and we will have the right to elect to continue with the development and commercialization of the GSK COVID Products ourselves. If we elect to continue with the development and commercialization of the COVID Products, GSK must grant us an exclusive license under any intellectual property developed under the GSK COVID Agreement and, at our election, a non-exclusive license under technology which was used by GSK for the development, manufacture or commercialization of the GSK COVID Products. In the case of termination for GSK's convenience and if we elect to obtain such non-exclusive license, we will be required to pay GSK a royalty ranging from a sub-single-digit percentage to a low single-digit percentage on net sales. In the case of our termination for cause, the grant of rights and transition of the assets from GSK will be subject to a payment to GSK to be mutually agreed by the parties. In the event GSK terminates the GSK COVID Agreement for cause, GSK will have the right to elect to continue the development and commercialization of the GSK COVID Products. If GSK declines to continue with the development and commercialization of the GSK COVID Products, all licenses granted under the GSK COVID Agreement will terminate. If GSK elects to continue development and commercialization, all licenses granted to GSK under the GSK COVID Agreement will survive termination, provided that for GSK COVID Products other than Combination Products a one-time payment from GSK to Curevac (in replacement of a continuous profit sharing mechanism) will be mutually agreed upon by the parties. All payment obligations for Combination Products will remain in effect. In each case, GSK will have the right to suspend payments until the amount of damages suffered by GSK has been agreed and set off against such payments.

Genmab Collaboration and License Agreement

In December 2019, we entered into a Collaboration and License Agreement with Genmab, which we refer to as the Genmab Agreement, to research and develop up to four potential differentiated mRNA-based antibody products, to be selected by Genmab, based on the combination of our proprietary RNAntibody technology with Genmab's proprietary antibody technology for the treatment of human diseases. Pursuant to the Genmab Agreement we granted Genmab an exclusive, worldwide, sublicensable (subject to certain conditions) license under our mRNA technology for the development, manufacture and commercialization of an mRNA antibody product designed to express a certain Genmab proprietary antibody, which we refer to as the Genmab First Program. The parties will collaborate on research to identify an initial product candidate under the Genmab First Program. We additionally granted Genmab an exclusive, worldwide, sublicensable license under our mRNA technology for the research and preclinical development of up to four additional mRNA antibody product concepts and an option to obtain an exclusive, worldwide, sublicensable (subject to certain conditions) license to develop, manufacture and commercialize product candidates for up to three of such product concepts. We have the option to share in the costs and profits in connection with the development, manufacture and commercialization of one of the additional mRNA antibody product concepts under predefined terms and conditions.

We may not, directly or indirectly, offer any rights to a third party under the technology we license to Genmab for the product concepts and targets being developed under the Genmab Agreement or conduct or participate in the development, manufacture or commercialization of any antibody product that is directed at a target being developed under the Genmab Agreement. For the Genmab First Program, these obligations will last for the duration of the Genmab Agreement. For the additional product concepts, certain time limitations apply to the above obligations. Genmab may not develop or commercialize any mRNA-based single antibody product or monoclonal recombinant antibody that is based on the Genmab First Program outside of the scope of the Genmab Agreement.

In partial consideration for entering into the Genmab Agreement, Genmab paid us an upfront fee of $10 million and made a €20 million equity investment. Genmab additionally will be obligated to pay us a $0.5 million reservation fee upon the selection of each additional product concept for development and $5 million upon selection of a product from the Genmab First Program for further development and commercialization. Genmab is additionally required to pay us up to $30 million in option exercise fees. If Genmab exercises any of its options to obtain commercial licenses for the additional mRNA antibody concepts, Genmab would fund all research and would develop and

commercialize any resulting product candidates. We are additionally eligible to receive up to between $25 million and $43 million in development milestone payments, $100 million and $125 million in regulatory milestone payments and $150 million and $200 million in commercial milestone payments for each product, depending on the specific product concept. In addition, we are eligible to receive a mid single-digit to low teens percentage tiered royalty on aggregate net sales of licensed products, on a per product basis and subject to certain customary reductions. Genmab's royalty obligation continues on a country-by-country and product-by-product basis until the later of the expiration of the last-to-expire valid claim in the licensed patents in such country covering such licensed product, expiration of regulatory exclusivity for such product in such country or ten years from the date of the first commercial sale of such product. If Genmab grants a sublicense to the Genmab First Program product before a certain milestone event, Genmab must pay us a one-time $10 million payment. We are responsible for a portion of the overall costs for development with respect to the Genmab First Program product until submission of an IND within an agreed budget, and Genmab will otherwise reimburse us for costs incurred in performing certain development activities in connection with the Genmab Agreement. We are responsible for any payments to third parties related to the LNP technology we license to Genmab for use in relation to the Genmab First Program and a portion of such payments with respect to LNP technology used in the additional product concepts. In the event we exercise our right to share in the development, manufacture and commercialization of a product, we must pay Genmab a one-time payment of $3 million and refund any option fee paid by Genmab with respect to such product. As of December 31, 2020, we have received approximately $0.6 million in development cost reimbursements and we have not received any reservation, product selection, option exercise or sublicense fees or milestone or royalty payments.

We are required to use commercially reasonable efforts to perform our obligations under the research and development plans established in connection with the Genmab Agreement. Genmab is required to use commercially reasonable efforts to identify and develop the Genmab First Program product and each additional product Genmab adds to the development program under the Genmab Agreement, and to further develop the Genmab First Program product and each optioned product to marketing authorization and to commercialize each product for which it obtains regulatory approval. We and Genmab are required to make available to the other party all preclinical development data for each program under development under the Genmab Agreement until filing of an IND for such program. Following IND filing for a product, we and Genmab will establish a collaboration committee where Genmab will share the status, progress and results of the development of the respective product.

The term of the Genmab Agreement will continue until the expiration of the royalty term, unless terminated earlier by either party. The Genmab Agreement may be terminated upon written notice by either party upon the other party's material breach or default of any of its obligations following a cure period. Genmab may terminate the Genmab Agreement for convenience after a certain notice period. Upon expiration of the Genmab Agreement, the license rights we granted to Genmab under the Genmab Agreement will become fully paid-up, perpetual and non-exclusive. In the event of termination for our material breach, we will grant Genmab an exclusive (even to us), worldwide and sublicensable license to exploit any product identified prior to termination, subject to Genmab's continued milestone and royalty obligations. In the event of termination by us for Genmab's material breach, or Genmab's termination for convenience, the licenses granted to Genmab will automatically terminate. Additionally, at our request, Genmab will grant us a non-exclusive, royalty-free, sublicensable, perpetual and worldwide license under certain Genmab intellectual property that is created under the Genmab Agreement and that is required to develop, manufacture and commercialize our own mRNA antibody products targeting the collaboration targets under the Genmab Agreement prior to termination. Such license would not include any license to Genmab background intellectual property or the specific products or antibodies developed by Genmab.

Arcturus Development and Option Agreement

In January 2018, we entered into a Development and Option Agreement with Arcturus, which we refer to as the Arcturus Agreement, pursuant to which Arcturus granted us the right to reserve a certain number of targets and an irrevocable offer to obtain a license to a certain number of such reserved targets to develop, manufacture and commercialize products containing Arcturus's LNP technology (LMD technology) and mRNA constructs intended to express such targets. The Arcturus Agreement was amended in May 2018, September 2018 and July 2019. As of December 31, 2020, we have not accepted the offer with respect to any targets.

Under the Arcturus Agreement, Arcturus is responsible for the LNP chemistry and formulation and characterization work and we are responsible for mRNA construct development.

Both parties will undertake certain allocated preclinical studies. Each party is required to use diligent efforts to perform its obligations under the work plans established in connection with the Arcturus Agreement and Arcturus is required to use diligent efforts to manufacture and supply us with certain formulated products. The Arcturus Agreement provides for the establishment of a joint development committee for the discussion of development efforts under the Arcturus Agreement.

We paid Arcturus an upfront fee of $5 million in connection with the Arcturus Agreement and must pay an extension fee of $1 million if we exercise our option to extend the initial term of the Arcturus Agreement beyond July 2023. We are further required to reimburse Arcturus for certain costs incurred in connection with development activities and provide certain FTE funding. We are additionally required to pay up to an aggregate of $5 million in connection with our acceptance of the irrevocable offer to obtain licenses for further development and commercialization of selected targets. Under each license agreement to be entered into in connection with our selection of targets, we will additionally be required to make certain royalty payments, which are not in excess of 10%, subject to certain customary reductions, on a country-by-country and a product-by-product basis until the later of the expiration of the last-to-expire valid patent in such country covering such licensed product, expiration of regulatory exclusivity for such product in such country or ten years from the date of the first commercial sale of such product in such country. We additionally must pay Arcturus up to $6 million in development milestone payments, $9 million in regulatory milestone payments and $8 million in commercial milestone payments in connection with each license agreement we enter into under the Arcturus Agreement. As of December 31, 2020, we have made payments totaling approximately $5.3 million to Arcturus reimbursing Arcturus for development costs and in connection with our FTE funding obligations and we have not accepted the irrevocable offer with respect to any target and therefore have not paid any acceptance fees or made any milestone or royalty payments to Arcturus.

Under the Arcturus Agreement, Arcturus granted us a worldwide, non-exclusive license under its LNP technology for research and preclinical development. We granted Arcturus a worldwide, non-exclusive license under our mRNA technology solely to enable Arcturus to perform development activities in connection with the Arcturus Agreement.

The Arcturus Agreement will expire in July 2023 unless earlier terminated or extended for an additional 18-month term. We have the right to terminate the Arcturus Agreement in full or on a target-by-target basis in the event of a material breach by Arcturus following a cure period. We additionally have the right to terminate the Arcturus Agreement for convenience following a certain notice period and for change of control of Arcturus. In the event we terminate for Arcturus's breach, for convenience or for Arcturus's change of control, Arcturus will transfer all deliverables created under the Arcturus Agreement to us and all licenses granted under the Arcturus Agreement will terminate. In the event we terminate for Arcturus's breach, Arcturus will transfer any technology and provide licenses as reasonably necessary for us to complete work contemplated under any work plan relating to the terminated target and the acceptance fee relating to such target and payments due under any associated license agreement will be reduced by a certain percentage. Arcturus has the right to terminate the Arcturus Agreement in the event of a material breach by us following a cure period, in which event all licenses granted under the Arcturus Agreement will terminate. Termination of the Arcturus Agreement shall not affect any then existing license agreements between us and Arcturus.

Acuitas Development and Option Agreement

In April 2016, we entered into a Development and Option Agreement with Acuitas, which as amended we refer to as the Acuitas Agreement, pursuant to which Acuitas granted us the right to reserve a certain number of vaccine and other targets and an option to obtain a license to a certain number of such reserved targets to develop, manufacture and commercialize products containing Acuitas's LNP technology and mRNA constructs intended to express such targets. With respect to a certain number of non-exclusive licenses to vaccine targets that we obtain under the Acuitas Agreement, Acuitas additionally granted us an option to exchange each vaccine target licensed under such non-exclusive license for an alternate vaccine target for a certain period. As of December 31, 2020, we have exercised our option to obtain a non-exclusive license to thirteen targets, and have not exercised our option to exchange a vaccine target licensed under any non-exclusive license.

Under the Acuitas Agreement, Acuitas is responsible for the LNP chemistry and formulation and characterization work, and we are responsible for mRNA construct development. Both parties will undertake certain allocated preclinical studies. Each party is required to use diligent efforts to perform its obligations under the work plans established in connection with the Acuitas Agreement. Acuitas is further required to use diligent efforts to manufacture and supply us with certain formulated

products. The Acuitas Agreement provides for the establishment of a joint development committee for the discussion of development efforts under the Acuitas Agreement. We are required to reimburse Acuitas for certain costs incurred in connection with development activities and certain FTE costs.

We are further required to pay Acuitas annual target reservation and maintenance fees of up to approximately $1.4 million if we reserve the maximum number of targets permitted under the Acuitas Agreement. We are additionally required to pay an option exercise fee ranging from $50,000 to $2 million upon each exercise of our option under the Acuitas Agreement, subject to certain additional fees ranging from $10,000 to $200,000 for the exercise of our option for certain other vaccine targets. We paid Acuitas a $5 million upfront fee in connection with an amendment to the Acuitas Agreement dated July 2020 and, upon each exercise of our option to exchange a vaccine target licensed under any non-exclusive license, we are required to pay an exchange fee of $3 million. We additionally are required to pay Acuitas a $3 million upfront fee in connection with an amendment to the Acuitas Agreement dated December 2020 and are required to pay an additional $250,000 in April 2022 and April 2023 for each of certain options not yet exercised. Under each license agreement we enter into in connection with our exercise of our option, we will additionally be required to make low single-digit percentage tiered royalty payments, subject to certain customary reductions, on a country-by-country and a product-by-product basis until the later of the expiration of the last-to-expire licensed patent in such country covering such licensed product, expiration of regulatory exclusivity for such product in such country or ten years from the date of the first commercial sale of such product in such country. Under each such license we additionally must pay up to between approximately $1.1 million and $9 million in development milestone payments, $1.3 million and $7 million in regulatory milestone payments and $1.3 million and $7 million in commercial milestone payments, depending on whether the license is exclusive or non-exclusive and the number of options exercised to date. As of December 31, 2020, we have exercised our option to obtain a non-exclusive license to thirteen targets. As of December 31, 2020, we have paid Acuitas approximately $3.3 million in reservation and option exercise fees and have made payments totaling approximately $6.1 million reimbursing Acuitas for development costs and LNP batches and in connection with our FTE funding obligations. Payments made under the license agreements entered into in connection with our exercise of our option under the Acuitas Agreement are described below.

Under the Acuitas Agreement, Acuitas granted us a worldwide, non-exclusive license under its LNP technology for us to perform development activities and we granted Acuitas a worldwide, non-exclusive license under our mRNA technology solely to enable Acuitas to perform development activities in connection with the Acuitas Agreement.

The Acuitas Agreement will expire in April 2025 unless earlier terminated or extended. Both parties have the right to terminate the Acuitas Agreement in whole or on a program-by-program basis in the event of a material breach by the other party following a cure period. We additionally have the right to terminate the Acuitas Agreement for convenience following a certain notice period or for Acuitas's change of control. In the event of termination for any reason, Acuitas will transfer all deliverables created under the Acuitas Agreement to us and in the event we terminate for reasons other than for Acuitas's material breach, we must make any payments owed to Acuitas up to the time of termination. In the event we terminate for Acuitas's material breach or for Acuitas's change of control, Acuitas will transfer any technology and provide licenses as reasonably necessary for us to complete work contemplated under the Acuitas Agreement and, in the case of termination for Acuitas's material breach, Acuitas must refund to us any target reservation and maintenance fees for the remainder of the contract year in which such termination is effective.

Acuitas Non-exclusive License Agreements

For each option we have exercised under the Acuitas Agreement, we have entered into a non-exclusive license agreement with Acuitas with respect to such optioned product, all based on the same form agreement, which we collectively refer to as the Acuitas License Agreements. Under the Acuitas License Agreements, Acuitas grants us a non-exclusive, non-transferable, sublicensable (subject to certain conditions) worldwide license under Acuitas's LNP technology to develop, manufacture and commercialize licensed products directed to the optioned targets. We may convert the non-exclusive licenses to exclusive licenses subject to certain additional financial obligations.

We must pay Acuitas up to between approximately $1.1 million and $1.6 million in development milestone payments, $1.3 million and $1.8 million in regulatory milestone payments and $1.3 million and $1.8 million in commercial milestone payments under each Acuitas License Agreement upon the occurrence of certain milestone events. We additionally are obligated to pay Acuitas annual fees ranging from $5,000 to $10,000 for any additional protein targeted by a vaccine product licensed under an Acuitas License Agreement after a certain milestone event. We are further required to pay

Acuitas a low single-digit tiered percentage royalty on net sales of licensed products, subject to certain potential customary reductions. Our royalty obligations continue under each Acuitas License Agreement on a country-by-country and product-by-product basis until the later of the expiration of the last-to-expire licensed patent claim covering such licensed product in such country, expiration of any regulatory exclusivity period for such product in such country and ten years following the first commercial sale of such product in such country. As of December 31, 2020, we have made $100,000 in development milestone payments to Acuitas with respect to the license agreement relating to Rabies RAV-G and we have made $0.6 million in development milestone payments (Phase I and Phase II milestone payments) to Acuitas with respect to the license agreement relating to the SARS-CoV-2 Spike protein S and have not made any royalty payments.

Each Acuitas License Agreement will continue on a product-by-product and a country-by-country basis until there are no more payments owed to Acuitas for such product in such country. Either party may terminate an Acuitas License Agreement in the event of a material breach by the other party following a cure period. We additionally have the right to terminate the Acuitas License Agreements for convenience following a certain notice period. Upon expiration of an Acuitas License Agreement, the licenses granted to us under such Acuitas License Agreement will become fully paid-up and will remain in effect. In the event of our termination of an Acuitas License Agreement for Acuitas's material breach, the rights and licenses granted to us under such agreement will become perpetual and irrevocable. Alternatively, instead of exercising our right to terminate in the event of Acuitas's material breach, we may elect to instead continue the license but reduce our milestone and royalty payment obligations to Acuitas by a certain percentage. In the event of termination of an Acuitas License Agreement by us for convenience or by Acuitas for our material breach, the licenses granted under such agreement will terminate, except that we will have the right to sell off any remaining inventories of licensed products for a certain period of time.

CRISPR Therapeutics Development and License Agreement

In November 2017, we entered into a Development and License Agreement with CRISPR Therapeutics, which, as amended, we refer to as the CRISPR Therapeutics Agreement, pursuant to which we will develop novel Cas9 mRNA constructs for use in gene editing therapeutics. Under the terms of the CRISPR Therapeutics Agreement, we granted CRISPR Therapeutics a worldwide, exclusive (even to us), sublicensable (subject to certain conditions) license under certain intellectual property rights that are reasonably necessary or useful to develop, manufacture or commercialize products comprising Cas9 mRNA constructs, and under any patents controlled by us that arise from inventions discovered under the CRISPR Therapeutics Agreement to develop, manufacture and commercialize three of CRISPR Therapeutics' *in vivo* gene-editing programs for certain diseases. CRISPR Therapeutics granted us an exclusive (even as to CRISPR Therapeutics), worldwide, cost-free sublicense to manufacture products comprising Cas9 mRNA constructs for CRISPR Therapeutics.

CRISPR Therapeutics was required to pay us an upfront one-time technology access fee of $3 million and we are eligible to receive up to $13 million in development milestone payments, $33 million in regulatory milestone payments and $133 million in commercial milestone payments, as well as mid single-digit percentage royalties from CRISPR Therapeutics on the net sales of licensed products on a product-by-product and country-by-country basis, subject to certain potential customary reductions. CRISPR Therapeutics' royalty obligations continue on a product-by-product and country-by-country basis until the later of the date when there are no valid patent claims under our licensed patents covering such licensed product in such country, the date when regulatory exclusivity for such licensed product in such country expires and ten years following the date of first commercial sale of such licensed product in such country. CRISPR Therapeutics is additionally required to reimburse us for our FTE costs and reasonable out-of-pocket expenses incurred performing development activities under the CRISPR Therapeutics Agreement. In the event CRISPR Therapeutics exercises its right to sublicense under the agreement, CRISPR Therapeutics must pay us a low teens to mid-twenties percentage of any non-royalty sublicense income, depending on the timing of the sublicense and whether the sublicense is granted through an affiliate of CRISPR Therapeutics. As of December 31, 2020, we have received approximately €0.9 million in payments for the supply of materials and FTE cost and development reimbursements and no milestone, royalty or sublicense fee payments.

We are required to use commercially reasonable efforts to perform our development obligations under the CRISPR Therapeutics Agreement and to supply certain materials to CRISPR Therapeutics. CRISPR Therapeutics is required to use commercially reasonable efforts to perform its obligations under the development plan and to develop and commercialize licensed products. We and CRISPR are required to keep the other party informed regarding the progress and results of performance of all development activities under the CRISPR Therapeutics Agreement.

The term of the CRISPR Therapeutics Agreement will continue on a product-by-product and country-by-country basis, until the last-to-expire royalty term expires in such country for such product, unless terminated earlier by either party. The CRISPR Therapeutics Agreement may be terminated (i) by CRISPR Therapeutics for convenience following a certain notice period, (ii) by us if CRISPR Therapeutics or any of its affiliates, either directly or indirectly, challenges or assists a third party to challenge the licensed patent rights or in the event CRISPR Therapeutics undergoes a change of control, or (iii) by either party in the event of the other party's material breach following a cure period (including on a program-by-program basis) or in the event of the other party's insolvency. Upon expiration, the license granted to CRISPR Therapeutics converts into a fully paid-up, royalty-free, perpetual and irrevocable license. Upon termination, the licenses granted to CRISPR Therapeutics will terminate and, in the case of termination for CRISPR Therapeutics' material breach or insolvency or for convenience by CRISPR Therapeutics, CRISPR Therapeutics must transfer all Cas9 mRNA constructs and related data to us.

Boehringer Ingelheim Exclusive Collaboration and License Agreement

In August 2014, we entered into an Exclusive Collaboration and License Agreement with Boehringer Ingelheim, which we refer to as the Boehringer Agreement, whereby we granted Boehringer Ingelheim an exclusive, worldwide, sublicensable (subject to certain conditions) license under certain of our intellectual property for the development and commercialization of our investigational therapeutic mRNA vaccine BI 1361849 (formerly CV9202) and products containing such vaccine for all uses for cancer in humans. We additionally granted Boehringer Ingelheim an option to obtain an additional exclusive license for no additional fee to develop and commercialize an additional vaccine derived from BI 1361849 (formerly CV9202) for all uses for cancer in humans, which option right expires in August 2024. As of December 31, 2020, Boehringer Ingelheim has not exercised its option right. The Boehringer Agreement was amended in June 2015, August 2016 and August 2019.

Under the collaboration, Boehringer Ingelheim agreed to start clinical investigation of BI 1361849 (formerly CV9202) in at least two different lung cancer settings: in combination with afatinib in patients with advanced or metastatic epidermal growth factor mutated non-small cell lung cancer, or NSCLC, and in combination with chemo-radiation therapy in patients with unresectable stage III NSCLC. This clinical development plan was later revised due to the establishment of checkpoint blocking antibody treatments as a new standard-of-care option for the treatment of advanced NSCLC and due to demonstrated synergy between mRNA vaccines and checkpoint blocking antibodies in preclinical models. BI 1361849 (formerly CV9202) is currently in Phase 1/2 of clinical investigation in combination with two checkpoint blocking antibodies, Durvalumab, a PD-L1 antibody, and Tremelimumab, a CTLA4 antibody, both by Medimmune, in a trial sponsored by the Ludwig Institute for Cancer Research.

Boehringer Ingelheim is obligated to use commercially reasonable efforts to progress the development and commercialization of BI 1361849 (formerly CV9202). We are required to use commercially reasonable efforts to progress certain research and development activities in respect of the manufacturing of BI 1361849 (formerly CV9202). We are required to provide all BI 1361849 (formerly CV9202) required for nonclinical and clinical development and for commercialization. In the event we fail to meet certain manufacturing benchmarks, Boehringer Ingelheim will have the right to assume the manufacture of BI 1361849 (formerly CV9202). The Boehringer Agreement provides for the creation of a joint steering committee which is responsible for the review of development plans, the monitoring of development activities and the exchange of development data and other technical information. With certain limited exceptions, Boehringer Ingelheim is responsible for all regulatory matters provided that we have the right and obligation to review and comment on all regulatory filings to the extent such filings relate to BI 1361849 (formerly CV9202). In the event Boehringer Ingelheim or its affiliates or sublicensees commence clinical trials or commercialization of any mRNA-based protamine-complex vaccine targeting any of the indications for which Boehringer Ingelheim is developing BI 1361849 (formerly CV9202), we have the right to convert the exclusive license granted to Boehringer Ingelheim under the Boehringer Agreement to a non-exclusive license and Boehringer Ingelheim will be required to grant us a non-exclusive license to any intellectual property developed under the Boehringer Agreement, subject to certain exceptions, for the development, manufacture and commercialization of BI 1361849 (formerly CV9202).

Under the terms of the Boehringer Agreement, Boehringer Ingelheim was required to pay us an upfront payment of €30 million and an additional upfront option fee of €5 million. As of December 31, 2020, we have received €7 million in development milestone payments and can further achieve up to an additional €73 million in development milestone payments, €250 million in regulatory milestone payments and €100 million in commercial milestone payments. In addition, Boehringer

Ingelheim agreed to pay us royalties in the low teens on net sales, subject to certain potential customary reductions. Boehringer Ingelheim's royalty obligations continue on a product-by-product and country-by-country basis in certain major markets until the latest of the date when there are no valid patent claims under our licensed patents covering such licensed product in such country, the date when regulatory exclusivity for such licensed product in the applicable country expires and 12 years following the date of the first commercial sale of such licensed product in such country if such country is designated as a major market or 15 years following the date of the first commercial sale of such licensed product in any non-major market country if such country is not designated as a major-market country. We are responsible for any payment obligations arising under certain existing third party license agreements and costs we incur in relation to the research and development of BI 1361849 (formerly CV9202) manufacturing technology. Boehringer Ingelheim is responsible for all other development and commercialization costs and is required to reimburse us for any such costs we may incur. As of December 31, 2020, Boehringer Ingelheim has made payments to us for a net amount of approximately €7.6 million for the supply of materials and reimbursing us for development costs. We have received no royalty payments.

Boehringer Ingelheim solely owns any intellectual property arising out of the collaboration that is both only dependent upon or covered by Boehringer Ingelheim's preexisting intellectual property and does not relate to the development or manufacture of BI 1361849 (formerly CV9202) or other RNA-based products owned or in-licensed by us, as well as any intellectual property that is solely directed to the composition of matter, the formulation or use of BI 1361849 (formerly CV9202) and not applicable to any other vaccine. We own any intellectual property arising out of the collaboration that is dependent upon or covered by our preexisting intellectual property and not Boehringer Ingelheim's preexisting intellectual property, and is not solely directed to the composition of matter, the formulation or use of BI 1361849 (formerly CV9202), as well as any intellectual property that is directed to the development or manufacture of BI 1361849 (formerly CV9202) or other RNA-based products owned or in-licensed by us. All other intellectual property developed under the Boehringer Agreement is jointly owned by us and Boehringer Ingelheim. Boehringer Ingelheim grants us a fully paid-up, irrevocable, perpetual, sublicensable and transferable license under any intellectual property developed under the Boehringer Agreement and owned by Boehringer Ingelheim for the manufacture of BI 1361849 (formerly CV9202), the exploitation of any product other than BI 1361849 (formerly CV9202) and for any use other than uses for cancer in humans. We grant Boehringer Ingelheim a cost-free, fully paid-up, non-exclusive, irrevocable, perpetual, sublicensable and transferable license under intellectual property developed under the Boehringer Agreement and assigned to us by Boehringer Ingelheim for exploitation outside of the scope of the Boehringer Agreement. Upon the occurrence of a certain milestone event, we must assign to Boehringer Ingelheim certain patent rights that relate specifically to BI 1361849 (formerly CV9202) and Boehringer Ingelheim will grant us an exclusive, irrevocable, perpetual, cost-free, sublicensable and transferable license to use such patent rights for the manufacture of BI 1361849 (formerly CV9202), the exploitation of any product other than BI 1361849 (formerly CV9202) and for any use other than uses for cancer in humans.

The term of the Boehringer Agreement will continue on a country-by-country and product-by-product basis until the expiration of the last to expire royalty term, unless terminated earlier by either party. Boehringer Ingelheim may terminate the Boehringer Agreement for convenience following a certain notice period. Either party may terminate the Boehringer Agreement upon the other's material breach, following a cure period. In addition, we may terminate the Boehringer Agreement if Boehringer Ingelheim or any of its affiliates, directly or indirectly, challenges or assists a third party to challenge the validity of licensed patent rights. Upon expiration of the Boehringer Agreement, Boehringer Ingelheim will retain the license granted to it under the Boehringer Agreement on an exclusive, irrevocable, perpetual, fully paid and royalty-free basis, with such license converting to a non-exclusive license after the later of a certain period following expiration of the Boehringer Agreement or such time as we no longer supply to Boehringer Ingelheim a certain percentage of its demand for BI 1361849 (formerly CV9202). Following expiration we are required to reasonably consider continuing to supply Boehringer Ingelheim with BI 1361849 (formerly CV9202) but in the event we cannot agree on the terms of such supply, we will be required to grant Boehringer Ingelheim a license to manufacture BI 1361849 (formerly CV9202) and provide technology transfer assistance in exchange for a €5 million fee. Upon termination of the Boehringer Agreement, the rights and licenses granted by us to Boehringer Ingelheim will revert back to us, provided that Boehringer Ingelheim has the right to sell off existing inventory of BI 1361849 (formerly CV9202) for a certain period. In the event of our material breach, Boehringer Ingelheim may elect to terminate the Boehringer Agreement, in which case we must reimburse Boehringer Ingelheim for all wind down expenses of ongoing clinical trials, or continue to exercise its rights and obligations under the Boehringer Agreement, receive damages from us determined in a dispute resolution proceeding and continue paying us milestone and royalty payments. In the event of termination by Boehringer Ingelheim for convenience or by us for Boehringer Ingelheim's patent

challenge or material breach, Boehringer Ingelheim must assign to us all regulatory approvals or applications and grant us a non-exclusive, cost-free, perpetual and worldwide license to intellectual property held by Boehringer Ingeheim that has been used in the development, manufacture or commercialization of BI 1361849 (formerly CV9202) or any other product developed under the Boehringer Agreement.

Bill & Melinda Gates Foundation Partnership

In May 2014, we entered into a grant agreement with the Bill & Melinda Gates Foundation for the development of a vaccine for rotaviruses. Under the terms of the grant, as amended by an amendment entered into November 2020, the Bill & Melinda Gates Foundation will provide up to approximately $2.8 million in funding and we are required to perform certain activities specified in a project collaboration plan. As of December 31, 2020, we have received approximately $2.7 million in funding under the agreement. We own all intellectual property created using grant funding; however, we must make any Bill & Melinda Gates Foundation-funded products available at an affordable price in a list of clearly defined low and lower middle-income countries. The term of the rotavirus agreement continues until October 2021. Both parties have the right to terminate the agreement for convenience following a notice period or in the event of the other party's material breach following a cure period. Our global access commitments survive termination or expiration of the agreement.

In March 2015, the Bill & Melinda Gates Foundation made an equity investment of $40 million to support continued development of our RNA technology platform and the construction of an industrial-scale cGMP production facility, and we entered into the Global Access Commitments Agreement with the Bill & Melinda Gates Foundation in February 2015 pursuant to which we are required to take certain actions to support the Bill & Melinda Gates Foundation's mission. In particular, we are required to conduct development activities for up to three concurrent projects to be proposed by the Bill & Melinda Gates Foundation, subject to our right to reject proposed projects where we believe there is a reasonable likelihood of a material adverse effect on us. The costs of such projects will be allocated on a project-by-project basis in proportion to the allocation of the expected benefits. All intellectual property developed in connection with such projects will be owned by us.

Under the terms of the Global Access Commitments Agreement, any Bill & Melinda Gates Foundation-funded products will be made available by us at an affordable price in a list of clearly defined low and lower middle-income countries, while we will be able to market such products in developed countries on our own or through licensees. In addition, the new manufacturing facility will have dedicated capacity to focus on products resulting from Bill & Melinda Gates Foundation-related projects for distribution in such low and lower middle-income countries.

Our global access commitments are perpetual, however, our obligation to commence new development programs expires in February 2025. In the event that we commit a material breach of the Global Access Agreement, following a cure period, we must grant the Bill & Melinda Gates Foundation a non-exclusive, perpetual, irrevocable, fully paid-up, royalty-free license under any intellectual property controlled by us covering any Bill & Melinda Gates Foundation-funded products to develop, manufacture and commercialize such products in low and lower middle-income countries, and the Bill & Melinda Gates Foundation will have certain withdrawal rights with respect to its equity investment in us. For more information on the Bill & Melinda Gates Foundation's withdrawal rights, see "section 7 — Related Party Transactions — Investment and Shareholders' Agreement."

In November 2016 in connection with and subject to the terms of the Global Access Agreement, we were awarded a grant for up to approximately $0.9 million in funding from the Bill & Melinda Gates Foundation for the development of a vaccine for picornaviruses. As of December 31, 2020, we have received approximately $0.7 million in funding under the grant agreement. We granted the Bill & Melinda Gates Foundation a non-exclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid-up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display any products developed using grant funding; however, in the event we demonstrate to the satisfaction of the Bill & Melinda Gates Foundation that we are able to meet its global access requirements, such license will be modified or terminated. The term of the picornavirus grant continues until January 2022; however, our global access commitments survive.

In November 2017, also in connection with and subject to the terms of the Global Access Agreement, we were awarded two additional grants for up to approximately $1.9 million and $1.5 million from the Bill & Melinda Gates Foundation for the development of a universal influenza vaccine and a malaria vaccine, respectively. By an amendment entered into November 2020, our

grant for the development of a malaria vaccine was increased by an additional approximately $0.8 million. As of December 31, 2020, we have received approximately $1.9 million and $2.2 million, respectively, in funding under each grant agreement. The programs will leverage our advanced RNActive® prophylactic vaccine technology to develop mRNA-based universal influenza and malaria vaccines. The malaria grant agreement continues until December 2021 and the universal influenza grant agreement continues until June 2021, unless terminated earlier by the Bill & Melinda Gates Foundation.

The Bill & Melinda Gates Foundation can terminate any of the three grant agreements entered into in connection with the Global Access Agreement early if it is not reasonably satisfied with our progress on a specific project, there are significant changes to our leadership, another issue arises which threatens a specific project's success, there is a change in our control or tax status, or we fail to comply with the grant agreement. Our global access commitments survive termination or expiration. Any grant funds that have not been used for, or committed to, the underlying project upon expiration or termination of a grant agreement must be returned to the Bill & Melinda Gates Foundation.

In July 2020, we amended the Global Access Agreement and entered into a Letter Agreement with GSK and the Bill & Melinda Gates Foundation. Pursuant to this letter agreement, the Bill & Melinda Gates Foundation released us of our global access commitments with respect to certain prophylactic and therapeutic vaccines based on our mRNA technology platform to be developed under the 2020 GSK Agreement. This release will remain in effect for a vaccine or medicine only for so long as it is in development or being commercialized under the 2020 GSK Agreement. The letter agreement does not release us from any of our obligations to initiate or continue projects under the Global Access Agreement or related grant agreements and GSK granted to us and the Bill & Melinda Gates Foundation a non-exclusive, royalty-free, perpetual license under intellectual property arising from certain activities under the 2020 GSK Agreement to make vaccines arising from those projects available in low and lower middle-income countries as set forth in the Global Access Agreement.

Coalition for Epidemic Preparedness Innovations Framework Partnering Agreement

In February 2019, we entered into a framework partnership agreement with CEPI, which as amended we refer to as the CEPI Agreement, to develop our RNA Printer using certain intellectual property controlled by us covering the development and manufacture of mRNA products as well as certain additional intellectual property licensed to us. In connection with the CEPI Agreement we have entered into work orders for the preclinical development of a Lassa virus vaccine, a yellow fever vaccine and our rabies virus vaccine. In addition, we entered into a work package for the preclinical development and a Phase 1 clinical trial for our SARS-CoV-2 vaccine, CVnCoV.

We are required to use reasonable efforts to achieve certain development milestones and are responsible for conducting certain clinical trials. We are required to share clinical trial data with CEPI, subject to the terms of specific work packages entered into in connection with the CEPI Agreement. In the event of an infectious disease outbreak, where such outbreak can be addressed by a Lassa virus, SARS-CoV-2 or future vaccine developed under the CEPI Agreement, we must manufacture such vaccine for use in the area affected by the outbreak on economic terms that satisfy CEPI's equitable access guidelines or otherwise allow CEPI or a third party to supply such vaccine in the affected area. For the initial term of the CEPI Agreement and for a certain period thereafter, in the event of an outbreak that cannot be addressed by a vaccine already developed under the CEPI Agreement, CEPI may request, and we may agree, that we will develop a product targeted against such outbreak or we will assist CEPI to develop a candidate product against such outbreak. In the event we decline to enter into such a development agreement, we will grant CEPI the right to develop and stockpile such vaccines under certain of our background intellectual property and intellectual property developed under the CEPI Agreement. We are additionally required to use reasonable efforts, at CEPI's request, to submit certain optimized antigen nucleotide sequences for up to three specified pathogens in order for CEPI to start its own product development program. We have a right of first refusal to manufacture any pharmaceutical products developed by CEPI using the antigen nucleotide sequences we provide. In certain scenarios, including if we fail to provide Lassa virus, SARS-CoV-2 or future vaccines developed under the CEPI Agreement at prices that comply with CEPI's equitable access guidelines, we must grant CEPI a license under certain of our background intellectual property and intellectual property developed under the CEPI Agreement to, among other things, develop our automation solution for use in treating such infectious diseases and to develop, manufacture and market such pharmaceutical products for use in geographic areas where there is a disease outbreak.

In connection with a December 2020 amendment to the CEPI Agreement, we agreed to provide CVnCoV to organizations operating under the COVAX Facility, a global collaboration to accelerate the development, production and equitable access to SARS-CoV-2 tests, treatments and vaccines. Under this amendment, we agreed to supply a certain percentage of our total capacity for distribution of CVnCoV to organizations participating in the COVAX Facility.

We are required to grant certain approved manufacturers all necessary rights to use certain of our preexisting intellectual property and intellectual property developed under the CEPI Agreement to further develop our automation solution and manufacture products for the treatment of certain diseases in geographic areas where there is an outbreak on economic terms that satisfy CEPI's equitable access guidelines. We must provide all necessary commercially reasonable support to such approved manufacturers to facilitate such efforts.

CEPI agreed to contribute up to approximately $34 million in funding for projects undertaken under the CEPI Agreement and an additional $15.3 million in connection with development of CVnCoV. In the event of our commercial use of the pharmaceutical products developed under the CEPI Agreement, other than CVnCoV, we must notify CEPI and agree in good faith how such commercial benefits are to be equitably managed between the parties. As of December 31, 2020, we have received approximately €26.4 million in funding for projects undertaken under the CEPI Agreement.

We solely own all intellectual property developed under the CEPI Agreement but are required to obtain CEPI's consent prior to exploiting any intellectual property developed under the CEPI Agreement if such exploitation is in conflict with or goes against CEPI's mission or policies.

The CEPI Agreement will continue until February 2022 unless earlier terminated. Either party may terminate the CEPI Agreement if the other party commits a material breach or in the event of the other party's insolvency following a cure period. CEPI has the right to terminate the CEPI Agreement immediately upon written notice in the event we take any action incompatible with CEPI's mission, we and CEPI are unable to reach agreement on a development or marketing plan or on a project lead, we undergo a change of control, we are unable to achieve certain milestones or certain material safety or quality issues arise. In the event that CEPI terminates the CEPI Agreement, we will grant CEPI a license under our background intellectual property and intellectual property developed under the CEPI Agreement to, among other things, develop and use our RNA Printer for use in treating certain infectious diseases and to manufacture products developed under the CEPI Agreement. In the event we terminate the CEPI Agreement for CEPI's material breach, CEPI must make all outstanding payments due to us under any work package relating to expenditures that we have already committed. Regardless of the cause of termination, our obligations in the event of an infectious disease outbreak will terminate and we must transfer any vaccines developed under the CEPI Agreement as well as all regulatory applications and regulatory approvals relating to such vaccines to CEPI and we retain the right to continue using intellectual property developed under the CEPI Agreement for any purpose. In certain situations, we may be required to return funding provided by CEPI. See note 3.6 to our financial statements contained elsewhere in this Annual Report for further information on the terms of the funding provided by CEPI.

Tesla Grohmann Development and Intellectual Property Agreement

In November 2015, we entered into a development and intellectual property agreement with Tesla Grohmann, which we refer to as the Tesla Grohmann Agreement, pursuant to which Tesla Grohmann agreed to design, develop and manufacture certain automated manufacturing machines on our behalf. We are obligated to pay Tesla Grohmann a fee for each machine delivered by Tesla Grohmann and up to $50 million to $60 million in commercial milestone payments as well as certain development costs under each associated work order. As of December 31, 2020, we have paid Tesla Grohmann approximately €5 million to €6 million in development costs under various work orders and we have not paid any fees for machines provided under the Tesla Grohmann Agreement or made any milestone payments.

The parties jointly own any intellectual property developed under the Tesla Grohmann Agreement and Tesla Grohmann granted us a non-exclusive, royalty-free, perpetual, irrevocable as to existing machines, worldwide license to use, sublicense and distribute Tesla Grohmann background intellectual property that is incorporated into any machine developed under the Tesla Grohmann Agreement and an exclusive (only with respect to the machines, and until a certain period after the first commercial use of a machine, after which the license shall be non-exclusive), royalty-free, perpetual, irrevocable as to existing machines, worldwide license under Tesla Grohmann's interest in any jointly owned intellectual property. We granted Tesla Grohmann a non-exclusive, non-

transferable, no-charge license during the term of the Tesla Grohmann Agreement under our background intellectual property for Tesla Grohmann's performance of its obligations under the Tesla Grohmann Agreement and a non-exclusive, royalty-free, perpetual, irrevocable as to existing machines, worldwide license under our interest in any jointly owned intellectual property to perform its obligations under the Tesla Grohmann Agreement and for applications and uses unrelated to the machines developed under the Tesla Grohmann Agreement.

The Tesla Grohmann Agreement continues on a machine-by-machine basis until ten years after the first commercial use of such machine. Either party may terminate any work order entered into in connection with the Tesla Grohmann Agreement for convenience upon written notice to the other party and either party may terminate a work order for the other party's material breach following a cure period, or for the other party's insolvency. In the event Tesla Grohmann terminates a work order for convenience or we terminate for Tesla Grohmann's material breach or insolvency, Tesla Grohmann must grant us a non-exclusive, fully paid-up, worldwide, irrevocable, perpetual, transferable and sublicensable license under Tesla Grohmann background intellectual property and Tesla Grohmann's interest in intellectual property developed under the Tesla Grohmann Agreement for us to complete, either on our own or with another supplier, the work under such terminated work order. In the event we terminate for convenience, we must pay Tesla Grohmann a termination fee. In the event Tesla Grohmann terminates for our material breach or insolvency, we must pay Tesla Grohmann a termination fee and grant Tesla Grohmann a non-exclusive, fully paid-up, sublicensable, worldwide irrevocable and perpetual license under our background intellectual property and our interest in the intellectual property developed under the Tesla Grohmann Agreement to manufacture machines relevant to the applicable work order.

Eli Lilly License and Collaboration Agreement

In November 2017, we entered into a global immuno-oncology collaboration with Eli Lilly, which we refer to as the Eli Lilly Agreement, focused on the development and commercialization of cancer vaccine products that can work as pre-manufactured vaccines for a well-defined patient subpopulation, to be selected by Eli Lilly, based on our proprietary RNActive® technology. In June 2020, we entered into a termination agreement with Eli Lilly, which we refer to as the Eli Lilly Termination Agreement.

Under the terms of the Eli Lilly Agreement, we granted Eli Lilly a worldwide, exclusive (even as to us), sublicensable (subject to certain conditions) license to develop, manufacture and commercialize licensed products comprised of mRNA constructs that express certain selected neoantigens for human use. We also granted Eli Lilly a worldwide, non-exclusive, sublicensable (subject to certain conditions) license to perform development activities under the Eli Lilly Agreement, including work required to select targets and related neoantigens. Eli Lilly granted us a worldwide, exclusive, non-sublicensable (except to our affiliates), royalty-free license under our licensed intellectual property solely to manufacture and supply Eli Lilly with vaccines for early clinical use. Eli Lilly also granted us a worldwide, non-exclusive, non-royalty bearing, non-sublicensable (except to our affiliates), fully paid-up license to perform development activities under the Eli Lilly Agreement. In 2017, we received an upfront payment of $50 million and an equity investment of €45 million and as of December 31, 2020, we have received approximately €14.6 million in payments for the supply of materials and reimbursements for development costs. Pursuant to the Eli Lilly Termination Agreement, all licenses granted under the Eli Lilly Agreement terminated and Eli Lilly has no further payment obligations to us under the Eli Lilly Agreement.

Under the terms of the Eli Lilly Termination Agreement, Eli Lilly is required to provide us access to certain analyses and data developed under the Eli Lilly Agreement and to transfer to us certain materials produced under the Eli Lilly Agreement. Eli Lilly additionally reassigned to us a certain composition of matter patent, which had been assigned from us to Eli Lilly under the Eli Lilly Agreement. We additionally have the option, for a certain period following the effective date of termination, to obtain a non-exclusive, royalty-bearing license under certain Eli Lilly intellectual property used in connection with the initial shared neoantigen product developed under the Eli Lilly Agreement to develop and commercialize such product and pay Eli Lilly a single-digit percentage royalty on net sales. Pursuant to the terms of the Eli Lilly Termination Agreement, we also granted Eli Lilly a right of first negotiation with respect to the initial shared neoantigen product developed under the Eli Lilly Agreement for a certain period following a certain milestone event.

Sponsored Collaboration Agreements

Yale Collaborative Research Agreement

In July 2019, we entered into a Collaborative Research Agreement, which we refer to as the Yale Agreement, for research in mRNA-based pulmonary therapeutic candidates with Yale University, or Yale. Under the Yale Agreement, Yale will perform discovery research on targets related to pulmonary diseases and present therapeutic candidates to us for preclinical and subsequent clinical development. We are required to reimburse Yale for approximately $0.8 million in costs incurred in connection with research activities conducted under the Yale Agreement and for certain patent prosecution and maintenance costs. As of December 31, 2020, we have provided approximately $0.4 million in funding to Yale under the Yale Agreement.

Each party will solely own inventions it solely develops and will jointly own jointly developed inventions. Yale is required to grant us an exclusive license under Yale's interest in any intellectual property developed under the Yale Agreement, subject to Yale's retained right to use such intellectual property for academic purposes. Under any such license agreement, we will be required to pay Yale up to approximately $1.2 million in development milestone payments and $1.5 million in commercial milestone payments, an annual maintenance fee of between $10,000 and $60,000 until the first commercial sale of a licensed product and a low single-digit percentage royalty on net sales on a product-by-product and country-by-country basis until the later of the expiration of the last to expire claim covering such product in such country or ten years after the first commercial sale of such product in such country. Yale additionally granted us an exclusive option to negotiate an exclusive or non-exclusive license to certain background intellectual property.

The Yale Agreement will continue until June 2021, unless extended by mutual agreement or earlier terminated. We have the right to terminate the Yale Agreement for convenience following a certain notice period. Both parties have the right to terminate the Yale Agreement for the other party's material breach following a cure period. If we terminate the Yale Agreement without reimbursing Yale for its research costs, Yale will have no obligation to grant us a license to intellectual property developed under the Yale Agreement.

Schepens Institute Research Agreement

In March 2019, we entered into a Sponsored Research Agreement, which we refer to as the Schepens Agreement, with SERI, pursuant to which SERI agreed to perform certain research activities for mRNA-based eye therapy candidates. Under the Schepens Agreement, SERI granted us an exclusive option to initiate negotiations for an exclusive or non-exclusive license to SERI's interest in any inventions developed under the Schepens Agreement. SERI additionally granted us an exclusive option to negotiate an exclusive license to certain background intellectual property. Under any such background intellectual property license, we will be required to pay SERI a $30,000 upfront payment, up to approximately $0.8 million in development milestone payments and $1.8 million in regulatory milestone payments, and a low single-digit percentage royalty on net sales subject to certain minimum annual payments. We are required to provide $1 million in funding to SERI in multiple payments during the term of the Schepens Agreement. As of December 31, 2020, we have provided approximately $0.9 million in funding to SERI under the Schepens Agreement.

Each party will solely own inventions it solely develops and will jointly own jointly developed inventions. We are responsible for all patent prosecution costs and if we elect not to cover the prosecution costs for SERI's interest in intellectual property developed under the Schepens Agreement, SERI will have the right to license such inventions to third parties and we will have no rights in such inventions.

The Schepens Agreement continues until July 2021, unless extended by mutual agreement or earlier terminated. Both parties have the right to terminate the Schepens Agreement for the other party's material breach following a cure period and SERI has the right to terminate in the event of our insolvency. We additionally have the right to terminate the Schepens Agreement for convenience following a notice period. In the event SERI terminates for our material breach or insolvency or we terminate for convenience, we must reimburse SERI for all costs incurred to date and provide certain additional funding for a three-month period. In the event we terminate for SERI's material breach, we must reimburse SERI for all noncancellable commitments.

Advance Purchase Agreements

European Commission — COVID-19 Vaccine Candidate

Advance Purchase Agreement for our COVID-19 Vaccine Candidate

On November 30, 2020, we entered into an APA with the EC, acting on behalf and in the name of all Member States of the European Union, which provides for the advance purchase by the Member States of 225 million doses of the vaccine to be allocated among the Member States and the option to purchase up to an additional 180 million doses. The option may be exercised by the EC on behalf and in the name of the Member States. The APA provides for support to our operations in the form of two upfront payments. The first upfront payment of €450 million has already been paid by the EC on behalf of the Member States. The second upfront payment of a mid nine-figure euro amount is to be paid directly by the Member States and is due after an interim data package has been submitted by us to the EMA for the purpose of obtaining EU marketing authorization for CVnCoV. Such upfront payments must be used solely for the development and commercial supply of CVnCoV. We will be required to return any unspent amounts of the upfront payments if, among others, we fail to successfully develop CVnCoV or if we successfully develop CVnCoV, but we do not receive EU marketing authorization or fail to supply any doses of CVnCoV to any of the Member States by late 2021, unless we and the EC mutually agree to a later date. In addition, if any Member State decides to purchase additional doses pursuant to the option granted under the APA, we will be entitled to additional upfront payments that are not subject to such restrictions on use or return of unused amounts upon termination of the APA.

The APA will be terminated automatically if we notify the EC that we are unable to provide the vaccine because (i) the clinical trial results are not satisfactory, (ii) the clinical trial results do not meet their endpoint in terms of efficacy or safety or (iii) the EU marketing authorization was not granted. The termination will be effective unless the EC objects within 30 calendar days; provided, however, that such objection may only be based on reasonable grounds and taking into account the severity of the impact that continuation of the APA would have on our business. In addition, the EC shall have the right to terminate the APA, and each Member State the respective individual vaccine purchase orders, for the reasons specified in Section 14.2 of the APA, which among others, provides the EC the right to terminate the APA if we do not obtain EU marketing authorization by late 2021, unless we and the EC mutually agree to a later date, or if we are in material breach of our obligation to (i) obtain EU marketing authorization and establish sufficient manufacturing capacities to enable the manufacturing and supply of the contractually agreed volumes of our vaccine pursuant to the agreement, (ii) provide the doses of the vaccine according to the estimated delivery schedule or (iii) manufacture (or have manufactured) doses designated to participating Member States within the European Union at sites outside the EU, UK, the EEA or Switzerland without the prior consent of the EC.

We currently estimate the total value of the APA to be in the low 10-figure euro amount assuming no exercise of the option discussed above, but this estimate is subject to our ability to successfully deliver CVnCoV pursuant to the terms of the APA, including obtaining EU marketing authorization and establishing manufacturing capacities to supply sufficient quantities of CVnCoV.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our product candidates and our core technologies and other know-how, defend and enforce our patents, preserve the confidentiality of our trade secrets, operate our business without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties and prevent third parties from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. We seek to protect our proprietary and intellectual property position by, among other methods, seeking and maintaining patents in the United States and other major markets. We also rely on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, which we generally seek to protect through contractual obligations with third parties.

Patents

As of January 15, 2021, we own approximately 63 issued U.S. patents, 125 pending U.S. patent applications, 882 issued foreign patents (including 57 European patents, which have been validated in various European countries resulting in a total of approximately 608 national patents in European countries), 390 pending foreign patent applications (including 73 pending European patent applications) and 23 pending Patent Cooperation Treaty, or PCT, patent applications, including four

pending U.S. patent applications, 18 foreign patent applications and two PCT patent applications that are jointly owned with third parties. These patents include claims relating to our RNAoptimizer technology platform, CV8102, BI 1361849 (formerly CV9202), CV7202, CV-SSIV, our COVID-19 vaccine candidate and our CVCM delivery system, as described further below.

RNAoptimizer

As of January 15, 2021, we own 20 issued U.S. patents, 17 pending U.S. patent applications, 81 issued foreign patents, including in Europe, Canada, China, India, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 115 pending foreign patent applications and four PCT patent applications relating to our RNAoptimizer technology, including patents and patent applications relating to ORF optimization, UTR optimization, protein optimization and formulation. Our RNAoptimizer technology is used in our BI 1361849 (formerly CV9202), CV7202, CV-SSIV and SARS-CoV-2 product candidates. The issued patents are expected to expire between 2022 and 2037, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending patent applications would be expected to expire between 2022 and 2041, excluding any additional term for patent term adjustments or patent term extensions.

CV8102

As of January 15, 2021, we own four issued U.S. patents, three pending U.S. patent applications, 31 issued foreign patents, including in Europe, Brazil, Canada, China, India, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 24 pending foreign patent applications relating to our CV8102 product candidate. The issued patents are expected to expire between 2028 and 2036, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending applications would be expected to expire between 2029 and 2037, excluding any additional term for patent term adjustments or patent term extensions.

BI 1361849 (Formerly CV9202)

As of January 15, 2021, we own 12 issued U.S. patents, eight pending U.S. patent applications, 64 issued foreign patents, including in Europe, Canada, China, India, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 60 pending foreign patent applications relating to our BI 1361849 (formerly CV9202) product candidate. The issued patents are expected to expire between 2022 and 2034, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending patent applications would be expected to expire between 2022 and 2034, excluding any additional term for patent term adjustments or patent term extensions.

CV7202

As of January 15, 2021, we own six issued U.S. patents, four pending U.S. patent applications, 19 issued foreign patents, including in Europe, Canada, China, India, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 28 pending foreign patent applications relating to our CV7202 product candidate. The issued patents are expected to expire between 2022 and 2034, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending patent applications would be expected to expire between 2022 and 2037, excluding any additional term for patent term adjustments or patent term extensions.

CV-SSIV

As of January 15, 2021, we own eight issued U.S. patents, nine pending U.S. patent applications, 20 issued foreign patents, including in Europe, Canada, China, India, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia and 36 pending foreign patent applications relating to our CV-SSIV product candidate. The issued patents are expected to expire between 2022 and 2033, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending patent applications would be expected to expire between 2022 and 2038, excluding any additional term for patent term adjustments or patent term extensions.

COVID-19 Vaccine

As of January 15, 2021, we own five issued U.S. patents, 13 pending U.S. patent applications, 19 issued foreign patents, including in Europe, Canada, China, India, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, 26 pending foreign patent applications and seven PCT patent applications relating to our COVID-19 product candidate. The issued patents are expected to expire between 2022 and 2033, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending patent applications would be expected to expire between

2022 and 2041, excluding any additional term for patent term adjustments or patent term extensions.

CVCM Delivery System

As of January 15, 2021, we own four issued U.S. patents, two pending U.S. patent applications, 12 issued foreign patents, including in Europe, Canada, China, India, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 11 pending foreign patent applications relating to our proprietary CVCM delivery system. The issued patents are expected to expire between 2030 and 2037, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending applications would be expected to expire between 2029 and 2037, excluding any additional term for patent term adjustments or patent term extensions.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed patent applications, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. For more information on patent term extension, see "— Government Regulation — Patent Term Restoration and Extension."

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our owned and licensed pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated, narrowed, held unenforceable, infringed or circumvented. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. See "section 4.3 — Risk Factors — Risks Related to Our Intellectual Property Rights."

Trademarks

As of December 31, 2020, we own trademark registrations or registration applications for CureVac, and the CureVac logo in the United States and in certain foreign jurisdictions including Europe.

Trade Secrets and Proprietary Information

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality, and invention assignment agreements with our employees, consultants, and independent contractors. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. See "section 4.3 — Risk Factors — Risks Related to Our Intellectual Property Rights."

Government Regulation

Government authorities in the United States, at the federal, state and local level, in other countries and jurisdictions and in the European Union, extensively regulate, among other things, the

research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other requirements of regulatory authorities, require the expenditure of substantial time and financial resources.

Patent Term Restoration and Extension

Depending upon the timing, duration and specifics of FDA approval of product candidates, some of a sponsor's U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration 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 generally is one-half the time between the effective date of an IND and the submission date of a BLA less any time the sponsor did not act with due diligence during the period, plus the time between the submission date of a BLA and the approval of that application less any time the sponsor did not act with due diligence during the period. Only one patent applicable to an approved biologic product is eligible for the extension, only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. Moreover, a given patent may only be extended once based on a single product. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see "section 4.3 — Risk Factors — Risks Related to Our Intellectual Property Rights."

Regulation and Procedures Governing Approval of Biological Products in the United States

In the United States, we expect our product candidates will be regulated as biological products, or biologics, under the Public Health Service Act, or PHSA, and the Federal Food, Drug, and Cosmetic Act, or FDCA, and their implementing regulations, and other federal, state, local and foreign statutes and regulations. The failure to comply with the applicable U.S. requirements at any time during the product development process, including during nonclinical testing, clinical testing, the approval process or post-approval process, may subject an applicant to delays in the conduct of a study or regulatory review and approval, and/or to administrative or judicial sanctions and adverse publicity. Sanctions may include, but are not limited to, the U.S. Food and Drug Administration, or FDA's, refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, debarment, disgorgement of profits and civil or criminal investigations and penalties brought by the FDA or the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- nonclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;

- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;

- approval by an Institutional Review Board, or IRB, or ethics committee representing each clinical site before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with applicable regulations, including with GCP regulations;

- after completion of all pivotal clinical trials, preparation and submission to the FDA of a BLA requesting authorization to market the product candidate for one or more proposed indications;

- satisfactory completion of an FDA advisory committee review, if applicable;

- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, safety, strength, quality and purity;

- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the BLA;

- payment of user fees and securing FDA approval of the BLA; and

- compliance with any post-approval requirements, including the potential requirement to implement a REMS and to conduct any post approval studies required by the FDA.

Nonclinical Studies and Investigational New Drug Application

Before testing any biologic product candidate in humans, the product candidate must undergo nonclinical testing. Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of an IND or similar application in other jurisdictions. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless within the 30-day time period, the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the trial on a clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or not be conducted on the terms originally specified by the sponsor in the IND. In addition, the FDA may raise concerns or questions at any time after the IND has become effective, and may impose a clinical hold even after clinical studies have initiated. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold issued by the FDA may therefore delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant difficulties in completing planned clinical trials in a timely manner.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A separate protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements, the trial is unlikely to meet its stated objectives or that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules, including the requirements for informed consent. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. 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 may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.

- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials.

- Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for physician labeling and product approval.

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials, or Phase 4. These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or

life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or 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 biological candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Review and Approval of a BLA

The results of product candidate development, nonclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting a license to market the product for one or more indications. The BLA must contain extensive chemistry manufacturing and controls information and detailed information on the composition of the product and proposed labeling. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is also subject to annual program fees. The FDA adjusts the Prescription Drug User Fee Act, or PDUFA, user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act, or FDASIA, requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the BLA is sufficient to accept for filing based on the agency's threshold determination that it is substantially complete so as to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of a standard application and respond to the applicant within ten months of the 60-day filing date, and for a priority review application within six months. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and its review goals are subject to change from time to time. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

The FDA reviews a BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in

compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA may issue a complete response letter indicating that the review cycle is complete and the application is not ready for approval. A complete response letter will describe the deficiencies that must be addressed in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. The FDA may also request additional information or clarification.

Sponsors that receive a complete response letter who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If the FDA approves a new product, it may limit the approved indications for use of the product, or limit the approval to specific dosages. It may also require development of adequate controls or specifications and that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval and may limit further marketing of the product based on the results of these post-marketing studies. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. Once approved, the FDA may withdraw the product approval if compliance with pre-and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development and/or review of new products intended for serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review and accelerated approval.

The FDA may issue a fast track designation to a product candidate if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA

designate the biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA during product development. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. However, the FDA's PDUFA goal for reviewing a BLA fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority review is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an original BLA from ten months to six months from the 60-day filing date.

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve

survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval. 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 decide that the time period for FDA review or approval will not be shortened.

Post-Approval Regulation

If regulatory approval for marketing of a product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising, promotional labeling, product sampling and distribution. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA-holder and its third party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third party manufacturers that we or our partners may decide to use. In addition, changes to the manufacturing process or facility are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA closely regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications

and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict marketing authorization holders' communications on the subject of off-label use of their products.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain financial incentives, including tax advantages, waiver of the BLA application user fee and, if the product receives the first FDA approval for the indication for which it has orphan designation, market exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years from the approval of the BLA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product.

In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, the manufacturer makes a showing of clinical superiority over the product with orphan exclusivity, or the sponsor is unable to provide sufficient quantities.

An orphan-designated product may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan exclusivity in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Biosimilars and Exclusivity

The BPCIA (under the Affordable Care Act) created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown

through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic 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 biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the Member States. Under this system, an applicant must obtain approval from the competent national authority of each European Union Member State in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the local competent ethics committee has issued a favorable opinion. In April 2014, the European Union adopted a new Clinical Trial Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20. This new legislation, which will be directly applicable in all Member States, aims at simplifying and streamlining the approval of clinical trials in the European Union by allowing for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications. The Clinical Trial Regulation harmonizes the assessment and supervision processes for clinical trials throughout the European Union, via a Clinical Trials Information System, or CTIS, which will contain the centralized European Union portal and database for clinical trials foreseen by the Regulation. The EMA will set up and maintain CTIS, in collaboration with the competent national authority of each European Union

Member Sate and the EC. The Clinical Trial Regulation will only become applicable six months after the EC confirms the conditions set by the Clinical Trial Regulation are met. On April 21, 2021, the EMA's Management Board confirmed that CTIS is fully functional following an independent and successful audit, and the EC announced January 31, 2022 as the target date of application for CTIS, pending confirmation that the conditions of the Clincial Trial Regulation were met by the audit.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must obtain Marketing Authorization, or MA. There are two types of MAs:

- The Community MA, which is issued by the EC through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy medicinal products (such as gene therapies, somatic cell therapies and tissue engineered products), and medicinal products that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum time frame for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210-day review period is reduced to 150 days.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

An MA may be granted only to an applicant established in the European Union. Regulation 1901/2006 on Medicinal Products for Pediatric Use provides that prior to obtaining a marketing authorization in the European Union in the centralized procedure, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the Pediatric Investigation Plan.

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization 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. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed,

the marketing authorization is valid for an unlimited period, unless the EC or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the European Union under Directive 2001/83.

Orphan Drug Designation and Exclusivity

Regulation 141/2000 and Regulation 847/2000 provide that a product can be designated as an orphan drug by the EC if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Orphan drugs also benefit from a 10-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the EC or the Member States can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as 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. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior, the applicant consents to a second orphan medicinal product application, or applicant cannot supply enough orphan medicinal product.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. In the United States, the Member States of the European Union and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third party payors to reimburse all or part of the associated healthcare costs. Reimbursement rules and levels are not harmonized in the European Union and therefore differ from Member State to Member State. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The process for determining whether a payor will provide coverage for a product may be

separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors are increasingly challenging the price and examining the medical necessity and cost effectiveness of medical products and services and imposing controls to manage costs.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacogenomic studies are conducted, product candidates may not be considered medically necessary or cost effective. A decision by a third party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that such coverage will continue or that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit a company's ability to generate revenue.

The containment of healthcare costs also has become a priority of federal, state and foreign governments as well as other third party payors such as statutory health insurance funds and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue from the sale of any approved products. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented or coverage may be ended in the future.

Outside the United States, we will face challenges in ensuring obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities or other third party payors such as statutory health insurance funds can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so-called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union Member States may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union Member States and parallel trade (arbitrage between low-priced and high-priced Member States) can further reduce prices. Special pricing and

reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any product. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare Laws and Regulations

Healthcare providers and third party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, physician payment transparency and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in-kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Moreover, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the CMS, within the HHS, information related to payments and other transfers of value made by that entity to physicians (as defined by statute), certain other healthcare providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;

- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary

compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Data Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by HIPAA and its implementing regulations, which established uniform standards for certain covered entities (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information, including, among other requirements, mandatory contractual terms and technical safeguards to protect the privacy, security and transmission of protected health information and notification to affected individuals and regulatory authorities in the event of certain breaches of security of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the HITECH makes HIPAA's privacy and security standards directly applicable to business associates, or independent contractors or agents of covered entities, that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce and be construed as a violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards and the FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information, or PHI, than HIPAA, and state laws may differ from each other, which may complicate compliance efforts. By way of example, the California Consumer Privacy Act, or CCPA, effective January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. In addition, other states may choose to adopt more stringent privacy legislation, which could increase our potential liability and compliance costs and adversely affect our business.

In the European Union, we may be subject to strict data protection regulations, in particular with regard to health data of individuals pursuant to Art. 4 Nr. 15 of the GDPR, effective since May 25, 2018. The GDPR, together with national legislation, regulations and guidelines of the European Union Member States and the United Kingdom governing the processing of personal data, impose strict

obligations with respect to, and restrictions on, the collection, use, retention, protection, disclosure, transfer and processing of personal data. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of data subjects, the transfer of personal data to countries outside the European Union, security breach notifications, and other requirements concerning the security and confidentiality of personal data. For example, in 2016, the European Union and United States agreed to a transfer framework for data transferred from the European Union to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. The standard contractual clauses issued by the European Commission for the transfer of personal data may be similarly invalidated by the Court of Justice of the European Union. It remains to be seen whether these standard contractual clauses will remain available and whether additional means for lawful data transfers will become available. The GDPR imposes special requirements concerning the protection of special categories of personal data which include health and genetic information of data subjects. These special categories of data may only be processed under certain circumstances, including if the data subject consented to such processing or if (i) processing is necessary in order to protect vital interests of the data subject or of another natural person, insofar as the data subject is unable to provide consent for physical or legal reasons; (ii) the data concerned have manifestly been made public by the data subject; (iii) processing is necessary in order to assert, exercise or defend legal claims; or (iv) processing is necessary for the purposes of scientific research and any additional requirements under applicable data protection laws, including national legislation, regulations and guidelines, are met.

Therefore, we may be subject to and our marketing activities may be limited by the regulations regarding the data protection of individuals according to the GDPR, the German Federal Data Protection Act and other applicable data protection laws. These regulations could also restrict the transfer of data from European Union member states to the United States. The general transfer of personal data outside of the European Union is prohibited unless the conditions laid out in Art. 44 et. seq. of the GDPR are fulfilled and an adequate level of data protection can be ensured. Currently the United States is not considered to be a country with an adequate level of data protection and further contractual arrangements must be adopted to permit the international transfer of personal data to the United States European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contributes to the complexity of processing personal data in or from the European Union. Guidance on implementation and compliance practices is regularly updated or otherwise revised. The GDPR has increased our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the relevant data protection regimes. Separately, Brexit could also lead to further legislative and regulatory changes and increase our compliance costs. As of January 1, 2021, and the expiry of transitional arrangements agreed to between the United Kingdom and the European Union, data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. Pursuant to the Trade and Cooperation Agreement, which went into effect on January 1, 2021, the United Kingdom and the European Union agreed to a specified period during which the United Kingdom will be treated like a European Union member state in relation to transfers of personal data to the United Kingdom for four months from January 1, 2021. This period will be extended by two further months automatically, unless the European Union or United Kingdom objects. The European Commission issued a draft adequacy decision for the United Kingdom on February 19, 2021, and on April 14, 2021, the European Data Protection Board issued an opinion broadly in favor of the draft adequacy decision, but the decision has not yet been adopted and it is unclear when the European Commission will reach a decision or how the European Commission will ultimately decide. Unless the European Commission adopts the adequacy decision in respect of the United Kingdom before the expiration of such specified period the United Kingdom will become an inadequate third country under the GDPR and transfers of data from the European Economic Area to the United Kingdom will require a transfer mechanism, such as the standard contractual clauses. Furthermore, following the expiration of the specified period, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and the European Union. For more information regarding the risks related to data security and privacy, see "section 4.3 — Risk Factors — Risks Related to Our Business and Industry."

Competition

We participate in an industry that is characterized by a rapidly growing understanding of disease biology, quickly changing technologies, strong emphasis on proprietary products, and a multitude of companies involved in the creation, development and commercialization of novel therapeutics. These companies are highly sophisticated and often collaborate strategically with each other.

We are developing a broad portfolio of product candidates that, coupled with our capabilities across mRNA technology, development and manufacturing, we believe position us at the forefront of targeted immune active and immune silent mRNA-based medicines. However, we compete with a wide range of pharmaceutical companies, biotechnology companies, academic institutions and other research organizations for novel therapeutic targets, new technologies, talent, financial resources, intellectual property rights and collaboration opportunities. As such, many of our competitors and potential competitors have substantially greater scientific, research and product development capabilities as well as greater financial, manufacturing, marketing and human resources than we do. In addition, there is intense competition to establish clinical trial sites and register patients for clinical trials. Many specialized biotechnology firms have formed collaborations with large, established companies to support the research, development and commercialization of products that may be competitive with ours. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. In addition, our competitors' products may be more effective or more effectively marketed and sold than any treatment we or our development partners may commercialize and may render our product candidates obsolete or noncompetitive before we can recover the expenses related to developing and commercializing any of our product candidates.

There are additional companies that are working on potential mRNA medicines. Companies with clinical programs with mRNA include BioNTech/Pfizer, Moderna, eTheRNA Immunotherapies, Translate Bio, GlaxoSmithKline Sanofi, AstraZeneca, Merck & Co. and Arcturus Therapeutics and those programs include, Ethris and Genevant Sciences. Specifically, our vaccine candidate, CVnCoV, against COVID-19 is currently the main focus of other pharmaceutical companies, some with more considerable capital resources than ours. For example, a limited number of products that utilize mRNA as a prophylactic vaccine against COVID-19 have been approved by the FDA, EMA and other regulatory agencies, such as BioNTech SE and Pfizer Inc.'s mRNA immunotherapy, BNT162b2, which was granted emergency approval by the FDA on December 11, 2020 and granted conditional marketing authorization by the EMA on December 21, 2020, and Moderna's mRNA immunotherapy, mRNA-1273, which was granted emergency approval by the FDA on December 18, 2020 and granted condiditional marketing authorization by the EMA on January 6, 2021. Thus, we expect intense competition for our vaccine candidate from other pharmaceutical companies not limited to the field of mRNA medicines. In addition, the oncology therapeutics landscape in general is highly competitive and includes large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. It includes both competition from marketed therapies as well as potential new therapeutics in development. We may compete with products with different mechanisms of action as well as against established standards of care. We expect our intratumoral immunotherapy candidates for the treatment of solid tumors to face direct competition from companies such as Moderna and BioNTech in collaboration with Sanofi in addition to several non-mRNA-based approaches.

2.3 Organizational Structure

Our major subsidiaries are incorporated by reference to Exhibit 21.1 to the Company's Form F-1 (File No. 333-240076) filed on August 10, 2020.

2.4 Property, Plant and Equipment

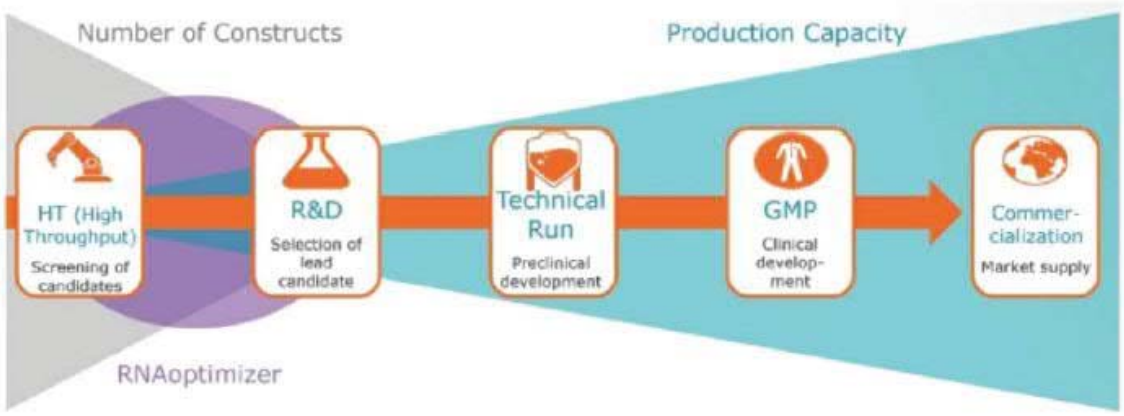
Our Manufacturing Platform

We are an integrated biopharmaceutical company with in-house manufacturing capabilities and expertise. We consider our manufacturing process an important part of our strategy that allows us to continuously improve our technology platform and maintain flexibility in clinical development. The close interaction of our technical development and research teams enables us to rapidly implement innovations to the manufacturing process and creates a feedback loop between manufacturing and research. Using this feedback loop, we have created processes and analytics. We control the critical steps of manufacturing in-house as well as for the integrated European vaccine manufacturing network that we are currently building up to increase existing manufacturing capacities with highly experienced Contract Development and Manufacturing Organization partners for each of the key manufacturing steps for CVnCoV. Both of which allow us to drive innovation and to maintain flexibility, and in turn allows us to pivot quickly in pandemic settings such as COVID-19.

All of our mRNA-based active ingredients for various fields of application originate from a common technology platform and are based on identical source materials. This enables us to produce all mRNA therapies using a substantially similar platform process concept. Given the differences in

the encoded protein only require alterations of the sequence of the mRNA molecule, leaving its physicochemical characteristics largely unaffected, we can use the same mRNA production strategy applying the same unit operations for diverse products. This allows us to save time and reduce costs compared to other manufacturing processes. Our approach supports a seamless production concept based on our experience and know-how in mRNA manufacturing.

Our GMP Manufacturing Facilities



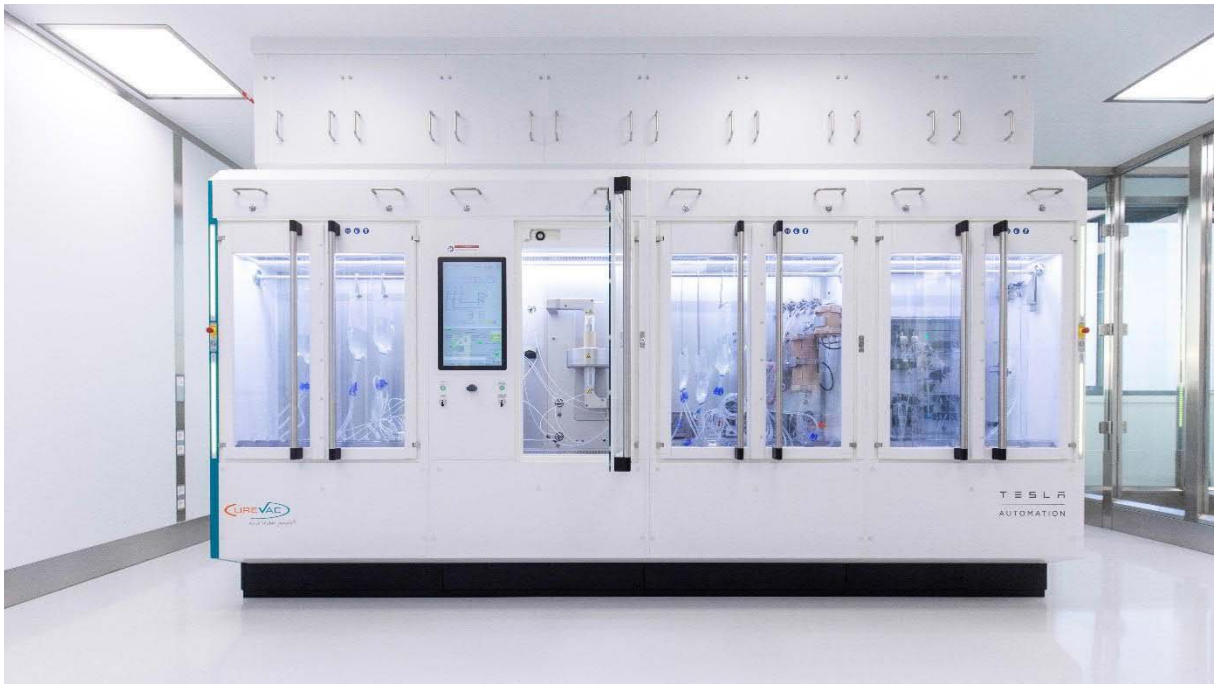
We have continued to invest significantly in building and expanding our manufacturing capabilities since 2006. We currently have the capacity to produce late-stage clinical trial RNA material and early commercial lots. Since 2006, we have manufactured thousands of mRNA constructs, from high throughput and small amounts for discovery and preclinical development to GMP level of quality.

We are currently operating three GMP-certified suites. Our GMP I/II facility was designed to run up to 14 different products in parallel, using a lab-scale process. The facility covers all steps from starting material pDNA, through mRNA manufacturing to fill and finish. Our GMP I/II facility is dedicated to provide supplies for early clinical development (Phase 1 and 2), with capacity to produce multiple batches per year. In 2019, we expanded our production capacity to meet the increasing demands for clinical studies and future initial commercial supply by adding a GMP III facility. In contrast to the GMP I/II facility, our GMP III facility allows us to achieve additional scale and reduce manufacturing process time. Our GMP III facility focuses on the production of mRNA, and we currently use CMOs for starting material plasmid DNA, or pDNA. We intend to add the formulation step by mid-2021. Our GMP III facility is intended to provide supply for our late-stage clinical studies and initial market supply, and is based on a new scalable process design compared to our GMP I/II facility. We are currently in the process of building a GMP IV facility, which is being designed to cover all manufacturing steps from starting material to formulation, to support our future commercial launches, as shown in the picture below. On November 17, 2020, we announced the build-up of a broad and integrated European vaccine manufacturing network with highly experienced Contract Development and Manufacturing Organization partners for each of the key manufacturing steps for CVnCoV to accelerate the delivery of pandemic-scale vaccine volumes.

GMP IV facility

The RNA Printer®

In addition to our GMP manufacturing facilities, we are currently developing a new automated and mobile production concept, The RNA Printer®. The RNA Printer® is a GMP production system that is being designed to downscale the manufacturing process and automate major manufacturing steps. This fully synthetic production process would allow us to have rapid manufacturing of products and offer reproducibility. It will also include automated cleaning and sanitization in place procedures and continuous process validation. Testing and process development of the first RNA Printer prototype is ongoing. We have successfully manufactured RNA batches with the first RNA Printer prototype and are currently establishing a first version of The RNA Printer® under cleanroom conditions to provide clinical trial material. In parallel, we are already developing a new version to further improve The RNA Printer® concept. These new prototypes for DNA and RNA production are being designed to cover automated down- and upstream production up to drug substance.



RNA Printer

The key characteristics of The RNA Printer® are rapid throughput, easy operator access to equipment, sophisticated precision control software and data capture, and the small footprint that allows for easy decentralization. With its modular design, it could be used for a rapid first response in outbreak scenarios or even be placed as a stand-alone device for epidemic areas. We view The RNA Printer® as complementary to our manufacturing strategy. For example, we expect that The RNA Printer® could be deployed to the front lines of pandemic outbreaks complementing our large-scale production facilities that can be used to generate supplies to protect the broader population.

Our vision is to have a flexible, mobile and automated end-to-end solution for the different fields of application. Our objective is to cover the entire production stream and we believe efficient accompanying analytics will help to rapidly produce high-quality material. All data generated during production would be collected to further improve production processes and product development.

Facilities

Our headquarters are in Tübingen, Germany, Friedrich-Miescher-Strasse 15, where we occupy approximately 123,000 square feet of office and laboratory space under a sublease agreement entered into with CureVac Real Estate GmbH that started on June 6, 2018. The fixed-term 15-year lease payment period began on March 1, 2020. We also occupy approximately 53,000 square feet of additional office and laboratory space in Tübingen, Germany, Paul-Ehrlich-Strasse 15, under sublease agreements also entered into with CureVac Real Estate GmbH, that started on February 1, 2018.

Since 2006, we have operated a manufacturing facility in Tübingen, Germany, the first worldwide GMP-compliant RNA production plant with two multi-product suites. This facility contains approximately 16,145 square feet of laboratory space, including 2,800 square feet of GMP facilities and is dedicated to provide supplies for early clinical development (Phases 1 and 2 of clinical trials).

In addition, we have established a third in-house production suit (GMP III) with an upscaled manufacturing process, which was certified in December 2019. We currently occupy 2,800 square feet of GMP III facility for the production of mRNA. Our GMP III facility is intended to provide supplies for our late-stage clinical studies and anticipated early market supply. These manufacturing facilities are located in Tübingen, Germany, Paul-Ehrlich-Strasse 15 and are leased via the abovementioned sublease agreements entered into with CureVac Real Estate GmbH. We are also building an integrated European network with highly experienced Contract Development and Manufacturing Organization partners for each of the key manufacturing steps for CVnCoV, and thereby expanding our manufacturing capacity through technology transfers.

We are also constructing a new manufacturing facility, designed for the development of a GMP production process on a large industrial-scale, from starting material to formulation, for future market supply (GMP IV). This GMP IV facility, which is intended to produce IMPs that serve our future late-stage clinical trials and market supply, is expected to be approximately 86,000 square feet. Currently, we have completed the shell of the GMP IV facility and expect to open it in the second half of 2022. The GMP IV facility is supported by the European Investment Bank. The expected cost of completion for GMP IV is €140.5 million, and as of December 31, 2020, we have spent €17.0 million on completing the GMP IV facility. In addition, we lease land and buildings for our offices. We lease an aggregate of approximately 210,000 square feet, in Germany and the United States. The following table summarizes information with respect to the principal facilities leased by us:

Location	**Area (Approximate Sq. Feet)**
Germany:	
Tübingen	189,000
Frankfurt am Main	8,600
Total	197,600
United States:	
Boston	12,900
Total	12,900
Total	210,500

Our leases expire on various dates from 2021 to 2035. The lease in Boston, United States, is held by our U.S. subsidiary, CureVac Inc.

Environmental Issues

To the best of our knowledge, currently there are no foreign, federal, state or local environmental laws, rules or regulations that will materially affect our results of operations or our position with respect to our competitors. However, we can provide no assurance of the effect that any possible future environmental laws will have on our operating results.

2.5 Material subsequent events

See note 20 in the Notes to the consolidated financial statements included in section 9 of this report (the "**Company Financial Statements**") for an overview of events which do not need to be discussed in the Company's statutory annual accounts and which might influence the Company's outlook.

3. Financial Overview

3.1 Selected financial data

The following selected consolidated financial data as of December 31, 2019 and 2020, and the consolidated financial data for the years ended December 31, 2018, 2019 and 2020 are derived from the consolidated financial statements appearing elsewhere in this Annual Report, which have been audited by Ernst & Young Accountants LLP, or Ernst & Young. The selected consolidated financial data as of December 31, 2018 is derived from audited consolidated financial statements not included in this Annual Report. The selected consolidated financial data and audited consolidated financial statements have been retrospectively adjusted to reflect the impact of the share split resulting from the Corporate Reorganization.

We maintain our books and records in euros, and we prepare our financial statements under IFRS as issued by the IASB and endorsed by the EU (cf. art. 362 par. 8 DCC).

Financial information presented in the consolidated financial statements of CureVac N.V. for periods prior to the completion of our Corporate Reorganization is that of CureVac AG, our wholly owned subsidiary. The consolidated financial statements of CureVac N.V. are a continuation of the historical consolidated financial statements of CureVac AG.

The information presented below is qualified by the more detailed historical consolidated financial statements set forth in this Annual Report, and should be read in conjunction with those consolidated financial statements, the notes thereto and the discussion under "section 3 – financial overview" included elsewhere in this Annual Report.

As an emerging growth company, the presentation of selected historic financial data is limited to periods for which audited financial statements have been presented in connection with our first registration statement that became effective under the Securities Act.

	For the Years Ended December 31,		
	2018	2019	2020
	(in EUR k, except per share amounts)		
Statement of Operations and Comprehensive Income (Loss) Data:			
Revenue	12,871	17,416	48,871
Cost of sales	(17,744)	(27,983)	(14,173)
Selling and distribution expenses	(1,085)	(1,755)	(733)
Research and development expenses	(41,722)	(43,242)	(113,808)
General and administrative expenses	(25,289)	(48,969)	(53,554)
Other operating income	808	5,587	24,150
Other operating expenses	(663)	(552)	(568)
Operating loss	**(72,824)**	**(99,498)**	**(109,815)**
Finance income	1,968	833	2,070
Finance expenses	(275)	(1,460)	(22,103)
Loss before income tax	**(71,131)**	**(100,125)**	**(129,848)**
Income tax benefit (expense)	(110)	252	726
Net loss	**(71,241)**	**(99,873)**	**(129,122)**
Other comprehensive income/loss:			
Items that may be subsequently reclassified to profit or loss			
Foreign currency adjustments	66	32	35
Total comprehensive loss	**(71,175)**	**(99,841)**	**(129,087)**
Loss per share—Basic and diluted (1)	0.74	1.03	(0.98)
Weighted average number of outstanding shares	96,693,265	96,693,265	132,195,792

(1) Basic and diluted loss per share is calculated by dividing loss for the year attributable to our equity holders by the weighted average number of shares outstanding during the same period, adjusted for the effect of the corporate reorganization and is represented in euros per share.

	For the Years Ended December 31,		
	2018	2019	2020
		(in EUR k)	
Statement of Financial Position Data:			
Cash and cash equivalents	21,380	30,684	1,322,593
Total assets	125,659	130,620	1,511,356
Total liabilities	93,576	173,422	800,009
Total equity	32,083	(42,802)	711,347

3.2 Operating results

The following discussion of our financial condition and results of operations should be read in conjunction with CureVac's audited consolidated financial statements as of December 31, 2019 and 2020 and for the years ended December 31, 2018, 2019 and 2020 and the notes thereto, included elsewhere in this Annual Report as well as the information presented under "section 3.1 — Selected Financial Data." Financial information presented in the consolidated financial statements for periods prior to the completion of our corporate reorganization is that of CureVac AG, our wholly owned subsidiary. The consolidated financial statements of CureVac N.V. are a continuation of the historical consolidated financial statements of CureVac AG. CureVac AG was acquired by CureVac B.V., which subsequently converted into CureVac N.V., on August 14, 2020 as part of our corporate reorganization. CureVac B.V. had no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Following the corporate reorganization, CureVac N.V. became the holding company of CureVac AG and the historical consolidated financial statements of CureVac AG included in this Annual Report became the historical consolidated financial statements of CureVac N.V. The following discussion is based on our financial information prepared in accordance with IFRS as issued by the IASB, which may differ in material respects from generally accepted accounting principles in the United States and other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "section 4.3 — Risk Factors" and elsewhere in this Annual Report.

Key Factors Affecting Our Results of Operations

We believe that the most significant factors affecting our results of operations include:

Research and Development Expenses

Our ability to successfully pioneer a robust mRNA technology platform and develop innovative product candidates will be the primary factor affecting our future growth and development. Our approach to the discovery and development of product candidates based on mRNA technology is still being demonstrated. As such, we do not know whether we will be able to successfully develop any products. Developing novel product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. We have chosen to leverage our platform to initially focus on advancing our product candidates in the areas of prophylactic vaccines, oncology and protein therapy.

For more information on our proprietary technology and clinical development pipeline, see "section 2 — Business Overview — Our Product Portfolio."

All of the product candidates are still in development, and we have incurred and will continue to incur significant research and development costs for preclinical studies and clinical trials. We expect that our research and development expenses will constitute the most substantial part of our expenses in future periods in line with the advance and expansion of the development of our product candidates. Due to our accelerated efforts to develop our COVID-19 vaccine candidate, CVnCoV, we incurred, and expect to incur in the near future significant research and development expenses that may significantly exceed our historical levels of research and developments expenses. Our current level of research and development expenses may not be representative of our future research and development expenses once our accelerated efforts to advance our vaccine candidate, CVnCoV, are completed. Once we conclude our research and development efforts related to our vaccine candidate, CVnCoV, we expect that our research and development expenses shall be consistent with our past

trends, but we may find it necessary to continue such current trend with respect to our research and developments expenses or we may continue to increase further our research and development expenses. For example, we may continue to increase our research and development expenses for future research and development related to the next-generation of our CVnCoV product candidate.

We have historically funded the research and development expenses primarily through our public offerings, private placements of equity securities, convertible loans, grants from government agencies and similar bodies and payments for collaborative research and development services with strategic partners. In addition, we recently signed an advance purchase agreement, or APA, with the EC that provides substantial support for our efforts to advance our vaccine candidate, CVnCoV. In connection with CVnCoV, we may enter into additional APAs with other parties in the future. However, APAs are unique for the COVID-19 pandemic and we do not expect similar government purchase agreements in connection with other product candidates in our portfolio.

Our and Our Collaborators' Ability to Commercialize Our Product Candidates

Our ability to generate revenue from our product candidates depends on our and our collaborators' ability to successfully advance clinical trials for our product candidates and receive regulatory approval, particularly in the United States, Europe and other major markets.

We believe that our broad portfolio of product candidates with both novel and validated targets enhances the likelihood that our research and development efforts will yield successful product candidates. Nonetheless, we cannot be certain if any of our product candidates will receive regulatory approvals. Even if such approvals are granted, we will thereafter need to maintain manufacturing and supply arrangements and engage in extensive marketing prior to generating any revenue from such products, and the ultimate commercial success of our products will depend on their acceptance by patients, the medical community and third party payors and their ability to compete effectively with other therapies on the market. See "section 4.3 — Risk Factors — Risks Related to the Development, Clinical Testing and Commercialization of Our Product Candidates."

The competitive environment is also an important factor with the commercial success of our product candidates, and our ability to successfully commercialize a product candidate will depend on whether there are competing product candidates being developed or already marketed by other companies.

We currently do not have any product candidates that have received regulatory approval. As such, we have not incurred any material commercialization expenses in connection with an approved product candidate. In February 2021, we initiated a rolling submission with the EMA, which will allow the EMA to assess CVnCoV's compliance with standards for vaccine efficacy, safety and pharmaceutical quality as a prerequisite for a formal market authorization application. The rolling submission process with the EMA was started with the submission of a first preclinical data package and was recently advanced with two additional packages, including CMC data as well as first clinical data from our dose-escalation Phase 1 trial. Subject to the clinical trial results of CVnCoV, we expect to apply for conditional regulatory approval in the second quarter of 2021. In addition, in April 2021, we initiated a rolling submission with Swissmedic, which will also allow Swissmedic to review the safety, effectiveness and pharmaceutical quality as a prerequisite for a formal market authorization application. We have already provided the first data package on CVnCoV to Swissmedic. In connection with the regulatory approval process, and in preparation for the commercialization of CVnCoV, our expenses related to commercialization are expected to increase significantly and will be inconsistent with past trends. As part of the commercialization process of CVnCoV, we also entered into strategic partnerships with Bayer AG for the development, production and distribution of CVnCoV. In addition, pursuant to a preliminary agreement regarding the secondary manufacturing of CVnCoV we entered into with GSK, GSK will support the secondary manufacturing of up to 100 million doses of CVnCoV in 2021. Additionally, we also partnered with Fareva, Wacker Chemie AG, Rentschler Biopharma SE, Novartis AG and Celonic Group, among others, to develop an integrated European manufacturing network. We expect this trend to continue and we may enter into additional agreements from time to time as we may find necessary.

Our Collaborations, Related License Agreements and Advance Purchase Agreements

Our results of operations have been, and we expect them to continue to be, affected by our collaborations with third parties for the development and commercialization of certain of our product candidates. In addition, our future results of operation may be affected by current or future advance purchase agreements for our COVID-19 vaccine candidate, CVnCoV. To date, our revenues have been recognized pursuant to license and collaboration agreements, which include upfront payments

for licenses or options to obtain licenses, milestone payments, payments for product sales and payments for research and development services. Grants from government agencies or similar bodies are recognized as other operating income or as a reduction to depreciation and amortization expense recognized from assets purchased under the associated arrangements.

We have entered into strategic collaborations and license agreements with third parties. In addition, on November 30, 2020, we entered into an advance purchase agreement, or APA, with the EC, which provides for the advance purchase by the commission of our vaccine candidate, CVnCoV. As part of our business development strategy, we aim to increase the number of our strategic collaborations and advance purchase agreements in order to derive further value from our platform and more fully exploit the potential of our collaborations and license agreements.

Certain key terms of our current material collaboration and license agreements, as well as our advance purchase agreement with the EC are summarized below. For further details on our collaboration agreements, see "section 2 — Business Overview — Collaborations" and "section 2 — Business Overview — Advance Purchase Agreements," respectively.

GlaxoSmithKline

In July 2020, we entered into the 2020 GSK Agreement with GSK, pursuant to which we are collaborating with GSK to research, develop and commercialize prophylactic and therapeutic non-replicating mRNA-based vaccines and antibodies targeting infectious disease pathogens.

GSK paid us an upfront payment of €120 million and is required to pay us a manufacturing capacity reservation fee of €30 million following a certain regulatory milestone event, which is creditable against future milestone payments. We are eligible to receive up to between €28 million to €45 million in development milestone payments, €32 million to €35 million in regulatory milestone payments and €70 million to €100 million in commercial milestone payments, depending on the product. Under the 2020 GSK Agreement, we granted GSK an exclusive option to add additional products in the field of infectious diseases to the license granted under the 2020 GSK Agreement and upon each exercise of such option, GSK is required to compensate us for certain development costs and pay any accrued milestone payments. If such additional product targets a coronavirus other than SARS-CoV-2 or a pandemic pathogen as listed on the WHO or CEPI list of priority diseases, at our election, such product will be developed and commercialized on a cost and profit split basis under the GSK COVID Agreement, or on a milestone and royalty basis under the 2020 GSK Agreement. GSK additionally has the right to replace products licensed under the 2020 GSK Agreement and if the replacement product was already under development by us, GSK must compensate us for certain development costs and pay any accrued milestone payments. We are additionally eligible to receive tiered royalty payments ranging from a single-digit percentage to a low teens percentage on net sales, subject to certain customary reductions. GSK is required to compensate us for certain development and regulatory costs we may incur in connection with our performance of our obligations under the 2020 GSK Agreement and we are eligible to receive up to €20,000 in reimbursements for expenses incurred recording or registering the licenses granted under the 2020 GSK Agreement. We retain the right to commercialize products developed under the 2020 GSK Agreement in Germany, Austria and Switzerland, as GSK's exclusive distributor in these markets. Under any such distribution agreement to be entered into between us and GSK, we will be required to purchase supply from GSK and pay GSK a low thirties percentage royalty on net sales. As of December 31, 2020, we have received the upfront payment amounting to €120 million and approximately €0.9 million in development cost reimbursements.

Additionally, in April 2021, we entered into the GSK COVID Agreement with GSK, pursuant to which we are collaborating with GSK to research, develop and manufacture next-generation mRNA vaccines targeting the original SARS-CoV-2 strain (other than CVnCoV) as well as emerging variants, including multivalent and monovalent approaches. These vaccine candidates may either be used to protect unvaccinated individuals or to serve as boosters in the event that SARS-CoV-2 immunity gained from an initial vaccination reduces over time.

Under the GSK COVID Agreement, GSK will pay us an upfront payment of €75 million. We also granted GSK an exclusive option, after a certain date, to obtain exclusive licenses to develop, manufacture and commercialize CVnCoV and boosters for such vaccine and upon GSK's exercise of such option, GSK is required to compensate us for certain development costs. We and GSK agreed to equally share all development costs for GSK COVID Products, subject to certain exceptions. We and GSK will share all net profits generated from sales of GSK COVID Products, other than Combination Products, under profit sharing arrangements that in certain cases vary depending upon the GSK COVID Product in question, the time of sale, the number of doses sold and the party to

whom the sale is made. We are eligible to receive tiered royalty payments ranging from a sub-teen percentage to a mid-teens percentage on net sales of Combination Products, subject to certain customary reductions. Under the GSK COVID Agreement we have the right to commercialize GSK COVID Products in Austria, Germany and Switzerland and if we exercise such right, our sales of GSK COVID Products, other than Combination Products will be subject to the profit share and we will be required to pay GSK a high-teen percentage royalty on net sales of all Combination Products in such countries.

Genmab

In December 2019, we entered into the Genmab Agreement with Genmab to research and develop up to four potential differentiated mRNA-based antibody products, to be selected by Genmab, based on the combination of our proprietary RNAntibody technology with Genmab's proprietary antibody technology for the treatment of human diseases. We will collaborate on research to identify an initial product candidate designed to express a certain Genmab proprietary antibody and we will contribute a portion of the overall costs for the development of such product candidate, until submission of an IND. Genmab will thereafter be responsible for the development and commercialization of the product candidate. Under the Genmab Agreement we further grant Genmab a license for the preclinical development of up to four additional mRNA antibody product concepts and options to obtain commercial licenses under our mRNA technology to develop, manufacture and commercialize product candidates for up to three of such product concepts.

Under the terms of the Genmab Agreement, Genmab paid us a $10 million upfront fee and made a €20 million equity investment in March 2020. Genmab will be obligated to pay us a $0.5 million reservation fee upon the selection of each additional product concept for development under the Genmab Agreement and $5 million upon selection of a product targeting Genmab's proprietary antibody for further development and commercialization. Genmab is additionally required to pay us up to $30 million in option exercise fees. If Genmab exercises any of its options to obtain commercial licenses for the additional mRNA antibody concepts, Genmab would fund all research and would develop and commercialize any resulting product candidates. We are additionally eligible to receive up to between $25 million and $43 million in development milestone payments, $100 million and $125 million in regulatory milestone payments and $150 million and $200 million in commercial milestone payments for each product, depending on the specific product concept. In addition, we are eligible to receive a mid single-digit to low teens percentage tiered royalty on aggregate net sales of licensed products, on a per-product basis and subject to certain customary reductions. If Genmab grants a sublicense to the initial product candidate developed under the Genmab Agreement before a certain milestone event, Genmab must pay us a one-time $10 million payment. We are responsible for any payments to third parties related to the LNP technology we license to Genmab for use in relation to the initial product candidate developed under the Genmab Agreement and a portion of such payments with respect to LNP technology used in the additional product concepts. We retain an option to participate in development and commercialization of one of the potential additional mRNA antibody product concepts under predefined terms and conditions. In the event we exercise such right, we must pay Genmab a one-time payment of $3 million and refund any option fee paid by Genmab with respect to such product. As of December 31, 2020, we have received approximately $0.6 million in development cost reimbursements and we have not received any reservation, product selection, option exercise or sublicense fees or milestone or royalty payments.

Arcturus

In January 2018, we entered into the Arcturus Agreement with Arcturus, which provides us with access to Arcturus LNP formulation technology which we use in combination with our mRNA technology. We paid Arcturus an upfront fee of $5 million and must pay an extension fee of $1 million if we exercise our option to extend the initial term of the Arcturus Agreement beyond July 2023. We are required to reimburse Arcturus for certain costs incurred in connection with development activities and provide certain FTE funding. We are additionally required to pay up to an aggregate of $5 million in connection with our acceptance of the irrevocable offer to obtain licenses for further development and commercialization of selected targets. Under each license agreement to be entered into in connection with our acceptance of the irrevocable offer, we will additionally be required to make certain royalty payments, which are not in excess of 10% on net sales of licensed products, and pay Arcturus up to $6 million in development milestone payments, $9 million in regulatory milestone payments and $8 million in commercial milestone payments. As of December 31, 2020, we have made payments totaling approximately $5.3 million to Arcturus reimbursing Arcturus for development costs and in connection with our FTE funding obligations, and we have not accepted the irrevocable offer with respect to any target and therefore have not paid any acceptance fees or made any milestone or royalty payments to Arcturus.

Acuitas

In April 2016, we entered into the Acuitas Agreement with Acuitas, which provides us with access to Acuitas LNP formulation technology that we use in combination with our mRNA technology. We are required to pay Acuitas annual target reservation and maintenance fees of up to approximately $1.4 million if we reserve the maximum number of targets permitted under the Acuitas Agreement and to reimburse Acuitas for certain costs incurred in connection with development activities and certain FTE costs. We are additionally required to pay an option exercise fee ranging from $50,000 to $2 million upon each exercise of our option to obtain a license for further development and commercialization with respect to a selected target, subject to certain additional fees ranging from $10,000 to $200,000 for the exercise of our option for certain other vaccine targets. We paid Acuitas a $5 million upfront fee in connection with an amendment to the Acuitas Agreement dated July 2020 and, upon each exercise of our option to exchange a vaccine target licensed under any non-exclusive license, we are required to pay an exchange fee of $3 million. We additionally are required to pay Acuitas a $3 million upfront fee in connection with an amendment to the Acuitas Agreement dated December 2020 and are required to pay an additional $250,000 in April 2022 and April 2023 for each of certain options not yet exercised. Under each license agreement in connection with our exercise of our option, we will additionally be required to make low single-digit percentage tiered royalty payments and must pay up to between approximately $1.1 million and $9 million in development milestone payments, $1.3 million and $7 million in regulatory milestone payments and $1.3 million and $7 million in commercial milestone payments, depending on whether the license is exclusive or non-exclusive and the number of options exercised to date. As of December 31, 2020 we have exercised our option to obtain a non-exclusive license to thirteen targets. As of December 31, 2020, we have paid Acuitas approximately $3.3 million in reservation and option exercise fees and have made payments totaling approximately $6.1 million reimbursing Acuitas for development costs and LNP batches and in connection with our FTE funding obligations.

For each option that we have exercised under the Acuitas Agreement, we have entered into a non-exclusive license agreement with Acuitas with respect to such optioned target, all based on the same form agreement, which we refer to as the Acuitas License Agreements. We are required to pay Acuitas up to between approximately $1.1 million and $1.6 million in development milestone payments, $1.3 million and $1.8 million in regulatory milestone payments and $1.3 million and $1.8 million in commercial milestone payments under each Acuitas License Agreement and we must pay Acuitas annual fees ranging from $5,000 to $10,000 for any additional protein targeted by a vaccine product licensed under each Acuitas License Agreement after a certain milestone event. We additionally are obligated to pay Acuitas a low single-digit percentage royalty on net sales of licensed products. As of December 31, 2020, we have made $100,000 in development milestone payments to Acuitas with respect to the license agreement relating to Rabies RAV-G and we have made $0.6 million in development milestone payments (Phase I and Phase II milestone payments) to Acuitas with respect to the license agreement relating to the SARS-CoV-2 Spike protein S and have not made any royalty payments.

CRISPR Therapeutics

In November 2017, we entered into the CRISPR Therapeutics Agreement with CRISPR Therapeutics, pursuant to which we will develop novel Cas9 mRNA constructs for use in gene editing therapeutics. Under the CRISPR Therapeutics Agreement, we granted CRISPR Therapeutics an exclusive worldwide license to use our improved Cas9 constructs for the development and commercialization of three of its *in vivo* gene-editing programs for certain diseases.

CRISPR Therapeutics was required to pay us an upfront one-time technology access fee of $3 million and we are eligible to receive up to $13 million in development milestone payments, $33 million in regulatory milestone payments and $133 million in commercial milestone payments, as well as mid single-digit percentage royalties from CRISPR Therapeutics on the net sales of licensed products on a product-by-product and country-by-country basis, subject to certain potential customary reductions. Additionally, CRISPR Therapeutics will make payments to us for services provided by us in conjunction with research programs under the CRISPR Therapeutics Agreement. In the event CRISPR Therapeutics exercises its right to sublicense under the agreement, CRISPR Therapeutics must pay us a low teens to mid-twenties percentage of any non-royalty sublicense income, depending on the timing of the sublicense and whether the sublicense is granted through an affiliate of CRISPR Therapeutics. As of December 31, 2020, we have received approximately €0.9 million in payments for the supply of materials and FTE cost and development reimbursements and no milestone, royalty or sublicense fee payments.

Boehringer Ingelheim

In August 2014, we entered into the Boehringer Agreement with Boehringer Ingelheim, whereby we granted Boehringer Ingelheim exclusive global rights for development and commercialization of our investigational therapeutic mRNA vaccine BI 1361849 (formerly CV9202).

We received an upfront payment of €30 million, as well as, an option fee payment of €5 million and an additional €7 million in development milestone payments. We are eligible to receive up to an additional €73 million in development milestone payments, €250 million in regulatory milestone payments and €100 million in commercial milestone payments, as well as royalties in the low teens on net sales of licensed products. We are responsible for any payment obligations arising under certain existing third party license agreements and costs we incur in relation to the research and development of BI 1361849 (formerly CV9202) manufacturing technology. Boehringer Ingelheim is responsible for all other development and commercialization costs and is required to reimburse us for any such costs we may incur. As of December 31, 2020, Boehringer Ingelheim has made payments to us for a net amount of approximately €7.6 million for the supply of materials and reimbursing us for development costs. We have received no royalty payments.

Bill & Melinda Gates Foundation

In May 2014, we were awarded a grant from the Bill & Melinda Gates Foundation for the development of a vaccine for rotaviruses, as amended in November 2020, for up to approximately $2.8 million. As of December 31, 2020, we have received approximately $2.7 million in funding under the agreement. In March 2015, the Bill & Melinda Gates Foundation made an equity investment of $40 million to support continued development of our RNA technology platform and the construction of an industrial-scale cGMP production facility. We entered into a Global Access Commitments Agreement with the Bill & Melinda Gates Foundation in February 2015 pursuant to which we are required to take certain actions to support the Bill & Melinda Gates Foundation mission. In connection with the investment by the Bill & Melinda Gates Foundation, we are required to conduct development activities for up to three concurrent projects to be proposed by the Bill & Melinda Gates Foundation. The costs of such projects will be allocated on a project-by-project basis in proportion to the allocation of the expected benefits.

In November 2016, in connection with the Global Access Commitments Agreement, we were awarded a grant for up to approximately $0.9 million in funding from the Bill & Melinda Gates Foundation for the development of a vaccine for picornaviruses. As of December 31, 2020, we have received approximately $0.7 million in funding under the picornaviruses grant agreement. In November 2017, we were awarded two additional grants each for up to approximately $1.9 million and $1.5 million in funding from the Bill & Melinda Gates Foundation for the development of a universal influenza and a malaria vaccine, respectively. By an amendment entered into November 2020, our grant for the development of a malaria vaccine was increased by an additional approximately $0.8 million. As of December 31, 2020, we have received approximately $1.9 million and $2.2 million, respectively, in funding under each grant agreement.

Coalition for Epidemic Preparedness Innovations

In February 2019, we entered into the CEPI Agreement with CEPI to develop our RNA Printer using certain intellectual property controlled by us covering the development and manufacture of mRNA products, as well as certain additional intellectual property licensed to us. In connection with the CEPI Agreement we have entered into work orders for the preclinical development of a Lassa virus vaccine, a yellow fever vaccine and our rabies virus vaccine. In addition, we entered into a work package for the preclinical development and a Phase 1 clinical trial for our COVID-19 vaccine candidate, CVnCoV. CEPI agreed to contribute up to approximately $34 million in funding for projects undertaken under the CEPI Agreement and an additional $15.3 million in connection with development of CVnCoV. As of December 31, 2020, we have received approximately €26.4 million in funding for projects undertaken under the CEPI Agreement.

Tesla Grohmann

In November 2015, we entered into the Tesla Grohmann Agreement with Tesla Grohmann, pursuant to which Tesla Grohmann agreed to design, develop and manufacture certain automated manufacturing machines on our behalf. We are obligated to pay Tesla Grohmann a fee for each machine delivered by Tesla Grohmann and up to $50 million to $60 million in commercial milestone payments as well as certain development costs under each associated work order. As of December 31, 2020, we have paid Tesla Grohmann approximately €5 million to €6 million in development costs

under various work orders and we have not paid any fees for machines provided under the Tesla Grohmann Agreement or made any milestone payments.

Eli Lilly License and Collaboration Agreement

In November 2017, we entered into the Eli Lilly Agreement with Eli Lilly focused on the development and commercialization of cancer vaccine products based on our proprietary RNActive® technology, which we refer to as the Eli Lilly Agreement. In 2017, we received an upfront payment of $50 million and an equity investment of €45 million and as of December 31, 2020, we have received approximately €14.6 million in payments for the supply of materials and reimbursements for development costs. In June 2020, we entered into a termination agreement with Eli Lilly, which we refer to as the Eli Lilly Termination Agreement, and all licenses, and Eli Lilly's payment obligations, under the Eli Lilly Agreement terminated.

Advance Purchase Agreement for our COVID-19 Vaccine Candidate

On November 30, 2020, we entered into an APA with the EC, acting on behalf and in the name of all Member States of the European Union, which provides for the advance purchase by the Member States of 225 million doses of the vaccine to be allocated among the Member States and the option to purchase up to an additional 180 million doses. The option may be exercised by the EC on behalf and in the name of the Member States. The APA provides for support to our operations in the form of two upfront payments. The first upfront payment of €450 million has already been paid by the EC on behalf of the Member States. The second upfront payment of a mid nine-figure euro amount is to be paid directly by the Member States and is due after an interim data package has been submitted by us to the EMA for the purpose of obtaining EU marketing authorization for CVnCoV. Such upfront payments must be used solely for the development and commercial supply of CVnCoV. We will be required to return any unspent amounts of the upfront payments if, among others, we fail to successfully develop CVnCoV or if we successfully develop CVnCoV, but we do not receive EU marketing authorization or fail to supply any doses of CVnCoV to any of the Member States by late 2021, unless we and the EC mutually agree to a later date. In addition, if any Member State decides to purchase additional doses pursuant to the option granted under the APA, we will be entitled to additional upfront payments that are not subject to such restrictions on use or return of unused amounts upon termination of the APA.

We currently estimate the total value of the APA to be in the low 10-figure euro amount assuming no exercise of the option discussed above, but this estimate is subject to our ability to successfully deliver CVnCoV pursuant to the terms of the APA, including obtaining EU marketing authorization and establishing manufacturing capacities to supply sufficient quantities of CVnCoV.

Results of Operations

Year Ended December 31, 2019 Compared to Year Ended December 31, 2020

We have based the following discussion of our financial condition and results of operations on our audited consolidated financial statements as of and for the years ended December 31, 2019 and 2020 and the notes thereto, included elsewhere in this Annual Report and which have been retrospectively adjusted to reflect the impact of the share split resulting from the Corporate Reorganization.

The following is a discussion of our consolidated results of operations for each of the years ended December 31, 2019 and December 31, 2020. This information is derived from our accompanying consolidated financial statements prepared in accordance with IFRS as issued by IASB.

The following table summarizes our results of operations for the fiscal year ended December 31, 2019 and 2020:

	For Years ended December 31,	
	2019	2020
	(in EUR k, except per share data)	
Statement of Operations and Comprehensive Income (Loss) Data:		
Revenue	17,416	48,871
Cost of sales	(27,983)	(14,173)
Selling and distribution expenses	(1,755)	(733)
Research and development expenses	(43,242)	(113,808)

	For Years ended December 31,	
	2019	2020
	(in EUR k, except per share data)	
General and administrative expenses	(48,969)	(53,554)
Other operating income	5,587	24,150
Other operating expenses	(552)	(568)
Operating loss	**(99,498)**	**(109,815)**
Finance income	833	2,070
Finance expenses	(1,460)	(22,103)
Loss before income tax	**(100,125)**	**(129,848)**
Income tax benefit (expense)	252	726
Net loss	**(99,873)**	**(129,122)**
Other comprehensive income/loss:		
Items that may be subsequently reclassified to profit or loss		
Foreign currency adjustments	32	35
Total comprehensive loss	**(99,841)**	**(129,087)**
Net loss per share (basic and diluted)	**(1.03)**	**(0.98)**

Revenue

Revenue was €48.9 million for the year ended December 31, 2020, representing an increase of €31.5 million, or 180.6%, from €17.4 million for the year ended December 31, 2019. The increase was primarily attributable to the new collaboration with GlaxoSmith Kline, or GSK, and the termination of our collaboration with Eli Lilly. In July 2020, we entered into a strategic collaboration agreement with GSK for the research and development, manufacturing and commercialization of mRNA-based vaccines and monoclonal antibodies targeting infectious disease pathogens. Pursuant to the agreement, GSK made a non-refundable payment of €120 million, which has been received, deferred and recognized as contract liability. For the year ended December 31, 2020, €7.8 million was released from contract liabilities and recognized as revenue from the GSK collaboration. In addition, in June 2020, the License and Collaboration Agreement with Eli Lilly was terminated. As a result, on the termination date, €33.1 million in contract liabilities from an upfront payment was recognized as revenue as no further associated performance obligations remained.

Cost of Sales

Cost of sales was €14.2 million for the year ended December 31, 2020, representing a decrease of €13.8 million, or 49.3%, from €28.0 million for the year ended December 31, 2019. The decrease was primarily attributable to the lower product costs as a result of the termination of the License and Collaboration Agreement with Eli Lilly. Additionally, during the year ended December 31, 2020, the Company recognized lower inventory write-downs in cost of sales and lower setup and quality assurance activities for the production processes as compared to in the year ended December 31, 2019. The increase of the amortization, depreciation and derecognition was due to a derecognition of fixed assets. The planned capacity of the new production plant, GMP IV was reassessed and management determined that that certain capitalized costs, consisting mainly of planning costs related to the previous design, did not have any further economic benefit, and therefore, that amount was derecognized from property, plant and equipment and recognized as cost of sales.

	For the Years Ended December 31,	
	2019	2020
	(in EUR k)	
Personnel	(9,855)	(2,896)
Materials	(7,542)	(1,598)
Third party services	(7,268)	(2,652)
Maintenance and lease	(1,060)	(1,016)
Amortization, depreciation and derecognition	(2,038)	(5,913)
Other	(220)	(98)
Total	**(27,983)**	**(14,173)**

Selling and Distribution Expenses

Selling and distribution expenses were €0.7 million for the year ended December 31, 2020, representing a decrease of €1.0 million, or 58.2%, from €1.8 million in the year ended December 31, 2019. The decrease was primarily attributable to lower personnel expenses resulting from less expense recognized on share-based payment awards made subsequent to the year ended December 31, 2019.

	For the Years Ended December 31,	
	2019	2020
	(in EUR k)	
Personnel	(1,263)	(631)
Amortization and depreciation	(81)	(98)
Other	(411)	(4)
Total	**(1,755)**	**(733)**

Research and Development Expenses

Research and development costs were €113.8 million for the year ended December 31, 2020, representing an increase of €70.6 million, or 163.4%, from €43.2 million in the year ended December 31, 2019. The increase was primarily attributable to higher development expenses from the CVnCoV program. These expenses consist primarily of cost incurred to clinical research organizations and for personnel costs for employees involved in the CVnCoV development, as well as materials used in the administration of CVnCoV clinical trials. Additionally, in the year ended December 31, 2020, we recognized €4.7 million in share-based payment expense (included in personnel), whereas none was recognized in the same period of 2019.

	For the Years Ended December 31,	
	2019	2020
	(in EUR k)	
Materials	(4,015)	(29,834)
Personnel	(14,385)	(21,313)
Amortization and depreciation	(474)	(2,578)
Patents and fees to register a legal right	(4,551)	(7,337)
Third party services	(18,626)	(51,306)
Maintenance and lease	(670)	(717)
Other	(521)	(723)
Total	**(43,242)**	**(113,808)**

The following table reflects our research and development costs for each of our programs for the year ended December 31, 2019 and 2020:

	For the Years Ended December 31,	
	2019	2020
	(in EUR k)	
Key Programs (CV8102, CV7202 and CVnCoV)		
CV8102	(4,511)	(11,129)
CV7202	(2,236)	(5,726)
CVnCoV	-	(52,701)
Other Research and Development Programs	(14,271)	(14,389)
Unallocated costs(1)	(22,224)	(29,863)
Total	**(43,242)**	**(113,808)**

(1) Unallocated costs primarily consist of costs associated with personnel expenses, patents and fees to register a legal right, amortization and depreciation, maintenance and lease expenses, certain third party service expenses and certain material expenses.

Our research and development expenses increased significantly compared to our expenses in 2019. Such increased research and development expenses primarily relate to the following key programs:

- Our mRNA vaccine program, CVnCoV against SARS-CoV-2, for which we initiated a Phase 1 clinical trial in June 2020 and a Phase 2a clinical trial in older adults in September 2020. For the Phase 1 clinical trial, we reported positive interim results on November 10, 2020, enabling us to select a recommended dose of 12µg to evaluate in a pivotal Phase 2b/3 trial. In December 2020, we initiated our pivotal Phase 2b/3 trial.

- Our lead oncology program, CV8102, which is currently in a Phase 1 dose escalating clinical trial for four types of solid tumors as a monotherapy and in combination with anti-PD-1.

- Our vaccine program, CV7202, which is currently in a Phase 1 clinical trial as a vaccine candidate for rabies.

General and Administrative Expenses

General and administrative expenses were €53.5 million for the year ended December 31, 2020, representing an increase of €4.5 million, or 9.1%, from €49.0 million in the year ended December 31, 2019. The increase was primarily attributable to increased depreciation of right-of-use assets relating to newly leased office space.

	For the Years Ended December 31,	
	2019	2020
	(in EUR k)	
Personnel	(31,645)	(29,884)
Maintenance and lease costs	(4,604)	(2,505)
Third party services	(5,970)	(6,914)
Legal and other professional services	(2,110)	(3,531)
Amortization and depreciation	(2,182)	(6,020)
Other	(2,458)	(4,700)
Total	**(48,969)**	**(53,554)**

Other Operating Income

Other operating income was €24.2 million in the year ended December 31, 2020, representing an increase of €18.6 million or 332%, from €5.6 million for the year ended December 31, 2019. The increase was due to an increase in amounts recognized from grants from government agencies and similar bodies, primarily CEPI and BMBF.

Other Operating Expense

Other operating expense was €0.6 million in the year ended December 31, 2020 and was relatively unchanged from the year ended December 31, 2019. Other operating expense related primarily to compensation expense for our supervisory board in both years.

Finance Income

Finance income was €2.1 million for the year ended December 31, 2020, representing an increase of €1.3 million, or 162.5%, from €0.8 million for the year ended December 31, 2019. The increase was mainly attributable to higher foreign exchange gains.

Finance Expenses

Finance expenses were €22.1 million for the year ended December 31, 2020, representing an increase of €20.6 million, or 1,373.3%, from €1.5 million for the year ended December 31, 2019. The increase mainly related to interest incurred on convertible loans, which were fully repaid prior to the consummation of our initial public offering and to negative interest on cash which is being held in liquid funds for use in our CVnCoV R&D and manufacturing activities. In addition, the increase was also attributable to higher foreign exchange losses.

Income Tax Benefit (Expense)

An income tax benefit of €0.7 million was generated for the years ended December 31, 2020 and 2019 as a result of higher deferred tax benefit recognized on taxable temporary differences.

Year Ended December 31, 2018 Compared to Year Ended December 31, 2019

We have based the following discussion of our financial condition and results of operations on our audited consolidated financial statements as of and for the years ended December 31, 2018 and 2019 and the notes thereto, included elsewhere in this Annual Report and which have been retrospectively adjusted to reflect the impact of the share split resulting from the Corporate Reorganization.

The following is a discussion of our consolidated results of operations for each of the years ended December 31, 2018 and December 31, 2019. This information is derived from our accompanying consolidated financial statements prepared in accordance with IFRS as issued by IASB.

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019:

	For the Years ended December 31,	
	2018	**2019**
	(in EUR k), except per share data)	
Statement of Operations and Comprehensive Income (Loss) Data:		
Revenue	12,871	17,416
Cost of sales	(17,744)	(27,983)
Selling and distribution expenses	(1,085)	(1,755)
Research and development expenses	(41,722)	(43,242)
General and administrative expenses	(25,289)	(48,969)
Other operating income	808	5,587
Other operating expenses	(663)	(552)
Operating loss	**(72,824)**	**(99,498)**
Finance income	1,968	833
Finance expenses	(275)	(1,460)
Loss before income tax	**(71,131)**	**(100,125)**
Income tax benefit (expense)	(110)	252
Net loss for the year	**(71,241)**	**(99,873)**
Other comprehensive income/loss:		
Items that may be subsequently reclassified to profit or loss		
Foreign currency adjustments	66	32
Total comprehensive loss for the year	**(71,175)**	**(99,841)**
Net loss per share (basic and diluted)	**(0.74)**	**(1.03)**

Revenue

Revenue was €17.4 million for 2019, representing an increase of €4.5 million, or 35%, from €12.9 million for 2018. The increase was primarily attributable to an increase of €2.7 million in research and development services and an increase of €1.9 million from product sales in 2019 under our collaboration agreements.

Cost of Sales

Cost of sales was €28.0 million for 2019, representing an increase of €10.3 million, or 58%, from €17.7 million for 2018. The increase was partially attributable to certain one-time effects as well as to higher product sales under our collaboration agreements, which resulted in increases in materials and third party services of €2.6 million and €4.9 million, respectively, as compared to 2018. The increase in materials expense was primarily due to €3.6 million higher inventory write-downs, partially offset by lower materials costs from the product sales mix. The increase in third party expenses was primarily due to €2.7 million additional costs for setup and quality assurance activities

for our production processes and €1.5 million as a result of additional costs for required rework of certain products.

	For the Years Ended December 31,	
	2018	2019
	(in EUR k)	
Personnel	(7,703)	(9,855)
Materials	(4,941)	(7,542)
Third party services	(2,340)	(7,268)
Maintenance and lease	(1,758)	(1,060)
Amortization and depreciation	(893)	(2,038)
Other	(109)	(220)
Total	**(17,744)**	**(27,983)**

Selling and Distribution Expenses

Selling and distribution expenses were €1.8 million for 2019, representing an increase of €0.7 million, or 64%, from €1.1 million in 2018. The increase was primarily attributable to increased personnel expenses resulting from share-based compensation.

	For the Years Ended December 31,	
	2018	2019
	(in EUR k)	
Personnel	(581)	(1,263)
Maintenance and lease costs	(300)	(167)
Amortization and depreciation	(95)	(81)
Other	(109)	(243)
Total	**(1,085)**	**(1,755)**

Research and Development Expenses

Research and development costs were €43.2 million for 2019, representing an increase of 4% from €41.7 million in 2018. The increase was primarily attributable to higher personnel expenses offset by reversal of provisions for share-based compensation in 2018.

	For the Years Ended December 31,	
	2018	2019
	(in EUR k)	
Materials	(5,867)	(4,015)
Personnel	(7,565)	(14,385)
Amortization and depreciation	(1,143)	(474)
Patents and fees to register a legal right	(4,847)	(4,551)
Third party services	(19,921)	(18,626)
Maintenance and lease	(1,156)	(670)
Other	(1,223)	(521)
Total	**(41,722)**	**(43,242)**

The following table reflects our research and development costs for each of our programs for the years ended December 31, 2018 and 2019:

	For the Years Ended December 31,	
	2018	2019
	(in EUR k)	
Key Programs (CV8102 and CV7202)		
CV8102	(1,525)	(4,511)
CV7202	(1,987)	(2,236)

	For the Years Ended December 31,	
	2018	2019
	(in EUR k)	
Other Research and Development Programs	(14,047)	(14,271)
Unallocated costs(1)	(24,163)	(22,224)
Total	**(41,722)**	**(43,242)**

(1) Unallocated costs primarily consist of costs associated with personnel expenses, patents and fees to register a legal right, amortization and depreciation, maintenance and lease expenses, certain third party service expenses and certain material expenses.

General and Administrative Expenses

General and administrative expenses were €49.0 million for 2019, representing an increase of €23.7 million, or 94%, from €25.3 million in 2018. The increase was primarily attributable to increased personnel expenses resulting from share-based compensation.

	For the Years Ended December 31,	
	2018	2019
	(in EUR k)	
Personnel	(10,084)	(31,645)
Maintenance and lease cost	(3,239)	(4,604)
Third party services	(4,006)	(5,970)
Legal and other professional services	(4,078)	(2,110)
Amortization and depreciation	(1,635)	(2,182)
Other	(2,247)	(2,458)
Total	**(25,289)**	**(48,969)**

Other Operating Income

Other operating income was €5.6 million in 2019, representing an increase of €4.8 million, from €0.8 million for 2018. The increase was due to an increase in amounts recognized from grants from government agencies and similar bodies.

Other Operating Expense

Other operating expense was €0.6 million in 2019 and was relatively unchanged from 2018. Other operating expense related primarily to compensation expense for our supervisory board in both years.

Finance Income

Finance income was €0.8 million in 2019, representing a decrease of €1.1 million, or 58%, from €2.0 million. The decrease was mainly attributable to higher unrealized foreign exchange gains in 2018.

Finance Expenses

Finance expenses were €1.5 million in 2019, representing an increase of €1.2 million, or 500%, from €0.3 million for 2018. The increase related to interest on convertible loans in 2019.

Income Tax Benefit (Expense)

An income tax benefit of €0.3 million was generated in 2019 compared to an income tax expense of €(0.1) million in 2018. The income tax benefit in 2019 results from income tax expenses from CureVac Inc., offset by recognition of deferred tax benefits relating to tax loss carryforwards.

Liquidity and Capital Resources

Overview

Since inception, we have incurred significant operating losses. For the year ended December 31, 2019 and 2020, we incurred net losses of €99.9 million and €129.1 million, respectively. To date, we have financed our operations primarily through the IPO in August 2020, the public offering in February 2021, private placements of equity securities, issuance of convertible debt, grants from government agencies and similar bodies and payments for collaborative research and development services. Our cash and cash equivalents as of December 31, 2020 were €1.32 billion, inclusive of the first upfront payment under the APA. Our primary cash needs are for working capital requirements, capital expenditures and to fund our non-clinical and clinical development programs. We believe our existing cash, cash equivalents, borrowings available to us and short-term investments will enable us to fund our operating expenses and capital expenditure requirements at least through the end of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We have also recently entered into an APA with the EC, acting on behalf and in the name of all Member States of the European Union, for the purchase of 225 million doses of the vaccine to be allocated among the Member States and the option to purchase up to an additional 180 million doses. The option may be exercised by the EC on behalf and in the name of the Member States. The APA provides for two mid nine-figure euro amount upfront payments, which shall be used solely for the development and commercial supply of CVnCoV. We will be required to return any unspent amounts of such upfront payments if, among others, we fail to successfully develop CVnCoV or if we successfully develop CVnCoV but we do not receive EU marketing authorization or fail to supply any doses of CVnCoV to any of the Member States by late 2021, unless we and the EC mutually agree to a later date. We expect such source of financing to be material to our accelerated efforts to develop and commercialize CVnCoV.

Our financial condition and liquidity is and will continue to be influenced by a variety of factors, including our ability to generate cash flows from our operations, future indebtedness and the interest we are obligated to pay on this indebtedness, the availability of public and private debt and equity financing, changes in exchange rates which will impact our generation of cash flows from operations when measured in euros and our capital expenditure requirements.

Convertible Loans

We entered into a convertible loan agreement on May 3, 2019 with Mr. Dietmar Hopp, managing director of dievini, under which Mr. Hopp disbursed to us the amount of €50 million, referred hereto as Convertible Loan I. On October 24, 2019, we entered into an additional convertible loan agreement with Mr. Hopp, as amended, under which we have the right to call for disbursements in two tranches of €20 million each and an additional final tranche of approximately €24 million, until December 31, 2021, referred hereto as Convertible Loan II, and together with Convertible Loan I, referred hereto as the Convertible Loans. The Convertible Loans bore an interest rate of 8.00% per annum. On June 26, 2020, Mr. Hopp disbursed to us an additional $26.8 million. On July 24, 2020, the First Loan and Second Loan were terminated and on August 7, 2020, the total principal of €94.8 million and total accrued interest of €5.6 million were repaid in full.

European Investment Bank Loan

In June 2020, we signed a financing arrangement with the European Investment Bank, or EIB, under which EIB agreed to provide us with a line of credit in an amount of up to €75 million for the partial financing of our clinical developments and large-scale production of our infectious diseases vaccine candidates including our vaccine against SARS-CoV-2, or the Investment, provided that the amount of financing does not exceed 50% of the cost of the Investment. The EIB financing falls under a joint initiative between EIB and the EC, which is intended as a new EIB financing instrument to finance inter alia research projects and research infrastructure under the Horizon 2020 framework program of the European Union for Research and Technological Development (2014-2020). The EIB financing will be provided in three €25 million tranches upon completion of predefined milestones that will be measured prior to the disbursement of each tranche. These predefined milestones are tied to evidence of successful progress in the development and large-scale production of our vaccine candidate against SARS-CoV-2. In addition, the disbursements of the second and third tranches are contingent upon the disbursement of the first and second tranches, respectively. Interest accrues on the outstanding balance of each tranche at a rate of 0.5% per annum. Such interest is due and payable on the maturity date of each tranche or where a tranche is canceled or prepaid, the

prepayment date. The maturity date for each tranche is seven years from the respective disbursement date of the relevant tranche. We are subject to several restrictive covenants on our business activities as described in Schedule H of the financing agreement, including limitations on certain merger and acquisition transactions, disposition of certain assets and mandatory maintenance of assets related to the Investment. As of December 31, 2020, we have drawn €25 million under the first of the three tranches. As we have achieved the predefined milestones required for disbursements under the first two tranches we expect to receive disbursements under the first and second tranches in the near term. In November 2020, a land charge (mortgage) amounting to €75 million was registered in favor of the EIB to secure the loan. The EIB may demand, without prior notice, the immediate repayment of outstanding principal together with any accrued interest upon certain events including, among others, our failure to continue the development of our Investment following a cure period.

BMBF Grant

The Company received from the German Federal Ministry of Education and Research, or BMBF, a grant to support the development of its COVID-19 vaccine candidate of up to €252 million. In July 2020, CureVac had applied to that grant as part of a special program to accelerate the research and development of urgently needed vaccines against SARS-CoV-2. In addition to the further development of CureVac's vaccine candidate against COVID-19, the grant is expected to be used for the rapid expansion of the vaccine production. Payments are contingent on reaching predefined milestones. Amounts incurred in 2020 and 2021 are eligible for reimbursement through the grant. CureVac expects funding of up to €103 million in 2020 and up to €149 million in 2021. As of December 31, 2020, we have drawn €103 million of the grant.

Advance Purchase Agreement for our COVID-19 Vaccine Candidate

On November 30, 2020, we entered into an APA with the EC, acting on behalf and in the name of all Member States of the European Union, which provides for the advance purchase by the Member States of 225 million doses of the vaccine to be allocated among the Member States, and the option to purchase up to an additional 180 million doses. The option may be exercised by the EC on behalf and in the name of the Member States.

In order to support our accelerated efforts to develop a safe and effective vaccine, the APA provides for support to our operations in the form of two upfront payments. The first upfront payment of €450 million has already been paid by the EC on behalf of the Member States. The second upfront payment of a mid nine-figure euro amount is to be paid directly by the Member States and is due after an interim data package has been submitted by us to the EMA for the purpose of obtaining EU marketing authorization for CVnCoV. Such upfront payments must be used solely for the development and commercial supply of CVnCoV. We will be required to return any unspent amounts of the upfront payments if, among others, we fail to successfully develop CVnCoV or if we successfully develop CVnCoV, but we do not receive EU marketing authorization or fail to supply any doses of CVnCoV to any of the Member States by late 2021, unless we and the EC mutually agree to a later date. In addition, if any Member State decides to purchase additional doses pursuant to the option granted under the APA, we will be entitled to additional upfront payments that are not subject to such restrictions on use or return of unused amounts upon termination of the APA.

The APA will be terminated automatically if we notify the EC that we are unable to provide the vaccine because (i) the clinical trial results are not satisfactory, (ii) the clinical trial results do not meet their endpoint in terms of efficacy or safety or (iii) the EU marketing authorization was not granted. The termination will be effective unless the EC objects within 30 calendar days; provided, however, that such objection may only be based on reasonable grounds and taking into account the severity of the impact that continuation of the APA would have on our business. In addition, the EC shall have the right to terminate the APA, and each Member State the respective individual vaccine purchase orders, for the reasons specified in Section 14.2 of the APA, which among others, provides the EC the right to terminate the APA if we do not obtain EU marketing authorization by late 2021, unless we and the EC mutually agree to a later date, or if we are in material breach of our obligation to (i) obtain EU marketing authorization and establish sufficient manufacturing capacities to enable the manufacturing and supply of the contractually agreed volumes of our vaccine pursuant to the agreement, (ii) provide the doses of the vaccine according to the estimated delivery schedule or (iii) manufacture (or have manufactured) doses designated to participating Member States within the European Union at sites outside the EU, UK, the EEA or Switzerland without the prior consent of the EC.

We currently estimate the total value of the APA to be in the low 10-figure euro amount assuming no exercise of the option discussed above, but this estimate is subject to our ability to successfully deliver CVnCoV pursuant to the terms of the APA, including obtaining EU marketing authorization and establishing manufacturing capacities to supply sufficient quantities of CVnCoV.

Comparative Cash Flows

Comparison of the years ended December 31, 2019 and 2020

	For the Year Ended December 31,	
	2019	2020
	(in EUR k)	
Net cash flow from (used in):		
Operating activities	(86,963)	522,403
Investing activities	28,181	(45,274)
Financing activities	67,979	819,833
Effect of currency translation gains on cash and cash equivalents	107	(5,053)
Overall cash inflow	**9,304**	**1,291,909**

Operating Activities

Net cash provided by operating activities for the year ended December 31, 2020 was €522.4 million as compared to net cash used in operating activities of €87.0 million for the year ended December 31, 2019. The increase in net cash in operating activities was primarily attributable to an increase of the contract liabilities due to the receipt of the upfront payment from the European Commission related to the Advance Purchase Agreement and the receipt of the upfront payment from GSK amounting to €120 million and the overall decrease in trade receivables and contract assets, as a result of collections, and receipts from grants from government agencies and similar bodies, partially offset by the increase of the loss before income taxes.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was €45.3 million as compared to net cash provided by investing activities of €28.1 million for the year ended December 31, 2019. The change in cash flows from investing activities was primarily attributable to increased purchases of property, plant and equipment and intangible assets offset by decreased proceeds from the sale of short-term investments (other financial assets).

Financing Activities

Net cash provided by financing activities was €819.8 million for the year ended December 31, 2020 as compared to €68.0 million for the year ended December 31, 2019. The increase in cash flow provided by financing activities was mainly attributable to proceeds from the issuance of shares to Genmab, in the 2020 Private Investment, in the initial public offering and to DH-LT-Investments GmbH, beneficially owned by Dietmar Hopp, in the concurrent private placement in the year ended December 31, 2020.

Comparison of the Year Ended December 31, 2018 and 2019

The following table summarizes our cash flows from operating, investing and financing activities for the periods indicated:

	For the years ended December 31,	
	2018	2019
	(in EUR k)	
Net cash flow from (used in):		
Operating activities	(74,110)	(86,963)
Investing activities	(4,264)	28,181
Financing activities	(112)	67,979
Effect of currency translation gains on cash and cash equivalents	213	107
Overall cash inflow (outflow)	**(78,273)**	**9,304**

Operating Activities

Net cash used in operating activities for the year 2019 was €87.0 million as compared to €74.1 million for 2018. The increase in net cash used in operating activities was primarily attributable to the increase of the loss before income taxes and due to an increase in trade receivables and inventory.

Investing Activities

Net cash from investing activities was €28.1 million for 2019 as compared to net cash used in investing activities of €4.3 million for 2018. The increase in net cash from investing activities was primarily attributable to proceeds from the sale of short-term investments and decreased purchases of intangible assets.

Financing Activities

Net cash from financing activities was €68.0 million for 2019 as compared to €0.1 million for 2018. The increase in cash flow from financing activities was primarily attributable to proceeds from convertible loans.

Research and Development, Patents and Licenses, etc.

Research and development expenses consist primarily of costs incurred for our research and preclinical and clinical development activities, including our product discovery efforts and certain activities relating to the design of GMP-manufacturing facilities. Research and development expenses contain wages and salaries, share-based compensation, fringe benefits and other personnel costs, the costs of clinical testing and the associated clinical production costs, research material production costs, fees for contractual partners, consultants and other third parties, fees to register legal rights, amortization of licensed software and intellectual property as well as costs for plant and facilities. Research and development expenses contain costs for independent research and development work as well as work carried out in the context of collaboration and licensing agreements; such expenses include all costs related to research and development services delivered under our collaboration arrangements. Additionally, prior to initial regulatory approval, if any, costs relating to production of products are expensed as research and development expenses in the period incurred. If pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales as they will have been recognized in research and development expense in the period incurred.

We also have partnered programs as further described under "section 2.2 — Business Overview — Collaborations" and "section 2.2 — Business Overview — Advance Purchase Agreements," for which we incur additional expenses. In addition, our research and development expenses relate to our preclinical studies of further product candidates and discovery activities. These expenses mainly consist of salaries, share based-compensation, costs for production of preclinical compounds and costs paid to contract research organizations.

We expense research and development expenses as incurred. We recognize costs for certain development activities, such as preclinical studies and clinical trials, based on an evaluation of the progress to completion of specific tasks. We use information provided to us by our vendors such as patient enrollment or clinical site activations for services received and efforts expended. We expect research and development costs, including manufacturing, to support these activities, to increase significantly for the foreseeable future as our current development programs progress and new programs are added.

Trend Information

For a discussion of trend information, see "section 3.2".

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, except for those noncancellable contractual obligations from certain of our arrangements with contract manufacturing organizations disclosed in "section 3.2 — Tabular Disclosure of Contractual Obligations."

Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020 and the effects, including estimated interest payments, that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payment Due by Period						
	Total(2)	**2021**	**2022**	**2023**	**2024**	**2025**	**Thereafter**
				(in EUR k)			
Contractual CMO commitments(1)	97,151	97,151	—	—	—	—	—
Lease liabilities	30,087	2,961	3,074	3,131	3,310	3,449	14,161
Long-term debt obligations	25,875	—	—	—	—	—	25,875
Total	**153,112**	**100,112**	**3,074**	**3,131**	**3,310**	**3,449**	**40,036**

(1) We enter into contracts in the normal course of business with third party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore, we believe that our noncancelable obligations under these agreements are not material and they are not included in the table above. However, as of December 31, 2020, in connection with our CVnCoV development program, we entered into arrangements with contract manufacturing organizations, or CMOs, which contain certain noncancellable contractual obligations totaling €97.2 million, and therefore, have included these in the table above.

(2) The amount does not reflect further remuneration payments for future periods starting 2023. The remuneration payments are dependent on future batch deliveries.

On November 30, 2020, we entered into an APA with the EC, acting on behalf and in the name of all Member States of the European Union, that provides substantial support focused on our efforts to advance CVnCoV. See "section 3.2 — Advance Purchase Agreement for our COVID-19 Vaccine Candidate."

We have entered into various agreements with collaborators, including licensing agreements. These agreements provide for us to make milestone and royalty payments that are conditional on the achievement of certain development, regulatory and commercial milestones and certain of these agreements provide us an option to obtain further licenses which could additionally require us to make such milestone and royalty payments. As of December 31, 2020, the aggregate amount of such potential milestone payments, including those relating to licenses acquired from exercised options, under all such collaboration agreements, was up to approximately $121.3 million. The timing of these payments, and whether they become due, is conditional on achieving the applicable milestones.

We have not included milestone or royalty payments or other contractual payment obligations in the table above if the timing and amount of such obligations are unknown or uncertain.

Safe Harbor

See "Forward-Looking Statements."

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB and endorsed by the EU (362-8 DCC). and endorsed by the EU (362-8 DCC). Some of the accounting methods and policies used in preparing the financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances concerned. The actual value of our assets, liabilities and shareholders' equity and of our earnings could differ from the value derived from these estimates if conditions changed and these changes had an impact on the assumptions adopted.

Our significant accounting policies that we believe to be critical to the judgments and estimates used in the preparation of our financial statements are included in "note 2 — Significant accounting policies" and "note 9 — Share-based payments" to our consolidated financial statements included elsewhere in this report.

4. Risk Management and Risk Factors

4.1 Risk management and control systems

As required by Rule 13a-15 under the Exchange Act, management, including our chief executive officer and our chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

Based on the foregoing, our chief executive officer and our chief financial officer have concluded that, as of December 31, 2020, our disclosure controls and procedures were not effective. This was due to the existence of a material weakness primarily related to (a) a lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training and (b) a lack of established accounting processes and procedures for new complex transactions and consistent application of existing accounting processes and procedures. This material weakness existed as of December 31, 2019 and, as the remediation plan to resolve it was not fully completed, it was unremediated as of December 31, 2020. See section 4.3 (Risk Factors). We and our independent registered public accountants have identified a material weakness in our internal control over financial reporting. If we are unable to remediate the material weakness, or if other control deficiencies are identified, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports as a public company in a timely manner.

4.2 In control statement

On the basis of reports and information provided to the Management Board and its committees, the Management Board is of the opinion that:

a. this report provides sufficient insight into any failings in the effectiveness of the Company's risk management and control systems;

b. the Company's risk management and control systems provide reasonable assurance that the Company's financial reporting does not contain material inaccuracies;

c. based on the Company's state of affairs as at the date of this report, it is justified that the Company's financial reporting is prepared on a going concern basis; and

d. this report states those material risks and uncertainties that are relevant to the expectation of the Company's continuity for a period of twelve months after the date of this report.

The Company has not fully established an internal audit function yet. Parts of our internal audit tasks with regards to the commercial and financial perspective has been outsourced to a third party. Among others, services related to the implementation of Internal Controls over financial reporting and IPO-readiness have been conducted. Over the next two years we intent to set-up and

transfer the internal audit function in-house and co-source with third parties if needed. The internal audit function with regards to the clinical and technical perspective has been already established inhouse by the function of corporate quality. In view of the foregoing, our management board is of the opinion that given the size, resources, personnel and experience of the Company, adequate alternative measures have been taken.

Furthermore, the Management Board confirms that:

a. to the best of its knowledge, the statutory annual accounts included in this report give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and its consolidated subsidiaries taken as a whole; and

b. this report includes a fair review concerning the position, on the balance sheet date, and the development and performance of the business of the Company and its consolidated subsidiaries taken as a whole, together with a description of the principal risks and uncertainties that they face.

4.3 Risk factors

Summary of Risk Factors

The following is a summary of the risk factors our business faces. The list below is not exhaustive, and investors should read this "Risk Factors" section in full. Some of the risks we face include:

- Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may face continued business disruption and related risks resulting from of the COVID-19 pandemic, which could have a material adverse effect on our business plan or clinical trials.
- We depend on strategic partnerships with other companies to assist in the research, development and commercialization of our platform and product candidates. If our existing or future partners do not perform as expected, if we fail to maintain any of these collaborations or if these collaborations are not successful, our ability to commercialize our product candidates successfully and to generate revenues through technology licensing or otherwise may be materially adversely affected.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. If clinical trials of our product candidates or production of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.
- Our proprietary product candidates are still in preclinical or clinical development. We cannot give any assurance that any of our product candidates will receive regulatory approval, and if we are unable to obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.
- We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
- Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if any.

- To date, a limited number of products that utilize mRNA as a prophylactic vaccine against COVID-19 have been approved in the United States and Europe, subject to certain limitations. In addition, no product that utilizes mRNA as a therapeutic vaccine has been approved in the United States or Europe. As such, mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of medicines.

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable and if we fail to obtain regulatory approval in any jurisdiction, we will not be able to commercialize our products in that jurisdiction and our business, results of operations, financial condition and prospects, may be materially adversely affected.

- A breakthrough therapy designation by the FDA for a product candidate may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval.

- The manufacture of mRNA-based medicines is complex and manufacturers often encounter difficulties in production, especially in the field of biologics. If we or any of our third party manufacturers encounter difficulties, our ability to provide product candidates for clinical trials or products, if approved, to patients or future customers could be delayed or halted.

- Undetected errors or defects in our production could harm our reputation or expose us to product liability claims.

- We rely on third parties to conduct our nonclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- If we or any third party manufacturer of our product candidates is unable to increase the scale of production of our product candidates, and/or increase the product yield of manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.

- If we fail to comply with our obligations under any license, collaboration or other intellectual property agreements, disagree over contract interpretation, or otherwise experience disruptions to our business relationships with our collaborators or licensors, we could lose intellectual property rights that are necessary to our business.

- Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

- Some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that products similar to our product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business.

Risks Related to Our Financial Position and Need for Additional Capital

We cannot assure you of the adequacy of our capital resources to successfully complete the development and commercialization of our product candidates, and a failure to obtain additional capital, if needed, could force us to delay, limit, reduce or terminate one or more of our product development programs or commercialization efforts.

As of December 31, 2020, we had cash and cash equivalents amounting to €1.32 billion, inclusive of the first upfront payment of €450 million under the Advance Purchase Agreement, or APA, as

described below. We believe that we will continue to expend substantial resources for the foreseeable future developing our proprietary product candidates. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, seeking regulatory approvals, as well as launching and commercializing products approved for sale, if any, costs associated with manufacturing products and maintaining manufacturing facilities. In addition, other unanticipated costs may arise. Because the outcomes of our anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our proprietary product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the numerous risks and uncertainties associated with developing product candidates and maintaining our mRNA technology platform;
- the number and characteristics of product candidates that we pursue;
- the rate of enrollment, progress, cost and outcomes of our clinical trials, which may or may not meet their primary endpoints;
- the timing of, and cost involved in, conducting non-clinical studies that are regulatory prerequisites to conducting clinical trials of sufficient duration for successful product registration;
- the cost of manufacturing clinical supply and establishing commercial supply of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful;
- the timing of, and costs involved in, conducting post-approval studies that may be required by regulatory authorities;
- the cost of commercialization activities for our product candidates, if any of our product candidates are approved for sale, including product manufacturing, marketing and distribution of product candidates generated from our mRNA technology platform and any other product opportunity for which we receive marketing approval in the future;
- the terms and timing of any collaborative, licensing and other arrangements that we are currently party to or may establish, including any required milestone and royalty payments thereunder and any non-dilutive funding that we may receive;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs, if any, and the outcome of any such litigation;
- the timing, receipt, and amount of sales of, or royalties or milestones on, our future products, if any;
- the costs to recruit and build the organization including key executives needed to transform to a commercial organization; and
- the costs of operating as a public company, including hiring additional personnel.

In addition, our operating plan may change as a result of many factors currently unknown to us. As a result of these factors, we may need additional funds sooner than planned. We expect to finance future cash needs primarily through a combination of public or private equity offerings, strategic collaborations, revenues from future product sales and debt financing. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, limit, reduce or terminate one or more of our product development programs or commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition.

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant losses since our inception. Our consolidated net loss for the for the year ended December 31, 2020 and 2019 was €129.1 million and €99.9 million, respectively. As of December 31, 2020, our accumulated deficit was €645.1 million. We expect to continue to incur losses in the future as we continue our research and development of, and seek regulatory approvals for, our product candidates and maintain and develop new technology platforms, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and development of our manufacturing technology and we anticipate that our expenses will continue to increase over the next several years as we continue these activities. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory agencies to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials, the partnering process for our proprietary product candidates or in the development of any of our proprietary product candidates.

Our revenue to date has been primarily revenue from the license of our proprietary technology platform and from milestone payments for the development of product candidates against targets provided by our collaborators. Our ability to generate revenue and achieve profitability in the future depends in large part on our ability, alone or with our collaborators, to achieve milestones and to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, our product candidates and technology platform. This will require us to be successful in a range of challenging activities, including developing product candidates, obtaining regulatory approval for such product candidates, and manufacturing, marketing and selling those product candidates for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable could depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations. A decline in the value of our company could also cause shareholders to lose all or part of their investment.

We require substantial financing, which may not be available on acceptable terms, or at all. Raising capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technology or product candidates.

We expect our expenses to continue to increase in connection with our planned operations. To the extent that we raise capital through the sale of common shares, convertible securities or other equity securities, the ownership interests of our shareholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect rights of our common shareholders. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. For example, in June 2020, we signed a financing arrangement with the European Investment Bank, or EIB under which EIB agreed to provide us with a line of credit in an amount of up to €75 million. Pursuant to the financing agreement we are subject to several restrictive covenants on our business activities as described in Schedule H of the financing agreement, including limitation on certain merger and acquisition transactions, disposition of certain assets and mandatory maintenance of such assets. See "section 3.2 — European Investment Bank Loan." In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We cannot be certain that funding will be available on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources, and therefore we intend to focus on developing product candidates for specific indications that we believe are most likely to succeed, in terms of both their potential for marketing approval and potential for successful commercialization, if approved. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

We depend on strategic partnerships with other companies to assist in the research, development and commercialization of our platform and product candidates. If our existing or future partners do not perform as expected, if we fail to maintain any of these collaborations or if these collaborations are not successful, our ability to commercialize our product candidates successfully and to generate revenues through technology licensing or otherwise may be materially adversely affected.

We have established strategic partnerships and intend to continue to establish strategic partnerships with third parties to research, develop and commercialize our platform and existing and future product candidates. We have entered into strategic partnerships with Acuitas, Arcturus, Boehringer Ingelheim, CEPI, CRISPR Therapeutics, Genmab, GSK, Tesla Grohmann and the Bill & Melinda Gates Foundation, among others. For certain of these programs, including our collaborations with Boehringer Ingelheim, CRISPR Therapeutics, Genmab and GSK, we will depend on our partners to design and conduct their clinical studies. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. While we have certain contractual rights to information about preclinical and clinical developments and results under certain of our collaboration agreements, including our agreements with Boehringer Ingelheim, CRISPR Therapeutics, Genmab and GSK, we cannot be certain that clinical trials conducted in connection with such collaboration programs will be conducted in a manner consistent with the best interests of our business. In addition, if any of these partners withdraw support for these programs or proposed products or otherwise impair their development, our business could be negatively affected. Also, our inability to find a partner for any of our product candidates, may result in our termination of that specific product candidate program or evaluation of a product candidate in a particular indication. Even if we found a partner for one or more of our product candidates, there is no assurance that upon the approval of one or more of such product candidates we will be able to successfully co-commercialize such products.

In addition, our existing licenses and collaboration agreements, including our agreements with Acuitas, Arcturus, Boehringer Ingelheim, CEPI, CRISPR Therapeutics, Genmab, GSK and the Bill & Melinda Gates Foundation impose, and any future licenses, collaborations or other intellectual property agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. Furthermore, our licenses and collaboration agreements impose, and any future agreement we enter into may also impose, restrictions on our ability to license certain of our intellectual property to third parties or to develop or commercialize certain product candidates or

technologies. In spite of our best efforts, our collaborators may conclude that we have breached our obligations under our agreements, in which case, we may be required to pay damages and the collaborator may have the right to terminate the agreement. Any of the foregoing could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, enable a competitor to gain access to the licensed technology or disrupt our right to receive funding or milestone or royalty payments. See "section 2 — Business Overview — Collaborations."

In the future, we may enter into additional collaborations to fund our development programs or to gain access to sales, marketing or distribution capabilities. Under certain of our collaboration agreements, including our collaborations with Boehringer Ingelheim, CRISPR Therapeutics, Genmab and GSK, we grant our partners an exclusive license to develop and commercialize certain classes of products containing our mRNA technology for specific targets and receive license fees, research and development funding, milestone payments and/or, if a product is approved for marketing, sales royalties in return. Following the discovery and preclinical testing phase, in certain cases, our partners are solely responsible for the further development of the product candidate and therefore exercise full control over its further development and potential commercialization. In certain cases, including under our collaboration with Genmab, we have a limited right to co-commercialize collaboration products. While certain of our existing licenses and collaboration agreements, including our agreements with Boehringer Ingelheim, CRISPR Therapeutics, Genmab and GSK, impose development or commercialization obligations on our collaborators, we cannot be certain that our collaboration partners will allocate sufficient resources or attention to our collaboration programs or that they will progress our collaboration programs consistent with the best interests of our business. Our existing collaborations, and any future collaborations we enter into, therefore may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected by us or by health authorities, such as the FDA, the EMA or comparable foreign regulatory authorities;
- collaborators may dissolve, merge, be bought or may otherwise become unwilling to fulfill the initial terms of the collaboration with us;
- collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities or the actual or perceived competitive situation in a specific indication;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or may require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, licensors or licensees, including disagreements over proprietary rights, contract interpretation and breach of contract claims, payment obligations or the preferred course of development, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities, including financial obligations for us with respect to products or product candidates, or delays or withholding of any payments due or might result in litigation or arbitration, any of which would be time consuming and expensive, and could limit our ability to execute on our strategies;

- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or may use our proprietary information in such a way that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and

- collaborators may infringe, misappropriate or otherwise violate the intellectual property of third parties, which may expose us to litigation and potential liability.

If our collaborations on research and development candidates do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our proprietary product candidates. Moreover, our relationships with our partners may divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our program collaborators.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators in a timely manner. For more information on our current collaboration agreements, see section 2 — Business Overview — Collaborations."

Risks Related to the Development, Clinical Testing and Commercialization of Our Product Candidates

Our approach to the discovery and development of product candidates based on mRNA is unproven, and we do not know whether we will be able to successfully develop any products.

We focus on delivering mRNA encoding functional versions of proteins into cells without altering the underlying DNA. Our future success depends on the successful development of this novel therapeutic or vaccine approach. Relatively few mRNA-based product candidates have been tested in animals or humans, and the data underlying the feasibility of developing mRNA-based products are both preliminary and limited. To date, a limited number of products that utilize mRNA as a prophylactic vaccine against COVID-19 have been approved in the United States and Europe, subject to certain limitations. In addition, no product that utilizes mRNA as a therapeutic vaccine has been approved in the United States or Europe. We have not yet succeeded and may not succeed in demonstrating to the FDA or EMA the efficacy and safety of any of our product candidates in clinical trials or in obtaining marketing approval thereafter. We completed an interim data readout of safety, reactogenicity and immunogenicity in our Phase 1 clinical trial for our COVID-19 product candidate, CVnCoV, which has completed recruitment and dosing, but we are still monitoring patients, and have ongoing Phase 2a and Phase 2b/3 clinical trials. We have also completed an interim data readout of safety and immunogenicity in an ongoing Phase 1 clinical trial for our CV7202 (Rabies vaccine) product candidate and have ongoing Phase 1 clinical trials for our CV8102 (cMEL, ACC, SCC and HNSCC), Phase 1/2 clinical trials for BI 1361849 (formerly CV9202) (Non-Small-Cell Lung Cancer, or NSCLC). We have not yet completed any late-stage clinical studies. As such, there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our technology platform, or any similar or competitive mRNA platforms, will result in the development and regulatory approval of any products. There can be no assurance that any development problems we experience in the

future related to our technology platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. If clinical trials of our product candidates or production of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our technology platform. If we and our collaborators are unable to obtain approval for and effectively commercialize our product candidates, our business would be significantly harmed. Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain, and we may not be able to obtain approvals for the commercialization of any product candidates we may develop.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, our Phase 2b clinical trial with CV9104, one of our first generation vaccines based on protamine formulation, that was designed to evaluate the investigational mRNA-based cancer vaccine in patients with asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, failed to meet the primary endpoint of improving overall survival despite proceeding through preclinical and Phase 1 studies. Progression-free survival was similar in both arms of the clinical trial. In addition, our past programs with protamine-based vaccines (CV9201, CV9103, CV9104 and CV7201) were discontinued because the level of immunogenicity achieved in clinical trials was considered insufficient. BI 1361849 (formerly CV9202) is the only protamine-based vaccine formulation in current clinical trials. While we have assessed the results of past trials and these have informed our approach going forward, we can provide no assurance that future clinical trials will not be discontinued or fail to meet their specified endpoints. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In this regard, we expect to report the interim and final results of our ongoing clinical trials with respect to our COVID-19 vaccine candidate, CVnCoV, in the near future. For example, we are expecting to report a first data readout of our Phase 2a clinical trial and conduct a first case-driven interim analysis of our Phase 2b/3 clinical trial in the second quarter of 2021. If such results, or others, differ from previous reports or market expectations, the price of our common shares could decrease substantially. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

Clinical trials must be conducted in accordance with the FDA, EMA and comparable foreign regulatory authorities' legal requirements, regulations or guidelines and are subject to oversight by these governmental agencies and Institutional Review Boards, or IRBs, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced in accordance with current good manufacturing practices, or cGMP, and other requirements. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with good clinical practice, or GCP, standards. Failure to follow and document adherence to such regulations or other regulatory requirements may lead to significant delays in the availability of product for our clinical trials, result in the termination of or a clinical hold being placed on one or more of our clinical trials, or delay or prevent submission or approval of marketing applications for our product candidates.

To the extent our CROs fail to enroll participants for our clinical trials, fail to conduct the trial in accordance with GCP requirements or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. To date, we have not advanced clinical trials sufficient for obtaining marketing approvals for any of our product candidates. Our most advanced candidate is CVnCoV against SARS-CoV-2, which is in clinical development. Our other product candidates, CV7202

(Rabies), BI 1361849 (formerly CV9202) (NSCLC), CV8102 (Melanoma, Adenoidcystic Carcinoma, Squamous Cell Cancer of Skin and Head and Neck), are in early clinical development. All other of our research programs are in the preclinical development stage.

The completion of clinical trials for our clinical product candidates may be delayed, suspended or terminated as a result of many factors, including but not limited to:

- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site and changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials, including as a result of COVID-19;
- the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects;
- negative or inconclusive results, which may require us to conduct additional preclinical or clinical trials or to abandon projects that we expect to be promising;
- shortage of materials required for the production of our product candidates including due to events surrounding COVID-19;
- safety or tolerability concerns causing us to suspend or terminate a trial if it is determined that the participants are being exposed to unacceptable health risks;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of the product candidate falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of the product candidate to complete clinical trials on time, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials;
- lack of adequate funding to continue the clinical trial;
- developments observed in trials conducted by competitors for related technology that raises general FDA or foreign regulatory authority concerns about risk to patients of gene therapy technology;
- determination that the product will not be producible at the manufacturing stage; and
- transfer of manufacturing processes to larger-scale facilities operated by a CMO or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process.

Disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. The FDA, the EMA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants.

If we are required to conduct additional clinical trials or other testing of our product candidates that we develop beyond the trials and testing that we contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are unfavorable or are only modestly favorable, or if there are safety concerns associated with our other product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- remove the product from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or receiving marketing approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which may harm our business and results of operations. In addition, some of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of our product candidates.

Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are

subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed and result in increased costs and longer development periods or otherwise be adversely affected.

We will be required to identify and enroll a sufficient number of patients for our planned clinical trials. Trial participant enrollment could be limited in future trials given that many potential participants may be ineligible because of preexisting conditions, medical treatments or other reasons. We may not be able to initiate or continue clinical trials required by the FDA, EMA or other foreign regulatory agencies or any of our other product candidates that we pursue if we are unable to locate and enroll a sufficient number of eligible patients or volunteers to participate in these clinical trials.

Patient enrollment is affected by other factors, including:

- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- perceived safety and tolerability of the product candidate;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including standard-of-care and any new drugs that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;

- effects of the COVID-19 pandemic on our clinical trial sites;
- patient referral practices of physicians; and
- our ability to monitor patients adequately during and after treatment.

We also may encounter difficulties in identifying and enrolling such patients with a stage of disease appropriate for our ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials.

We may face continued business disruption and related risks resulting from of the COVID-19 pandemic, which could have a material adverse effect on our business plan or clinical trials.

The development of our product candidates could be disrupted and materially adversely affected by the COVID-19 global pandemic. The extent to which the COVID-19 pandemic impacts our business will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the evolving actions to contain COVID-19 or treat its impact, among others. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed (or continue to be paused or delayed) due to changes in hospital or university policies, federal, state or local regulations or restrictions, prioritization of hospital resources toward pandemic efforts, travel restrictions, concerns for patient safety in a pandemic environment, or other reasons related to the pandemic. Patient recruitment for our product candidates may be adversely impacted. For example, our ongoing trials for CV8102 may be delayed as a result of new oncology sites being inaccessible in Europe and the resulting increase in the competition for new patients. In addition, while we have not had any participants withdraw from our clinical trials or be prevented from accessing the clinical testing sites due to the COVID-19 pandemic, we can provide no assurance that patients will not withdraw from our trials in the future, which could delay our clinical development efforts for the relevant product candidates. Over the period from February to May 2020, sites in France, Italy and Spain were not available for trials. While these sites have resumed screening participants in June 2020, we can provide no assurance that sites will not be inaccessible again. In addition, participants enrolled in our CV7202 clinical trial could not access clinical sites for three months for blood draw samples, resulting in the need for us to adapt our clinical protocol to address the timing of site visits. We closely monitor the situation with the ongoing COVID-19 pandemic.

We are currently devoting significant resources to the development of a vaccine against COVID-19. Although there is no assurance that we will be able to complete development of the vaccine successfully or in a timely manner, such development may impair our ability to timely progress other product candidates in clinical trials and increases our costs. Upon the outbreak of the COVID-19 pandemic, we determined to make the development of a vaccine candidate against COVID-19 a priority and to use our large-scale GMP III facility to provide required material for a potential vaccine product candidate. While there is currently no larger production batch required for our other product candidates, this prioritization could impact clinical development of our other product candidates if such a production need arises. Our research personnel dedicated to infectious diseases initially focused its efforts on optimizing vaccine constructs in preparation of a Phase 1 clinical trial for our COVID-19 vaccine candidate, CVnCoV, and such team is currently focused on our expanding COVID-19 clinical programs, including our ongoing pivotal Phase 2b/3 clinical trial for CVnCoV, and finalizing the analysis of the Phase 1 clinical trial for CVnCoV and the first data readout for the Phase 2a clinical trial for CVnCoV. This focus may delay development of other potential infectious disease product candidates. We also postponed initially planned preclinical work on an influenza vaccine with the Bill & Melinda Gates Foundation to later in 2021. We can provide no assurances that our focus on clinical development of a vaccine candidate against COVID-19 will not adversely impact clinical development of our other product candidates.

Some of our clinical trial sites are located in countries, which have experienced a shortage of medical staff due to the COVID-19 pandemic. In the event that clinical trial sites are adversely impacted or closed to enrollment in our trials, such impacts or closures could have a material adverse effect on our clinical trial plans and timelines. We may face difficulties enrolling or retaining patients in our ongoing and planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to our clinical trial sites because of the pandemic. In addition, due to the disruption of the pandemic to the global business outlook, we may face a shortage in the supply of materials that are necessary for the production of our product candidates. We cannot predict whether we will be

able to continue to enroll new patients in our clinical trials, whether the clinical sites will continue to operate in a reduced capacity for the long term and whether strict restrictions on social distancing and mobility will resume due to the next wave of COVID-19. For example, some countries that recently lifted restrictions imposed due to COVID-19 have reported increasing number of COVID-19 cases and as a result reimposed restrictions that could delay our clinical trials. Due to the evolving situation with respect to COVID-19, we are unable to predict the long-term consequences of COVID-19 on our business and ability to progress clinical development of our product candidates.

Moreover, if COVID-19 continues to spread, we may experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions in preclinical studies due to restricted or limited operations at our research and development laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies; and
- interruption or delays to our sourced discovery and clinical activities.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

In addition, quarantines, travel restrictions, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. We have taken a series of actions aimed at safeguarding our employees and business associates, including regular PCR-based COVID-19 testing, implementing a work-from-home policy for employees except for those related to our production and laboratory operations, and these arrangements may cause reduced productivity of our employees and/or delays or disruptions of our business operations.

Our suppliers, licensors or collaborators could also be disrupted by conditions related to COVID-19, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations. If our suppliers, licensors, CMOs, CROs or collaborators are unable or fail to fulfill their obligations to us for any reason, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and during the duration of, COVID-19 may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. COVID-19 and actions taken to reduce its spread continue to rapidly evolve. We continue to assess the impact COVID-19 may have on our clinical trial timelines, our ability to enroll candidates for clinical trials and obtain the materials that are required for the production of our product candidates, but there can be no assurance that this assessment will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences. The extent to which COVID-19 and global efforts to contain its spread may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section, such as those relating to the timing and results of our clinical trials, our ability to obtain materials that are required for the production of our product candidates, and our financing needs.

Our proprietary product candidates are still in preclinical or clinical development. We cannot give any assurance that any of our product candidates will receive regulatory approval, and if we are unable to obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

Our proprietary product candidates are still in preclinical or clinical development. Although we may receive certain payments from our collaboration partners, including upfront payments, payments for achieving certain development, regulatory or commercial milestones and royalties, our ability to generate revenue from our product candidates' sales is dependent on receipt of regulatory approval for, and successful commercialization of, such product candidates, which may never occur. Our business and future success is in particular dependent on our ability to develop, either alone or in partnership, successfully, receive regulatory approval for and then successfully commercialize our proprietary product candidates. Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales or royalties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical and/or clinical studies;
- negative or inconclusive results from our clinical trials, the clinical trials of our collaborators or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- successful enrollment of patients in, and completion of, clinical trials;
- strategic commitment to particular product candidates and indications by us and our collaborators;
- receipt of regulatory authorizations from applicable regulatory authorities for future clinical trials;
- receipt of product approvals, including marketing approvals, from applicable regulatory authorities;
- successful completion of all safety studies required to obtain regulatory approval in the United States, the European Union and other jurisdictions for our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;

- acceptance of the product candidates, if and when approved, by patients, the medical community and third party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement from third party payors;
- obtaining, maintaining, enforcing and defending intellectual property and intellectual property-related claims;
- maintaining a continued acceptable safety and quality profile of the product candidates following approval; and
- maintaining a continued, sufficient supply of drug substance in acceptable quality.

If we do not achieve one or more of these factors in a complete and timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially adversely affect our business, financial condition, results of operations and prospects and, in case of product candidates, technologies and licenses we have acquired, may result in a significant impairment of assets.

Although we expect to submit biologics license applications, or BLAs, for our mRNA-based product candidates in the United States, and in the European Union, mRNA-based medicines have been classified as gene therapy medicinal products, other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications. In addition, we have not previously submitted a BLA, to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and the EU, and potentially in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We commenced operations in 2000 and have a long track record of performing clinical trials with multiple product candidates since 2008. Our operations to date have been limited to establishing our company, raising capital, developing our proprietary mRNA technology platform, identifying and testing potential product candidates and conducting clinical trials. We have not yet demonstrated an ability to successfully conduct late-stage clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control.

Accordingly, shareholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us, our collaboration partners or the regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive regulatory approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates and require us to take our approved product(s) off the market;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication, or submission of field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- actual or potential drug-related side effects could negatively affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates;
- market acceptance of our products by patients and physicians may be reduced and sales of the product may decrease significantly;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which 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;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide or be required to remove such product candidates from the marketplace;
- we could be sued and potentially held liable for injury caused to individuals exposed to or taking our product candidates;
- sales of the product(s) may decrease substantially; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and therefore could have a material adverse effect on our business, financial condition, results of operations and prospects.

To date, a limited number of products that utilize mRNA as a prophylactic vaccine against COVID-19 have been approved in the United States and Europe, subject to certain limitations. In addition, no product that utilizes mRNA as a therapeutic vaccine has been approved in the United States or Europe. As such, mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of medicines.

No product that utilizes mRNA as a therapeutic vaccine has been approved in the United States or Europe. In addition, a limited number of products that utilize mRNA as a prophylactic vaccine against COVID-19 have been approved by the FDA, EMA and other regulatory agencies. Such approvals were provided after parallelized clinical trials, and may be subject to ongoing review by the FDA, EMA or other regulatory agencies, and in some cases may be canceled, expire or subject to lengthy renewal. Successful discovery, development and continued market presence of mRNA-based (and other) products by either us or our collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic or clinical holds, fail to reach the market or stay in the market for many reasons, including:

- discovery efforts aimed at identifying potential immunotherapies may not be successful;
- nonclinical or preclinical study results may show product candidates to be less effective than desired or have harmful or problematic side effects;
- clinical trial results may show the product candidates to be less effective than expected, including a failure to meet one or more endpoints or have unacceptable side effects or toxicities;
- manufacturing failures or insufficient supply of GMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make our product candidates commercially unattractive;
- our improvements in the manufacturing processes may not be sufficient to satisfy the clinical or commercial demand of our product candidates or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of GMP materials could impact the safety, tolerability and efficacy of our product candidates;
- pricing or reimbursement issues or other factors could delay clinical trials or make any immunotherapy uneconomical or noncompetitive with other therapies;
- the failure to timely advance our programs or receive the necessary regulatory approvals, or a delay in receiving such approvals, due to, among other reasons, 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, BLA, MAA or the equivalent application, discussions with the FDA or the 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; and
- the proprietary rights, products and technologies of our competitors may prevent our immunotherapies from being commercialized.

Although we expect to submit biologics license applications, or BLAs, for our mRNA-based product candidates in the United States and in the European Union, mRNA-based medicines have been classified as gene therapy medicinal products. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA-based medicines are designed not to irreversibly change cell DNA. Side effects observed in other gene therapies, however, could negatively impact the perception of immunotherapies despite the differences in mechanism. Due to the circumstances surrounding the approval of mRNA-based vaccines against COVID-19, the regulatory pathway for future mRNA products in the United States and other jurisdictions for approval is uncertain. The length of time necessary to complete clinical trials and submit an application for marketing approval by a regulatory authority varies significantly from one pharmaceutical product to the next and may be difficult to predict.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable and if we fail to obtain regulatory

approval in any jurisdiction, we will not be able to commercialize our products in that jurisdiction and our business, results of operations, financial condition and prospects, may be materially adversely affected.

The time required to obtain approval by the FDA, EMA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval laws, regulations, policies or the type and amount of clinical data or other information necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the designs or our execution of clinical trials might not be considered adequate, or the results of clinical trials may not meet the level of statistical significance required, by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected may not be sufficient to support the submission of a BLA or other submission, or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of third party manufacturers with which we contract for clinical and commercial supplies; and
- the laws, regulations or policies of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data or other regulatory submissions insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. The FDA, the EMA and other regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In order to commercialize our products in more than one jurisdiction, we will be required to obtain separate regulatory approvals in each market and to comply with numerous and varying regulatory requirements. The approval procedures vary from country to country and may require additional testing, administrative review periods, agreements with pricing authorities or other steps. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, in many countries outside the United States and in particular in many of the Member States of the European Union, a product must undergo health economic assessments to agree on pricing and/or be approved for reimbursement before it can be approved for sale in that country, or before it becomes commercially viable. The FDA and the EMA may come to different conclusions regarding approval of a marketing application. Approval by the FDA or EMA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA or EMA. In addition, our failure to obtain regulatory approval in any

country may delay or have negative effects on the process for regulatory approval in other countries. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. We may not obtain regulatory approvals on a timely basis, if at all. We may not be able to submit applications for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. We may be required to conduct additional preclinical studies or clinical trials, which would be costly and time consuming. If we or any future partner are unable to obtain regulatory approval for our product candidates in one or more significant jurisdictions, then the commercial opportunity for our product candidates, and our business, results of operations, financial condition and prospects, may be materially adversely affected.

The regulatory landscape that will govern our product candidates is uncertain. Regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

The regulatory requirements to which our product candidates will be subject are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and authorizes its initiation. Conversely, the FDA can place an Investigational New Drug Application, or IND, on clinical hold even if such other entities have provided a favorable review. Furthermore, gene therapy clinical trials may also require evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. The IBC assesses the safety of the research and identifies any potential risk to the public health or the environment, and such assessment may result in some delay before initiation of a clinical trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union a special committee called the Committee for Advanced Therapies, or CAT, was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products, or ATMPs, to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As the regulatory landscape for our product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product sales revenue to maintain our business.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may materially adversely affect our business, prospects, financial condition and results of operations. We have not previously submitted a BLA, to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate and never received regulatory approval for any of our product candidates. Even if the FDA, EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, product sampling, adverse event reporting, storage, advertising, marketing, promotion and recordkeeping for the product will be

subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. There also are continuing, annual program user fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product. For example, the FDA has the authority to require a REMS as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory;
- product recalls;
- fines, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA, EMA or a comparable foreign regulatory authority to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- requirements to conduct additional clinical trials, change our product labeling or submit additional applications or application supplements;
- product seizure or detention, or refusal to permit the import or export of products;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, regulatory policies may change or additional government regulations or legislation may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we fail to comply with existing requirements, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained or face regulatory or enforcement actions, which may materially adversely affect our business, prospects, financial condition and results of operations.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular,

a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our product candidates.

Further, the policies of FDA, EMA and other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or to adopt new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

A breakthrough therapy designation by the FDA for a product candidate may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval.

We may in the future seek a breakthrough therapy designation for one or more product candidates. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

Because we are developing product candidates for the treatment or prevention of diseases in which there is little clinical experience using new technologies, there is increased risk that the FDA, the EMA or other regulatory authorities may not consider

the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

As we are developing novel treatments and preventative measures for diseases in which we believe there is limited clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, EMA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union or other jurisdictions, if ever. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

During the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. Because our initial focus is to identify and develop product candidates to treat or prevent diseases in which there is little clinical experience using new technologies, there is heightened risk that the FDA, the EMA or other regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results. In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA determines that our success criteria is sufficiently validated and clinically meaningful, we may not achieve the prespecified endpoints to a sufficient degree of statistical significance.

This may be a particularly significant risk for many of the genetically defined diseases for which we plan to develop product candidates because many of these diseases have small patient populations, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Further, even if we do achieve the prespecified criteria, the results may be unpredictable or inconsistent with the results of the non-primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. The EMA and other regulatory authorities may make similar comments with respect to these endpoints and data. Any product candidate we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

We and our collaboration partners have conducted and intend to conduct additional clinical trials for selected product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or may require additional U.S.-based trials.

We and our collaboration partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, particularly in the European Union where we are headquartered. In addition, in September, we initiated a Phase 2a clinical trial for our COVID-19 vaccine candidate, CVnCoV, in Peru and Panama, and, in December, we initiated a Phase 2b/3 clinical trial for CVnCoV in Europe and Latin America.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be conducted by qualified investigators in accordance with GCPs, and the FDA must be able to validate the trial data through an on-site inspection, if necessary. Generally, the patient population for any clinical trial conducted outside of the United States must be representative of the population for which we intend to seek approval in the United States. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any clinical trials that we or our collaboration partners conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our ability to develop and market these or other product candidates in the United States. In other jurisdictions, for instance, in Japan, there is a similar risk regarding the acceptability of clinical trial data conducted outside of that jurisdiction.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;

- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

If any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third party payors, in which case revenue generated from their sales would be limited.

The commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling for a product candidate;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of coverage and extent of reimbursement from managed care plans and other third party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second or third-line therapy for particular diseases;
- whether the product can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third party payors on the benefits of our product candidates may require significant resources and may never be successful.

The United Kingdom's withdrawal from the European Union, or Brexit, could result in increased regulatory and legal complexity, and impose additional challenges in securing regulatory approval of our product candidates in the European Union and the rest of Europe.

We could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and the European Union entered

into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. We cannot predict whether or not the United Kingdom will significantly alter its current laws and regulations in respect of the pharmaceutical industry or how the Trade and Cooperation Agreement will be interpreted and, if so, what impact any such alteration or interpretation would have on us or our business. Moreover, we cannot predict the impact that Brexit will have on (i) the marketing of pharmaceutical products, (ii) the process to obtain regulatory approval in the United Kingdom for product candidates or (iii) the award of exclusivities that are normally part of the European Union legal framework.

Brexit may also result in a reduction of funding to the EMA if the United Kingdom no longer makes financial contributions to European institutions, such as the EMA. If the United Kingdom funding is so reduced, it could create delays in the EMA issuing regulatory approvals for our products and product candidates and, accordingly, have a material adverse effect on our business, financial position, results of operations and future growth prospects.

As a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union would have and how such withdrawal would affect us, and the full extent to which our business could be adversely affected.

In addition, following the Brexit vote, the European Union decided to move the headquarters of the EMA from the United Kingdom to the Netherlands. The EMA is currently finishing its relocation process to the Netherlands. However, as a result of the move, the EMA has lost a significant percentage of its employees and was not able to hire at least the same amount of employees that left the EMA upon the movement of its headquarters from the United Kingdom to the Netherlands. This raises the possibility that new drug approvals in the European Union could be delayed as a result of such employee shortage.

Our product candidates for which we may seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

To the extent any of our product candidates approved as a biological product under a BLA qualifies for a 12-year period of exclusivity, for which we make no assurances, there is a risk that such exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA 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 any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being

developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to the Manufacturing of Our Product Candidates

The manufacture of mRNA-based medicines is complex and manufacturers often encounter difficulties in production, especially in the field of biologics. If we or any of our third party manufacturers encounter difficulties, our ability to provide product candidates for clinical trials or products, if approved, to patients or future customers could be delayed or halted.

The manufacture of mRNA-based medicines is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and analytics. We and our third party manufacturers must comply with cGMP, regulations and guidelines for the manufacturing of our product candidates used in preclinical studies and clinical trials and, if approved, marketed products. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up and validating initial production. Before 2020, the mRNA quantities produced globally were very limited compared to the quantities produced since mRNA vaccines were approved as prophylactic vaccines to protect from SARS-CoV-2. Large-scale mRNA vaccine production requires a high level of (i) equipment to build and run new facilities and (ii) raw materials to produce mRNA and to formulate the drug substance in the required volumes. The current demand for mRNA vaccines is unprecedented and bears the risk of overloading and hence delaying regular supply chains. This risk is further extended by export restrictions imposed by countries to protect their own supplies, some of which can only be resolved on a political level.

Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities where our product candidates are made, such manufacturing facilities may be closed for an extended period of time to investigate and remedy the contamination. Shortages of raw materials may also extend the period of time required to develop our product candidates.

Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products

before and after such changes. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, there are risks associated with large-scale manufacturing for clinical trials or commercial-scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If we or our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We cannot assure you that any disruptions or other issues relating to the manufacture of any of our product candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could delay or impede the development and commercialization of any of our product candidates or products and could have an adverse effect on our business, prospects, financial condition and results of operations.

We and our third party manufacturers and suppliers could be subject to liabilities, fines, penalties or other sanctions under federal, state, local and foreign environmental, health and safety laws and regulations if we or they fail to comply with such laws or regulations or otherwise incur costs that could have a material adverse effect on our business.

We manufacture and produce mRNA-based active ingredients for our product pipeline. We also currently rely on and expect to continue to rely on third parties for the manufacturing and supply of active pharmaceutical ingredients, or API, and drug products of our product candidates. We and these third parties are subject to various federal, state, local and foreign environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, labeling, transportation, use, manufacture, storage, treatment and disposal of hazardous materials and wastes and worker health and safety. We do not have control over a manufacturer's or supplier's compliance with environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or in certain circumstances, an interruption in operations, any of which could adversely affect our business and financial condition.

With respect to any hazardous materials or waste which we are currently, or in the future will be, generating, handling, transporting, using, manufacturing, storing, treating or disposing of, we cannot eliminate the risk of contamination or injury from these materials or waste, including at third party disposal sites. In the event of such contamination or injury, we could be held liable for any resulting damages and liability. We also could be subject to significant civil or criminal fines and penalties, cessation of operations, investigation or remedial costs or other sanctions for failure to comply with applicable environmental, health and safety laws. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts or otherwise have a material adverse effect on our business.

Undetected errors or defects in our production could harm our reputation or expose us to product liability claims.

Defects in the cGMP materials we produce may damage the third parties' businesses we work with and could harm their and our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in products

made with our cGMP materials. In addition, if we do not meet industry or quality standards, if applicable, such products may be subject to recall. A material liability claim, recall or other occurrence that harms our reputation or decreases market acceptance of such products could harm our business and operating results.

Risks Related to Our Reliance on Collaborators and Other Third Parties

We rely on third parties to conduct our nonclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third party CROs to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, GCP, Good Laboratory Practice, or GLP, and other regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and comparable foreign regulatory authorities for all of our product candidates in nonclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, trial sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our nonclinical and clinical trials may be deemed unreliable and the EMA, FDA, or other regulatory authorities may require us to perform additional nonclinical and clinical trials before approving our marketing applications. In addition, even if, for example, the EMA finds our data generated in our nonclinical and clinical trials reliable for approving a marketing application, there is no assurance that other regulatory authorities like the FDA will find such data reliable and sufficient for approving a similar market application. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third party CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

If we or any third party manufacturer of our product candidates is unable to increase the scale of production of our product candidates, and/or increase the product yield of manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates in our pipeline or that we may develop, our third party manufacturers will be required to increase their production and optimize their

manufacturing processes while maintaining the quality of the product. The transition to larger scale and more robust production could prove difficult or costly. Further, any claims in our manufacturing process as a result of scaling up or optimization of the manufacturing, supply and fill and finish process may result in the need to obtain regulatory approvals. If we or our third party manufacturers are not able to optimize manufacturing process to increase the product yield for our product candidates or cGMP production requirement for clinical studies, or are unable to produce increased amounts of our product candidates while maintaining the quality of the product or generally unable to produce the right quality, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits. Difficulty in achieving commercial-scale-up production or production optimization or the need for additional regulatory approvals as a result could have a material adverse impact on our business and results of operations.

Risks Related to Our Intellectual Property Rights

If we are unable to obtain, maintain and enforce intellectual property protection for our products or product candidates, or if the scope of our intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be materially adversely affected.

Our success depends on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our current and future proprietary product candidates. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technology, manufacturing processes, products and product candidates. We and our collaborators have primarily sought to protect our proprietary positions by filing patent applications in the United States and abroad related to our proprietary technology, manufacturing processes, and product candidates that are important to our business. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, we or our collaborators, may only pursue, obtain or maintain patent protection in a limited number of countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate or narrow the scope of an issued patent or prevent our pending patent applications from issuing as patents. Because patent applications in the United States, Europe and many other non-U.S. jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or any in-licensed issued patents or pending patent applications, or that we or our licensors were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Even if patents do successfully issue, our owned or in-licensed patents may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or otherwise provide us with a competitive advantage. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. In addition, third parties may challenge the validity, enforceability, ownership, inventorship or scope of any of our patents. Any successful challenge to any of our patents could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop and could impair or eliminate our ability to collect future revenues and royalties with respect to such products or product candidates. If any of our patent applications with respect to our product candidates fail to issue as patents, if their breadth or strength of protection is narrowed or threatened, or if they fail to provide meaningful exclusivity or competitive position, it could dissuade companies from collaborating with us or otherwise adversely affect our competitive position.

The patent position of pharmaceutical companies is generally uncertain because it involves complex legal, scientific and factual considerations for which legal principles remain unsolved. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably, and can change. Additionally, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain

countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement, misappropriation, or other violation of our patents or other intellectual property, including the unauthorized reproduction of our manufacturing or other know-how or the marketing of competing products in violation of our intellectual property rights generally. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Further, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize the patented product candidate. Third parties may have or obtain rights to patents which they may use to prevent or attempt to prevent us from practicing our patented technology or commercializing any of our patented product candidates. If any of these other parties are successful in obtaining valid and enforceable patents, and establishing our infringement of those patents, we could be prevented from selling our products unless we were able to obtain a license under such third party patents, which may not be available on commercially reasonable terms or at all. In addition, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency of competent jurisdiction may find our patents invalid or unenforceable. Our competitors and other third parties may also be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us. Proceedings to enforce our patent rights, whether or not successful, 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 held unenforceable, 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 intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop, acquire or license.

Our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our patents and technology, including patents and technology relating to our yellow fever product candidate, was funded in part by the U.S. government. As a result, the U.S. government has certain rights to such patent rights and technology, which include march-in rights. When new technologies are developed with government funding, in order to secure ownership of such patent rights, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. Additionally, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. Accordingly, we have granted the U.S. government a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States, the inventions described in the patents and patent applications relating to our technology or one or more of our product candidates. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The government's rights may also permit it to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use such government-funded technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. If we fail to comply with those requirements, we could lose our ownership of or other rights to any patents subject to such regulations. Any exercise by the government of any of the foregoing rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In Germany, the German federal government, and the Federal Ministry of Health and downstream authorities in the event of a national epidemic, have the right to order the use of our owned and in-licensed patents in the interest of the public welfare or the security of the Federal Republic. The German government may issue such an order with respect to our owned or in-licensed patents and we may lose exclusivity with respect to the technologies and product candidates covered by such patents. For example, if the German government determines that we are unable to develop our COVID-19 vaccine candidate on a timeline or at a scale that is necessary to respond to the COVID-19 pandemic, it may issue a use order for the patents covering our development of the COVID-19 vaccine. We would be entitled to compensation in the event a use order is issued with respect to our owned or in-licensed patents; however, such compensation may be less than what we could otherwise receive and any such use order could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Additionally, the research resulting in certain of our patents and technology, including patents and technology relating to our CV8102 and RSV product candidates, was funded in part by the German Ministry of Education and Research, or the BMBF. Results of such government funded research projects must, subject to certain conditions, be made available free of charge for academic research and teaching in Germany and must be published in half-yearly interim reports and a final report following completion of the funded work. Information relating to intellectual property generated, commercial expectations, scientific chances of success and next steps and certain additional information must be disclosed to the German government and must be disclosed to third parties for academic research and teaching upon request under a written confidentiality agreement. The BMBF additionally has, in the case of a special public interest, a non-exclusive and transferable right to use intellectual property generated as part of the funded work. Contracts with third parties relating the exploitation of the results of the funded work must be disclosed to the BMBF and any such contracts with parties outside of the European Union require the prior consent of the BMBF to the extent they deviate from an exploitation plan previously approved by the BMBF. Additionally, if we fail to use or commercialize the results of the funded work we may be required to grant third parties licenses to use such results. In certain scenarios, including if we come under the decisive influence of foreign investors, the funded results are exclusively or predominantly used outside Germany without the prior consent of the BMBF or if we are in breach of our obligations under the grant, the grant funding, including funding already received, can be revoked.

Furthermore, certain of our patents and technology, including patents and technology relating to our rotavirus, malaria, Lassa virus and SARS-CoV-2 product candidates, were funded in part by grants from nonprofit third parties, including the Bill & Melinda Gates Foundation and CEPI. We are required to fulfill certain contractual obligations with respect to products created using such grant funding, including making certain products available at an affordable price in a list of clearly defined low and lower-middle income countries and ensuring that certain products are available in geographic regions where there has been an outbreak of an infectious disease at certain reduced economic rates. See "section 2 — Business Overview — Collaborations."

Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available, however, the life of a patent and the protection it affords is limited. Given the amount of time required for the development, testing, regulatory review and approval of new product candidates, our patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be further reduced. Even if patents covering our product candidates are obtained, once such patents expire, we may be vulnerable to competition from similar or biosimilar products. The launch of a similar or biosimilar version of one of our products would likely result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under any license, collaboration or other intellectual property agreements, disagree over contract interpretation, or otherwise experience disruptions to our business relationships with our collaborators or licensors, we could lose intellectual property rights that are necessary to our business.

We rely, in part, on license, collaboration and other intellectual property agreements. These may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future.

In addition, our existing licenses and collaboration agreements, including our agreements with Acuitas, Arcturus, Boehringer Ingelheim, CEPI, CRISPR Therapeutics, Genmab, GSK and the Bill & Melinda Gates Foundation impose, and any future licenses, collaborations or other intellectual property agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. Our licenses and collaboration agreements, including our agreement with Genmab, impose, and any future agreement we enter into may also impose, restrictions on our ability to license certain of our intellectual property to third parties or to develop or commercialize certain product candidates or technologies. In spite of our best efforts, our licensors, licensees and collaborators may conclude that we have breached our obligations under our agreements, or that we have used the intellectual property licensed to us in an unauthorized manner, in which case, we may be required to pay damages and the licensor, licensee or collaborator may have the right to terminate the agreement. Any of the foregoing could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, enable a competitor to gain access to the licensed technology or disrupt our right to milestone or royalty payments. We might not have the necessary rights or the financial resources to develop, manufacture or market our current or future product candidates without the rights granted under our licenses, and the loss of sales or potential sales in such product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

Disputes may arise regarding intellectual property subject to licensing, collaboration or other intellectual property agreements, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- 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;
- our financial obligations under the license agreement;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. We cannot be certain that these patents and applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such intellectual property, or lose rights to such intellectual property, the rights we have licensed and our exclusivity may be reduced or eliminated and our right to develop and commercialize any of our products that are subject to such licensed rights could be adversely affected.

Moreover, our rights to our in-licensed patents and patent applications may depend, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be

adversely affected. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. In addition, the development of certain of our product candidates is funded by grants that impose certain pricing limitations on such product candidates and limit our ability to commercialize such product candidates and to achieve or maintain profitability. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have on reasonable terms or at all, we may have to abandon development of the relevant program or product candidate and our business, financial condition, results of operations and prospects could suffer.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful and could result in a court or administrative body finding our patents to be invalid or unenforceable.

Even if the patent applications we own or license are issued, third parties may infringe our patents. To counter infringement, we may be required to file infringement claims, which can be expensive and time consuming. If we initiate legal proceedings against a third party to enforce a patent covering any of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness (or inventive step), written description or enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. In an infringement proceeding, a court may decide that one or more of our patents is not valid, is unenforceable or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates or provide any competitive advantage. For example, one of our manufacturing related U.S. patents was invalidated in an *inter partes* review proceeding and certain of our European patents relating to RNA-based adjuvants/immunostimulants and RNA-coded antibodies have been revoked in European opposition proceedings. Some of these decisions are currently on appeal and continuation or divisional applications of certain of the revoked patents have been filed and are currently under examination, although there can be no assurance that any such appeal will be successful or that any such patent applications will issue as patents that provide us with any competitive advantage. Additionally, several of our European and Australian patents relating to sequence optimization of mRNA, RNA-based adjuvants/immunostimulants, mRNA formulation, mRNA-based vaccination of specific patient populations, combination of mRNA-based vaccination and inhibition of the PD-1 pathway, combination of mRNA-based vaccination and agonistic OX40 antibodies, methods for RNA analysis, intratumoral (m)RNA treatment, and production of mRNA cocktails are currently subject to opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose part or all of the patent protection on one or more of our product candidates, which could result in our competitors and other third parties using our technology to compete with us. Such a loss of patent protection could have a material adverse impact on our business.

Interference proceedings, or other similar enforcement and revocation proceedings, provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could

be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, infringement, misappropriation or other violation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights of third parties with respect to our product candidates, including interference and post-grant proceedings before the USPTO. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, formulation, use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that we may or may not be aware of which may later result in issued patents that our product candidates may be accused of infringing. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction based on interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims at issue are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us, especially as we gain greater visibility and market exposure as a public company.

Third parties have, and may in the future have, U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds or methods of use for the treatment of the disease indications for which we are developing our product candidates that may cover our product candidates. For example, we are aware of certain third party U.S. and non-U.S. issued patents and patent applications, including those of our competitors, that relate to RNA-encoded antibodies or antigens in LNPs and LNP-formulated RNA that may be construed to cover the LNP-formulated RNA technology used in our vaccines and protein and antibody therapies. We are also aware of certain third party U.S. and non-U.S. patents and patent applications, including those

of our competitors, that relate to coronavirus vaccines and treatments and vaccines against other infectious diseases and we expect such third parties to have filed additional patent applications, which have not yet been published and to file additional patent applications in the future.

In the event that any of these patent rights were asserted against us, we believe that we have defenses against any such action, including that such patents would not be infringed by our product candidates and/or that such patents are not valid. However, if any such patent rights were to be asserted against us and our defenses to such assertion were unsuccessful, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are required to obtain a license from any third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate, we may not be able to obtain such required license on commercially reasonable terms or at all. In particular, any of our competitors that control intellectual property that we are found to infringe may be unwilling to provide us a license under any terms. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. Further, if a patent infringement suit is brought against us or our third party service providers and if we are unable to successfully obtain rights to required third party intellectual property, we may be required to expend significant time and resources to redesign our product candidates, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis, and may delay or require us to abandon our development, manufacturing or sales activities relating to our product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation and other proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, intellectual property litigation or other legal proceedings relating to our, our licensor's or other third parties' intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. Patent litigation and other proceedings may also absorb significant management time. If not resolved in our favor, litigation may require us to pay any portion of our opponents' legal fees. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Our competitors or other third parties may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from our participation in patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in certain jurisdictions in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common shares may decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes to the patent law in the United States and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the

enforcement or defense of our issued patents, thereby impairing our ability to protect our technologies and product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Specifically, the America Invents Act reforms United States patent law in part by changing the U.S. patent system from a "first to invent" system to a "first inventor to file" system. Under a "first inventor to file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor was the first to invent the invention. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications. Circumstances may arise that could prevent us from promptly filing patent applications on our inventions and allow third parties to file patents claiming our inventions before we are able to do so. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings, including reexamination proceedings, *inter partes* review, post grant review and derivation proceedings. These adversarial proceedings at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than in a litigation in a U.S. federal court. One of our manufacturing related patents has been invalidated in an *inter partes* proceeding and if any of our other patents are challenged by a third party in a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss or narrowing of the challenged patent right to us.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways. In addition, the complexity and uncertainty of European patent laws have also increased in recent years. Complying with these laws and regulations could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We may be subject to claims by third parties asserting that our employees, consultants, independent contractors or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property and proprietary technology.

Many of our current and former employees, consultants, and independent contractors including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of such individual's current or former employers, or that patents and applications we have filed to protect inventions of these individuals, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against such claims.

If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on an exclusive basis or on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and independent contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, or such agreements may be breached or alleged to be ineffective, and the assignment may not be self-executing, which may result in claims by or against us related to the ownership of such intellectual property or may result in such intellectual property becoming assigned to third parties. If we fail in enforcing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection, including patents licensed from third parties, depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our patents and patent applications and any patent rights we may own or license in the future. Additionally, the USPTO and various government patent agencies outside the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors fail to maintain the patents and patent applications covering or otherwise protecting our product candidates, it could have a material adverse effect on our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent applications in-licensed from a third party, any failure on our part to maintain the in-licensed intellectual property could jeopardize our rights under the relevant license and may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extensions and data exclusivity for each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. In the European Union, a maximum of five and a half years of supplementary protection can be achieved for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection. However, we may not receive an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Certain employees and patents are subject to German law.

A significant number of our personnel work in Germany and are subject to German employment law. Inventions which may be the subject of a patent or of protection as a utility model as well as technical improvement proposals for other technical innovations that may not be the subject of a patent or of protection as a utility model made by such employees are subject to the provisions of the German Act on Employees' Inventions (*Gesetz über Arbeitnehmererfindungen*), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes may occur between us and our current or former employees pertaining to the sufficiency of compensation paid by us, allocation of rights to inventions under this act, or alleged non-adherence to the provisions of this act, any of which may be costly to resolve and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees retain rights to patents they invented or co-invented and disclosed to us prior to October 1, 2009 if the employee inventions were not actively claimed by us after notification by the employee inventors. While we believe that all of our current and past German employee inventors have assigned to us their interest in inventions and patents they invented or co-invented, there can be no assurance that all such assignments are fully effective. Therefore, there can be no assurance that present or former employees do not hold rights to intellectual property used by us or that such employees will not demand the registration of intellectual property rights in their name or demand damages pursuant to the German Act on Employees' Inventions or other applicable laws. Even if we lawfully own all inventions of our employee inventors who are subject to the German Act on Employees' Inventions, we are required under German law to reasonably compensate such employees for the use of the inventions. If we are required to pay increased compensation or face other disputes under the German Act on Employees' Inventions, our business, financial condition, results of operations and prospects could be adversely affected.

The German Act on Employees' Inventions does not generally apply to managing directors, supervisory directors, freelancers or agents who are not employees under German labor law. Unless the German Act on Employees' Inventions has been referred to in the respective services agreements, inventions and intellectual property rights created by such inventors must be assigned to us by contract. While we believe that all of our managing directors, supervisory directors, freelancers or agents which are not employees have assigned to us their interest in inventions and patents required for our course of business, there can be no assurance that all such assignments are fully effective. If any of our current or past employees, managing directors, supervisory directors, freelancers or agents obtain or retain ownership of any inventions or related intellectual property rights that we believe we own, we may lose valuable intellectual property rights and be required to obtain and maintain licenses from such persons to such inventions or intellectual property rights, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain a license to any such person's interest in such inventions or intellectual property rights, we may need to cease the development, manufacture, and commercialization of one or more of our product candidates or the product candidates we may develop. In addition, any loss of exclusivity of our intellectual property rights could limit our ability to stop others from using or commercializing similar or identical technologies and products. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be materially adversely affected.

In addition to patent protection, we also rely on trade secrets and confidentiality agreements to protect other proprietary information that is not patentable or that we elect not to patent. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, independent contractors, collaborators, CMOs, CROs and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or entity or made known to the individual or entity by us during the course of the individual's or entity's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees as well as our personnel policies also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property (to the extent not covered by the German Act on Employees' Inventions) or that we may obtain full rights to such inventions at our election. However, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes and cannot guarantee that individuals with whom we have these agreements will comply with their terms. We also face the risk that present or former employees could continue to hold rights to intellectual property used by us, may demand the registration of intellectual property rights in their name, and demand damages

pursuant to the Patent Act. In addition, present or former employees may demand damages due to violation of obligations under the German Act on Employees' Invention. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets.

We may not have adequate remedies in the event of unauthorized use or disclosure of our proprietary information in the case of a breach of any such agreements and our trade secrets and other proprietary information could be disclosed to third parties, including our competitors. Many of our partners also collaborate with our competitors and other third parties. The disclosure of our trade secrets to our competitors, or more broadly, would impair our competitive position and may materially harm our business, financial condition, results of operations and prospects. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how. In addition, others may independently discover or develop substantially equivalent or superior proprietary information and techniques, and the existence of our own trade secrets affords no protection against such independent discovery.

We may not be successful in obtaining necessary intellectual property rights to product candidates for our development pipeline through acquisitions and in-licenses.

Although we intend to develop product candidates through our own internal research, we may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any product candidates from third parties on an exclusive basis or commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify product candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such product candidates.

The in-licensing and acquisition of third party intellectual property is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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. Third parties may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property 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 intellectual property 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 intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary 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, could put 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 intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. 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 such patent. 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.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business, financial condition, results of operations and prospects may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names or marks which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business, financial condition, results of operations and prospects may be adversely affected.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our proprietary and intellectual property rights is uncertain because such rights offer only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop products that are similar to, or better than, our product candidates in a way that is not covered by the claims of the patents we license or may own currently or in the future;
- we, or our licensing partners or current or future collaborators, might not have been the first to make the inventions covered by issued patents or pending patent applications that we license or may own currently or in the future;
- we, or our licensing partners or current or future collaborators, might not have been the first to file patent applications for certain of our or their inventions;
- our pending owned or in-licensed patent applications may not lead to issued patents;
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;

- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business;

- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found not to be owned by us, invalid or unenforceable; or

- we may not develop additional proprietary technologies that are patentable.

Should any of these events occur, they could significantly harm our business, financial conditions, results of operations and prospects.

Risks Related to Our Business and Industry

Our current and future relationships with third party payors, healthcare professionals and customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency and other healthcare laws and regulations, which could expose us to significant penalties.

Healthcare providers, physicians and third party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research, sell, market and distribute any products for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Further, several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated;

- federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act (that can be enforced through civil whistleblower or qui tam actions), and the civil monetary penalties law, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. Public Health Service Act, or PHSA, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- the Physician Payments Sunshine Act, created under Section 6002 of the Affordable Care Act, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, certain other healthcare providers beginning in 2022, and teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members by the 90th day of each calendar year. All such reported information is publicly available; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase or prescribe our product candidate, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third party payors have attempted to control costs by limiting coverage and the amount of reimbursement. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain and failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to generate revenue. Third party payors may not view our product candidates, if approved, as cost-effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. If coverage and reimbursement are not available, or reimbursement is available only to limited levels, we, or any

future collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. Cost-control initiatives could also cause us to decrease any price we might establish for our product candidates, which could result in lower than anticipated product revenues. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including our costs related to research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. If the prices for our product candidates, if approved, decrease or if governmental and other third party payors do not provide adequate coverage or reimbursement, our business, prospects, operating results and financial condition will suffer, perhaps materially.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, including genetic treatments. In the United States, the Centers for Medicare & Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program, make the principal decisions about coverage and reimbursement for new treatments under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. In addition, certain Affordable Care Act marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the U.S. Centers for Disease Control's, or CDC's, Advisory Committee on Immunization Practices, or ACIP, without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. For Medicare beneficiaries, vaccines may be covered for reimbursement under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine candidates, once approved, are reimbursed only under the Part D program, physicians may be less willing to use our products because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payment associated with the Part D program.

Outside the United States, certain countries, including a number of Member States of the European Union, set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our product candidates, in those countries would be negatively affected. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, an increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run healthcare systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. In some countries, in particular, in many Member States of the European Union, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. In addition, publication of discounts by third party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially adversely affected. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Price controls may be imposed in certain markets, which may adversely affect our future profitability.

In some countries, particularly Member States of the European Union, the pricing of prescription drugs is subject to governmental control or control by associations of health insurers. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, in particular, in many Member States of the European Union, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially adversely affected.

Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition.

Potential future expense and revenue may be incurred or derived from outside the European Union, particularly the United States. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the euro and other currencies, particularly the U.S. dollar, which may also have a significant impact on our reported results of operations and cash flows from period to period. In addition, the abandonment of the euro by one or more members of the European Union could lead to the re-introduction of individual currencies in one or more European Union Member States, or in more extreme circumstances, the dissolution of the European Union. The effects on our business of the abandonment of the euro as a currency, the exit of one or more European Union Member States from the European Union (such as Brexit) or a potential dissolution of the European Union, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

We could be subject to strict restrictions on the movement of cash and the exchange of foreign currencies.

In some countries, we could be subject to strict restrictions on the movement of cash and the exchange of foreign currencies, which would limit our ability to use this cash across our global operations. This risk could increase as we continue our geographic expansion, and in particular if we seek to expand into emerging markets, which are more likely to impose these restrictions than more established markets.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

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 product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In March 2010, President Obama signed the Affordable Care Act into law. Among the provisions of the Affordable Care Act of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- a requirement that certain Affordable Care Act marketplace and other private payor plans include coverage for preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Since its enactment, there have been judicial and congressional challenges to numerous aspects of the Affordable Care Act. By way of example, the 2017 Tax Reform Act included a provision repealing the individual mandate, effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the Affordable Care Act is an essential and inseverable feature of the Affordable Care Act, and therefore because the mandate was repealed, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional, but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case. On November 10, 2020, the U.S. Supreme Court heard oral arguments regarding the constitutionality of the individual mandate, although it is unclear when a decision will be made or how the Supreme Court will rule. However, on February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act. However, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining policies that create unnecessary barriers to obtaining access to health insurance coverage through the Affordable Care Act. We are continuing to monitor any changes to the Affordable Care Act that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our product candidates, if approved, and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform

government program reimbursement methodologies for drug products. On November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita to the United States. The MFN Model regulations mandate participation by identified Part B providers and is intended to apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, on December 28, 2020, the U.S. District Court for the Northern District of California issued an order enjoining HHS from implementing the MFN Model, and therefore, the MFN Model was not implemented on January 1, 2021. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point of sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, individual states in the United States have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

The policies of the FDA or similar regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation, but it has not yet been implemented and its ultimate implementation is unclear. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We cannot predict whether future healthcare legislative or policy changes will be implemented at the federal or state level or in countries outside the United States in which we may do business, or the effect any future legislation or regulation will have on us, but we expect there will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare.

Cyberattacks or other failures in our or our third party vendors', contractors' or consultants' telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations.

We utilize information technology, or IT, systems and networks and cloud computing services to process, transmit and store electronic information in connection with our business activities. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data centers and cloud-based data centers. We utilize external security and infrastructure vendors to manage our information technology systems and data centers. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit

and modify our controls over our critical information. This risk extends to the third party vendors and subcontractors we use to manage this sensitive data. Despite the implementation of security measures, given the size and complexity of our internal IT systems and those of our third party vendors, contractors and consultants, and the increasing amounts of confidential information that they maintain, such IT systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war, and telecommunication and electrical failures. Such IT systems are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third party vendors, contractors, consultants, business partners, and/or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information). These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business.

Cyber threats are persistent and constantly evolving. Such threats have increased in frequency, scope and potential impact in recent years, which increase the difficulty of detecting and successfully defending against them. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. There can be no assurance that we or our third party service providers, contractors or consultants will be successful in preventing cyberattacks or successfully mitigating their effects. Similarly, there can be no assurance that such third party service providers, contractors or consultants will be successful in protecting our clinical and other data that is stored on their systems. If the IT systems of our third party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Any cyberattack or destruction or loss of data could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, if such an event were to occur and cause interruptions in our operations, or those of our third party vendors and other contractors and consultants, it could result in a material disruption or delay of the development of our product candidates. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyberattacks or other data security breaches and may incur significant additional expense to implement further data protection measures. As cyber threats continue to evolve, we may be required to incur material additional expenses in order to enhance our protective measures or to remediate any information security vulnerability.

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development and regulatory affairs, as well as to support our public company operations. We are currently constructing a new facility, designed for the development of a cGMP production process on a large industrial-scale for market supply. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Moreover, our expected growth could require us to relocate to a different geographic area of the country. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful development and

commercialization of our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business, financial condition, results of operations and prospects.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Additionally, if we are unable to properly protect the privacy and security of personal information, including protected health information, we could be found to have breached our contracts.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. The HHS has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce and be construed as a violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The Federal Trade Commission, or the FTC, expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards and the FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In addition, many states in which we operate have laws that protect the privacy and security of personal information. For example, the California Consumer Privacy Act of 2018, or CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted.

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in the European Union, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation, or the GDPR, in addition to other applicable laws and regulations. The GDPR came into effect in May 2018, repealing and replacing the European Union Data Protection Directive, and imposing revised data privacy and security requirements on companies in relation to the processing of personal data of European Union and United Kingdom data subjects. The GDPR, together with national legislation, regulations and guidelines of the European Union Member States and the United Kingdom governing the processing of personal data, impose strict obligations with respect to, and restrictions on, the collection, use, retention, protection, disclosure, transfer and processing of personal data. The GDPR imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States. For example, in 2016, the European Union and United States agreed to a transfer framework for data transferred from the European Union to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. The standard contractual clauses issued by the European Commission, or the EC, for the transfer of personal data may be similarly invalidated by the Court of Justice of the European Union. It remains to be seen whether these standard contractual clauses will remain available and whether additional means for lawful data transfers will become available. The GDPR authorizes fines for certain violations of up to 4% of the total global annual turnover of the preceding financial year or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by data subjects. Separately, Brexit could also lead to further legislative and regulatory changes and increase our compliance costs. As of January 1, 2021, and the expiry of transitional arrangements agreed to between the United Kingdom and the European Union, data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. Pursuant to the Trade and Cooperation Agreement, which went into effect on January 1, 2021, the United Kingdom and the European Union agreed to a specified period during which the United Kingdom will be treated like a European Union member state in relation to transfers of personal data to the United Kingdom for four months from January 1, 2021. This period will be extended by two further months automatically, unless the European Union or United Kingdom objects. The European Commission issued a draft adequacy decision for the United Kingdom on February 19, 2021, and on April 14, 2021, the European Data Protection Board issued an opinion broadly in favor of the draft adequacy decision, but the decision has not yet been adopted and it is unclear when the European Commission will reach a decision or how the European Commission will ultimately decide. Unless the European Commission adopts the adequacy decision in respect of the United Kingdom before the expiration of such specified period, the United Kingdom will become an inadequate third country under the GDPR and transfers of data from the European Economic Area to the United Kingdom will require a transfer mechanism, such as the standard contractual clauses. Furthermore, following the expiration of the specified period, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and the European Union. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with noncompliance. We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve.

It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties under such laws, orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which have a material adverse effect on our business, financial condition, results of operations and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from third parties that use mRNA, gene editing or gene therapy

development platforms and from third parties focused on other therapeutic modalities, such as small molecules, antibodies, biologics and nucleic acid-based therapies. The competition is likely to come from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even greater concentration of resources among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approvals for their products faster or earlier than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For example, some of our competitors have already received approval from the FDA and other regulatory agencies for their mRNA-based COVID-19 vaccines. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors' products. In addition, the availability of our competitors' products could limit the demand and the prices we are able to charge for any products that we may develop and commercialize.

We depend heavily on our executive officers and managing directors, and the loss of their services would materially harm our business.

Our success depends, and will likely continue to depend, upon our ability to retain the services of our current executive officers, managing directors, principal consultants and other service providers, and our ability to hire new highly qualified personnel. We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers, managing directors, principal consultants and other service providers. In addition, we have established relationships with universities and research institutions which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel.

In most cases, our personnel may only terminate their employment upon first providing notice. A limited number of agreements provide for at-will termination. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

We may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates (i) FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing and clinical trial conduct standards, (iii) federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities and (iv) laws that require the reporting of financial information or data accurately. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may

not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

As a result of our geographically diverse operations, we are more susceptible to certain risks.

We have offices and operations in three cities and in two countries. If we are unable to manage the risks of our global operations, including fluctuations in foreign exchange and inflation rates, international hostilities, natural disasters, security breaches, failure to maintain compliance with our clients' control requirements and multiple legal and regulatory systems, our results of operations and ability to grow could be materially adversely affected.

Changes in our level of taxes, and audits, investigations and tax proceedings, could have a material adverse effect on our results of operations and financial condition.

Although limited in terms of magnitude due to ongoing losses incurred so far, we are subject to income taxes in Germany and the United States. We calculate and provide for income taxes in each tax jurisdiction in which we operate. Tax accounting often involves complex matters and judgment is required in determining our worldwide provision for income taxes and other tax liabilities. We are subject to ongoing tax audits in Germany. In the future, tax authorities may disagree with our judgments or may take increasingly aggressive positions with respect to the judgments we make. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax liabilities. However, our judgments might not be sustained as a result of these audits, and the amounts ultimately paid could be different from the amounts previously recorded. In addition, our effective tax rate in the future could be adversely affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws. Tax rates in the jurisdictions in which we operate may change as a result of macroeconomic or other factors outside of our control. Increases in the tax rate in any of the jurisdictions in which we operate could have a negative impact on our profitability. In addition, changes in tax laws, treaties or regulations, or their interpretation or enforcement, may be unpredictable, particularly in less developed markets, and could become more stringent, which could materially adversely affect our tax position. Any of these occurrences could have a material adverse effect on our results of operations and financial condition.

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

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or the TCJA, which significantly amends the Internal Revenue Code of 1986. Subject to the discussion of the Families First Coronavirus Response Act, or FFCR Act, and the CARES Act below, the TCJA, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted taxable income, eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits, including a reduction of the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs." We continue to examine the impact these changes may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected.

As part of Congress's response to the COVID-19 pandemic, the FFCR Act was enacted on March 18, 2020, and the CARES Act was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the tax deduction

cap from 30% to a 50% cap of adjusted taxable income. Regulatory guidance under the TCJA, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act. Moreover, it is possible that Congress will enact additional legislation in connection with the COVID-19 pandemic, which could have an impact on our company.

We urge our shareholders to consult with their legal and tax advisers with respect to the TCJA, the FFCR Act and the CARES Act and the potential tax consequences of investing in our common shares.

Uninsured losses arising from third party claims brought against us could result in payment of substantial damages, which would decrease our cash reserves and could harm our profit and cash flow.

Our products are used in applications where the failure to use our products properly or their malfunction could result in serious bodily injury or death. We may not have adequate insurance to cover the payment of any potential claim related to such injuries or deaths. Insurance coverage may not continue to be available to us or, if available, may be at a significantly higher cost.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products.

The use of our investigational medicinal products in clinical trials and the sale of any approved products in the future may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

To cover such liability claims, we purchase clinical trial insurances in the conduct of each of our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We also intend to expand our insurance coverage to include the sale of commercial products if we receive marketing approval for any of our proprietary products. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations, including, but not limited to:

- decreased demand for our future product candidates;
- adverse publicity and injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- compensation in response to a liability claim;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize our products or product candidates.

We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our business, financial condition, results of operations or prospects.

Some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that products similar to our product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates or negatively impact our platform or our business.

There have been few approvals of gene therapy products in the United States and other jurisdictions, and there have been well-reported significant adverse events associated with their testing and use. Gene therapy products have the effect of introducing new DNA and potentially irreversibly changing the DNA in a cell. In contrast, mRNA is highly unlikely to localize to the nucleus, integrate into cell DNA or otherwise make any permanent changes to cell DNA. Consequently, we expect that our product candidates will have a different potential side effect profile from gene therapies because they lack risks associated with altering cell DNA irreversibly. Further, we may avail ourselves of ways of mitigating side effects in developing our product candidates to address safety concerns that are not available to all gene therapies, such as lowering the dose of our product candidates during repeat dosing or stopping treatment to potentially ameliorate undesirable side effects.

Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future, and the implications for mRNA-based medicines is unknown. For example, the FDA has established the Office of Tissues and Advanced Therapies within 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 European Union, mRNA has been characterized as a Gene Therapy Medicinal Product. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us. Specifically, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. Notwithstanding the differences between our mRNA product candidates and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the United States, the European Union and potentially other counties could adversely impact our ability to develop our product candidates, and could negatively impact our platform and our business. For instance, a clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly may apply to our mRNA product candidates irrespective of the mechanistic differences between gene therapies and mRNA.

Adverse events reported with respect to gene therapies or genome editing therapies could adversely impact one or more of our programs. Although our mRNA product candidates are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapy products caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our mRNA investigational therapies, and as a result may delay one or more of our trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory review agencies may have a negative effect on 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 product candidates or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, 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 product candidates.

Risks Related to Our Common Shares

An active trading market for our common shares may not be sustainable. If an active trading market is not maintained, investors may not be able to resell their shares at or above the purchase price and our ability to raise capital in the future may be impaired.

Although our common shares are listed and trade on Nasdaq, an active trading market for our shares may not be maintained. If an active market for our common shares is not maintained, it may be difficult for shareholders to sell shares they purchase without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. In addition to the risks described above, the market price of our common shares may be influenced by many factors, some of which are beyond our control, including:

- the failure of financial analysts to continue to cover our common shares or changes in financial estimates by analysts;
- actual or anticipated variations in our operating results;
- changes in financial estimates by financial analysts, or any failure by us to meet or exceed any of these estimates, or changes in the recommendations of any financial analysts that elect to follow our common shares or the shares of our competitors;
- announcements by us or our competitors of significant contracts or acquisitions;
- future sales of our shares; and
- investor perceptions of us and the industries in which we operate.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general has from time to time experienced extreme price and volume fluctuations, including in recent months, that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of our common shares, regardless of our operating performance. In the past, following periods of volatility in the market price of certain companies' securities, securities class action litigation has been instituted against these companies. This litigation, if instituted against us, could adversely affect our financial condition or results of operations.

Sales of substantial amounts of our common shares in the public market, or the perception that these sales may occur, could cause the market price of our common shares to decline.

Sales of substantial amounts of our common shares in the public market, or the perception that these sales may occur, could cause the market price of our common shares to decline. This could also impair our ability to raise additional capital through the sale of our equity securities. We cannot predict the size of future issuances of our shares or the effect, if any, that future sales and issuances of shares would have on the market price of our common shares.

We have broad discretion in the use of our cash on hand and may invest or spend it in ways with which shareholders do not agree and in ways that may not yield a return on their investment.

As of December 31, 2020, we had cash and cash equivalents amounting to €1.32 billion, inclusive of the first upfront payment under the APA. Our management will have broad discretion in the use of such cash and could spend it in ways that do not improve our results of operations or enhance the value of our common shares. Individual shareholders will not have the opportunity to influence our decisions on how to use our cash on hand. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending its use, we may invest our cash on hand in a manner that does not produce income or that loses value.

Concentration of ownership by our principal shareholders may conflict with your interest and may prevent you from influencing significant corporate decisions.

As of April 10, 2021, our principal shareholders dievini ("dievini"), beneficially own approximately 42.37% of our common shares, and Kreditanstalt für Wiederaufbau ("KfW"), beneficially owns approximately 16.01% of our common shares.

In addition, dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) has the right under our articles of association to make a binding nomination for the following number of supervisory directors[1] until dievini (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) and its affiliates as defined by our articles of association and ultimate beneficiaries as defined by our articles of association (individually or collectively) ceases to own at least 10% of our issued share capital or an earlier change of control over dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) as defined by our articles of association, which period we refer to as the initial nomination period for dievini:

- four (4) supervisory directors for as long as dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) and its affiliates (as defined by our articles of association) and ultimate beneficiaries (as defined by our articles of association) (individually or collectively) owns at least 70% of our issued share capital;
- three (3) supervisory directors for as long as dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) and its affiliates (as defined by our articles of association) and ultimate beneficiaries (as defined by our articles of association) (individually or collectively) owns at least 50% (but less than 70%) of our issued share capital;
- two (2) supervisory directors for as long as dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) and its affiliates (as defined by our articles of association) and ultimate beneficiaries (as defined by our articles of association) (individually or collectively) owns at least 30% (but less than 50%) of our issued share capital; and
- one (1) supervisory director for as long as dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) and its affiliates (as defined by our articles of association) and ultimate beneficiaries (as defined by our articles of association) (individually or collectively) owns at least 10% (but less than 30%) of our issued share capital.

Dievini and Mr. Dietmar Hopp may be able to significantly influence all matters requiring shareholder approval. Even when dievini ceases to own common shares representing a majority of the total voting power, for so long as dievini continues to own a significant percentage of our common shares, dievini will still be able to significantly influence the composition of our supervisory board and the approval of actions requiring shareholder approval. Accordingly, for such period of time, dievini will continue to have significant influence with respect to our management, business plans and policies, including the appointment and removal of our managing directors, decisions on whether to raise future capital and amending our organizational documents, which govern the rights attached to our common shares. In particular, for so long as dievini continues to own a significant percentage of common shares, it will be able to cause or prevent a change of control of us or a change in the composition of our supervisory board and could preclude any unsolicited acquisition of us.

In addition, KfW (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) has the right, and has exercised the right under our articles of association, the KfW dievini Shareholders' Agreement and the ISA to make a binding nomination for one (1) supervisory director until KfW or any KfW affiliates as defined by our articles of association (individually or together with any other KfW affiliate) ceases to own at least 10% of our issued share capital, which period we refer to as the initial nomination period for KfW. Certain

[1] During the initial nomination period (as defined by our articles of association), our supervisory board shall consist of up to eight (8) supervisory directors.

decisions require, and cannot be taken without, a resolution of our supervisory board that the KfW nominee, and a dievini nominee, have approved. These relate in particular to the location within the European Union of certain of our activities. The KfW dievini Shareholders' Agreement includes provisions relating to voting together and in a coordinated fashion on certain specified matters as further described under "section 7 — Related Party Transactions."

The concentration of ownership and these nomination rights could deprive shareholders of an opportunity to receive a premium for their common shares as part of a sale of us and ultimately might affect the market price of our common shares. In addition, the concentration of voting power and these nomination rights could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in the management of our company in ways with which other shareholders disagree.

We may be required to redeem for cash all, or to facilitate the purchase by a third party of all, the shares of us held by the Bill & Melinda Gates Foundation (BMGF) as per the date of the Investor and Shareholder Agreement (ISA) if we default under the Global Access Agreement, which could have an adverse impact on us and limit our ability to make distributions to our shareholders.

We entered into a Global Access Agreement with our shareholder, the Bill & Melinda Gates Foundation, in February 2015 pursuant to which we are required to take certain actions to support the Bill & Melinda Gates Foundation's mission. In the event that we commit a material breach of the Global Access Agreement or certain provisions of the ISA, following a cure period, we may be required to redeem for cash all, or to facilitate the purchase by a third party of all, the shares of our company held by the Bill & Melinda Gates Foundation as per the date of the ISA at certain terms that may not be favorable to us. If this occurs, cash used for this purpose may, adversely affect our liquidity, cause us to reduce expenditures in other areas of our business, or curtail our growth plans. If we do not have sufficient cash on hand to purchase the shares, we would have to seek financing alternatives in order to meet our obligations, and there is no certainty that financing would be available on reasonable terms or at all. For the period that we are unable to redeem the shares held by the Bill & Melinda Gates Foundation or arrange for a third party to purchase such shares, we will generally not be allowed to pay dividends, redeem the shares of any other shareholder or otherwise make any other distribution to any of our shareholders in connection with their shares. Therefore, meeting this purchase obligation, if necessary, could have a material adverse effect on our business and financial results. For more information on the Bill & Melinda Gates Foundation's withdrawal rights, see "section 7 — Related Party Transactions — Investment and Shareholders' Agreement."

Transformation into a public company may continue to increase our costs and disrupt the regular operations of our business.

In August 2020, we completed our initial public offering. After the completion of our initial public offering we incurred and expect to continue to incur, including, but not limited to, costs and expenses for managing directors' and supervisory directors' fees, increased directors and officers insurance, investor relations, and various other costs of a public company.

We also anticipate that we will continue to incur increasing costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. We expect these rules and regulations to continue to increase our legal and financial compliance costs and make some management and corporate governance activities more time consuming and costly, particularly after we are no longer an "emerging growth company." These rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. This could have an adverse impact on our ability to retain, recruit and bring on a qualified independent supervisory board. We expect that the additional costs we will incur as a public company, including costs associated with corporate governance requirements, will be considerable relative to our costs as a private company.

The additional demands associated with being a public company may disrupt regular operations of our business by diverting the attention of some of our senior management team away from revenue producing activities to management and administrative oversight, adversely affecting our ability to attract and complete business opportunities and increasing the difficulty in both retaining professionals and managing and growing our businesses. Any of these effects could harm our business, financial condition and results of operations.

For as long as we are an "emerging growth company" under the recently enacted JOBS Act, our independent registered public auditing firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years. Furthermore, after the date we are no longer an emerging growth company, our independent registered public auditing firm will only be required to attest to the effectiveness of our internal control over financial reporting depending on our market capitalization. Even if our management concludes that our internal controls over financial reporting are effective, our independent registered public auditing firm may issue a report that is qualified if it is not satisfied with our controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, in connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. Failure to comply with Section 404 could subject us to regulatory scrutiny and sanctions, impair our ability to raise capital, cause investors to lose confidence in the accuracy and completeness of our financial reports and negatively affect our share price.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, shareholders may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. If in the future we are not a foreign private issuer as of the last day of the second fiscal quarter in any fiscal year, we would be required to comply with all of the periodic disclosure, current reporting requirements and proxy solicitation rules of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our managing directors, supervisory directors and executive officers may not be United States citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business

must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified managing directors and supervisory directors.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we follow certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares. Although we must provide shareholders with an agenda and other relevant documents for the general meeting, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires, among other things, an issuer to have a compensation committee that consists entirely of independent directors, Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations, and Nasdaq Listing Rule 5605(b)(1), which requires an issuer to have a majority of independent directors on its board. We also rely on the phase-in rules of the SEC and Nasdaq with respect to the independence of our audit committee. These rules require that a majority of our supervisory directors must be independent and all members of our audit committee must meet the independence standard for audit committee members within one year from the effective date of the registration statement, filed in connection with our initial public offering. In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of our company and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, shareholders may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

Although we do not believe that we were a "passive foreign investment company," or a PFIC, for U.S. federal income tax purposes for our 2020 taxable year, we may be a PFIC for 2021 or one or more future taxable years. A U.S. holder of common shares may suffer adverse U.S. federal income tax consequences if we are a PFIC for any taxable year.

Under the Internal Revenue Code of 1986, as amended, or the Code, we will generally be a PFIC for any taxable year in which, after the application of certain look-through rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, "passive income." Passive income generally includes dividends, interest, certain non-active rents and royalties, and capital gains. The value of a non-U.S. corporation's goodwill that is associated with activities that produce or are intended to produce active income is generally an active asset for purposes of the asset test unless, for U.S. federal income tax purposes, the non-U.S. corporation is a "controlled foreign corporation" (CFC) that is not publicly traded "for the taxable year." If a non-U.S. corporation is a CFC that is not publicly traded for the taxable year, its PFIC status under the asset test is determined by using the U.S.

tax basis of its assets rather than their fair market value and therefore the market value of its goodwill is generally disregarded. Generally, a non-U.S. corporation is a CFC if more than 50% of its shares' voting power or value is owned, directly, indirectly or constructively, by "United States shareholders" (as defined in Section 951(b) of the Code). Although it is not certain, we may be or may have been a CFC in the 2020 taxable year. However, under recently promulgated Treasury regulations, the fair market value of our assets (including goodwill) can be used for purposes of the asset test provided that (i) we are publicly traded on the majority of days during our taxable year or (ii) we would not be a CFC if certain constructive ownership rules were not applied. We believe, and the remainder of this discussion assumes, that we are eligible to use the fair market value of our assets for purposes of the asset test for our 2020 taxable year.

Based on the composition of our income and assets during 2020, we do not believe that we were a PFIC for our 2020 taxable year. However, there can be no assurance that the Internal Revenue Service (the "IRS") will agree with our conclusion. Whether we will be a PFIC in 2021 or any future year is uncertain because, among other things, (i) we currently own a substantial amount of passive assets, including cash, (ii) the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time, (iii) the treatment of grants as income for U.S. federal income tax purposes is unclear, and (iv) the composition of our income may vary substantially over time. Accordingly, there can be no assurance that we will not be a PFIC in 2021 or any future taxable year.

If we are a PFIC for any taxable year during which a U.S. investor holds common shares, we generally would continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds common shares, even if we ceased to meet the threshold requirements for PFIC status. Such a U.S. investor may be subject to adverse U.S. federal income tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements. There is no assurance that we will provide information that will enable investors to make a qualified electing fund election, also known as a QEF Election, that could mitigate the adverse U.S. federal income tax consequences should we be classified as a PFIC.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We cannot predict if investors will find our common shares less attractive because we will rely on these exemptions. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We would cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer" with at least $700 million of equity securities; (iii) the issuance, in any three-year period, by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

Insiders have substantial control over us and could limit individualshareholders ability to influence the outcome of key transactions, including a change of control.

As of April 10, 2021, our principal shareholders, managing directors, supervisory directors and executive officers and entities affiliated with them own approximately 67.17% of the outstanding common shares. As a result, these shareholders, if acting together, would be able to influence or control matters requiring approval by our general meeting, including the appointment of managing directors and supervisory directors, changes to our articles of association and approval of mergers or other extraordinary transactions. They may also have interests that differ from other shareholders and may vote in a way with which you disagree and which may be adverse to your interests. The concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our shareholders of an opportunity to receive a premium for their common shares as part of a sale of our company and might ultimately affect the market price of our common shares.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If securities or industry analysts do not continue to cover our company, the trading price for our common shares would likely be negatively impacted.

In addition, if one or more of the analysts who cover us downgrades our common shares or publishes inaccurate or unfavorable research about our business, our share price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our shares could decrease, which might cause our share price and trading volume to decline.

We do not anticipate paying any cash dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, for the foreseeable future, to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common shares. As a result, capital appreciation in the price of our common shares, if any, will be shareholders only source of gain on an investment in our common shares.

If we do pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands.

We do not intend to pay any dividends to holders of our common shares. See "— We do not anticipate paying any cash dividends in the foreseeable future." However, if we do pay dividends, we may need to withhold tax on such dividends both in Germany and the Netherlands.

As an entity incorporated under Dutch law, any dividends distributed by us are subject to Dutch dividend withholding tax on the basis of Dutch domestic law. However, on the basis of the 2012 Convention between the Federal Republic of Germany and the Kingdom of the Netherlands for the avoidance of double taxation with respect to taxes on income, or the "double tax treaty between Germany and the Netherlands," the Netherlands will be restricted in imposing these taxes if we are also a tax resident of Germany and our effective management is located in Germany, or the "withholding tax restriction." See also "— We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us." The withholding tax restriction does, however, not apply, and Dutch dividend withholding tax is still required to be withheld from dividends, if and when paid to Dutch resident holders of our common shares (and non-Dutch resident holders of our common shares that have a permanent establishment in the Netherlands to which their shareholding is attributable). As a result, upon a payment of dividends, we will be required to identify our shareholders in order to assess whether there are Dutch residents (or non-Dutch residents with a permanent establishment in the Netherlands to which the common shares are attributable) in respect of which Dutch dividend

withholding tax has to be withheld. Such identification may not always be possible in practice. If the identity of our shareholders cannot be determined, withholding of both German and Dutch dividend withholding tax may occur upon a payment of dividends.

Furthermore, the withholding tax restriction referred to above is based on the current reservation made by Germany under the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting, or the "MLI," with respect to the tie-breaker provision included in Article 4(3) of the double tax treaty between Germany and the Netherlands, or the "MLI tie-breaker reservation." If Germany changes its MLI tie-breaker reservation, we will not be entitled to any benefits of the double tax treaty between Germany and the Netherlands, including the withholding tax restriction, as long as Germany and the Netherlands do not reach an agreement on our tax residency for purposes of the double tax treaty between Germany and the Netherlands, and, as a result, any dividends distributed by us during the period no such agreement has been reached between Germany and the Netherlands, may be subject to dividend withholding tax both in Germany and the Netherlands.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

Our ability to utilize our net operating losses, or NOLs, is currently limited, and may be limited further, under Section 8c of the German Corporation Income Tax Act (*Korperschaftsteuergesetz*, or KStG) and Section 10a of the German Trade Tax Act (*Gewerbesteuergesetz*, or GewStG). These limitations apply if a qualified ownership change, as defined by Section 8c KStG, occurs and no exemption is applicable.

Generally, a qualified ownership change occurs if more than 50% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. A qualified ownership change may also occur in case of a transaction comparable to a transfer of shares or voting rights or in case of an increase in capital leading to a respective change in the shareholding.

In the case of such a qualified ownership change tax loss carryforwards expire in full. To the extent that the tax loss carryforwards do not exceed the built-in gains (*stille Reserven*) in the assets and liabilities taxable in Germany, they may be further utilized despite a qualified ownership change. In case of a qualified ownership change within a group, tax loss carryforwards will be preserved if certain conditions are satisfied. In case of a qualified ownership change, tax loss carryforwards will be preserved (in the form of a "*fortfuhrungsgebundener Verlustvortrag*") if the business operations have not been changed and will not be changed within the meaning of Section 8d KStG.

According to an appeal filed by the fiscal court of Hamburg dated August 29, 2017, Section 8c, paragraph 1, sentence 1 KStG is not in line with the German constitution. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case.

As of December 31, 2020, there are NOLs of CureVac AG and CureVac Real Estate GmbH for German corporate tax purposes of approximately €776.0 million: €738.3 million for CureVac AG, €19.3 million for CureVac Real Estate GmbH and €18.4 million for CureVac N.V. and for German trade tax purposes of approximately €773.2 million: €736.0 million for CureVac AG, €18.8 million for CureVac Real Estate GmbH and € 18.4 million for CureVac N.V. available. The contribution of 100% of CureVac AG's shares into CureVac B.V. was qualified as an ownership change within the meaning of Section 8c KStG and Section 10a GewStG. The available tax loss carryforwards of CureVac AG and CureVac Real Estate GmbH will generally expire in full. However, the NOLs would not be forfeited to the extent that CureVac AG and CureVac Real Estate GmbH have built-in gains in their assets that are fully taxable in Germany. The built-in gains are determined by comparing the Fair Market Value of the respective entity with the entity's tax book equity. A preliminary determination of the built-in gains has shown that all of the tax loss carryforwards would be maintained.

Future changes in share ownership may also trigger an ownership change and, consequently, a Section 8c KStG or a Section 10a GewStG limitation. Any limitation may result in the expiration of a portion or the complete tax operating loss carryforwards before they can be utilized. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to reduce German income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

Shareholders may not be able to exercise preemptive rights and, as a result, may experience substantial dilution upon future issuances of common shares.

In the event of an issuance of common shares, subject to certain exceptions, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder. These preemptive rights may be restricted or excluded by a resolution of the general meeting or by another corporate body designated by the general meeting. Our management board, subject to approval of our supervisory board, has been authorized, for a period of five years to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time and to limit or exclude preemptive rights in connection therewith. This could cause existing shareholders to experience substantial dilution of their interest in us.

We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us.

Since our incorporation we have had, on a continuous basis, our place of "effective management" in Germany. We will therefore qualify as a tax resident of Germany on the basis of German domestic law. As an entity incorporated under Dutch law, however, we also qualify as a tax resident of the Netherlands on the basis of Dutch domestic law. However, based on our current management structure and the current tax laws of the United States, Germany and the Netherlands, as well as applicable income tax treaties, and current interpretations thereof, we should qualify solely as a tax resident of Germany for the purposes of the double tax treaty between Germany and the Netherlands due to the "effective management" tie-breaker included in Article 4(3) of the double tax treaty between Germany and the Netherlands and the current MLI tie-breaker reservation.

The test of "effective management" is largely a question of fact and degree based on all the circumstances, rather than a question of law. Nevertheless, the relevant case law and OECD guidance suggest that our company is likely to be regarded as having become a German tax resident from incorporation and remaining so if, as our company intends, (i) most meetings of its management board are prepared and held in Germany (and none will be held in the Netherlands) with a majority of managing directors present in Germany for those meetings; (ii) at those meetings there are full discussions of, and decisions are made regarding, the key strategic issues affecting our company and its subsidiaries; (iii) those meetings are properly minuted; (iv) a majority of our managing directors, together with supporting staff, are based in Germany; and (v) our company has permanent staffed office premises in Germany. We may, however, become subject to limited income tax liability in other countries with regard to the income generated in the respective other country, for example, due to the existence of a permanent establishment or a permanent representative in such other country.

The applicable tax laws or interpretations thereof may change, including the MLI tie-breaker reservation. Furthermore, whether we have our place of effective management in Germany and are as such tax resident in Germany is largely a question of fact and degree based on all the circumstances, rather than a question of law, which facts and degree may also change. Changes to applicable laws or interpretations thereof, changes to applicable facts and circumstances (for example, a change of directors or the place where board meetings take place), or changes to applicable income tax treaties, including a change to the MLI tie-breaker reservation, may result in us becoming (also) a tax resident of the Netherlands or another jurisdiction. See "— If we do pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands." As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects, which could cause our share price and trading volume to decline. In addition, as a consequence, dividends distributed by us, if any, may become subject to dividend withholding tax in more than one jurisdiction. The double taxation of income and the double withholding tax on dividends may be reduced or avoided entirely under the double tax treaty between Germany and the Netherlands or under a double tax treaty between the Netherlands and the respective other country.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of the Netherlands, and our headquarters is located in Germany. Most of our assets are located outside the United States. The majority of our managing directors and supervisory directors reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

There is currently no treaty between the United States and the Netherlands for the mutual recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. federal securities laws, would not be enforceable in the Netherlands unless the underlying claim is relitigated before a Dutch court of competent jurisdiction. Under current practice, however, a Dutch court will generally, subject to compliance with certain procedural requirements, grant the same judgment without a review of the merits of the underlying claim if such judgment (i) is a final judgment and has been rendered by a court which has established its jurisdiction vis-à-vis the relevant Dutch companies or Dutch company, as the case may be, on the basis of internationally accepted grounds of jurisdiction, (ii) has not been rendered in violation of principles of proper procedure (*behoorlijke rechtspleging*), (iii) is not contrary to the public policy of the Netherlands, and (iv) is not incompatible with (a) a prior judgment of a Dutch court rendered in a dispute between the same parties, or (b) a prior judgment of a foreign court rendered in a dispute between the same parties, concerning the same subject matter and based on the same cause of action, provided that such prior judgment is capable of being recognized in the Netherlands and except to the extent that the foreign judgment contravenes Dutch public policy (*openbare orde*). Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure.

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, in civil and commercial matters. Consequently, a final judgment for payment or declaratory judgments given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgments awarding punitive damages are generally not enforceable in Germany. A German court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

In addition, actions brought in a German court against us, our managing directors, our supervisory directors, our senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. German procedural law does not provide for pre-trial discovery of documents, nor does Germany support pre-trial discovery of documents under the 1970 Hague Evidence Convention. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our managing directors, our supervisory directors, our senior management and the experts named in this Annual Report.

Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce against us or managing directors, supervisory directors, executive officers or certain experts named herein who are residents of or possessing assets in the Netherlands, Germany, or other countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction.

We are a public company (*naamloze vennootschap*) organized under the laws of the Netherlands. Our corporate affairs are governed by our articles of association, the rules of our management board and those of our supervisory board and by the laws governing companies incorporated in the Netherlands. However, there can be no assurance that Dutch law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

The rights of shareholders and the responsibilities of managing directors and supervisory directors may be different from the rights and obligations of shareholders and directors in companies governed by the laws of U.S. jurisdictions. In the performance of their duties, our managing directors and supervisory directors are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, other shareholders.

For more information on relevant provisions of Dutch corporation law and of our articles of association, see "section 5".

The ability for our shareholders to alter the members of our management board or supervisory board may be limited by Dutch cooling-off period in face of shareholder activism or hostile take-over

As of May 1, 2021, a statutory cooling-off period of up to 250 days was introduced in the Netherlands. When such cooling-off period is invoked, our general meeting of shareholders cannot dismiss, suspend or appoint members of the management board or supervisory board (or amend the provisions in our articles of association dealing with those matters), unless those matters would be proposed by the management board. This cooling-off period could be invoked by the management board in the following instances, provided that, in each of these instances, the management board believes that such proposal or offer materially conflicts with the interests of the Company and its business:

- shareholders, using either their shareholder proposal right or their right to request a general meeting of shareholders, propose an agenda item to dismiss, suspend or appoint a member of the management board or supervisory board (or to amend any provision in the articles of association dealing with those matters) at a general meeting of shareholders; or
- a public offer for the Company is made or announced without the Company's support.

The cooling-off period, if invoked, ends at occurrence of the earliest of the following events:

- the expiration of 250 days from:

  (i) in the case of shareholders using their shareholder proposal right, the day after the deadline for making such proposal expires;

  (ii) in the case of shareholders using their right to request a general meeting of shareholders, the day when the shareholders obtain court authorization to request a general meeting of shareholders; or

  (iii) in the case of a hostile offer being made, the first following day;
- in the instance of a hostile offer being made, the day after the hostile offer is declared unconditional; or
- the management board voluntarily terminates the cooling-off period.

In addition, shareholders representing at least 3% of the Company's issued share capital may request the Dutch Enterprise Chamber of the Amsterdam Court of Appeals for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- the management board, in light of the circumstances when the cooling-off period was invoked, could not reasonably have come to the conclusion that the relevant shareholder proposal or hostile offer constituted a material conflict with the interests of the Company and its business;

- the management board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or

- if other defensive measures have been activated during the cooling-off period and the other defensive measures have not been terminated or suspended at the relevant shareholders' request within a reasonable period following the request (i.e., no "stacking" of defensive measures).

During the cooling-off period, if invoked, the management board must gather all relevant information necessary for a careful decision-making process. In this context, the management board must at least consult with shareholders representing at least 3% of the Company's issued share capital at the time the cooling-off period was invoked and with the Company's works council. Formal statements expressed by these stakeholders during such consultations must be published on the Company's website to the extent these stakeholders have approved that publication.

Ultimately, one week after the last day of the cooling-off period, the management board must publish a report describing its policy and conduct of affairs during the cooling-off period on the Company's website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at the Company's office and must be tabled for discussion at the next general meeting of shareholders.

Provisions of our articles of association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent, delay or frustrate any attempt to replace or remove our managing directors or supervisory directors.

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. In this respect, our general meeting shall authorize our management board, subject to the approval by our supervisory board, to grant a call option to an independent foundation under Dutch law (if and when incorporated), or protective foundation, to acquire preferred shares pursuant to a call option agreement, or the call option agreement, that may be entered into between us and such protective foundation after the later of (a) dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) and its affiliates as defined by our articles of association and ultimate beneficiaries as defined by our articles of association (individually or collectively) no longer holding at least 25% of our issued share capital (or an earlier change of control over dievini, as defined in our articles of association), which we refer to as the initial period, or (b) the termination or expiry of the KfW dievini Shareholders' Agreement (see "section 7 — Related Party Transactions — Shareholders' Agreement Among KfW, dievini and Mr. Hopp" for further information on that agreement), which we refer to as the initial approval period.

This call option, if and when granted, shall be continuous in nature and can be exercised repeatedly on multiple occasions. If the protective foundation, if and when incorporated, would exercise such call option, if and when granted, a number of preferred shares up to 100% of our issued share capital held by others than the protective foundation, minus one share, will be issued to the protective foundation. These preferred shares would then be issued to the protective foundation under the obligation to pay 25% of their nominal value upon issuance. In order for the protective foundation to finance the issue price in relation to the preferred shares, the protective foundation may enter into a finance arrangement with a bank or other financial institution. As an alternative to securing this external financing, subject to applicable restrictions under Dutch law, the call option agreement, if and when entered into, will provide that the protective foundation may request us to provide, or cause our subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy the payment obligation (or part thereof) in cash and/or to charge an amount equal to the payment obligation (or part thereof) against our profits and/or reserves in satisfaction of such payment obligation. The articles of association of the protective foundation, if and when incorporated, will provide that it will promote and protect the interests of the company, the business connected with the company and the company's stakeholders from time to time, and repressing possible influences which could threaten the strategy, continuity, independence and/or identity of the company or the business connected with it, to such an extent that this could be considered to be damaging to

the aforementioned interests. These influences may include a third party acquiring a significant percentage of our common shares, the announcement of an unsolicited public offer for our common shares, shareholder activism, other concentration of control over our common shares or any other form of undue pressure on us to alter our strategic policies. The protective foundation, if and when incorporated, shall be structured to operate independently of us.

The voting rights of our shares are based on nominal value and, as we expect our common shares to trade substantially in excess of their nominal value, preferred shares issued at 25% of their nominal value can carry significant voting power for a substantially reduced price compared to the price of our common shares and thus can be used as a defensive measure. These preferred shares, if and when issued, will have both a liquidation and dividend preference over our common shares and will accrue cash dividends at a fixed rate calculated over the amount paid-up on those preferred shares pro rata tempore for the period during which they were outstanding. The protective foundation would be expected to require us to cancel its preferred shares, if and when issued to the protective foundation, once the perceived threat to the company and its stakeholders has been removed or sufficiently mitigated or neutralized. However, subject to the same limitations described above, the protective foundation would, in that case, continue to have the right to exercise the call option in the future in response to a new threat to the interests of us, our business and our stakeholders from time to time.

In addition, certain provisions of our articles of association may make it more difficult for a third party to acquire control of us or effect a change in our management board and supervisory board. These include:

- a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination, the binding nature of which can only be overruled by a simple majority of votes cast representing at least one-third of our issued share capital;
- a provision that our managing directors and supervisory directors may only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the dismissal is proposed by the supervisory board or, with respect to supervisory directors nominated by dievini or KfW, by dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) during the nomination period for dievini or by KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) during the nomination period for KfW, respectively, in which case a simple majority of the votes would be sufficient);
- a provision that certain provisions of our articles of association can only be amended with the affirmative vote of (i) during the nomination period for dievini, dievini (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) and (ii) during the nomination period for KfW, KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement);
- a provision that if a supervisory director is no longer in office or is unable to act, he or she may be replaced temporarily by a person who the supervisory board has designated for that purpose and, where a supervisory director who has been appointed upon a nomination of dievini or KfW, as applicable, is no longer in office or unable to act, such supervisory director may only be temporarily replaced by a person designated for such purposes by dievini or KfW, as applicable. Such person shall become a full member of the supervisory board with the rights of the relevant supervisory director appointed upon a nomination of dievini or KfW, as applicable, as soon as a written designation to that effect has been received by the chairman or vice-chairman of our supervisory board, subject to limitations, under applicable law regarding dievini's rights under this provision;
- a provision allowing, among other matters, a former chairman of our supervisory board, a former nominee of dievini, and a former nominee of KfW to jointly take on the supervisory functions, which persons jointly may designate one or more other persons to be charged with the supervision of our company (instead of or together with the former chairman of our supervisory board), as applicable, to supervise our affairs if all of our supervisory directors are removed from office and to appoint others

to be charged with the supervision of our affairs, until new supervisory directors are appointed by the general meeting on the basis of a binding nomination discussed above;

- a provision allowing the management board to temporarily replace a managing director who is no longer in office or unable to act, with another person or persons designated for this purpose by the management board and attributing the management of the company to the supervisory board in case all managing directors are no longer in office or unable to act; and
- a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our management board with the approval of our supervisory board.

In addition, Dutch law allows for staggered multi-year terms of our managing directors and supervisory directors, as a result of which only part of our managing directors and supervisory directors may be subject to appointment or reappointment in any one year.

We are not obligated to, and do not, comply with all best practice provisions of the Dutch Corporate Governance Code.

We are subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains both principles and best practice provisions on corporate governance that regulate relations between the management board, the supervisory board and the general meeting and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a "comply or explain" principle. Accordingly, companies are required to disclose in their annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If they do not comply with those provisions (for example, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such noncompliance. The DCGC applies to Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. We do not comply with all best practice provisions of the DCGC. See "section 5". This may affect the rights of shareholders and may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

We and our independent registered public auditors have identified a material weakness in our internal control over financial reporting. If we are unable to remediate the material weakness, or if other control deficiencies are identified, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports as a public company in a timely manner.

We have recently become a public company and have been historically operating as a private company that was not required to comply with the obligations of a public company with respect to internal controls over financial reporting. We have historically operated with limited accounting personnel and other resources with which to address our internal controls over financial reporting.

In connection with the audit of our consolidated financial statements for the years ended December 31, 2018 and 2019, we and our independent registered public auditor identified a material weakness in our internal control over financial reporting. As of December 31, 2020, this material weakness was not fully remediated. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that was identified was primarily related to (a) a lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training and (b) a lack of established accounting processes and procedures for new complex transactions and consistent application of existing accounting processes and procedures. These deficiencies constitute a material weakness in our internal controls over financial reporting in both design and operation. As a result of the material weakness, we failed to identify adjustments in various areas, including but not limited to grants from government agencies and similar bodies and accrued liabilities due to third party service organizations. Additionally, certain of our documentation was insufficient for assessment of critical accounting guidance for complex or judgmental areas. We have relied on the assistance of outside advisors with expertise in these matters to assist us in the preparation of our financial statements and in our compliance with SEC reporting obligations and expect to continue to do so while we complete the remediation of this material weakness.

We have begun to implement a remediation plan to address this material weakness; however, our overall control environment may expose us to errors, losses or fraud. To date, this plan has included engaging external advisors to assist in improving our risk assessment process as well as the design, implementation and documentation of our internal control environment. Additionally, starting in the fourth quarter of 2020, we began to take additional steps to remediate the material weakness and improve our accounting function, including hiring additional senior level and staff accountants to support the timely completion of financial close procedures, implement robust processes and provide additional needed technical expertise. We have and plan to continue to engage third parties, as required, to assist with technical accounting, application of new accounting standards, tax matters and valuations of equity instruments. Additionally, we are developing and implementing consistent accounting policies and procedures and provide additional training to our accounting and finance staff as part of our effort to complete the remediation of the material weakness and for our management to fulfill its obligations in 2021, under Section 404(a) of the Sarbanes-Oxley Act of 2002, for developing and implementing internal controls over financial reporting and evaluating the effectiveness thereof.

While we are working to remediate the weakness as quickly and efficiently as possible, we cannot at this time, provide an estimate of the time frame we expect in connection with implementing our plan to remediate this material weakness. These remediation measures may be time consuming, costly and might place significant demands on our financial and operational resources. If we are unable to successfully remediate this material weakness, or other material weaknesses occur in the future, or successfully supervise and rely on outside advisors with expertise in these matters to assist us in the preparation of our financial statements, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our shares to decline significantly.

As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting in order to comply with Section 404 of the Sarbanes-Oxley Act. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in us and, as a result, the value of our common shares. In addition, because of our status as an emerging growth company, you will not be able to depend on any attestation from our independent registered public auditor as to our internal control over financial reporting for the foreseeable future.

As we completed our initial public offering in August 2020, we are required by Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in our second annual report. The process of designing and implementing internal control over financial reporting required to comply with this requirement is time consuming, costly and complicated. If during the evaluation and testing process we identify one or more other material weaknesses in our internal control over financial reporting or determine that existing material weaknesses have not been remediated, our management will be unable to assert that our internal control over financial reporting is effective. See "— We and our independent registered public auditors have identified a material weakness in our internal control over financial reporting. If we are unable to remediate the material weakness, or if other control deficiencies are identified, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports as a public company in a timely manner." In addition, if we fail to achieve and maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act.

Even if our management concludes that our internal control over financial reporting is effective, our independent registered public auditing firm may issue a report that is qualified if it is not satisfied with our controls or the level at which our controls are documented, designed, operated or reviewed. However, our independent registered public auditing firm will not be required to attest formally to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until the filing of our annual report following the date we are no longer an "emerging growth company," as defined in the JOBS Act. Accordingly, you may not be able to depend on any attestation concerning our internal control over financial reporting from our independent registered public accountants for the foreseeable future.

We cannot be certain as to the timing of completion of our evaluation, testing and any remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or with adequate compliance, our independent registered public auditing firm may issue an adverse opinion due to ineffective internal controls over financial reporting, and we may be subject to sanctions or investigation by regulatory authorities, such as the SEC. As a result, there could be a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, we may be required to incur costs in improving our internal control system and the hiring of additional personnel. Any such action could negatively affect our results of operations and cash flows.

5. Corporate Governance

5.1 Dutch corporate governance code

For the fiscal year ended December 31, 2020, the Dutch Corporate Governance Code 2016 (the "**DCGC**") applied to the Company. The text of the DCGC is publicly available on the website of the Dutch Corporate Governance Code Monitoring Committee: http://www.mccg.nl.

Except as set out below, during the fiscal year to which this report relates, the Company complied with the principles and best practice provisions of the DCGC, to the extent that these are directed at the Management Board and the Supervisory Board.

The financial year to which this report relates, was a year of transition for our Company as we moved from a private to a publicly listed company in August 2020. As a consequence of such transition, the DCGC has only become applicable to our Company for part of the financial year 2020 (as from August 2020 onwards). In this year of transition, we have not yet complied with the following recommendations from the DCGC (i) to discuss the effectiveness of the design and operation of our internal risk management and control systems with our audit committee and to render account this to our Supervisory Board, (ii) to carry-out the scenario analyses in advance of formulating our remuneration policy and (iii) to determine the pay ratios within our Company and its affiliated enterprise. Our Management Board, audit committee and Supervisory Board envisage to comply with such recommendations of the DCGC in the financial year 2021.

The Company has not fully established an internal audit function. The management board and supervisory board have considered whether setting up an internal audit department would be advisable and believes that given the size, resources, personnel and experience of the Company, adequate alternative measures have been taken as outlined elsewhere in this report (see also section 4.2).

Under our articles of association, managing directors and supervisory directors can only be dismissed by the general meeting by simple majority, if the supervisory board or, with respect to supervisory directors nominated by dievini or KfW, by dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) during the nomination period for dievini or by KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) during the nomination period for KfW, respectively, proposes the dismissal. In other cases, the general meeting can only pass such resolution by a two-thirds majority representing at least half of the issued share capital. The DCGC recommends that the general meeting can pass a resolution to dismiss a managing director or supervisory director by simple majority, representing no more than one-third of the issued share capital.

The DCGC recommends that, for each shareholder or group of affiliated shareholders, who directly or indirectly hold more than ten percent of our issued share capital, there should be no more than one member of our supervisory board who is affiliated with that shareholder or group of shareholders. During the initial nomination period, dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) has the right under our articles of association to make a binding nomination for one or more supervisory directors, depending on its shareholding at that time (see above under "Appointment of Managing Directors and Supervisory Directors") who may be affiliated with dievini. As of the date of this report, two members of our supervisory board are not independendent within the meaning of the DCGC.

The DCGC recommends that more than half of the members of our compensation committee and our nomination and corporate governance committee be independent within the meaning of the DCGC. As of the date of this report, more than half of the members of our compensation committee and our nomination and corporate governance committee are not independent within the meaning of the DCGC (see "Committees").

The DCGC recommends against providing equity awards as part of the compensation of a supervisory director. However, we expect to deviate from this recommendation and grant equity awards to our supervisory directors, consistent with U.S. market practice.

Our equity incentive plan (the "Plan") allows us to set the terms and conditions of equity awards granted thereunder. Under the Plan, we may grant common shares that are not subject to a lock-up period of at least five years after the date of grant, and we may grant options without restricting the exercisability of those options during the first three years after the date of grant. In those cases, this would cause additional deviations from the DCGC.

5.2 Code of conduct and ethics and other corporate governance practices

The Company has adopted a code of conduct and ethics which can be accessed at https://www.curevac.com. The Company does not voluntarily apply other formal codes of conduct or corporate governance practices.

5.3 Risk management and control systems

See section 4.1 of this report for an overview of the main characteristics of the Company's risk management and control systems relating to the process of financial reporting by the Company and the Company's group companies whose financial information is included in the Company Financial Statements.

5.4 General meeting of shareholders

5.4.1 Functioning of the General Meeting

Annually, at least one general meeting of the Company (the "**General Meeting**") must be held. This annual General Meeting must be held within six months after the end of the Company's fiscal year. A General Meeting must also be held within three months after the Management Board has decided that it is likely that the Company's equity has decreased to or below 50% of its paid up and called up share capital. In addition, without prejudice to the relevant best practice provisions of the DCGC with respect to invoking a 'response period', a General Meeting must be held when requested by one or more shareholders and/or others with meeting rights under Dutch law collectively representing at least 10% of the Company's issued share capital, provided that certain criteria are met. Any additional General Meeting shall be convened whenever the Management Board or the Supervisory Board would so decide. Each General Meeting must be held in the Netherlands in any of the cities of Arnhem, Assen, The Hague, Haarlem, 's-Hertogenbosch, Groningen, Leeuwarden, Lelystad, Maastricht, Middelburg, Rotterdam, Schiphol (Haarlemmermeer), Utrecht or Zwolle.

For purposes of determining who have voting rights and/or meeting rights under Dutch law at a General Meeting, the Management Board may set a record date. The record date, if set, shall be the 28th day prior to that of the General Meeting. Those who have voting rights and/or meeting rights under Dutch law on the record date and are recorded as such in one or more registers designated by the Management Board shall be considered to have those rights at the General Meeting, irrespective of any changes in the composition of the shareholder base between the record date and the date of the General Meeting. The Company's articles of association require shareholders and others with meeting rights under Dutch law to notify the Company of their identity and their intention to attend the General Meeting. This notice must be received by the Company ultimately on

the seventh day prior to the General Meeting, unless indicated otherwise when such General Meeting is convened.

5.4.2 Powers of the General Meeting

All powers that do not vest in the Management Board or the Supervisory Board pursuant to applicable law, the Company's articles of association or otherwise, vest in the General Meeting. The main powers of the General Meeting include, subject in each case to the applicable provisions in the Company's articles of association:

a. the appointment, suspension and dismissal of Managing Directors and Supervisory Directors;

b. the approval of certain resolutions of the Management Board concerning a material change to the identity or the character of the Company or its business;

c. the reduction of the Company's issued share capital through a decrease of the nominal value, or cancellation, of shares in its capital;

d. the adoption of the Company's statutory annual accounts;

e. the appointment of the Dutch independent auditor to examine the Company's statutory annual accounts;

f. amendments to the Company's articles of association;

g. approving a merger or demerger by the Company, without prejudice to the authority of the Management Board to resolve on certain types of mergers and demergers if certain requirements are met; and

h. the dissolution of the Company.

In addition, the General Meeting has the right, and the Management Board and the Supervisory Board must provide, any information reasonably requested by the General Meeting, unless this would be contrary to an overriding interest of the Company.

5.4.3 Shareholder rights

Each share in the Company's capital carries one vote. Shareholders, irrespective of whether or not they have voting rights, have meeting rights under Dutch law (including the right to attend and address the General Meeting, subject to the concept of a record date as described in section 5.4.1). Furthermore, each share in the Company's capital carries an entitlement to dividends and other distributions as set forth in the Company's articles of association. Pursuant to the Company's articles of association, any such dividend or other distribution shall be payable on such date as determined by the Management Board and the Management Board may also set a record date for determining who are entitled to receive any such dividend or other distribution (irrespective of subsequent changes in the shareholder base). The record date for dividends and other distributions shall not be earlier than the date on which the dividend or other distribution is announced. In addition,

shareholders have those rights awarded to them by applicable law.

5.5 Management Board and Supervisory Board

5.5.1 Board Structure

We have a two-tier board structure consisting of a management board (*bestuur*) and a separate supervisory board (*raad van commissarissen*). There are no family relationships among any of our managing directors and supervisory directors.

5.5.2 Management Board

The Management Board is charged with managing the Company's affairs and the implementation of its strategy. In performing their duties, our managing directors shall be guided by the interests of the Company and of the business connected with it. Our senior management has an average of 17 years of experience in the biopharmaceutical industry. Many of the members of our management team have worked together as a team for many years.

Our Management Board has developed a view on long-term value creation by the Company and has formulated a strategy consistent with that view. The Supervisory Board has been actively engaged at an early stage in formulating the Company's strategy and supervises the manner in which the strategy is implemented.

As at December 31, 2020, the Management Board[2] was composed as follows:

Name and age	**Gender**	**Nationality**	**Date of initial Appointment***	**Expiration of current term of office**	**Attendance rate at meetings of the board**
Franz-Werner Haas, LLD, LLM (51)	M	German	6/2012	2022	100%
Florian von der Mülbe, Ph.D., MBA (48)	M	German	9/2015	2023	91%
Mariola Fotin-Mleczek, Ph.D. (54)	F	Polish	9/2015	2023	97%
Pierre Kemula, B.Sc. (47)	M	French	11/2016	2023	97%
Antony Blanc, Ph.D. (53)*	M	French	12/2020	2023	100%
Igor Splawski, Ph.D., MSc (53)	M	Polish	7/2020	2023	97%

* The date of initial appointment includes the term of office served as managing director of CureVac AG.

** We consider Mr. Blanc an executive officer and a member of our senior management team but he is not formally appointed as managing director of the Company.

The following is a brief summary of the prior business experience and principal business activities performed outside of CureVac of our managing directors. Unless otherwise indicated, the current

[2] Bernd Winterhalter was a member of the management team until 02/2021. We consider Mr. Winterhalter an executive officer and a member of our senior management team but he is not registered in Germany as a member of our management board and will not be appointed as a member of the management board of CureVac N.V. He serves as our interim chief development officer under a consulting agreement that specifies his service is indefinite and may be terminated by either party with four weeks' notice.

business addresses for each managing director is Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany.

Franz-Werner Haas, LLD, LLM has been our chief executive officer and chief operating officer since August 2020 and June 2018, respectively. Mr. Haas was our chief corporate officer from 2012 until 2018 and our deputy chief executive officer from March 2020 until August 2020. Before joining CureVac, he was Vice President of Operations and Chief Compliance Officer of SYGNIS Pharma AG from May 2005 until March 2012, where he was responsible for the execution of M&A and capital market transactions. Mr. Haas started his professional career as an Assistant to the Executive Board of a privately held international commercial and service enterprise before assuming several management positions in the life science industry, including Vice President and General Counsel of LION bioscience from 2002 until December 2004. Mr. Haas also served as the General Counsel of Sirona Dental Systems from January 2005 to May 2005. He studied law at the University of Saarbruecken, K.U. Leuven and also holds an LLM from the University of Edinburgh.

Florian von der Mülbe, Ph.D., MBA is our chief production officer since October 2018 and managing director of CureVac Real Estate GmbH since February 2017. Dr. von der Mülbe founded CureVac in 2000 together with Dr. Hoerr. Prior to his current position as chief production officer, Dr. von der Mülbe served as our chief operating officer, accountable for a variety of internal functions such as IT, project management, quality, including technical development and manufacturing, where he established the first GMP production for mRNA worldwide. He started his professional career as a trainee at Roche AG. Dr. von der Mülbe is trained in biochemistry and business administration, and he received his Ph.D. in biochemistry from Tübingen University and an MBA from the European School of Business in Reutlingen.

Mariola Fotin-Mleczek, Ph.D. is our chief technology officer since October 2018. She joined CureVac in May 2006 and was responsible for the development and preclinical testing of mRNA technology applied in different therapeutic areas such as: infectious diseases, oncology and protein delivery. Her scientific expertise includes immunology, cell biology, signal transduction, apoptosis and mechanism of cellular uptake. Dr. Fotin-Mleczek was trained in biology at the University of Stuttgart. She is the inventor of multiple mRNA technology-related key patents and she authored more than 30 scientific publications with a focus on mRNA technology.

Pierre Kemula, B.Sc. is our chief financial officer since 2016. Previously, he was the chief financial officer of Pixium Vision from 2014 until 2016, where he successfully contributed to the listing of the company on Euronext in Paris, and Vice President of Corporate Finance, Treasury and Financial Markets, as well as Director of Investor Relations, Vice-President of Investor Relations and Investor Relations Officer at Ipsen from 2008 until 2014. Earlier in his career, Mr. Kemula worked with major strategy consulting firms (Roland Berger, Bossard Consultants and Gemini Consulting). He holds a Bachelor of Science in Management Sciences from the London School of Economics, or LSE, in the United Kingdom.

Igor Splawski, Ph.D., MSc is our chief scientific officer since July 2020. Prior to joining us, Dr. Splawski was an executive director at the Novartis Institutes for BioMedical Research (NIBR) Biologics Center since 2018, and director from 2016 until 2018. Previously, he was a director in the cardiovascular and metabolism disease area at NIBR from 2009 until 2016 and a senior investigator in ophthalmology at NIBR from 2005 to 2009. At NIBR, Dr. Splawski successfully led over 100 scientists in identifying and evaluating protein, mRNA and AAV targets, and discovered mRNA technology for antibody generation. His work at Novartis contributed to 10 clinical antibodies and proteins, which have achieved eight positive proof-of-concept trials. Earlier in his career, he served as an associate at both the Howard Hughes Medical Institute and the Children's Hospital in Boston. Dr. Splawski acted as an assistant professor and instructor at Harvard Medical School, where he identified genes for inherited and drug-induced disorders. Dr. Splawski is the inventor on 28 patents and author of 22 research publications. Dr. Splawski holds a Ph.D. in human genetics from the University of Utah and an MSc in biotechnology from Sofia University.

Antony Blanc, Ph.D. is our chief business officer and our chief commercial officer since December 2020. Previously, Dr. Blanc served biotech clients in Europe as consultant and as an Associate Partner with McKinsey & Company. Between 2009 and 2017, Dr. Blanc developed deep and broad cross-functional expertise in vaccines by serving in several senior roles at GSK Vaccines, including leading strategic marketing, strategic pricing, joint ventures and the integration of the Novartis Vaccines business unit. From 2000 to 2009, Dr. Blanc held leadership roles in several biotechs companies as Chief Business Officer, such as Synosia, as the Head of Biopharma at Syngenta, where he built a business unit of over 100 people focusing on biologicals and plant-made antibodies, and as VP Business Development at Synt:em. Dr. Blanc started his career at the strategy

consulting firm McKinsey & Company in 1994, focusing on pharma and biotech. He holds a Ph.D. in Molecular Biology (control of mRNA translation) and a BS.c. in Biochemistry from McGill University in Montreal, Canada.

5.6 Supervisory board

The Supervisory Board is charged with the supervision of the policy of the Management Board and the general course of affairs of the Company and of the business connected with it. The Supervisory Board provides the Management Board with advice. In performing their duties, our supervisory directors shall be guided by the interests of the Company and of the business connected with it. The Management Board provides the Supervisory Board with the information necessary for the performance of its supervisory tasks in a timely fashion. At least once a year, the Management Board also informs the Supervisory Board in writing of the main features of the strategic policy, the general and financial risks and the administration and control system of the Company.

As at December 31, 2020, the Supervisory Board was composed as follows:

Name and age	Gender	Nationality	Date of initial appointment	Expiration of current term of office	Attendance rate at Supervisory Board meetings
Baron Jean Stéphenne, MSc, MBA (71)	M	Belgian	8/2015	2024	91 %
Ralf Clemens, MD, Ph.D. (68)	M	German	8/2015	2024	82%
Mathias Hothum, Ph.D. (53)	M	German	8/2015	2024	100%
Hans Christoph Tanner, Ph.D. (69)	M	Swiss	8/2015	2024	100%
Friedrich von Bohlen und Halbach, Ph.D. (58)	M	German	8/2015	2022	91%
Timothy M. Wright, MD (65)	M	USA	6/2019	2022	100%
Craig A. Tooman, MBA (55)	M	USA	6/2019	2022	100%
Viola Bronsema, Ph.D. (58)	F	German	8/2020	2024	100%

The following is a brief summary of the prior business experience and principal business activities performed outside of CureVac of our supervisory directors. Unless otherwise indicated, the current business addresses for each of our supervisory directors is Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany.

Baron Jean Stéphenne, MSc, MBA has served as a supervisory director since 2015. Since 2018 Mr. Stéphenne serves as the Chairman of the board at Bone Therapeutics. Mr. Stéphenne was the CEO of GSK Biologicals from 1989 until 2012 and the President of GSK Biologicals from 2002 until 2012, where he was instrumental in building one of the world's leading vaccine companies. In 1974, Mr. Stéphenne joined SmithKline-Rit, as engineer in biology in research and development. He also served as the President of UWE (Union Wallonne des Entreprises) from 1997 until 2000. Mr. Stéphenne was the chairman of BESIX Group S.A./N.V. and TiGenix N.V., IBA Wallonia Foreign Trade and Investment Agency, Henogen S.A., Aseptic Technologies. He was also a director of Fortis bank, GBL and Bone Therapeutics.

Ralf Clemens, MD, Ph.D. has served as a supervisory director since 2015. Dr. Clemens is the principal and founder of Grid Europe Ltd. Consulting (Global Research in Infectious Diseases) since 2015. Dr. Clemens has been working in the pharmaceutical industry since 1988 in various senior scientific and business positions. He served as a Senior Vice President and Head of Development for the Global Vaccine Business Unit at Takeda Pharmaceuticals International, Inc. from 2012 until 2014. Prior to this position, Dr. Clemens led the global vaccine development at Novartis from 2006 until 2012, and before that, he was the Head of GSK Biologicals' vaccine development and Latin American business strategy from 1992 until 2006. During these years, Mr. Clemens developed and brought to licensure more than 25 different vaccines globally. He currently serves as a Member of the Board of Trustees of the International Vaccine Institute IVI in Seoul, Korea and as external scientific advisor to the Bill & Melinda Gates Foundation as well as chairing the Scientific Advisory Board (COVID-19

Vaccine Program) at Clover Biopharmaceuticals. He is a member of the Selection Committee of GHIT Tokyo, Japan and has been a member of the Scientific Committee of CEPI, Oslo, Norway (ending May 2021). He graduated with an M.D. from the University of Mainz, Germany and holds an executive business degree from the Wharton Business School.

Mathias Hothum, Ph.D. has served as a supervisory director since 2015. Dr. Hothum is the managing director of dievini Hopp BioTech holding GmbH & Co. KG, or dievini. dievini manages the biotech investments of SAP co-founder Dietmar Hopp. For the past 25 years, Dr. Hothum has worked as a health economist in the healthcare, health services and life sciences sectors. Dr. Hothum specializes in financing, pricing, reimbursement and in the evaluation of mid-sized companies, as well as of publicly owned/ market-listed companies. He is the owner and founder of HMM-Consulting. Furthermore, Dr. Hothum serves as a supervisory director of a few biotech companies, including Heidelberg Pharma AG, Apogenix GmbH, Cytonet GmbH, Novaliq GmbH, Molecular Health GmbH and Joimax GmbH. He received his Ph.D. in economics from the University of Magdeburg and degree in economics from the University of Mannheim.

Hans Christoph Tanner, Ph.D. has served as a supervisory director since 2015. Dr. Tanner served as the chief financial officer and head of investor relations of Cassiopea S.p.A. from 2015 until December 31, 2020. He served as Cosmo Pharmaceuticals N.V.'s chief financial officer from 2006 until 2016, head of investor relations from 2006 until 2017 and head of transactions office from 2017-2020. Dr. Tanner has also served as a board member of Cosmo Pharmaceuticals N.V. since 2006, where in 2020 he became a Non-Executive Director (ended in May 2021). Dr. Tanner is also a member of the supervisory board or advisory board (Verwaltungsrat/Beirat) of DKSH AG, Paion AG since 2017, Qvanteq AG since 2011, and Joimax GmbH since 2003. From 1998 to 2001 he was a partner of Dr. Ernst Mueller-Moehl and co-founder of the 20 Minuten group of newspapers and founded A&A Active Investor, a SIX listed investment company. From 1992 to 1998 Dr. Tanner was the head of corporate finance & capital markets of UBS in Zurich and from 1976 to 1991 he had various functions in the Corporate Banking Department of UBS in Zurich, Madrid and Los Angeles. He received his Ph.D. in economics from the University of St. Gallen and degree in economics from the University of St. Gallen.

Friedrich von Bohlen und Halbach, Ph.D. has served as a supervisory director since 2015. Dr. von Bohlen und Halbach is the managing partner and co-founder of dievini. dievini manages the life science activities and investments of Dietmar Hopp, co-founder of SAP, and his family. Between 1992 to 1997 he held various positions at Fresenius AG, FAG Kugelfischer KGaA and WASAG Chemie AG. In 1997, Dr. von Bohlen und Halbach founded LION bioscience, AG and served as its CEO until 2003. He is chairman of the Board of Apogenix AG and Novaliq GmbH, and board member of CureVac NV, Heidelberg Pharma AG and Co-Chair of the Evaluation Board of the Wyss Translational Center Zurich. Friedrich is also co-founder and managing director of Molecular Health GmbH. Dr. von Bohlen und Halbach received his Ph.D. in neurobiology from the Swiss Federal Institute of Technology (ETH) in Zurich and a diploma in biochemistry from the University of Zurich.

Timothy M. Wright, MD has served as a supervisory director since 2019. Since 2019, Dr. Wright is a General Partner at TIME BioVentures, and has also served as director of Schrodinger since 2015. Dr. Wright served as the Chief Research and Development Officer for Regulus Therapeutics from 2016 until 2019. Prior to Regulus, he served as Executive Vice President of Translational Science at California Institute for Biomedical Research Between from 2015 until 2016. Between 2004 to 2014, Dr. Wright held positions of increasing importance at Novartis and Novartis Institute for Biomedical Research, culminating as Global Head of Pharma Development. He also served in roles of increasing importance at Pfizer, ultimately as Senior Director, Clinical Sciences / Clinical Exploratory Head — Inflammation between 2001 until 2004. Dr. Wright was Assistant Professor, Associate Professor with tenure, Chief of Rheumatology and Clinical Immunology, and Director of the UPMC Arthritis Institute at the University of Pittsburgh from 1991 until 2001. From 1983 to 1991, Dr. Wright was a post-doctoral fellow, Instructor and Assistant Professor at the Johns Hopkins University School of Medicine. Dr. Wright received a B.A. in Biology from the University of Delaware and an M.D. from the Johns Hopkins University School of Medicine, where he also completed post-doctoral training.

Craig A. Tooman, MBA has served as a supervisory director since 2019. Since January of 2021, Mr. Tooman has served as the Chief Financial Officer for Silence Therapeutics, Inc. Prior to that position, he served as the COO/CFO of Vyome Therapeutics, Inc. Prior to this, he was the President, CEO and Board Director at Aratana Therapeutics Inc. and led the merger of Aratana with Elanco Animal Health in July of 2019. He has served at Aratana since 2013. From 2012 to 2014, Mr. Tooman served as the Chief Executive Officer and Treasurer of Avanzar Medical, Inc., a company focused on oncology. He also founded Stockbourne LLC in 2011 and remains a Principal. Mr. Tooman served as

the Chief Financial Officer and Senior Vice President of Finance at Ikaria, Inc. from 2010 until 2011. Before that, he served as the Executive Vice President of Finance and Chief Financial Officer of Enzon Pharmaceuticals Inc. from 2005 until 2010 and played a key role in the merger with Sigma Tau. Mr. Tooman was the Senior Vice President of Strategic Planning and Corporate Communications of ILEX Oncology Inc., and led the integration of the company with the Genzyme Corporation in 2004. Prior to this, he served in senior positions of increasing responsibility, including Vice President of Investor Relations, at Pharmacia Corporation and its predecessor company, Pharmacia & Upjohn. He received a Master of Business Administration degree in finance from the University of Chicago and a Bachelor of Arts degree in economics from Kalamazoo College.

Viola Bronsema, Ph.D. has served as a supervisory director since August 2020. Dr. Bronsema has been Secretary General and CEO of BIO Deutschland, Germany's Biotechnology Industry Association, since 2006. With its 350 corporate members, the sector association represents the interests of Germany's biotechnology industry nationally and internationally. Currently, she is member of the Advisory Boards of the German Federal Government (Bioeconomy Advisory Board), the German Life Sciences Association (VBIO e. V.) and one of the oldest German economic policy associations (WPCD e.V.). Previously, Dr. Bronsema was Head of Communications of Roche Diagnostics GmbH and of Roche Diagnostics Europe, Middle East, Africa, and before that, of Lilly Pharma Holding GmbH. She earned her Ph.D. at the Centre for Molecular Biology (ZMBH) at the University of Heidelberg, Germany.

All of our supervisory directors, except for Mathias Peter Hothum and Friedrich Harald von Bohlen und Halbach, are independent within the meaning of the DCGC.

5.7 Evaluation

During the fiscal year to which this report relates, the Supervisory Board has evaluated its own functioning, the functioning of the committees of the Supervisory Board and that of the individual managing directors and supervisory directors on the basis of self-evaluation form distributed to, and completed by, the managing directors and supervisory directors. As part of these evaluations, the Supervisory Board has considered (i) substantive aspects, mutual interaction and the interaction between the Supervisory Board and the Management Board, (ii) events that occurred in practice from which lessons may be learned and (iii) the desired profile, composition, competencies and expertise of the Supervisory Board. In addition, the Management Board has evaluated its own functioning and that of the individual managing directors. These evaluations are intended to facilitate an examination and discussion by the Management Board and the Supervisory Board of their effectiveness and areas for improvement. On the basis of these evaluations, the Supervisory Board has concluded that the Management Board and Supervisory Board are functioning properly.[3]

5.8 Committees

5.8.1 General

The Supervisory Board has established an audit committee, a compensation committee, a nomination and corporate governance committee and a special committee. Each committee operates pursuant to its charter.

5.8.2 Audit Committee

The audit committee consists of Hans Christoph Tanner (as chairman), Jean Stéphenne, Mathias Hothum, Craig A. Tooman and Timothy M. Wright, MD. The audit committee assists the supervisory board in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee is responsible for the appointment, compensation, retention and oversight of the work of our independent registered public auditing firm. Our supervisory board has determined that Hans Christoph Tanner, Baron Jean Stephenne and Craig A. Tooman satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act and qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC. The composition of our audit committee is consistent with the best practice provisions of the DCGC.

We are relying on the phase-in rules of the SEC and Nasdaq with respect to the independence of our audit committee. These rules require that all members of our audit committee must meet the

[3] If there are other relevant conclusions that were drawn from the evaluations, those should be disclosed as well.

independence standard for audit committee membership by August 13, 2021. The audit committee is governed by a charter that complies with applicable Nasdaq rules, which charter has been posted on our website.

During the fiscal year to which this report pertains, the Audit Committee met 5 times and discussed matters relating to the following topics, among others: IPO readiness, HGB and IFRS financial statements, Treasury,Budget; and the Audit Committee's self-assessment.

5.8.3 Compensation Committee

The compensation committee consists of Mathias Hothum (as chairman), Friedrich von Bohlen und Halbach, Hans Christoph Tanner, Craig A. Tooman and Viola Bronsema. The compensation committee assists the supervisory board in determining compensation for our executive officers and our managing directors and supervisory directors. The composition of our compensation committee deviates from the best practice provisions of the DCGC, because half of its members are not independent within the meaning of the DCGC because of their affiliation with dievini.

Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard director fees. As permitted by the listing requirements of Nasdaq, we opted out of Nasdaq Listing Rule 5605(d), which requires that a compensation committee consist entirely of independent supervisory directors. The compensation committee is governed by a charter that has been posted on our website.

During the fiscal year to which this report pertains, the Compensation Committee exchanged topcis on occurance via email relating to the following topics, among others: Separation agreement with Dan Menichella, contract negotiations with potential CDO candidate, Salary Negotiations with Management, Contract extension; and the Compensation Committee's self-assessment.

5.8.4 Nomination and Corporate Governance Committee

The nomination and corporate governance committee consists of Mathias Hothum (as chairman), Friedrich von Bohlen und Halbach, Hans Christoph Tanner, Craig A. Tooman and Viola Bronsema. The nomination and corporate governance committee assists our supervisory board in identifying individuals qualified to become our managing directors or supervisory directors consistent with criteria established by us and in developing our code of business conduct and ethics. The composition of our nomination and corporate governance committee deviates from the best practice provisions of the DCGC, because more than half of its members are not independent within the meaning of the DCGC because of their affiliation with dievini or KfW.

As permitted by the listing requirements of Nasdaq, we opted out of Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations. The nominating and corporate governance committee is governed by a charter that is posted on our website.

During the fiscal year to which this report pertains, the Nomination and Corporate Governance Committee exchanged topcis on occurance via email relating to the following topics, among others: Appointment of Franz-Werner Haas as CEO, Appointment of Mr Splawski as member of the management board~~,~~ appointment of management board and supervisory board members at the time CureVac B.V. was converted into CureVac N.V. as part of the IPO process; and the Nomination and Corporate Governance Committee's self-assessment.

The Compensation as well as the Nomination and Corporate Governance Committee meetings were hold together and topics discussed.

5.8.5 Special Committee

Under the internal rules applicable to our supervisory board, resolutions of our supervisory board to approve a resolution of our management board to exclude or limit pre-emption rights (except in connection with the ordinary operation of our equity incentive plans) or to issue shares against non-cash contribution, shall require the approval of a special committee consisting of one supervisory director nominated by dievini (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) (during the initial nomination period for dievini), the supervisory director nominated by KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) (during the initial nomination period for KfW) and, if

applicable, one supervisory director nominated by a nomination concert. In this special committee, the affirmative votes of one supervisory director nominated by dievini (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) (during the initial nomination period for dievini) and the supervisory director nominated by KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) (during the initial nomination period for KfW) shall be required. Similarly, the affirmative votes of at least one supervisory director nominated by dievini (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) (during the initial nomination period for dievini) and the supervisory director nominated by KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) (during the initial nomination period for KfW) shall be required for certain resolutions of the supervisory board specified by our articles of association and the internal rules applicable to our supervisory board.

5.9 Diversity policy

The Company has a diversity policy with respect to the composition of the Management Board and the Supervisory Board. The Company is committed to supporting, valuing and leveraging the value of diversity. However, the importance of diversity, in and of itself, should not set aside the overriding principle that someone should be recommended, nominated and appointed for being "the right person for the job". Although the Company has not set specific targets with respect to particular elements of diversity, the Company believes that it is important for the Management Board and the Supervisory Board to represent a diverse composite mix of personal backgrounds, experiences, qualifications, knowledge, abilities and viewpoints. The Company seeks to combine the skills and experience of long-standing members of the Management Board and the Supervisory Board with the fresh perspectives, insights, skills and experiences of new members. To further increase the range of viewpoints, perspectives, talents and experience within the Management Board and the Supervisory Board, the Company strives for a mix of ages in the composition of those bodies, but also does not set a specific target in this respect. The Company recognises and welcomes the value of diversity with respect to age, gender, race, ethnicity, nationality, sexual orientation and other important cultural differences. The Company is committed to seeking broad diversity in the composition of the Management Board and the Supervisory Board and will consider these attributes when evaluating new candidates in the best interests of the Company and its stakeholders. In terms of experience and expertise, the Company intends for the Management Board and the Supervisory Board to be composed of individuals who are knowledgeable in one or more specific areas detailed in the Company's diversity policy.

The Company believes that the composition of the Management Board and the Supervisory Board is such, that the Company's diversity objectives, as outlined above, have been achieved.

5.10 Corporate values and code of conduct and ethics

The Supervisory Board and Management Board have adopted a written Code of Conduct and Ethics that applies to our managing directors, supervisory directors, officers and employees, including our officers, permanent and temporary employees, leased and contract employees of CureVac or our subsidiaries. The Code of Conduct and Ethics is available on our website, https://www.curevac.com. Our management board is responsible for administering the Code of Conduct and Ethics. The management board is allowed to amend, alter or terminate the Code of Business Conduct and Ethics. In addition, we intend to post on our website all disclosures that are required by law or the rules of Nasdaq, concerning any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics.

6. Compensation report

6.1 Compensation policy

Pursuant to Section 2:135(1) DCC, our General Meeting has adopted a compensation policy for our Management Board members (the "**Compensation Policy**").

The Compensation Policy is designed to:

- attract, retain and motivate Management Board members with the leadership qualities, skills and experience needed to support and promote the growth and sustainable success of the Company and its business;
- drive strong business performance, promote accountability, incentivize Management Board members to achieve short and long-term performance targets with the objective of substantially increasing the Company's equity value;
- assure that the interests of the Management Board members are closely aligned to those of the Company, its business and its stakeholders; and
- ensure the overall market competitiveness of the compensation packages which may be granted to the Management Board members, while providing the Supervisory Board sufficient flexibility to tailor the Company's compensation practices on a case-by-case basis, depending on the market conditions from time to time.

We believe that this approach and philosophy will benefit the realization of the Company's long-term objectives while keeping with the Company's risk profile.

The Supervisory Board is currently not contemplating to propose any change to the Compensation Policy or the implementation thereof in the upcoming fiscal years.

6.2 Compensation of managing directors

For the year ended December 31, 2020, the aggregate compensation accrued or paid to our managing directors for services in all capacities was €4,650,582 (including an approximate conversion of Mr. Menichella's, Mr. Voliotis's and Mr. Splawski's compensation from USD). The following table sets forth the compensation and benefits provided to our management board in the year ended December 31, 2020.

Name*	Salary (€)	Bonus(1) (€)	All Other Compensation (2) (€)	Total Compensation (3) (€)
Daniel L. Menichella(4)	129,843	318,218	651,025(5)	1,099,086
Florian von der Mulbe	258,533	235,375	25,482	519,390
Mariola Fotin-Mleczek	226,866	221,875	19,492	468,233
Franz-Werner Haas	264,866	312,150	24,865	601,881
Pierre Kemula	250,199	235,375	99,928	585,502
Bernd Winterhalter(6)	455,955	—	—	455,955
Dimitris Voliotis(7)(8)	11,283	—	306,935	318,218
Igor Splawski(9)(10)	146,883	—	74,154	220,037
Antony Blanc(11)	26,667	—	1,380	28,047
Ulrike Gnad-Vogt(12)	250,000	91,406	12,827	354,233

(1) This amount represents the annual variable payment received based on a percentage of yearly gross remuneration for reaching certain targets agreed upon with the supervisory board. Performance criteria for bonus pay outs include a. ensure financing of CV group; b. Research & Development in all therapeutic areas; c. Technology Development & Manufacturing. Moreover, due to termination of contract (see 4), Covid and IPO challenges there are also special bonuses for 2020 paid out and included.

(2) All other compensation includes other monetary benefits and contributions to social security insurance, if any.

(3) This column does not include the virtual shares held by certain of the management board members. Information can be found in consolidated Notes 9 (share-based payment).

(4) On March 10, 2020, the service agreement with Daniel Menichella (the former CEO) was discontinued. He was succeeded on the management board by Dr. Hoerr on that same day. Dr. Hoerr was a managing director of CureVac AG at the time of the Corporate Reorganization but is no longer a managing director of CureVac AG and is not a managing director of CureVac N.V.

(5) This amount includes the $750,000 severance payment Mr. Menichella received in connection with the discontinuation of his service agreement. The table reflects an approximate conversion of Mr. Menichella's severance payment in EUR.

(6) We considered Mr. Winterhalter an executive officer and a member of our senior management team but he was not registered in Germany as a member of our management board and was not appointed as a member of the management board of CureVac N.V. upon the closing of the initial public offering. He served as our interim chief development officer under a consulting agreement dated as of December 14, 2019 that specified his service was indefinite and may be terminated by either party with four weeks' notice. The consulting agreement with Mr. Winterhalter was terminated in February 2021. Amount included in his total compensation column includes reimbursement for travel and out-of-pocket expenses.

(7) Mr. Voliotis commenced employment effective January 28, 2019 and resigned from our management board effective December 2019, with his actual employment ending on January 11, 2020. During this period, he was paid in USD. The table reflects an approximate conversion of Mr. Voliotis' compensation in EUR.

(8) This amount includes the $376,250 severance payment Mr. Voliotis received in connection with the discontinuation of his service agreement. The table reflects an approximate conversion of Mr. Voliotis' severance payment in EUR.

(9) Dr. Splawski became a managing director on July 15, 2020.

(10) Compensation is expressed in EUR. Dr. Splawski was based in Boston and paid by CureVac Inc. from July 15, 2020 until August 31, 2020. During this period, he was paid in USD. Dr. Splawski moved to Tübingen and was paid by CureVac AG beginning on September 1, 2020. During this period, he was paid in EUR. The table reflects an approximate conversion of Dr. Splawski's compensation in EUR.

(11) Dr. Blanc did not become a managing director of CureVac AG until November 30, 2020. Mr. Blanc has not yet been formally appointed as a managing director of CureVac N.V.

(12) Dr. Gnad-Vogt did not become the interim chief development officer until March 2021 and has not yet been formally appointed as a managing director of CureVac N.V.

We did not provide pension, retirement or similar benefits to our managing directors and supervisory directors board in the year ended December 31, 2020.

Bonus Plan

We maintain and implement a management bonus plan for the members of our management. Under the management bonus plan, we provide a variable bonus payment as a component of management compensation that ranges from 45% to 55% of the individual's annual base salary, depending on management level. We agree upon the respective individual amount of the target bonus with each employee on an individual contractual basis. The annual performance review is used to measure the achievement of objectives. In the individual's annual performance review, we measure the achievement of objectives (performance criteria) for the past year and define the objectives for the coming year. The calculation of the respective bonus payment is based on the individual degree of target achievement, which is then calculated as a percentage of the annual base salary and is usually paid out in March of the following year. The bonus is calculated on a pro rata basis if the individual joins or leaves CureVac during the year.

Equity Incentive Plans

Certain members of our management received share-based compensation under the legacy management stock option plan, or Legacy Management Stock Option Plan, in the form of share option awards. These options granted the holder the right to purchase series A shares of CureVac AG for a purchase price of €1 per share. All of the outstanding options have vested and will expire on December 31, 2021. From the time of our Corporate Reorganization until December 31, 2021, the optionholders will have the option to convert these options into option awards exercisable for common shares of CureVac N.V. on a 1 to 133.0778 basis. Following this conversion, subject to the vesting, exercise and expiration terms discussed above, these option awards will be governed by the

new equity incentive plan, or the Plan, that was established in connection with the completion of our Corporate Reorganization.

In addition to the management share option awards described above, we maintain a virtual share plan for members of the management board and other key employees of CureVac, or Prior VSOP. As of December 31, 2020, there are 7,964,573 awards outstanding and 43,383 awards available for issuance under the Prior VSOP. Ten percent (10%) of each award under the Prior VSOP became exercisable upon expiry of the 180 day lock-up period following the closing of CureVac's initial public offering, which occurred at the end of February 9, 2021. The remaining part of each award may be exercised (in whole or in part) upon the occurrence of certain defined triggering events, including, but not limited to, drug approval, or the sale by a majority shareholder of 5% of our outstanding shares, in each case subject to the conditions of the Prior VSOP. The rights under the Prior VSOP will terminate after the expiry of the ninth calendar year after the listing of our common shares on Nasdaq. The Prior VSOP was restructured upon the completion of our Corporate Reorganization. Following this restructuring, upon vesting of virtual shares, the Company will provide the holder (in whole or in part) with cash or common shares of CureVac N.V. (instead of shares of CureVac AG) on a 1 to 133.0778 basis.

Due to the increase in value of CureVac prior to our Corporate Reorganization, we modified our incentive program to allow members of the management board and other employees to participate in the value-increased business based on CureVac's valuation at the time of its reorganization and conditional upon the occurrence of certain enumerated exercise cases reflecting such value-increase, or New VSOP. Each virtual share tracked one underlying series A share of CureVac AG. The New VSOP provided a cash-claim against CureVac in the amount of the positive difference between the value of CureVac per virtual share at the grant date (as determined by CureVac when the New VSOP was established) and the value per virtual share at the time of exercise of such virtual share (such value to be derived from the valuation of CureVac in the relevant triggering event) and gave CureVac discretion to provide tradable shares against payment of the value of CureVac per virtual share at the grant date. Such awards provided under the New VSOP had a term of ten years from the date of grant and vest over four years, where 25% vest after the first anniversary of the hire date and the remainder vests monthly with vesting on the last day of the month. These virtual shares were assumed by CureVac N.V. upon the completion of our Corporate Reorganization. At this time, the virtual shares were converted into options, exercisable for common shares of CureVac N.V. on a 1 to 133.0778 basis. Following this conversion, subject to the vesting, exercise and expiration terms discussed above, these option awards are governed by the Plan.

In connection with our initial public offering, we established the Plan pursuant to which we may grant options, restricted stock, restricted stock units, share appreciation rights and other equity and equity-based awards. As of December 31, 2020, there are 13,917,808 awards outstanding and 13,256,713 awards available for issuance under the Plan. The maximum number of common shares underlying awards granted pursuant to the Plan, including the awards granted in connection with the conversion of awards under the Legacy Management Stock Option Plan and the New VSOP, as discussed above, plus the common shares underlying awards under the Prior VSOP to the extent such awards have not yet been exercised or settled, will in total not exceed an equivalent of 15% of our issued share capital from time to time. The Plan is administered by our management board and supervisory board, where appropriate, on the basis of a recommendation of our compensation committee (the body administering the Plan, the, or Committee. Awards under the Plan may be granted to our employees, our managing directors and supervisory directors, consultants or other advisors. Awards under the Plan may be conditioned upon the achievement or satisfaction of performance criteria. The vesting conditions for awards under the Plan will be determined by the Committee, and will be set forth in the applicable award documentation. The Plan provides for special provisions for good leavers and bad leavers as well as for a change in control of our company.

6.3 Compensation of supervisory directors

For the year ended December 31, 2020, the aggregate compensation accrued or paid to our supervisory directors for services in all capacities was €557,192. The following table sets forth the aggregate compensation and benefits provided to our supervisory board members in the year ended December 31, 2020.

Name	Fixed Compensation (€)	Attendance Fees (€)	Total Compensation (€)
Baron Jean Stéphenne	102,747	—	102,747
Ralf Clemens	55,000	27,500	82,500
Mathias Hothum	55,000	27,500	82,500
Hans Christoph Tanner	55,000	27,500	82,500
Friedrich von Bohlen und Halbach	55,000	—	55,000
Ingmar Hoerr(1)	21,301	—	21,301
Timothy M. Wright	55,000	—	55,000
Craig A. Tooman	55,000	—	55,000
Dr. Viola Bronsema(2)	20,644	—	20,644

(1) On March 10, 2020, the service agreement with Daniel Menichella (the former CEO) was discontinued. He was succeeded on the management board by Dr. Hoerr on that same day. Dr. Hoerr was a managing director of CureVac AG at the time of the Corporate Reorganization but is no longer a managing director of CureVac AG and is not a managing director of CureVac N.V.

(2) Dr. Bronsema became a supervisory director in August 2020.

7. Related party transactions

The following is a description of related party transactions we have entered into since January 1, 2018 with any of our management and supervisory directors and the holders of more than 5% of our common shares.

BePharBel Manufacturing S.A.

As from December 4, 2020, CureVac Real Estate GmbH and BePharBel Manufacturing S.A., are bound by a commercial supply agreement to develop and manufacture the diluent that is expected to be used to dilute our concentrated COVID-19 vaccine candidate, CVnCoV, to the amount specified by each dose level. Pursuant to the terms of the agreement, BePharBel Manufacturing will manufacture and deliver to CureVac Real Estate GmbH a low seven figure amount of commercial batches of diluent per year, in 2021 and 2022. CureVac Real Estate GmbH paid €1 million at the signing of the agreement to cover the estimated capex financing. The total payments pursuant to the agreement, including the €1 million, will be approximately in the range of €5.96 million and €6.83 million. CureVac Real Estate GmbH may terminate the agreement, without notice, prior to December 2022, if CureVac does not obtain marketing authorization for CVnCoV, but will be required to pay a termination fee of €590,750 and reimburse all artwork, primary, secondary and tertiary packing that BePharBel Manufacturing has in stock or ordered up to the date of the receipt of the notice of termination. Baron Jean Stéphenne, our supervisory board member, holds directly and indirectly 15.61% of BePharBel Manufacturing's equity and is a director of BePharBel Manufacturing, and Baron Jean Stéphenne's son, Vincent Stéphenne, holds 1.43% of BePharBel Manufacturing's equity and is a managing director of BePharBel Manufacturing.

dievini Hopp BioTech holding GmbH & Co. KG, Walldorf

dievini is the largest holder of our capital stock and is the controlling shareholder. Molecular Health GmbH, or Molecular Health, is a subsidiary of dievini. In December 2017, we concluded a contract with Molecular Health, according to which Molecular Health provides services in conjunction with the Modeling of the biological and clinical effects of Toll-like receptor 7 and 8 agonists in cancer and immune cells. In fiscal years 2018, 2019 and 2020, payments to Molecular Health with respect to research and development amounted to €30,000, €0 and €0, respectively.

Convertible Loans with Mr. Hopp

We entered into a convertible loan agreement on May 3, 2019 with Mr. Dietmar Hopp, managing director of dievini, under which Mr. Hopp disbursed to us the amount of €50,000,000, or Convertible Loan I. On October 24, 2019, we entered into an additional convertible loan agreement with Mr. Hopp, as amended, under which we have the right to call for disbursements in two tranches of €20,000,000 and a final tranche of €23,926,900, until December 31, 2021, or Convertible Loan II, and together with Convertible Loan I, or the Convertible Loans. The Convertible Loans bear an interest rate of 8.00% per annum. We repaid the Convertible Loans on August 7, 2020, and as of

December 31, 2020, no Convertible Loans were outstanding. See note 12 to our Condensed Consolidated Financial Statements elsewhere in this Annual Report for further information on the Convertible Loans.

Rittershaus law firm, Mannheim

A consulting agreement dated December 15, 2005 was in place for an indefinite term with the law firm Rittershaus Rechtsanwälte Partnerschaftsgesellschaft mbB, Mannheim (Rittershaus). The agreement was replaced by a new consulting agreement dated January 1, 2015.

The agreement can be terminated without notice by us and with notice of three months to the end of the quarter by Rittershaus. In fiscal years 2018, 2019 and 2020, consulting fees of €144,900, €208,000 and €990,000 were paid to Rittershaus. Prof. Dr. Christof Hettich, one of the managing directors of dievini is a partner of Rittershaus.

Dr. Ingmar Hörr

In June 2018, an advisory agreement was implemented between Dr. Ingmar Hoerr and CureVac. Dr. Hoerr received €144,000, €240,000 and €45,000 for consulting services in fiscal years 2018, 2019 and 2020, respectively. The advisory agreement with Dr. Ingmar Hoerr was terminated in March 2020.

2020 Private Investment

On July 17, 2020, we entered into a binding agreement with KfW, Glaxo Group Limited, or GSK, QIA and other investors, pursuant to which we agreed to issue new Series B shares in CureVac AG, representing approximately 36% of the shares in CureVac AG in exchange for an aggregate investment of approximately €560 million.

According to the mandate of KfW by the Federal Republic of Germany pursuant to and in accordance with Article 2 paragraph 4 of the KfW Law (Zuweisungsgeschäft) KfW, acquired approximately 19% shareholding in CureVac AG for an aggregate investment of approximately €300 million. In addition, GSK acquired approximately a 9% shareholding in CureVac AG for an investment of approximately €150 million and QIA acquired approximately 4% shareholding in CureVac AG for an investment of approximately €60 million. We refer to the investment of KfW as the KfW Investment and to the investment by GSK as the GSK Investment. In addition, the other several shareholders purchased an aggregate 3% shareholding in CureVac AG for an aggregate investment of approximately €50 million. As part of our Corporate Reorganization, outstanding shares of all series in CureVac AG have been exchanged for common shares in CureVac B.V., which subsequently were converted into shares of CureVac N.V.

As part of the 2020 Private Investment those investors who have subscribed for our Series A, B and C shares, or the pre-IPO shareholders, became parties to an Investment and Shareholders' Agreement, as amended, pursuant to which certain of our pre-IPO shareholders holding at least 10% of our shares have entered into a Registration Right Agreement, as further described below. In addition, KfW has become a party to a Relationship Agreement and entered into a separate Shareholders' Agreement with dievini and Mr. Hopp as further described below. As part of the GSK Investment, we also entered into a collaboration agreement with GSK pursuant to which we are collaborating with GSK to research, develop and commercialize prophylactic and therapeutic non-replicating mRNA-based vaccines and antibodies targeting infectious disease pathogens. For further information regarding our collaboration agreement with GSK please refer to "section 2 — Business Overview — Collaborations."

We are obligated to use the funds raised in the 2020 Private Investment solely to fund the (i) development of our proprietary pipeline, including earlier stage assets currently in preclinical development, (ii) research and development activities to expand our mRNA platform technology, in particular with respect to our vaccine candidate against SARS-CoV-2 and other infectious diseases and (iii) manufacturing capacities for mRNA-based drug product candidates and future approved products.

Shareholders' Agreement Among KfW, dievini, DH-LT Investments GmbH and Mr. Hopp

In connection with the KfW Investment, KfW, dievini and Mr. Hopp entered into a shareholders' agreement on June 16, 2020, or the KfW dievini Shareholders' Agreement, agreeing to certain transfer restrictions and rights of first refusal relating to their interests in our company, nomination rights as provided elsewhere in this Annual Report, and a voting agreement relating to certain

specified actions. In particular, dievini and Mr. Hopp agree to vote a specified number of their shares as directed by KfW on certain specified actions, subject to certain exceptions. These specified actions include, inter alia: (1) transferring the tax domicile of CureVac N.V. and/or the approval of the transfer of the corporate or administrative seat of CureVac AG; (2) relocating or ceasing activities in specified areas to a state outside the European Union to the extent (in particular in the area of the development of vaccines) material for the protection of the health of the population of the European Union; (3) entering into material mergers and acquisitions; and (4) amendments to the articles of association of CureVac AG which would affect the foregoing matters. Under the terms of KfW dievini Shareholders' Agreement, Mr. Hopp agreed to purchase an aggregate of €100 million of our common shares in a private placement that took place with our initial public offering, in August 2020, at a price per share equal to our initial public offering price concurrently. Mr. Hopp effected this purchase through DH-LT-Investments GmbH, an affiliated entity. In connection with such concurrent private placement DH-LT-Investments GmbH has become a party to the KfW dievini Shareholders' Agreement. The KfW dievini Shareholders' Agreement has an initial fixed term that expires on December 31, 2023, subject to a right to extend for one year for the benefit of KfW and dievini, and may be terminated after the initial fixed term, or the extended term, if applicable, by either party subject to six months' notice prior the end of the applicable calendar year. In addition, the agreement shall automatically terminate if KfW sells all or a part of its interest in our company to a third party, subject to certain exceptions.

Investment and Shareholders' Agreement

We and our pre-IPO shareholders, entered into an investment and shareholders' agreement July 17, 2020, or the ISA. The ISA provides for certain particular shareholders' rights and also envisages restrictions on the shareholders party thereto, including the obligation to enter into a registration rights agreement, restrictions on transfer, as well as certain tag-along rights, drag-along rights, demand rights, rights of first offer and rights of first refusal.

Upon the listing of our shares on Nasdaq, only certain limited provisions of the ISA survived the Corporate Reorganization. Pursuant to such surviving provisions, we and/or our pre-IPO shareholders are subject to certain obligations, as listed below.

- We agreed to prepare and provide KfW our interim financials not later than 30 days after the end of each quarter. In addition, not later than 30 days prior to the start of each fiscal year we agreed to prepare and provide KfW our operating plans that shall include certain projections regarding our financials, our business plan relating to the succeeding fiscal year including our development plans, financial and investment plans, budgeted and projected figures and other information and forecasts. Our supervisory board needs to approve the planning by a simple majority vote. In addition, subject to certain limitations, the member of our supervisory board designated (nominiert) by KfW shall, to the extent not prohibited by any mandatory law and/or Nasdaq rules, be entitled to pass on and discuss any information received in his or her capacity as a member of the supervisory board with KfW and certain governmental agencies and offices of the federal government of the federal republic of Germany, however, restricted to the extent required for KfW and any of the aforementioned institutions to comply with their respective obligations. We are obligated to also provide to KfW upon its request such information that is reasonably requested by KfW for the management and the controlling of KfW's shareholding in us in order for KfW and certain other institutions as of the Federal Republic of Germany to comply with their respective obligations;

- KfW has the right to designate (nominieren) one member of our supervisory board for appointment by the general meeting (and to prompt the recall of such member of the supervisory board at its sole discretion) as long as KfW's shareholding in our share capital is at least 10% in accordance with the arrangements included in our articles of association. Furthermore, our pre-IPO shareholders shall, to the extent legally permissible, ensure that any established advisory board or any other comparable panel of our subsidiaries or affiliate shall also provide KfW the right, upon its discretion, to include a member to be designated (nominieren);

- We need to reasonably cooperate with each of our pre-IPO shareholders to provide them with information that is mandatory for their tax obligations;

- If we fail to withhold taxes on certain amounts paid to a pre-IPO shareholder, its affiliates and certain related persons of such pre-IPO shareholder (excluding a shareholder that was not our shareholder prior to the 2020 Private Investment), and such certain amounts are

reimbursable or creditable to such pre-IPO shareholder, its affiliates and certain related persons of such pre-IPO shareholder, then such pre-IPO shareholder needs to use his or her best efforts in order to obtain a credit or reimbursement from the applicable tax authority and such credit or reimbursement shall be paid to us;

- We are obligated to use the funds raised in the 2020 Private Investment solely to fund the (i) development of our proprietary pipeline, including earlier stage assets currently in preclinical development, (ii) research and development activities to expand our mRNA platform technology, in particular with respect to our vaccine candidate against SARS-CoV-2 and other infectious diseases and (iii) manufacturing capacities for mRNA-based drug product candidates and future approved products;

- We entered into a Global Access Agreement with the Bill & Melinda Gates Foundation in February 2015 pursuant to which we are required to take certain actions to support the Bill & Melinda Gates Foundation's mission. We may be required to redeem all, or to facilitate the purchase by a third party of all, the shares held in us by the Bill & Melinda Gates Foundation as per the date of the ISA on certain terms that may not be favorable to us, if we receive from the Bill & Melinda Gates Foundation a notification that we have (a) committed a material breach of certain commitments under the Global Access Agreement, (b) used the funds received from the Bill & Melinda Gates Foundation for purposes other than those described in the Global Access Agreement, including not for the (i) finance of our facility to be used inter alia to manufacture vaccines and drugs in support of the Bill & Melinda Gates Foundation's charitable purpose, (ii) continued development of technology for prophylactic and therapeutic mRNA vaccines and drugs against infectious diseases and vaccine adjuvants, comprised of long, non-coding RNA molecules and formulation/delivery technology necessary to develop the mRNA vaccines and drugs, or the Platform Technology, (iii) the use of the Platform Technology to advance vaccine and drug candidates in support of the Bill & Melinda Gates Foundation charitable purpose and/or (c) failed to comply with certain U.S. regulatory and tax obligations, or together the BMGF Default, and the BMGF Default continues to exist following a cure period. In addition, if we are required but fail to purchase all of the shares held in us by the Bill & Melinda Gates Foundation as per the date of the ISA, we shall not be allowed to pay dividends, redeem the shares of any other shareholder (other than repurchases at cost of shares from our employees, officers, directors, consultants or other persons performing services for us pursuant to agreements under which we have the option to repurchase our shares upon the occurrence of the termination of employment or service) or otherwise make any other distribution to any of our shareholders in connection with their shares. In addition, if within 12 months after such redemption or sale, we close an underwritten public financing or a change of control occurs and the valuation used for such underwritten public financing or a change of control, as the case may be, is in excess of 200% of the valuation used for the redemption or the sale of the shares held by the Bill & Melinda Gates Foundation, we will need to pay the Bill & Melinda Gates Foundation compensation equal to the excess of what it would have received in such transaction if it still held its shares at the time of such underwritten public financing or a change of control over what it received in the sale or redemption of its shares had the BMGF Default not occurred. For further information regarding the Global Access Agreement see "section 2 — Business Overview — Collaborations — Bill & Melinda Gates Foundation Partnership;"

- Upon the consummation of our initial public offering, we agreed to file, and filed, an application for continuation of tax book value (Antrag auf Buchwertfortführung acc. to Sec. 21 par. 1 second and third sentences of the German Tax Conversion Act — UmwStG) regarding the shares of CureVac AG that has been transferred as part of our initial public offering, as set out above, with the respectively competent tax authorities within four (4) months after the date of the ISA at the latest; and

- We agreed to provide pre-IPO shareholders holding at least 10% of our share capital certain information required to facilitate the disposition of our shares held by any such pre-IPO shareholder, or in some circumstances to provide information that we intend to file with the SEC and in such case we may be required to take into account the input of such pre-IPO shareholder holding prior to the filing with the SEC. In addition, we agreed that upon a written request of such a pre-IPO shareholder, we will add such pre-IPO shareholder holding to our liability insurance as a named insured in connection with the consummation of a registered offering, but any related premium shall be borne by such pre-IPO shareholder holding at least 10% of our share capital; and dievini and certain other limited pre-IPO shareholders agreed to bear the economics with respect to the Prior VSOP for a total of up to 60,175 participation rights corresponding with 10% of our share capital as of February 1, 2015 in

the amount of altogether EUR 601,750. In case of an exercise event under the Prior VSOP, dievini and such other limited pre-IPO shareholders agreed to transfer common shares up to a pre-determined amount to allow us to fulfill any claims of the beneficiaries under the Prior VSOP.

Registration Rights Agreement

We entered into a registration rights agreement upon the consummation off our initial public offering, pursuant to which each holder of at least 10% of our common shares and certain other holders of our common shares is entitled to various rights with respect to the registration of their common shares under the Securities Act. Each holder party to the registration rights agreement or an Eligible Shareholder shall continue to have various rights with respect to the registration of its common shares under the Securities Act, until 90 days after such shareholder, including its affiliates, cease to hold at least 10% of our common shares, or any other future class of shares. The registration of these common shares under the Securities Act would result in these common shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. We are not required to register such common shares if an exemption from the registration requirements of the U.S. Securities Act is available with respect to the number of our common shares desired to be sold.

Form F-1 Registration Statement

As of February 9, 2021, any Eligible Shareholder or group of Eligible Shareholders, is entitled to demand in writing that we effect the registration under the Securities Act of the sale or other transfer of such shareholder or shareholders' common shares, provided that we are not required to effect more than three such registrations and that the aggregate anticipated offering price from the sale of such shares equals at least $35 million, subject to certain exemptions.

Form F-3 Registration Statement

After we become eligible to file a registration statement on Form F-3, which will not be until August 13, 2021, each Eligible Shareholder or group of Eligible Shareholders may request in writing, not more than three times within 12-month period, that we effect a registration of the sale or other transfer of such shares, provided that the aggregate anticipated offering price from the sale of such shares equals at least $15 million, subject to certain exemptions. We will not be obligated to file a registration statement on Form F-3 in certain customary cases, subject to certain exemptions.

Piggyback Registration Rights

The registration rights agreement provides our Eligible Shareholders with "piggy back" registration rights in the event that we determine to register the sale of any of our securities. With respect to such registration rights, we are committed to use our reasonable best efforts to include in a registration statement a prospectus relating to the resale of certain securities held by certain of our Eligible Shareholders.

Relationship Agreement

In connection with the KfW Investment, KfW, dievini and CureVac B.V. entered into a relationship agreement on July 17, 2020, or the KfW dievini Relationship Agreement. Pursuant the KfW dievini Relationship Agreement the parties provide for our agreed form of the articles of association, the supervisory board rules and the management board rules. In addition, the KfW dievini Relationship Agreement establishes that if at any time during the effectiveness of the KfW dievini Shareholders' Agreement any of our shareholders other than KfW or dievini is granted a nomination right to our supervisory board or the supervisory board of any of our subsidiaries, then all of the parties to the KfW dievini Relationship Agreement shall use best efforts to exercise their shareholder rights to ensure that KfW and dievini shall each be given a nomination right as well. We also agreed not to procure, not to propose or implement during the terms of the KfW dievini Shareholders' Agreement and the ISA, any amendment to the corporate documents of CureVac AG or CureVac B.V. or CureVac N.V., which would violate or not observe the Relationship Agreement, the ISA or other agreements concluded with us and KfW in connection with KfW's investment.

Indemnification Agreements

Our articles of association require us to indemnify our current and former managing directors and supervisory directors to the fullest extent permitted by law, subject to certain exceptions. We entered into indemnification agreements with all our managing directors and supervisory directors, and may enter into additional indemnification agreements with future managing directors and supervisory directors.

Employment Agreements

Certain of our managing directors and supervisory directors have entered into service agreements with us as set forth below.

Supervisory Board Service Contract

With the approval of the supervisory board, Dr. Clemens, one of our supervisory directors, has entered into a service agreement with us, which provides for notice of termination periods and include restrictive covenants, as described further below.

Consulting Agreement with Ralf Clemens

We entered into a consulting agreement with Dr. Clemens in March 2013, referred hereto as the Clemens Consulting Agreement, whereby Dr. Clemens agreed to provide consulting services and agreed to act as a member of our scientific advisory board for an indefinite period. The Clemens Consulting Agreement provides for a notice of termination period of four weeks, payment of certain travel and out-of-pocket expenses in addition to his consulting fee and restrictive covenants, including covenants related to confidentiality and proprietary information.

Employment Agreements and Consultancy Agreement with Ingmar Hoerr

We entered into several management agreements with Dr. Hoerr in 2003, 2005 and 2011, which were superseded by the management agreement we entered into with him in 2015, which is substantially similar to the Management Contracts entered with the management board members as described above.

In June 2018, Dr. Hoerr was elected as a supervisory director. We subsequently entered into a Consultancy Agreement with Dr. Hoerr, or the Hoerr Consultancy Agreement, whereby Dr. Hoerr agreed to provide consulting services. The Hoerr Consultancy Agreement provides for a notice of termination period of four weeks, payment of certain travel and out-of-pocket expenses in addition to his consulting fee and restrictive covenants, including a four-year non-competition and covenants related to confidentiality and ownership of work product. For additional details of Dr. Hoerr's Consultancy Agreement, see "section 7 — Related Party Transactions – Dr. Ingmar Hörr."

On March 10, 2020, Dr. Hoerr succeeded Mr. Menichella as a managing director on the management board. Dr. Hoerr was a managing director of CureVac AG at the time of the Corporate Reorganization but is no longer a managing director of CureVac AG and is not a managing director of CureVac N.V.

Management Board Service Contracts

We entered into a management board services contract with the following managing directors: Mr. Mülbe, Ms. Fotin-Mleczek, Mr. Haas, Mr. Kemula, Mr. Splawski and Dr. Blanc, referred hereto as the Management Contracts. The Management Contracts generally provide for a term of either three, four or five years and a base salary and an annual variable payment expressed as a percentage of annual base salary that is dependent on the achievement of the objectives agreed to by the supervisory board. The supervisory board is also entitled to grant managing directors additional compensation at its discretion.

The Management Contracts also provide for additional allowances. The managing directors are also eligible to participate in a virtual stock plan or equivalent plan that is established in a manner substantially similar to other of the senior executives. Specifically, within Mr. Splawski's Management Contract, we awarded him 266,155 options under the Plan (as defined below) on November 16, 2020, which vests over a period of 48 months.

The Management Contracts provide for the following restrictive covenants: (i) a non-compete during employment and for 12 months after termination; (ii) a non-solicit of employees during

employment and for two years after termination; and (iii) a perpetual confidentiality covenant. Under the Management Contracts, we are obligated to pay the managing directors compensation for the duration of their post-employment non-compete in monthly installments that are equal to half of the total compensation they received prior to their termination.

We may in the future enter into service agreements with other individuals, the terms of which may provide for, among other things, cash or equity-based compensation and benefits.

Arrangements with Daniel Menichella

In June 2018, we entered into an employment agreement with Daniel Menichella, referred hereto as the Menichella Employment Agreement, which terminated and replaced his prior employment agreement, under which Mr. Menichella became the CEO of CureVac AG in addition to CureVac Inc.

Under the Menichella Employment Agreement, Mr. Menichella was also entitled to receive up to 29,053 options, which provided Mr. Menichella with a cash claim against CureVac AG, which could be settled in shares of CureVac AG, subject to the terms and conditions of his employment agreement, equal to an amount by which the price per share calculated on the basis of the value to the company with 726,592 outstanding shares of $800,000,000 is surpassed by the price per share calculated on the basis of the fair market value of CureVac AG at the time of the exercise of the option. Such options were exchanged for 3,866,309 options for common shares in CureVac N.V. in connection with the Corporate Reorganization. Such options expire on June 21, 2028.

Between August 2020 and December 2020, Mr. Menichella exercised 3,766,309 of the 3,866,309 options he was entitled to under the Menichella Employment Agreement (after exchange for options for common shares in CureVac N.V. in connection with the Corporate Reorganization).

If Mr. Menichella's employment is terminated for convenience or if he resigns with good reason (as such term is defined in the Menichella Employment Agreement), subject to his execution and nonrevocation of a release, he is entitled to the following: (i) 18 months of his then base salary (or 24 months if such termination is within one year following the consummation of a change in control), (ii) a pro rata portion of his discretionary bonus, if any, for the year of termination, (iii) reimbursement of the employer-contributed portion of Mr. Menichella's healthcare premiums for 18 months, (iv) 18-month acceleration of stock option vesting if employment is terminated within one year following the consummation of a change in control and (v) acceleration of all unvested stock options if CureVac is merged with another company or CureVac completes an IPO.

The Menichella Employment Agreement provides for the following restrictive covenants: (i) a non-compete during employment and for 18 months after termination, (ii) a non-solicit of customers and employees during employment and for 18 months after termination, (iii) a perpetual confidentiality and non-disparagement covenant and (iv) ownership of intellectual property and inventions covenant.

On March 10, 2020, the Menichella Employment Agreement was discontinued and Mr. Menichella ceased to be a member of our management board. He was succeeded on the management board by Dr. Hoerr on that same day. Dr. Hoerr was a managing director of CureVac AG at the time of the Corporate Reorganization but is no longer a managing director of CureVac AG and is not a managing director of CureVac N.V.

Consulting Agreement with Bernd Winterhalter

We entered into a consulting agreement with Dr. Winterhalter in June 2018, referred hereto as the Winterhalter Consulting Agreement, whereby Dr. Winterhalter agreed to provide consulting services for an indefinite period of time. The Winterhalter Consulting Agreement provides for a notice of termination period of four weeks, payment of certain travel and out-of-pocket expenses in addition to his consulting fee and restrictive covenants, including covenants related to confidentiality and proprietary information. The Winterhalter Consulting Agreement was terminated in February 2021.

Employment Contract with Senta Ulrike Gnad-Vogt

We entered into an employment contract with Dr. Gnad-Vogt in July 2011, as amended in September 2019, referred hereto as the Gnad-Vogt Employment Contract, whereby Dr. Gnad-Vogt is employed for an indefinite period of time. The Gnad-Vogt Employment Contract provides for a notice of termination period of six months, which can be initiated in writing by either party, and restrictive covenants, including non-compete and non-solicitation covenants and a covenant related to confidentiality.

Offer Letter with Pierre Kemula

We entered into an offer letter with Pierre Kemula in April 2019, referred hereto as the Kemula Offer Letter, to prolong his service on the management board pursuant to the Management Contract, entered into in June 2016, and to include additional terms, including the reimbursement of certain costs. The Kemula Offer Letter also provides that Mr. Kemula will receive, under the VSOP program, 665,389 Beteiligungspunkte (virtual shares) pre-IPO. See note 9 to our consolidated financial statements, contained elsewhere in this Annual Report, for further information on Mr. Kemula's award.

For further information on related party transactions, see note 19 in the Notes to the Company Financial Statements (section 9).

Where applicable, best practice provisions 2.7.3, 2.7.4 and 2.7.5 of the DCGC have been observed.

8. Protective measures

Established Dutch law allows Dutch companies to have certain protective measures in place, in order to safeguard the interests of a company, its business and its stakeholders. We adopted an anti-takeover measure pursuant to which our management board, subject to the approval by our supervisory board, may issue preferred shares without shareholder approval pursuant to a call option agreement with a special purpose foundation, or the protective foundation. Such call option agreement may be entered into between us and such protective foundation after the later of (a) dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) and its affiliates as defined by our articles of association and ultimate beneficiaries as defined by our articles of association (individually or collectively) no longer holding at least 25% of our issued share capital (or an earlier change of control over dievini, as defined in our articles of association), which we refer to as the initial period, or (b) the termination or expiry of the KfW dievini Shareholders' Agreement, which we refer to as the initial approval period. We may issue an amount of preferred shares up to the lesser of (i) the total number of shares (of whichever class) comprised in the Company's issued share capital when the call option is exercised pursuant to the call option agreement on the relevant occasion, less the number of preferred shares already held by the protective foundation at that time (if any) and less one (1); or (ii) the maximum number of preferred shares that may be issued under the Company's authorized share capital as included in the Company's articles of association when the call option is exercised.

In addition, certain provisions of our articles of association may make it more difficult for a third party to acquire control of us or effect a change in our management board and supervisory board. These include:

- a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination, the binding nature of which can only be overruled by a simple majority of votes cast representing at least one-third of our issued share capital;

- a provision that our managing directors and supervisory directors may only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the dismissal is proposed by the supervisory board or, with respect to supervisory directors nominated by dievini or KfW, by dievini (or its legal successor or permitted assigns under the KfW dievini Shareholders' Agreement) during the nomination period for dievini or by KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) during the nomination period for KfW, respectively, in which case a simple majority of the votes would be sufficient);

- a provision that certain provisions of our articles of association can only be amended with the affirmative vote of (i) during the nomination period for dievini, dievini (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement) and (ii) during the nomination period for KfW, KfW (or its legal successors or permitted assigns under the KfW dievini Shareholders' Agreement);

- a provision that if a supervisory director is no longer in office or is unable to act, he or she may be replaced temporarily by a person who the supervisory board has designated for that purpose and, where a supervisory director who has been appointed upon a nomination of

dievini or KfW, as applicable, is no longer in office or unable to act, such supervisory director may only be temporarily replaced by a person designated for such purposes by dievini or KfW, as applicable. Such person shall become a full member of the supervisory board with the rights of the relevant supervisory director appointed upon a nomination of dievini or KfW, as applicable, as soon as a written designation to that effect has been received by the chairman or vice-chairman of our supervisory board, subject to limitations, under applicable law regarding dievini's rights under this provision;

- a provision allowing, among other matters, a former chairman of our supervisory board, a former nominee of dievini, and a former nominee of KfW to jointly take on the supervisory functions, which persons jointly may designate one or more other persons to be charged with the supervision of our company (instead of or together with the former chairman of our supervisory board), as applicable, to supervise our affairs if all of our supervisory directors are removed from office and to appoint others to be charged with the supervision of our affairs, until new supervisory directors are appointed by the general meeting on the basis of a binding nomination discussed above;

- a provision allowing the management board to temporarily replace a managing director who is no longer in office or unable to act, with another person or persons designated for this purpose by the management board and attributing the management of the company to the supervisory board in case all managing directors are no longer in office or unable to act; and

- a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our management board with the approval of our supervisory board.

In addition, Dutch law allows for staggered multi-year terms of our managing directors and supervisory directors, as a result of which only part of our managing directors and supervisory directors may be subject to appointment or re-appointment in any one year.

Financial Statements 2020

9. Consolidated Financial Statement

CureVac N.V.

Consolidated Financial Statements

As of December 31, 2020 and 2019 and for the years ended December 31, 2020, 2019 and 2018

Consolidated Statements of Operations and Other Comprehensive Income (Loss)

		Year ended December 31,		
	Note	**2018**	**2019**	**2020**
(in EUR k, except per share amounts)				
Revenue	3.1	12,871	17,416	48,871
Cost of sales	3.2	(17,744)	(27,983)	(14,173)
Selling and distribution expenses	3.3	(1,085)	(1,755)	(733)
Research and development expenses	3.4	(41,722)	(43,242)	(113,808)
General and administrative expenses	3.5	(25,289)	(48,969)	(53,554)
Other operating income	3.6	808	5,587	24,150
Other operating expenses		(663)	(552)	(568)
Operating loss		**(72,824)**	**(99,498)**	**(109,815)**
Finance income		1,968	833	2,070
Finance expenses		(275)	(1,460)	(22,103)
Loss before income tax		**(71,131)**	**(100,125)**	**(129,848)**
Income tax benefit/ (expense)	13	(110)	252	726
Net loss for the period		**(71,241)**	**(99,873)**	**(129,122)**
Other comprehensive income:				
Items that may be subsequently reclassified to profit or loss				
Foreign currency adjustments		66	32	35
Total comprehensive loss for the period		**(71,175)**	**(99,841)**	**(129,087)**
Net loss per share (basic and diluted)		**(0.74)**	**(1.03)**	**(0.98)**

The accompanying notes are an integral part of these consolidated financial

Consolidated Statements of Financial Position

(in EUR k)	Note	December 31, 2019	December 31, 2020
Assets			
Non-current assets			
Intangible assets	4.1	5,698	14,146
Property, plant and equipment	4.1	48,075	66,605
Right-of-use assets	4.2	13,611	33,984
Other assets	4.3	6,061	6,322
Deferred tax assets	13	-	445
Total non-current assets		**73,445**	**121,502**
Current assets			
Inventories	5	6,197	14,531
Trade receivables		15,690	1,014
Contract assets		1,463	808
Other financial assets	6	1,458	2,619
Prepaid expenses and other assets	7	1,683	48,289
Cash and cash equivalents		30,684	1322,593
Total current assets		**57,175**	**1,389,854**
Total assets		**130,620**	**1,511,356**
Equity and liabilities			
Equity	8		
Issued capital		11,603	21,655
Capital reserve		461,520	1,334,704
Accumulated deficit		(515,947)	(645,069)
Other comprehensive income		22	57
Total equity		**(42,802)**	**711,347**
Non-current liabilities			
Convertible loans	12	65,018	-
Finance Liabilities	12	-	25,189
Lease liabilities	2	12,126	26,853
Contract liabilities	3.1	66,040	500,061
Deferred tax liabilities	13	1,623	-
Other liabilities		529	284
Total non-current liabilities		**145,336**	**552,387**
Current liabilities			
Lease liabilities	2	2,004	3,234
Trade and other payables	10	6,475	21,685
Other liabilities	11	12,015	64,326
Income taxes payable	13	111	392
Contract liabilities	3.1	7,481	157,985
Total current liabilities		**28,086**	**247,622**
Total liabilities		**173,422**	**800,009**
Total equity and liabilities		**130,620**	**1,511,356**

Consolidated Statements of Changes in Shareholders' Equity

(in EUR k)	Issued capital	Capital reserve	Accumulated deficit	Currency translation reserve	Total equity
Balance as of January 1, 2020	**11,603**	**461,520**	**(515,947)**	**22**	**(42,802)**
Net loss	-	-	(129,122)	-	(129,122)
Other comprehensive income (loss)	-	-	-	35	35
Total comprehensive income (loss)	**-**	**-**	(129,122)	35	(129,087)
Equity component of convertible loans (net of tax)	-	87	-	-	87
Share-based payment expense	-	15,432	-	-	15,432
Exercise of options	383	(383)	-	-	-
Issuance of share capital (net of transaction costs)	9,669	858,048	-	-	867,717
Balance as of December 31, 2020	**21,655**	**1,334,704**	**(645,069)**	**57**	**711,347**

(in EUR k)	Issued capital	Capital reserve	Accumulated deficit	Currency translation reserve	Total equity
Balance as of January 1, 2019	**11,603**	**436,564**	**(416,074)**	**(10)**	**32,083**
Net loss	-	-	(99,873)	-	(99,873)
Other comprehensive income	-	-	-	32	32
Total comprehensive income (loss)	**-**	**-**	(99,873)	32	(99,841)
Share-based payment expense	-	19,564	-	-	19,564
Equity component of convertible loans (net of tax)	-	7,604	-	-	7,604
Deferred taxes on convertible loan	-	(2,212)	-	-	(2,212)
Balance as of December 31, 2019	**11,603**	**461,520**	**(515,947)**	**22**	**(42,802)**

(in EUR k)	Issued capital	Capital reserve	Accumulated deficit	Currency translation reserve	Total equity
Balance as of January 1, 2018	**11,603**	**436,562**	**(345,320)**	**(76)**	**102,769**
Effects from the first-time adoption of IFRS 9			(183)		(183)
Effects from the first-time adoption of IFRS 15			670		670
Adjusted balance as of January 1, 2018	**11,603**	**436,562**	(344,833)	(76)	103,256
Net loss	-	-	(71,241)	-	(71,241)
Other comprehensive income (loss)	-	-	-	66	66
Total comprehensive income (loss)	**-**	**-**	(71,241)	66	(71,175)
Share-based payment expense		2	-	-	2
Balance as of December 31, 2018	**11,603**	**436,564**	**(416,074)**	**(10)**	**32,083**

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

CureVac N.V.

Consolidated Statements of Cash Flows

	Year ended December 31,		
(in EUR k)	**2018**	**2019**	**2020**
Loss before income tax	**(71,131)**	**(100,125)**	**(129,848)**
Adjustments to reconcile loss before tax to net cash flows			
Finance income	(1,968)	(833)	(2,070)
Finance expense	275	1,460	22,103
Depreciation and amortization	3,781	7,164	10,671
Loss on disposal of fixed assets	52	241	5,921
Share-based payment expense	(4,248)	19,564	14,240
Working capital changes			
Decrease / (increase) in trade receivables and contract assets	(5,595)	(10,117)	15,332
Decrease / (increase) in inventory	878	(3,246)	(8,334)
Decrease / (increase) in prepaid expenses and other assets	(6,106)	630	(47,578)
Receipts from grants from government agencies and similar bodies	214	9,304	31,599
(Decrease) / increase in trade and other payables and contract liabilities	9,402	(9,584)	620,305
(Decrease) / increase in other current financial and other liabilities	336	(334)	(55)
Decrease / (increase) in deferred taxes	-	-	(1,096)
Income taxes paid	(26)	(345)	(93)
Interest received	15	81	-
Interest paid	11	(823)	(8,694)
Net cash flow provided by (used in) operating activities	(74,110)	(86,963)	522,403
Investing activities			
Purchase of property, plant and equipment	(9,406)	(11,172)	(36,329)
Purchase of intangible assets	(5,317)	(1,052)	(11,023)
Proceeds from asset-related grants	-	2,325	3,239
Purchases of financial assets	-	-	(1,161)
Proceeds from sale of other financial assets	10,459	38,080	-
Net cash flow provided by (used in) investing activities	(4,264)	28,181	(45,274)
Financing activities			
Payments on lease obligation	(112)	(1,910)	(2,995)
Proceeds from the issuance of shares (net of transaction costs)	-	-	867,717
Proceeds from the EIB loan	-	-	25,000
Proceeds from the convertible loan	-	69,889	24,860
Repayments of convertible loan	-	-	(94,749)
Net cash flow provided by financing activities	(112)	67,979	819,833
Net increase (decrease) in cash and cash equivalents	(78,486)	9,197	1,296,962
Effect of currency translation gains on cash and cash equivalents	213	107	(5,053)
Cash and cash equivalents, beginning of period	99,653	21,380	30,684

Cash and cash equivalents, end of period	21,380	30,684	1,322,593

1. Corporate Information

CureVac N.V. ("CureVac" or "CV" or the "Company") is the parent company of CureVac Group ("Group") and, along with its subsidiaries, is a global biopharmaceutical company developing a new class of transformative medicines based on the messenger ribonucleic acid (mRNA) that has the potential to improve the lives of people.

The Company is incorporated in the Netherlands and is registered in the commercial register at the Netherlands Chamber of Commerce under RSIN 861149336. The Company's registered headquarters is Friedrich-Miescher-Strasse 15, 72076 Tuebingen, Germany. The major shareholder and ultimate parent company of the Group is dievini Hopp BioTech holding GmbH & Co. KG (dievini), which is an investment company dedicated to the support of companies in health and life sciences.

On August 14, 2020, the Company completed an initial public offering (IPO) on the Nasdaq Global Market; in connection with the IPO, the Company underwent a corporate reorganization by which CureVac N.V. became the parent holding company with 100% interest in CureVac AG. Prior to the reorganization, CureVac AG was the parent holding company of the Group; as part of the reorganization, CureVac B.V. was formed and existing shareholders of CureVac AG subscribed for new common shares in CureVac B.V. and agreed to transfer their respective shares in CureVac AG to CureVac B.V. as a contribution in kind against issuance of the common shares in CureVac B.V. shares (share split) on a 1-to-133.0778 basis. As a result, CureVac B.V. became the holding company of CureVac AG, while the existing shareholders had a 100% shareholding in CureVac B.V. Effective with the IPO, CureVac B.V. changed its legal form and became CureVac N.V. and the common shares of CureVac B.V. were converted to common shares of CureVac N.V. These consolidated financial statements and corresponding financial statement notes reflect the retrospective effect of the share split, where applicable.

2. Significant accounting policies

These consolidated financial statements are prepared on a historical cost basis under the going concern assumption. The significant accounting policies adopted in the preparation of these consolidated financial statements are described below. These accounting policies have been consistently applied to all years presented, unless otherwise stated. The corporate reorganization, as described above, is considered a continuation of the CureVac Group resulting in no change in the carrying values of assets or liabilities. As a result, the financial statements for periods prior to the IPO and the corporate reorganization are the financial statements of CureVac AG as the predecessor to the Company for accounting and reporting purposes.

The preparation of financial statements requires the use of certain accounting estimates. It also requires management to exercise its judgment in applying the Group's accounting policies. The areas that require a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed below.

Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and were authorized by the Management Board for presentation to the Supervisory Board on April 27, 2021. The Group's consolidated financial statements are presented in Euros ("EUR"), which is also the parent company's functional currency. Unless otherwise stated, the numbers are rounded to thousands of Euros, except per share amounts.

Basis of consolidation

The consolidated financial statements include the Company's wholly owned subsidiaries CureVac AG (Tuebingen, Germany), CureVac Inc. (Cambridge, Massachusetts, USA) and CureVac Real Estate GmbH (Tuebingen, Germany). Control is achieved when the Company is

exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee.

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated upon consolidation.

The fiscal year of all Group entities corresponds to the calendar year ending December 31.

Current and non-current classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification.

Current assets include assets that are sold, consumed or realized as part of the normal operating cycle (operating cycle is assumed to be 12 months), or cash and cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period. All other assets are classified as non-current.

Current liabilities, such as trade payables, lease liabilities or employee benefits with a term of up to 12 months, and payables for operating costs or social security charges, are part of the working capital used in the Group's normal operating cycle. Such operating items are classified as current liabilities even if they are due to be settled more than 12 months after the reporting period. All other liabilities are classified as non-current.

Foreign currency translation

For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions are initially translated at the spot rate applicable between the functional currency and the foreign currency on the date of the transaction. Monetary assets and liabilities in foreign currencies are translated to the functional currency using the prevailing rate at the reporting date. Foreign currency exchange differences are recorded to the statement of operations. Upon consolidation, the assets and liabilities of foreign operations are translated into Euro at the rate of exchange prevailing at the reporting date and their statements of operations are translated at the average exchange rate of the fiscal period. The exchange differences arising on translation for consolidation are recognized in other comprehensive income (loss).

Revenue recognition

Revenue from the sale of products and services is recognized when the Group transfers control to the customer. Control generally transfers when the customer gains the ability to direct the use of and obtain substantially all of the remaining benefits from the good or service. If the contract contains more than one performance obligation, the consideration which the Group expects to receive is allocated to each of the performance obligations, using the relative stand-along selling price method. Revenue is recognized at the amount of consideration that the Group is expected to receive in exchange for these goods or services. The Group has concluded that it acts as a principal in sales transactions as it has control over the goods or services before transferring control to the customer.

The Group primarily generates revenue from its licensing and development agreements with collaboration partners for the development of mRNA medicines against a variety of targets in diseases and conditions. These arrangements contain multiple contractual promises, including (i) licenses, or options to obtain licenses, to the Group's mRNA technology, (ii) delivery of products and (iii) research and development services. Such arrangements provide for various types of payments to the Group, including upfront fees, funding of research and development services, payment for delivered products, development, regulatory and commercial milestone payments, license fees and royalties on product sales, all of which may

be satisfied at different points in time. Outlicensing agreements may be entered into with or without any further significant contractual obligations.

Goods or services promised in collaborative arrangement are accounted for as separate performance obligations if such promises are distinct (i.e., if the customer can benefit from the good or service on its own or together with other resources readily available to it and if the promise is separately identifiable from other promises in the contract).

In determining whether contractual promises are separately identifiable, the Group considers whether:

- It provides a significant service of integrating the goods or services with other goods or services that represent the combined output or outputs for which the other party has contracted

- One or more of the goods or services significantly modifies or customizes one or more of the other goods or services promised in the agreement.

- The good or services the Group promised to transfer or to provide are highly interdependent or highly interrelated.

Based on these criteria, management evaluates whether the intellectual property (IP) licenses granted, and to which further research and development activities may apply under the terms of a collaboration agreement, are distinct from the unperformed obligations to the collaboration partner, considering the relevant facts and circumstances of each arrangement. Factors considered in this determination include the nature of the IP license, the stage of development of the IP license granted, the research capabilities of the partner and the availability of mRNA technology research expertise in the general marketplace.

When an IP license is not considered to be distinct from research services, the Group generally recognizes revenue, including any upfront payment, attributable to the license on a straight-line basis, which reflects the performance of services by the Group towards satisfaction of the obligation, over the contractual or estimated performance period, which is typically from the effective date of the related collaboration agreement through the estimated date of market entry of a product developed under the agreement. The determination of the estimated date of market entry requires a significant amount of judgment given the uncertainty inherent in developing innovative pharmaceutical products and is based upon development plans with the customer, which are subject to change, clinical trials and approval of regulatory authorities. Changes in the estimated date of market entry could have a material impact on the amount and timing of revenue the Group records in future periods.

When an IP license is considered to be distinct, the Group determines whether it provides the customer with either (1) a right to access the IP throughout the license period (for which revenue is recognized over the license period) or (2) a right to use the IP as it exists at the point in time that the license is granted (for which revenue is recognized at a point in time where the customer can first use and benefit from the license).

If the transaction price in an agreement includes a variable amount, the Group estimates the amount of consideration to which the Group will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable consideration is estimated based on the most likely amount of consideration expected from the transaction and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect the variable consideration is subsequently resolved. The estimated deferred contract liability is updated at each reporting date to reflect the current facts and circumstances.

Collaboration agreements may also provide a customer with the option to acquire additional goods or services. The accounting treatment for such options depends on the nature

of these options. Options are considered to be substantive if, at the inception of an agreement, the Group is at risk as to whether the customer will choose to exercise the options to secure additional licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the customer might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the customer as a result of exercising the options.

Product sales related to collaboration agreements include RNA products and are recognized over time as goods are produced because such goods have no alternative use and the Group has enforceable right to payment. Otherwise, revenue for product sales is recognized at a point in time. In 2020, 2019 and 2018, no revenue from product sales was recognized on a point in time basis. Revenue from certain research and development services, delivered as a distinct performance obligation under the collaboration agreements, are recognized over time as the services provided have no alternative use and the Group has an enforceable right to payment.

A receivable is recognized when the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant contractually agreed pricing in force at the date of customer placing the respective order for such goods or services. Amounts received prior to satisfying the above revenue recognition criteria are recorded as contract liability in the statements of financial position.

The Group may present the following contract balances:

- Contract assets — Represents the Group's right to consideration in exchange for goods or services that the Group has transferred to the customer when that right is conditioned on something other than the passage of time

- Trade receivables — Represents the Group's right to an amount of consideration that is unconditional (i.e., only the passage of time is required before payment of the consideration is due)

- Contract liabilities — Represents the Group's obligations to transfer goods or services to a customer for which the Group has received consideration (or consideration is due) from the customer

The Group recognizes revenue from contracts with customers relating to its core business. All other operating proceeds are presented as other operating income in the statements of operations.

Grants from government agencies and similar bodies

The Group receives grants from government agencies and similar bodies for the active participation in specific research and development projects. Each grant agreement is assessed to determine whether there are elements of supply of product which are recognized separately from the grant. For the supply of products, the standalone selling price is determined by reference to observed prices with other customers. The grants are recognized when there is reasonable assurance that the grant will be received and all grant conditions will be met. If grant funds are received prior to qualifying expenses being incurred or assets purchased, they are recorded as a liability in other liabilities. If the funds reimburse expenses, the liability is amortized into other operating income on a systematic basis over the period in which the corresponding expenses are incurred. If the funds reimburse purchased assets, the liability is reduced with a corresponding amount deducted from the asset's carrying amount upon recording of the qualified asset. According to the terms of the grants, grantors generally have the right to audit qualifying expenses submitted by the Group.

Financial instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

i) Financial assets

Initial recognition and measurement

Financial assets are initially measured at fair value. After the initial measurement, the financial assets are subsequently classified as either amortized cost, fair value through other comprehensive income, or fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. The Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component are measured at the transaction price determined under IFRS 15.

For a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, it needs to give rise to cash flows that are "solely payments of principal and interest (SPPI)" on the principal amount outstanding. This assessment is referred to as the SPPI test and is performed at an instrument level.

Subsequent measurement

For purposes of subsequent measurement, financial assets are classified into four categories:

- financial assets at amortized cost (debt instruments);
- financial assets at fair value through other comprehensive income with recycling of cumulative gains and losses (debt instruments);
- financial assets designated at fair value through other comprehensive income with no recycling of cumulative gains and losses upon derecognition (equity instruments); or
- financial assets at fair value through profit or loss.

In fiscal 2018, 2019 and 2020, the Group only had the following financial assets to be measured at amortized cost:

- Cash and cash equivalents
- Other financial assets
- Trade receivables and contract assets

Financial assets at amortized cost are subsequently measured using the effective interest (EIR) method and are subject to impairment. Gains and losses are recognized in the statement of operations when the asset is derecognized, modified or impaired.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized when the Group no longer has the contractual rights to the asset or the right to receive cash flows from the asset have expired.

Impairment of financial assets

An allowance for expected credit losses (ECLs) is recognized for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all of the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12- months (a 12- month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

For cash and cash equivalents, trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date.

The Group considers a financial asset in default when contractual payments are 180 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

ii) Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings or as payables.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include lease liabilities, convertible loans and trade payables.

Subsequent measurement

After initial recognition, interest-bearing loans and borrowings, trade payables and other financial liabilities are subsequently measured at amortized cost using the EIR method. Gains and losses are recognized in the statement of operations when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of operations.

This category generally applies to interest-bearing loans and borrowings, including the convertible loans.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires.

Acquired Intangible assets

Acquired intangible assets are initially measured at cost. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and any accumulated impairment losses.

The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite useful lives are amortized over their useful life, generally using the straight-line method. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least annually at each fiscal year end. Changes in the expected useful life or the expected pattern of consumption of future economic benefits are accounted for prospectively. Amortization of an intangible asset is reported in the consolidated statement of operations in accordance with the function of the intangible asset.

Gains or losses arising from derecognition of an intangible asset are measured as the difference between the net disposal proceeds and the carrying amount of the asset and are recognized in the consolidated statement of operations in the period in which the asset is derecognized.

Acquired intangible assets are mainly comprised of software and licenses. The Group has entered into non-exclusive license agreements for patent rights and/or know-how with reputable universities, cancer research institutes and other research partners. The cost of these licenses includes fixed as well as contingent consideration mainly linked to specified events in the collaborations for which the licenses are used. The licenses are measured initially at cost which comprises the fixed purchase price components. The Group records a liability for contingent consideration and capitalizes such amounts as part of the cost of the acquired intangible asset, when the future event, upon which the contingent consideration depends, occurs or a present obligation exists.

The estimated useful lives for each intangible asset class are as follows:

Software	3 to 5 years
Licenses	8 to 20 years

The Group does not have any intangible assets with indefinite useful lives.

Property, plant and equipment

Property, plant and equipment are stated at cost less accumulated depreciation and accumulated impairments. These costs also comprise the costs for replacement parts, which are recognized at the time they are incurred, providing they meet the recognition criteria. All other repair and maintenance costs are expensed as incurred. Depreciation is recognized on a straight-line basis over the estimated useful lives as follows:

Leasehold Improvements	1 to 10 years
Technical equipment and machines:	3 to 14 years
Other equipment, furniture and fixtures:	3 to 14 years

Property, plant and equipment are derecognized upon disposal or when no further economic benefits are expected from their continued use or sale. The gain or loss on derecognition is determined as the difference between the net disposal proceeds and the carrying amount and recognized in profit or loss in the period in which the item is derecognized.

The residual values of the assets, useful lives and depreciation methods are reviewed at the end of each fiscal year and any changes are accounted for prospectively.

The estimated useful lives and depreciation methods remained unchanged from fiscal 2018 through fiscal 2020. The residual values of the assets are generally considered to be zero.

Impairment of assets

At each reporting date, the Group assesses whether there is an indication that an asset may be impaired. If there is any indication of impairment or if an annual impairment test is required, the Group estimates the recoverable amount of the asset. The recoverable amount of an asset is the higher of the asset's fair value less costs of disposal and its value-in-use. It is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case it is determined at the level of the cash-generating unit. If the carrying amount of an asset exceeds its recoverable amount, the asset is impaired and written down to its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre -tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

When there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized, any impairment loss previously recognized is reversed. The reversal may not exceed the carrying amount that would have been determined after amortization or depreciation had no impairment loss been recognized for the asset in prior periods. The amount of the reversal is recognized in profit or loss for the period.

There were no impairments or reversals of impairments in 2018, 2019 or 2020.

Non-current other assets — costs to obtain a contract

Amortization of assets recognized from the costs to obtain a contract with a customer within the scope of IFRS 15 is recognized on a straight-line basis over their associated estimated useful lives.

Borrowing costs

Borrowing costs directly attributable to the acquisition, construction or production of an asset that necessarily takes a substantial period of time to get ready for its intended use or sale are capitalized as part of the cost of the asset. All other borrowing costs are expensed in the period in which they occur. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

The Group capitalizes borrowing costs when it meets all the following conditions: (a) it incurs expenditures for the asset; (b) it incurs borrowing costs; and (c) it undertakes activities that are necessary to prepare the asset for its intended use or sale.

The Group capitalized EUR 1,989k borrowing costs during fiscal 2020 (2019: 2,188k). The capitalization rate used to determine the amount of the borrowing costs eligible for capitalization during fiscal 2020 was a weighted average of 8.90% (2019: 9.13%).

Leases

Through December 31, 2018, the Group applied the following policy: leases where the lessor retains substantially all the risks and benefits of ownership of the asset were classified as operating leases. Lease payments on operating leases were recorded as an expense in the statement of operations on a straight-line basis over the term of the lease. However, a lease was classified as a finance lease if it transferred substantially all the risks and rewards incidental to ownership. If this were the case, the leased assets were initially recognized and measured at the fair value of the leased asset, or, if lower, the present value of the future minimum lease payments and depreciated using the straight-line method over the minimum contract term, taking any existing residual value into consideration. When it was reasonably certain that ownership passed to the Group at the end of the lease period, such assets were depreciated over their useful lives. The present value of the payment obligations associated with the minimum future lease payments was recognized as a liability.

Effective January 1, 2019, the Group adopted IFRS 16 and applied the accounting policy for leases described below.

Right-of-use assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received as well as any estimated costs to be incurred by the lessee for dismantling and removing the underlying asset. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life, indicated below, and the lease term. Right-of-use assets are subject to impairment according to IAS 36.

Land and Buildings:	1 to 15 years
Vehicles:	3 to 4 years
Other equipment:	2 to 5 years

Lease liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in- substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating a lease, if the lease term reflects the Group exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period on which the event or condition that triggers the payment occurs. In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount for the right-of-use asset or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value. Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term. Furthermore, the Group also elected to use the recognition exemptions for lease contracts that, at January 1, 2019, had a remaining lease term of 12 months or less.

Separation of lease and non-lease components

As a practical expedient, the Group elected not to separate the fixed (but not variable) portion of non-lease components in respect of leases of building and instead accounts them as a single lease component.

Inventories

Inventories are valued at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the

estimated costs necessary to make the sale. Inventories are comprised of raw materials, work in progress and finished goods.

Costs incurred in bringing each product to its present location and condition are accounted for, as follows:

- Raw materials: purchased cost on a first-in/first-out basis
- Finished goods and work in progress: cost of direct materials and labor and a proportion of manufacturing overhead based on normal operating capacity, but excluding borrowing costs

Pre-launch products

Prior to initial regulatory approval, costs relating to production of products are expensed as research and development expenses in the period incurred unless recoverable through means other than sale. If pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales. For the year ended December 31, 2020 and 2019, no revenues have been recorded related to pre-launch products.

Cash and cash equivalents

Cash and cash equivalents include cash on hand, bank balances on demand and short-term deposits with an original maturity of three months or less.

Share-based payment awards

The Group operates a number of share-based payment programs.

An equity-settled share-based payment award is accounted for by recognizing the related expense over the vesting period of the award, with corresponding increase recorded in equity. The expense is based on the fair value determined at the grant date of the award and the number of awards expected to vest. The fair value remains unchanged after grant date. If there is no final grant date due to terms that have yet to be implemented, the fair value is based on an estimated grant date. Once the award has vested, there is no reversal of expense related to the award.

When a share-based payment award provides for different ways of settlement (i.e. cash versus shares) depending on the occurrence of contingent events, the award is accounted for based on the manner of settlement that is most probable. A change in the expected manner of settlement is accounted for as a modification.

Expenses for employer taxes arising upon the exercise of equity-settled share-based payments are recognized in profit or loss.

The related share-based payment expense is recorded in the functional cost category to which the award recipient's costs are classified.

Taxes

Current tax assets and liabilities

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities based on the tax rates and tax laws that are enacted or substantively enacted at the end of the reporting period.

Deferred taxes

Deferred tax is recognized using the liability method on all temporary differences as of the end of the reporting period between the carrying amounts of assets and liabilities and their tax bases.

Deferred tax liabilities are recognized for all taxable temporary differences. The only exception is if the deferred income tax arises from initial recognition of an asset or liability in a transaction other than a business combination which, at the time of the transaction, affects neither accounting profit nor loss nor taxable profit or loss.

Deferred tax assets are recognized for deductible temporary differences and to the extent that it is probable that future taxable income will allow the deferred tax asset to be realized.

Deferred tax assets and deferred tax liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

In the event that transactions and other events are recognized directly in equity, any related taxes on income are also recognized directly in equity.

Deferred tax assets and deferred tax liabilities are offset if there is a legally enforceable right to offset current tax assets and current tax liabilities and these relate to income taxes levied by the same tax jurisdiction.

Segments

An operating segment is defined as a component of an entity for which discrete financial information is available and whose operating results are regularly reviewed by the Chief Operating Decision Maker (CODM). The CODM is comprised of the Management Board of the Group. The Group operates as a single segment dedicated to the discovery and development of biotechnological applications and the CODM makes decisions about allocating resources and assessing performance based on the Group as a whole. Accordingly, the Group has determined it operates in one operating and reportable segment.

Significant accounting judgments, estimates and assumptions

The preparation of financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the reported amounts in the financial statements.

Management continually evaluates its judgments and estimates in relation to assets, liabilities, contingent liabilities, revenues and expenses. Management bases its judgments and estimates on historical experience and on other various factors, it believes to be reasonable under the circumstances, the result of which forms the basis of 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 and conditions and may materially affect the financial results or the financial position reported in future periods.

Significant judgments

In the process of applying the accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements.

Accounting for share-based payments

The Group has multiple share-based payment programs. Significant judgments include classification as cash or equity-settled awards of the share-based payments and the determination of the fair value of the awards.

Since 2009 and through 2020, members of management and other key employees were awarded rights in a virtual shares program which is described under Note 9.2. Furthermore, as described under Note 9.3 and 9.4, in 2019 rights were awarded in a new virtual shares program and other terms specific

to certain individuals and the former CEO of the Group. Under the terms of these programs, participants are entitled to cash payments that are contingent on the occurrence of specified exit events, which includes an initial public offering (IPO) of the Group. In the case of an IPO, the Group has a choice of settling the awards in either cash or shares. The Group's intention has been to settle in shares in the case of an IPO and has been the actual settlement in the case of any exercises until these financial statements have been authorized for issue. As the Group had considered an IPO scenario in the past as more probable than other, cash-settled, scenarios, and the IPO has materialized, it has accounted for the virtual shares program as equity-settled as of December 31, 2019 and 2020.

The awards granted in 2020 are also accounted for as equity-settled share-based payments and described under Note 9.5.

Revenue recognition and collaboration agreements

The Group applied the following judgments in determining the amount and timing of revenue from collaboration agreements:

- Identification and determination of the nature of performance obligations in collaboration and license agreements.

The Group generates revenues from collaboration and license agreements under which the Group grants licenses to use, research, develop, manufacture and commercialize candidates and products. As these agreements comprise several promises, it must be assessed whether these promises are capable of being distinct within the context of the contract. If these promises are not distinct, they are combined until the bundle of promised goods and services is distinct. For some agreements, this results in the Group accounting for all goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress.

For these combined performance obligations, it must be assessed which of these promises is the predominant promise to determine the nature of the performance obligation. The Group determined that the grant of the license is the predominant promise within the (combined) performance obligation to grant a license to the customers. It was assessed that the Group grants its customers a right to access or a right to use the Group's IP due to the collaboration and license agreements.

As a result, the promise to grant a license is accounted for as a performance obligation satisfied over time as the Group's customer simultaneously receive and consumes the benefits from the Group's performance.

- Estimation of variable consideration and assessment of the constraint when determining the amount of revenue of which to defer recognition

The Group's collaboration and license agreements comprise variable considerations which are contingent on the occurrence or non-occurrence of a future event (i.e., reaching a certain milestone). When determining the deferral of revenue in a collaboration and license agreement, the Group is required to estimate the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to the customer.

As there are usually only two possible outcomes (i.e., milestone is reached or not), the Group has assessed that the method of the most likely amount is the best method to predict the amount of consideration to which the Group will be entitled.

The most likely amount of these milestone payments (i.e., the full milestone payment) is only included in the transaction price if the occurrence of reaching future milestone is highly probable. The Group has assessed that the likelihood of achieving the respective milestone decreases depending on how far the expected date of achieving the milestone lies in the future.

The Group has concluded that future milestone payments are fully constrained at each of the fiscal years. Future milestone payments would become unconstrained at the satisfaction of the milestone event, specifically a development event, a regulatory approval or achievement of a sales milestone.

Clinical trial accruals and related research and development costs

The value of goods and services received from contract research organizations (CROs) and contract manufacturing organizations (CMOs) in the reporting period are estimated based on the level of services performed and progress made in the respective period. Amounts are recorded as accrued expenses in cases where the Company has not received an invoice from the service provider. Advance payments for goods or services that will be used or rendered for future research and development activities are recognized as (current) prepaid expenses and other assets or in (non-current) other assets if the benefit is expected to be received more than a year from the statement of financial position date. These amounts are recognized as an expense as the related goods are delivered or the services performed. Management's estimates are based on the best information available at the time. However, additional information may become available in the future and management may adjust the estimate in such future periods. In this event, the Company may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. The Company considers resulting increases or decreases in cost as changes in estimates and reflects such changes in research and development expenses in the period identified.

Accounting for EIB loan

In 2020, the Group received from the European Investment Bank, or EIB, a line of credit which is available in three tranches, each of which can be drawn separately. In addition, any of the tranches carry a fixed interest but also a specified amount of variable remuneration. The agreement provides for multiple rights and obligations, including rights to terminate and repay the agreement early with varying amounts of variable remuneration.

The Group accounts for the first tranche of EUR 25 million drawn in 2020 as a financial liability at amortized cost, using the effective interest method based on expected cashflows including any amount of variable remuneration. In doing so, the Group assessed what is the most probable scenario for the exercise of its rights as the borrower. In addition, the Group determined an effective interest rate which is consistent with the accounting for other financing arrangements. For further information on the EIB loan, see Note 12.

Accounting for convertible loans

IFRS requires that a convertible loan be bifurcated into a debt component and a conversion right if the latter is an equity instrument.

In 2019, the Group assessed that the conversion right of the convertible loan is not an equity instrument, but a liability with an insignificant value.

The debt component of the convertible loan was measured using the market interest rate obtainable on similar debt instruments. The debt component was measured as liability at amortized cost until it is converted into equity or becomes due for repayment. The carrying amount of the debt component was based on an expected repayment in 2021, which was the earliest possible date at which repayment could be required by the lender, unless specified events occurred.

The component of the loan proceeds allocated to equity represents the residual value between the consideration received for each single tranche and the fair value of the corresponding financial liabilities at initial recognition.

For further information on the convertible loan, see Note 12.

Accounting for determining the lease term of contracts with renewal options

The Group determines the lease term as the non-cancelable term of the lease, together with any periods covered by an option to extend the lease if it is reasonably certain to be exercised, or any periods covered by an option to terminate the lease, if it is reasonably certain not to be exercised.

The Group has the option, under some of its leases to lease the assets for additional terms of five to ten years. The Group applies judgment in evaluating whether it is reasonably certain to exercise the option to renew. The Group considers all relevant factors that create an economic incentive for it to exercise the renewal.

After the lease commencement date, the Group reassesses the lease term if there is a significant event or change in circumstances that is within its control and affects its ability to exercise (or not to exercise) the option to renew (e.g., a change in business strategy).

The Group included the renewal period (five years) as part of the lease term for certain building lease arrangements. Optional lease payments from both of these aforementioned extension options not included in the measurement of the lease liability exist in a gross amount of EUR 34,201k (2019: 12,548k)

Estimating the incremental borrowing rate

In most cases, the Group cannot readily determine the interest rate implicit in the lease. Therefore, it uses its incremental borrowing rate (IBR) to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group "would have to pay," which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when they need to be adjusted to reflect the terms and conditions of the lease. The Group estimates the IBR using observable inputs (such as market interest rates, country risk premiums and credit spreads) when available and is required to make certain entity-specific

Changes in accounting policies and disclosures

Summary of significant accounting policies

This section describes significant accounting policies adopted in the preparation of these consolidated financial statements. These policies have been consistently applied to all the years presented, unless otherwise stated.

The below listed amendments and interpretations apply for the first time in 2020, but do not have a material impact on the consolidated financial statements of the Group:

- Conceptual Framework Amendments, References to the Conceptual Framework in IFRS Standards (IFRS 2 Share-Based Payment, IFRS 3 Business Combinations, IAS 1 Presentation of Financial Statements, IAS 8 Accounting Policies, IAS 34 Interim Financial Reporting, IAS 37 Provisions, Contingent Liabilities and Contingent Assets, IFRIC 12 Service Concession Arrangements, IFRIC 19 Extinguishing Financial Liabilities with Equity Instruments IFRIC 22 Foreign Currency Transactions and Advance Consideration, SIC 32 Intangible Assets — Web Site Costs,)
- IFRS 3 Business Combinations, Definition of a business

- IAS 39 Financial Instruments: Recognition and Measurement, IFRS 7 Financial Instruments Disclosures, IFRS 9 Financial Instruments, Interest Rate Benchmark Reform — Phase 1
- IAS 1 Presentation of Financial Statements, IAS 8 Accounting Policies, Definition of Material

The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

Standards issued but not yet effective

The following amendments will be adopted effective January 1, 2021, or at a later effective date, and are not expected to have a material impact on the consolidated financial statements of the Group:

- Interest Rate Benchmark Reform — Phase 2, Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16
- COVID-19-related Rent Concessions, Amendment to IFRS 16

The following standards issued will be adopted in a future period and the potential impact, if any, they will have on the Group's consolidated financial statements is being assessed:

- Amendments to IFRS 4 Insurance Contracts
- IFRS 17 Insurance Contracts, including Amendments to IFRS 17
- Amendments to IAS 37 Onerous Contracts
- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current (effective 1 January 2023)
- Amendments to IFRS 3 Business Combinations; IAS 16 Property, Plant and Equipment; IAS 37 Provisions, Contingent Liabilities and Contingent Assets; Annual Improvements 2018-2020
- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates

Impact of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic, which continues to spread throughout the United States, the European Union and around the world. In response, the Group began development of CVnCoV, its mRNA-based COVID-19 vaccine candidate, for which it initiated a Phase 1 clinical trial in healthy volunteers in June 2020, a Phase 2a clinical trial in older adults in September 2020 and a Phase 2b/3 clinical trial in December 2020. The connection with the CVnCoV development, the Group signed agreements providing for government grants and for future supply of vaccine (see Note 3.1. on BMBF and EC APA). During 2020, the Company began production of vaccine doses which will be available for supply under these arrangements and which are recorded in inventory as of December 31, 2020 as the costs were determined to be recoverable under existing arrangements regardless of whether regulatory approval is obtained. Additionally, following December 31, 2020, the Group signed agreements to expand its existing manufacturing capacities at its headquarters in Tuebingen, thereby allowing for broad-scale manufacturing of CVnCoV and other mRNA-based vaccines, and to collaborate with pharmaceutical partners to develop and manufacture vaccines against SARS-CoV-2 variants (refer to Note 20 Subsequent Events for additional information). In February 2021, the Group announced initiation of a rolling submission with the European Medicines Agency (EMA) for CVnCoV and was in late-stage clinical testing.

As the Group is currently devoting significant resources to the development of CVnCoV, such development may impair the ability to timely progress other product candidates in clinical trials. In addition, enrollment in other programs may be delayed as a result of the COVID-19 pandemic and could have a negative impact on revenue recognition related to non-COVID-19 collaborations. For instance, the Group's flu program with Bill & Melinda Gates Foundation was delayed. The partial disruption, even temporary, may negatively impact the Company's operations and overall business by delaying the progress of its clinical trials and preclinical studies. The Group's operations, including research and manufacturing, could also be disrupted due to the potential of the impact of staff absences as a result of self-isolation procedures or extended illness. However, the Group has taken a series of actions aimed at safeguarding the its employees and business associates, including implementing a work-from-home policy for employees except for those related to its laboratory and production operations. The Group has been running COVID PCR (polymerase chain reaction) tests on a weekly basis for employees on the premises. As the Group advances its clinical programs, it is in close contact with its principal investigators and clinical sites, which are located in jurisdictions affected by the COVID-19 pandemic, and is assessing the impact of the COVID-19 pandemic on its clinical trials, expected timelines and costs on an ongoing basis. The rapid development and fluidity of the situation presents uncertainty and risk with respect to the Group, its performance and its financial results.

3. Notes to the consolidated financial statements

3.1 Revenue from contract with customers

The Group recognized the following revenues in 2018, 2019 and 2020:

	December 31		
	2018	**2019**	**2020**
	EUR k	**EUR k**	**EUR k**
United States			
Eli Lilly	8,927	14,319	34,854
Germany			
Boehringer Ingelheim	3,337	2,474	1,885
Others	5	104	-
Switzerland			
CRISPR	602	519	695
Netherlands			
Genmab	-	-	2,628
Belgium			
GSK	-	-	8,809
Total	**12,871**	**17,416**	**48,871**

Of these revenues, all of which were recognized over time as part of collaboration agreements, in 2020, EUR 46,597k (2019: EUR 5,777k, 2018: EUR 5,861k) related to delivery of research services combined with an IP license (recognized from the upfront payments as further illustrated in the table below), EUR 556k (2019: EUR 8,617k, 2018: 6,713k) related to delivery of products and EUR 1,718k (2019: EUR 3,022k, 2018: 297k) were recognized from those research and development services considered distinct within the agreements.

The Group has received upfront payments which were initially deferred and are subsequently recognized as revenue as the Group renders services over the performance period. Below is a summary of such payments and the related revenues recognized:

Customer	Upfront payments	Upfront payments included in contract liabilities at	Revenue recognized from upfront payments		
	December 31, 2020	December 31, 2020	2018	2019	2020
	(EUR k)	(EUR k)		(EUR k)	
Eli Lilly	USD 50,000 (EUR 42,200)*	-	3.516	3.516	34.854
CRISPR	USD 3,000 (EUR 2,524)*	1.549	310	310	310
Boehringer Ingelheim	EUR 30,000	14.003	2.035	1.951	1.867
Genmab	USD 10,000 (EUR 8,937)*	7.150	-	-	1.787
GSK	EUR 120,000	112.222	-	-	7.778
BMBF	EUR 61,122	61,122	-	-	-
European Commission	EUR 450,000	450.000	-	-	-
Total		**646,046**	**5.861**	**5.777**	**46.597**

**Translated at the currency exchange rate prevailing on the transaction date.*

Contract balances:

	December 31, 2019 (EUR k)	December 31, 2020 (EUR k)
Trade receivables	15,690	1,014
Contract assets	1,463	808
Contract liabilities	73,521	658,046

Contract liabilities include advances received from the Group's major license and collaboration agreements and from other customers. The outstanding balances of these accounts increased in 2020 and 2019 due to upfront and milestone payments received or receivable of EUR 631,122k and EUR 8,937k, respectively, which were deferred and exceeded the revenues recognized from contract liabilities recorded under the collaboration or other customer agreements in each respective year.

Contract liabilities allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at year-end are as follows:

		December 31, 2019 (EUR k)	December 2020 (EUR k)
	Within one year	7,481	157,985
	More than one year	66,040	500,061
Total		**73,521**	**658,046**

Trade receivables are non-interest bearing and are generally settled within 30 to 45 days.

At December 31, 2020, the Group had four collaboration partners (2019: three) that owed 100% (2019: four) of all the receivables and contract assets outstanding. There were two collaboration partners (2019: two) with balances greater than 10% of the total amounts of receivable and contract assets.

In June 2020, the Group and Eli Lilly terminated their collaboration and the following agreements: License and Collaboration Agreement dated November 29, 2017, Early Clinical Supply Agreement dated July 5, 2018 and related Quality Agreement dated June 29, 2018. As a result, on the termination date, EUR 33,100k in contract liabilities from an upfront payment was recognized as no further associated performance obligations remained.

GlaxoSmithKline

In July 2020, the Group entered a collaboration with GlaxoSmithKline (GSK) for the research, development, manufacture and commercialization of mRNA-based vaccines and monoclonal antibodies targeting infectious disease pathogens. In addition to an equity investment of EUR 150,000k as part of the 2020 Private Investment (see Note 8.2), GSK made a non-refundable upfront cash payment of EUR 120,000k which was deferred upon receipt and recognized as a contract liability. Additionally, the Company is eligible to receive a one-time reimbursable payment of EUR 30,000k for manufacturing capacity reservation, upon certification of CureVac's commercial scale manufacturing facility currently under construction in Germany as well as to receive development and regulatory milestone payments of up to EUR 320,000k, commercial milestone payments of up to EUR 380,000k and tiered royalties on product sales. GSK will fund R&D activities incurred by CureVac related to the development projects covered by the collaboration. CureVac will be responsible for the preclinical- and clinical-development through the Phase 1 trials of these projects, after which GSK will be responsible for further development and commercialization. CureVac will be responsible for the manufacturing of the product candidates, including for commercialization, and will retain commercialization rights for selected countries for all product candidates. Revenue is being recognized in accordance with the Company's accounting policy for collaboration arrangements with the exception that the upfront payment, attributable to the IP license, is being recognized straight-line from the effective date of the collaboration agreement through the estimated completion date of Phase 1 clinical trials, at which time GSK will be responsible for further development and commercialization. Refer to Note 20 Subsequent events for additional information regarding an additional collaboration agreement entered into with GSK following December 31, 2020.

German Federal Ministry of Education and Research

During 2020, the Company received from the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung), or BMBF, a German government-related entity, a grant to support the development and production of its COVID-19 vaccine candidate of up to EUR 252 million. In July 2020, CureVac applied for this grant as part of a special program to accelerate the research and development of urgently needed vaccines against SARS-CoV-2. Grant payments are contingent on reaching predefined milestones. Amounts incurred in 2020 and 2021 are eligible for reimbursement through the grant. The Company reached all the predefined milestones for 2020. CureVac received funding of EUR 103 million in 2020 and is eligible to receive up to EUR 149 million in 2021. Based on the terms and conditions of the arrangement, the Company assesses the arrangement as having two components: a grant component (in the scope of IAS 20) and a supply component (in the scope of IFRS 15) which have been separated. EUR 61.1 million has been allocated to the supply of future deliveries in the scope of IFRS 15 (to be made after no further supply obligation under the EC APA exists). The amount attributed to the supply of future deliveries was determined based on the relative stand-alone selling price of the vaccine observed in similar arrangements and is presented in contract liabilities. Refer to Note 3.6 for additional information on the recognition of the grant component of this arrangement.

Advance Purchase Agreement with European Commission

On November 30, 2020, CureVac entered into an Advance Purchase Agreement (APA) with the European Commission (EC), acting on behalf and in the name of all Member States of the European Union, which provides for the advance purchase by the Member States of 225 million doses of our SARS-CoV-2 vaccine to be allocated among the Member States, and the option to purchase up to an additional

180 million doses. The option may be exercised by the EC on behalf and in the name of the Member States. In order to support our accelerated efforts to develop a safe and effective vaccine, the APA provides for support to our operations in the form of two up-front payments. The first up-front payment of EUR 450,000k has been paid by the EC on behalf of the Member States and is included in contract liabilities. The second up-front payment of a mid nine-figure euro amount is to be paid directly by the Member States and is due after an interim data package has been submitted by us to the EMA for the purpose of obtaining EU marketing authorization for CVnCoV. Such up-front payments must be used solely for the development and commercial supply of CVnCoV and will be recognized in revenue as doses are supplied following EU marketing authorization. We will be required to return any unspent amounts of the up-front payments if, among others, we fail to successfully develop CVnCoV or if we successfully develop CVnCoV, but we do not receive EU marketing authorization or fail to supply any doses of CVnCoV to any of the Member States by late 2021, unless we and the EC mutually agree to a later date. In addition, if any Member State decides to purchase additional doses pursuant to the option granted under the APA, we will be entitled to additional up-front payments that are not subject to such restrictions on use or return of unused amounts upon termination of the APA.

The APA will be terminated automatically if we notify the EC that we are unable to provide the vaccine because (i) the clinical trial results are not satisfactory, (ii) the clinical trial results do not meet their end point in terms of efficacy or safety or (iii) the EU marketing authorization was not granted. The termination will be effective unless the EC objects within 30 calendar days; provided, however, that such objection may only be based on reasonable grounds and taking into account the severity of the impact that continuation of the APA would have on our business. In addition, the EC shall have the right to terminate the APA, and each Member State the respective individual vaccine purchase orders, for the reasons specified in Section 14.2 of the APA, which among others, provides the EC the right to terminate the APA if we do not obtain EU marketing authorization by late 2021, unless we and the EC mutually agree to a later date, or if we are in material breach of our obligation to (i) obtain EU marketing authorization and establish sufficient manufacturing capacities to enable the manufacturing and supply of the contractually agreed volumes of our vaccine pursuant to the agreement, (ii) provide the doses of the vaccine according to the estimated delivery schedule or (iii) manufacture (or have manufactured) doses designated to participating Member States within the European Union at sites outside the EU, UK, the EEA or Switzerland without the prior consent of the EC.

The nature of expenses recognized in the functional categories of the statement of operations are as follows:

3.2 Cost of sales

The cost of sales consists of the following:

	2018	2019	2020
	(EUR k)	(EUR k)	(EUR k)
Personnel	(7,703)	(9,855)	(2,896)
Materials	(4,941)	(7,542)	(1,598)
Third-party services	(2,340)	(7,268)	(2,652)
Maintenance and lease	(1,758)	(1,060)	(1,016)
Amortization, depreciation and derecognition	(893)	(2,038)	(5,913)
Other	(109)	(220)	(98)
Total	**(17,744)**	**(27,983)**	**(14,173)**

During the fiscal year ended December 31, 2020, cost of sales decreased compared to the same period 2019 mainly due to increased focus by the Group on research and development activities, primarily for CVnCoV and lower product costs because of the termination of the collaboration with Eli Lilly (see Note 3.1. for additional information). Additionally, during 2020, the Group recognized lower inventory write-downs in cost of sales and lower set-up and quality assurance activities for the production processes as compared to the same period of 2019. In fiscal 2020, EUR 5,579k was recognized as loss on derecognition of production-related property, plant and equipment; refer to Note 4.1 for additional information.

3.3 Selling and distribution expenses

Selling and distribution expenses consist of the following:

	2018	2019	2020
	(EUR k)	(EUR k)	(EUR k)
Personnel	(581)	(1,263)	(631)
Maintenance and lease	(300)	(167)	(1)
Amortization and depreciation	(95)	(81)	(98)
Other	(109)	(243)	(3)
Total	**(1,085)**	**(1,755)**	**(733)**

Personnel expenses mainly include salary and salary-related expenses of EUR 370k (2019: 520k, 2018: 581k) and expenses from share-based payments of EUR 261k (2019: 743k, 2018: 0k). Refer to Note 9 for further information.

3.4 Research and development expenses

R&D expenses consists of the following:

	2018	2019	2020
	(EUR k)	(EUR k)	(EUR k)
Materials	(5,867)	(4,015)	(29,834)
Personnel	(7,565)	(14,385)	(21,313)
Amortization and depreciation	(1,143)	(474)	(2,578)
Patents and fees to register a legal right	(4,847)	(4,551)	(7,337)
Third-party services	(19,921)	(18,626)	(51,306)
Maintenance and lease	(1,156)	(670)	(717)
Other	(1,223)	(521)	(723)
Total	**(41,722)**	**(43,242)**	**(113,808)**

During the fiscal year ended December 31, 2020, research and development expenses increased in comparison compared to the same period of 2019 mainly due to increased focus by the Group on research and development activities, primarily for CVnCoV. The expenses consist primarily of costs incurred to CROs involved in the CVnCoV development (recognized in third-party services) as well as material used in the administration of clinical trials. As of December 31, 2020, the Group had no development expenditures that met the requirement for capitalization and thus none have been capitalized.

Personnel expenses mainly include salary and salary-related expenses of EUR 16,543k (2019: 14,127k, 2018: 11,806k) and expenses from share-based payments of EUR 4,770k (2019: nil); additionally, 2018 includes a EUR 4,241k benefit recognized upon reversal of provisions due to expiration of certain virtual shares awarded under our Prior VSOP. Refer to Note 9 for further information.

3.5 General and administrative expenses

General and administrative expenses include the following:

	2018	2019	2020
	(EUR k)	(EUR k)	(EUR k)
Personnel	(10,084)	(31,645)	(29,884)
Maintenance and lease	(3,239)	(4,604)	(2,505)
Third-party services	(4,006)	(5,970)	(6,914)
Legal and other professional services	(4,078)	(2,110)	(3,531)
Amortization and depreciation	(1,635)	(2,182)	(6,020)
Other	(2,247)	(2,458)	(4,700)
Total	**(25,289)**	**(48,969)**	**(53,554)**

Personnel expenses mainly include salary and salary-related expenses of EUR 20,442k (2019: 13,083k, 2018: 10,105k) and expenses from share-based payments of EUR 9,442k (2019: 18,562k, 2018: 0k). Other mainly consists of insurance expenses of EUR 1,401k (2019: 115k, 2018: 167k) and real estate transfer taxes of EUR 930k (2019: nil, 2018nil).

3.6 Other operating income

Other operating income relates to:

	2018	2019	2020
	(EUR k)	(EUR k)	(EUR k)
Grants and other reimbursements from government agencies and similar bodies	808	5,385	23,736
Other	-	202	414
Total	**808**	**5,587**	**24,150**

In 2020 and 2019 income from grants with government agencies and similar bodies resulted from the following:

German Federal Ministry of Education and Research

As discussed in Note 3.1, the Company received a grant from BMBF to support the development of its COVID-19 vaccine candidate for which it was determined the arrangement contained two components: a grant component (in the scope of IAS 20) and a supply component (in the scope of IFRS 15). With regard to the grant component, as of December 31, 2020, the Group has recognized grant income in the amount of EUR 6,602k. The unrecognized grant component of 28,630k is presented in (current) other liabilities.

Coalition for Epidemic Preparedness Innovations

The Coalition for Epidemic Preparedness Innovations (CEPI) is an innovative partnership between public, private, philanthropic, and civil organizations, launched at the World Economic Forum in Davos in 2017, to develop vaccines to stop future epidemics. CEPI's priority diseases include Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and

Chikungunya virus. CEPI also invests in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (i.e., Disease X).

In February 2019, CureVac entered into a partnership agreement worth up to USD 34,000k with CEPI to further develop CureVac's The RNA Printer™ prototype. Under the three-year partnership agreement, CureVac will use its mRNA platform for the preclinical development of a Lassa virus vaccine (a high-priority disease on the World Health Organization R&D list), a yellow fever vaccine and CureVac's rabies virus vaccine. Funds are to be received semi-annually in advance, to cover costs for the next six months. These payments are allocated to the agreed and signed statements of work. Management concluded that the arrangement should be accounted for by analogy to IAS 20.

CureVac is required to use reasonable efforts to achieve certain development milestones and is responsible for conducting certain clinical trials. In the event of an infectious disease outbreak, where such outbreak can be addressed by a Lassa virus, SARS-CoV-2 or future vaccine developed under the agreement, CureVac must manufacture such vaccine for use in the area affected by the outbreak on economic terms that satisfy CEPI's equitable access guidelines or otherwise allow CEPI or a third party to supply such vaccine in the affected area.

CureVac is required to grant certain approved manufacturers all necessary rights to use certain of CureVac's pre-existing IP and IP developed under the CEPI Agreement to further develop CureVac's automation solution and manufacture products for the treatment of certain diseases in geographic areas where there is an outbreak on economic terms that satisfy CEPI's equitable access guidelines. CureVac must provide all necessary commercially reasonable support to such approved manufacturers to facilitate such efforts.

CureVac solely owns all IP developed under the CEPI Agreement but is required to obtain CEPI's consent prior to exploiting any IP developed under the CEPI Agreement if such exploitation is in conflict with or goes against CEPI´s mission or policies.

In the event that CEPI terminates the agreement, CureVac will grant CEPI a license under CureVac's background IP and IP developed under the agreement to, among other things, develop and use CureVac's RNA Printer for use in treating certain infectious diseases and to manufacture products developed under the agreement.

In January 2020, CureVac and Coalition for Epidemic Preparedness Innovations (CEPI) entered a collaboration to develop a vaccine against the new coronavirus SARS-CoV-2. The aim of the cooperation is to safely advance vaccine candidates into clinical testing as quickly as possible. The agreement builds upon the existing partnership between CureVac and CEPI to develop a rapid-response vaccine platform and included additional initial funding of up to USD 8,300k. In May 2020, CEPI increased its grant award to the Group for SARS-CoV-2 vaccine development to up to USD 15,300k.

During the year ended December 31, 2020, CureVac recognized the reimbursement of approved expenses of EUR 15,953k (2019: EUR 3,607k) as "other operating income" and EUR 3,239 (2019: EUR 2,325k) were deducted from the carrying amount of qualifying assets recorded in property, plant and equipment.

As of December 31, 2020, EUR 1,325k in grant funds received have been deferred and are presented within other liabilities (as of December 31, 2019: EUR 2,886k).

Bill & Melinda Gates Foundation (BMGF)

BMGF finances, in the form of grants, various programs that CureVac operates for the development of vaccines, hence promoting and accelerating the development of CureVac's technology platform. Through its equity investment, BMGF supports mainly the development of CureVac's technology platform including the construction of a production plant in accordance with the GMP (Good Manufacturing Practice) standard on an industrial scale.

In 2015, CureVac entered into a Global Access Commitments Agreement with the Bill & Melinda Gates Foundation pursuant to which the Company is required to take certain actions to support the Bill & Melinda Gates Foundation's mission.

In November 2016, in connection with the Global Access Agreement, CureVac received a grant of USD 653k (EUR 614k) in funding for the development of a vaccine for picornaviruses. In November 2017, also in connection with the Global Access Agreement, the company received two additional grants: an amount of USD 1,000k (EUR 852k) was received for the development of a universal influenza vaccine and an amount of USD 800k (EUR 673k) was received for a malaria vaccine. In August 2019, the Company received a second payment for the universal influenza program amounting to USD 540k (EUR 486k). In November 2020, the Company received a third payment for the universal influenza program amounting to USD 322k (EUR 280k). In November and December 2020, the Company received further payment for the malaria program amounting to USD 1,449k (EUR 1,208k).

During the year ended December 31, 2020 CureVac recognized 1,183 (2019: EUR 768k, 2018: EUR 486k) from the amortization of the grants on a straight-line basis as other operating income.

As of December 31, 2020, EUR 2,164k in grant funds received have been deferred and presented within other liabilities (as of December 31, 2019: EUR 1,262k).

3.7 Other operating expenses

Other operating expenses relates to:

	2018	2019	2020
	EUR k	EUR k	EUR k
Renumeration of Supervisory Board	(343)	(521)	(566)
Other	(320)	(31)	(2)
Total	**(663)**	**(552)**	**(568)**

4. Fixed Assets

4.1 Development of property, plant and equipment and intangible assets

The development of property, plant and equipment and of intangible assets for the years ended December 31, 2019 and 2020 were as follows:

Intangible assets

(in EUR k)		Software	Licenses	Advance payments	Total
Acquisition costs					
	As of January 1, 2019	7,331	1,386	238	8,955
	Additions	738	-	44	782
	Disposals	(6)	-	-	(6)
	As of December 31, 2019	8,063	1,386	282	9,731
Cumulative amortization and impairment charges					
	As of January 1, 2019	2,296	446	-	2,742
	Amortization	1,295	-	-	1,295
	Disposals	(4)	-	-	(4)
	As of December 31, 2019	3,587	446	-	4,033

Acquisition costs					
	As of January 1, 2020	8,063	1,386	282	9,731
	Additions	1,919	8,501	598	11,018
	Disposals	-	-	-	-
	Reclassifications	192	-	(192)	-
	Currency translation	(2)	-	-	(2)
	As of December 31, 2020	10,172	9,887	688	20,747
Cumulative amortization and impairment charges					
	As of January 1, 2020	3,587	446	-	4,033
	Amortization	913	1,656	-	2,569
	Currency translation	(1)	0	-	(1)
	As of December 31, 2020	4,499	2,102	-	6,601
Carrying amount					
	As of January 1, 2019	5,035	940	238	6,213
	As of December 31, 2019	4,476	940	282	5,698
	As of December 31, 2020	**5,673**	**7,785**	**688**	**14,146**

Property, plant and equipment

(in EUR k)		**Buildings**	**Technical equipment and machines**	**Other equipment, furniture and fixtures**	**Assets under construction**	**Total**
Acquisition costs						
	As of January 1, 2019	5,888	14,336	5,247	33,025	58,496
	Additions	854	2,152	712	7,435	11,153
	Disposals	(65)	(319)	(248)	0	(632)
	Reclassifications	167	883	187	(1,237)	0
	Currency translation	0	0	3	6	9
	As of December 31, 2019	6,844	17,052	5,901	39,229	69,026
Cumulative amortization and impairment charges						
	As of January 1, 2019	1,708	5,810	3,388	7,120	18,026
	Depreciation	779	1,637	899	0	3,315
	Disposals	(37)	(190)	(164)	0	(391)
	Currency translation	0	0	1	0	1
	As of December 31, 2019	2,450	7,257	4,124	7,120	20,951

Acquisition costs						
	As of January 1, 2020	6,844	17,052	5,901	39,229	69,026
	Additions	5,690	4,622	3,772	14,522	28,606
	Disposals	(77)	(839)	(398)	(5,579)	(6,893)
	Reclassifications	7,493	1,549	9	(9,052)	0
	Currency translation	0	0	(41)	0	(41)
	As of December 31, 2020	19,950	22,384	9,243	39,120	90,698
Cumulative amortization and impairment charges						
	As of January 1, 2020	2,450	7,257	4,124	7,120	20,951
	Depreciation	1,042	1,813	1,277	0	4,132
	Disposals	(77)	(739)	(133)	0	(949)
	Attributions	0	(23)	(1)	0	(24)
	Currency translation	0	0	(17)	0	(17)
	As of December 31, 2020	3,415	8,308	5,250	7,120	24,093
Carrying amount						
	As of January 1, 2019	4,180	8,526	1,859	25,905	40,470
	As of December 31, 2019	4,394	9,795	1,777	32,109	48,075
	As of December 31, 2020	**16,535**	**14,076**	**3,993**	**32,000**	**66,605**

In fiscal 2020, EUR 5,579k was recognized as loss on derecognition. The planned capacity of the new production plant GMP IV was reassessed and management determined that certain capitalized costs, consisting mainly planning costs related to the previous design, and classified in assets under construction, were determined not to have any further economic benefit and therefore were derecognized from property, plant and equipment and were recognized as expense in cost of sales.

4.2 Right of use assets

Set out below, are the carrying amounts of the Group's right-of-use assets and the movements during the period:

	Right-of-use assets			
	Land and Buildings	Vehicles	Other equipment	Total
	EUR k	EUR k	EUR k	EUR k
As at January 1, 2020	13,375	126	110	13,611
Additions	23,738	58	638	24,434
Disposals	0	0	(51)	(51)
Depreciation expense	(3,525)	(70)	(124)	(3,719)

Foreign currency translation	(292)	(1)	2	(291)
As at December 31, 2020	**33,296**	113	575	33,984

Below are the carrying amounts of lease liabilities and the movements during the period:

	EUR k
As at January 1, 2020	14,130
Additions	19,310
Disposals	(42)
Accretion of interest	1,665
Payments	(4,661)
Foreign currency translation	(315)
As at December 31, 2020	**30,087**
Current	3,234
Non-current	26,853

A maturity analysis of lease liabilities is disclosed in Note 15.

The following are the amounts recognized in the statement of operations:

	EUR k
Depreciation expense of right-of-use assets	(3,719)
Interest expense on lease liabilities	(1,665)
Expense relating to short-term leases (included in cost of sales)	(48)
Expense relating to leases of low-value assets (included in administrative expenses)	(30)
Total amount recognized in profit or loss	**(5,462)**

Set out below, are the carrying amounts of the Group's right-of-use assets and the movements of prior period:

	Right-of-use assets			
	Land and Buildings	**Vehicles**	**Other equipment**	**Total**
	EURk	**EURk**	**EURk**	**EURk**
As at January 1, 2019	15,536	132	239	15,907
Additions	82	59	13	154
Disposals	-	-	-	-
Depreciation expense	(2,322)	(65)	(142)	(2,529)
Foreign currency translation	79	-	-	79
As at December 31, 2019	**13,375**	**126**	**110**	**13,611**

	EUR k
As at January 1, 2019	15,887
Additions	153
Disposals	-
Accretion of interest	824
Payments	(2,812)
Foreign currency translation	78
As at December 31, 2019	**14,130**
Current	2,004
Non-current	12,126

The following are the amounts recognized in the statement of operations in 2019:

	EUR k
Depreciation expense of right-of-use assets	(2,529)
Interest expense on lease liabilities	(824)
Expense relating to short-term leases (included in cost of sales)	(167)
Expense relating to leases of low-value assets (included in administrative expenses)	(94)
Total amount recognized in profit or loss	**(3,614)**

Commitments for leases not yet commenced at December 31, 2020, relate to a lease of technical equipment for GMP IV in Tuebingen, Germany over a 10-year term with fixed lease payments in the gross amount of EUR 3,904k with a starting date of March 1, 2022 (and a respective earliest end date in 2032). In addition, optional lease payments for the renewal of this lease term for five-year extension option exist which could lead to further payments in a gross amount of EUR 291k.

4.3 Non-current other assets

Non-current other assets of EUR 6,322k (2019: EUR 6,061k) consist of costs to obtain a contract of EUR 1,034k (2019: EUR 966k) and deposits paid for dedicated equipment for CureVac production at the CMOs of EUR 4,203k (2019: nil). In 2019 non-current other assets also included a security deposit for a building of EUR 390k as well as a deposit payment for a lease of EUR 4,705k.

The amortization of capitalized costs to obtain a contract in 2020 was EUR 215k (2019: EUR 25k).

5. Inventories

Inventories include the following:

	2019	2020
	EUR k	EUR k
Raw materials	6,177	13,790
Finished goods	20	741
Total	**6,197**	**14,531**

Raw materials were written down by EUR 787k (2019: EUR 4,136k) due to obsolescence and net selling prices being lower than carrying cost related to a specific collaboration arrangement and are recognized in cost of sales.

6. Other financial assets

Other financial assets include the following:

	2019	2020
	EUR k	EUR k
Short-term investments	430	430
Other	1,028	2,189
Total	**1,458**	**2,619**

7. Prepaid expenses and other current assets

Prepaid expenses and other current assets of EUR 48,289k (2019: 1,683k) mainly include prepayments for future service agreements (e.g. for the CROs and CMOs) in the amount of EUR 40,054k (2019: EUR 1,150k), a receivable against the BMBF related to the grant in the amount of EUR 8,235k (2019: nil). At December 31, 2019, outstanding VAT refund claims of EUR 533k were included in the other current assets. At December 31, 2020, the net amount of VAT is reflected in the other current liabilities. These net amounts of VAT refund claims and VAT payables do not bear interest and are reported to the tax authorities on a monthly basis.

8. Equity

Overview

According to the Company's articles of association, the Company's authorized shares are divided into 386,250,000 common shares and 386,250,000 preferred shares, each having a nominal value of EUR 0.12. As of December 31, 2020, no preferred shares had been issued and all issued common shares issued and outstanding were fully paid. However, in certain events, BMGF has the right to require the Company to redeem or facilitate the purchase by a third-party of all common shares it holds and Genmab has the right to subscribe once for common shares at a certain price under an anti-dilution and down round-protection clause effective through February 2022.

All payments received from shareholders in excess of the nominal value of the shares issued and net of transaction costs are recognized in capital reserves. Capital reserves also consists of recognition of share-based payments and the equity components of convertible loans. The Company may only make distributions, whether a distribution of profits or of freely distributable reserves, to shareholders to the extent shareholders' equity exceeds the sum of the paid-in and called-up share capital plus any reserves required by Dutch law or by the Company's articles of association.

Due to the effect of the corporate reorganization described in Note 1, the number of shares issued and outstanding has been retrospectively adjusted to reflect the impact of the resulting 1:133.0778 share split and developed as follows in fiscal 2020:

Common shares issued and outstanding at December 31, 2019	96,693,265
Genmab Investment	2,175,157
2020 Private Investment	55,688,535
Initial Public Offering and Private Placement	22,708,332
Share option exercises	3,195,276
Common shares issued and outstanding at December 31, 2020	180,460,565

No share transactions occurred in fiscal 2019 and, as such, the number of shares outstanding was unchanged as of December 31, 2019 as compared with as of December 31, 2018. The share transactions which occurred in fiscal 2020 were as described below. Refer to Note 20 for additional information on share transactions occurring after December 31, 2020.

Genmab Investment

Pursant to an Investment and Shareholders` Agreement ("ISA"), effective December 19, 2019, Genmab, agreed to purchase 2,175,157 Series B shares in the Company in exchange for EUR 20,000k in cash. As of December 31, 2019, the Group had received a total amount of EUR 16,345, corresponding to the par value of EUR 1 per share agreed to be purchased under the ISA. However, as the shares were not yet registered in the commercial register as of December 31, 2019, according to German law, the shares were not considered issued as of this date. The remaining amount of EUR 19,983,655 was paid at the beginning of 2020 and the shares were finally issued on February 18, 2020.

2020 Private Investment

In July 2020, the Group issued to Kreditanstalt für Wiederaufbau (or "KfW," a German government-related entity), GSK and various other investors a total of 55,688,534 common shares in exchange for an aggregate investment of EUR 559,280k (2020 Private Investment).

Initial Public Offering and Private Placement

In August 2020, the Group completed its IPO whereby it sold 13,333,333 common shares at USD 16.00 per share. In addition, the underwriters exercised their option to purchase an additional 1,999,999 common shares at the public offering price less the underwriting discount. The aggregate proceeds, net of underwriting discounts, received by the Group from these transactions were USD 228,200k (EUR 192,946k). Additional offering costs for legal, accounting, printing and registration fees of USD 5,200k (EUR 4,397k) were recognized as a reduction to capital reserve against the proceeds from the IPO.

Additionally, in August 2020, DH-LT Investments GmbH, a company beneficially owned by Dietmar Hopp, managing director of dievini, the Group's largest shareholder, purchased EUR 100,000k of the Group's common shares at a price of USD 16.00 per share.

Exercises of share options by the former CEO

Between August and October 2020, the Group's former CEO exercised 3,766,309 options against the issuance of 3,195,276 common shares of CureVac N.V. for no cash consideration (i. e., cashless exercise). Refer to Note 9.4 for additional information regarding this share-based payment.

Shareholders' Agreement among KfW, dievini, DH-LT Investments GmbH and Dietmar Hopp

In connection with the KfW's investment as part of the 2020 Private Investment, KfW, dievini and Dietmar Hopp entered into a shareholders' agreement on June 16, 2020, or the KfW dievini Shareholders' Agreement, agreeing to certain transfer restrictions and rights of first refusal relating to their interests in CureVac, nomination rights, and a voting agreement relating to certain specified actions. In particular, dievini and Mr. Hopp agree to vote a specified number of their shares as directed by KfW on certain specified actions, subject to certain exceptions. These specified actions include, inter alia: (1) transferring the tax domicile of CureVac N.V. and/or the approval of the transfer of the corporate or administrative seat of CureVac; (2) relocating or ceasing activities in specified areas to a state outside the European Union to the extent (in particular in the area of the development of vaccines) they are material for the protection of the health of the population of the European Union; (3) entering into material mergers and acquisitions; and (4) amendments to the articles of association of CureVac which would affect the foregoing matters. The KfW dievini Shareholders' Agreement has an initial fixed term that expires on December 31, 2023, subject to a right to extend for one year for the benefit of KfW and dievini, and may be terminated after the initial fixed term, or the extended term, if applicable, by either party subject to six months' notice prior the end of the applicable calendar year. In addition, the agreement shall automatically terminate if KfW sells all or a part of its interest in the Company to a third party, subject to certain exceptions.

9. Share-based payments

Amounts in this Note reflect the retrospective effect of the share split resulting from the corporate reorganization described in Note 1.

During the years ended December 31, 2020, December 31, 2019, and December 31, 2018, the Group operated the following share-based plans for members of management and other key employees of the Group:

- Virtual shares program I (Prior VSOP)
- Virtual shares program II (New VSOP) – for US employees
- LTIP
- Former Chief Executive Officer Grant
- Legacy Plan

Exercise and/or vesting of these plans is dependent on the occurrence of specified exit events, such as IPO or trade sale, and/or additional contingent events, such as financing rounds or product approvals. The virtual shares entitle to a cash payment. However, in the case of an IPO the Group has a choice to settle any grants in shares.

As CureVac has considered the IPO-scenario most probable at the end of fiscal 2019 and had the discretion and the stated intent to settle in shares instead of cash in the case of an IPO, CureVac accounted for this program as equity-settled as of December 31, 2019. In August 2020 the IPO materialized and confirmed the Group's settlement choice. The Prior VSOP has a term of nine years after the day of the Group's initial listing in the case of an IPO.

In addition, the Group made a grant to the former CFO during his tenure. Finally, former and existing members of management hold vested share options under the terms of a legacy plan.

All share-based programs were accounted for as equity-settled.

Measurement of the grant date fair value is based on valuation techniques appropriate in the circumstances, such a Black Scholes option pricing models or a Monte Carlo simulation. Expected volatility, a key input to such models, was based on an evaluation of the historical volatilities of comparable listed biotech-companies over the historical period commensurate with the expected option life. The expected option life was based on the assumptions that the beneficiary would exercise his option in equal installments from the date of the first time

possible (taking into account lock-up and potential trading windows restrictions) until maturity. The risk-free interest was derived from German or US-Government bonds, as appropriate.

Prior VSOP

The development of the virtual shares in this program granted to management and key employees was as follows:

	2018	2019	2020
Outstanding at the beginning of the period	7,972,425	6,640,449	7,305,838
Granted during the period	0	665,389	658,735
Expired during the period	(1,331,976)	0	(13,308)
Outstanding at the end of the period	6,640,449	7,305,838	7,951,265
Thereof vested	6,640,449	7,305,838	7,582,906
Thereof exercisable	none	none	none

658,735 (2019: 665,389; 2018: none) virtual shares were awarded in May and June 2020 18 key employees (respectively the Chief Financial Officer of the company in April 2019).

As of December 31, 2019, and 2018, none of the virtual shares of the Prior VSOP were exercisable because an exit event or capital market transaction had not occurred. The IPO on August 14, 2020, triggered the right to exercise 10 % of the vested virtual shares at the end of the lock-up period, which ended on February 10, 2021. Until March 10, 2021, the beneficiaries declared the exercise of all their then exercisable 759,677 virtual shares and CureVac received 759,677 shares from their shareholders on that day.

All the remaining outstanding virtual shares can be exercised in full if there is a non-conditional drug approval. Furthermore, another 10 % portion of the (vested) virtual shares might be exercisable at the first anniversary after IPO, i.e. on August 14, 2020, if certain minimum trading volumes and liquidity levels in the CureVac NV shares are reached.

The future settlement of all virtual shares would result in an employer tax expense of EUR 26 million.

(Expense) / benefit recognized in the statement of operations and other comprehensive income (loss)

The (expense) / benefit recognized for share-based payment plans during the years ended 31, December is as follows:

	2018	2019	2020
	EUR k	EUR k	EUR k
Selling and distribution expenses			(213)
Research and development expenses	4,229	—	(1,840)
General and administrative expenses	21	(6,074)	(3,135)
Total	**4,250**	**(6,074)**	**(5,188)**

Measurement of Fair Values

The grant date fair value of the 658,735 (2019: 665,389) virtual shares granted in May and June 2020 (2019: April 18, 2019) was derived from the estimated equity value of CureVac on these dates, which lead to a fair value of one virtual share of EUR 10.04 (2019: EUR 9.13) at that time.

The vested virtual share entitlements of former employees who are not participating in the modified award are accounted for as cash-settled and are measured by reference to the Company's value at the time they left the Company. In 2020, provisions in the amount of EUR 191k (2018: EUR 4,250k) were reversed due to the expiration of virtual shares. On December 31, 2020, no virtual share entitlements for these former employees were outstanding.

New VSOP

Effective November 25, 2019, the Group granted 745,236 share options key employees of CureVac Inc. under the New VSOP program. Furthermore, in the first quarter of fiscal 2020, the Group granted another 267,822 share options. The share options have an exercise price: USD 6.21.

The awards vest over a period of four years, which starts on the date the awardee was hired by the Group, with 25% vesting after 12 months and the rest n monthly installments. The awards have a term of 10 years.

In addition, the Group set up a provision for employer taxes arising according to US regulations for future exercises of EUR 1,052k as of December 31, 2020.

Measurement of Fair Values

An advanced Black-Scholes Model (Enhanced American Stock Option Model) has been used to measure the fair value at the grant date of November 25, 2019. For the grants in the first quarter of 2020, the same model has been used as in fiscal 2019.The inputs used in the measurement of the fair value at grant date were as follows:

The inputs used in the measurement of the fair value at grant dates in the first quarter of 2020 were as follows:

	Grant Date	
	Q4 2019	Q1 2020
Weighted average fair value	EUR 3.80	EUR 4.05
Weighted average share price	EUR 9.19	EUR 8.91
Exercise price (USD 6.21)	EUR 5.64	EUR 5.60
Expected volatility (%)	50.0%	55.0%
Expected life (years)	1.16	1.11
Risk-free interest rate (%)	1.77%	1.79%

The remaining life of the option awards as of December 31, 2020, is between 4.7 and 9.2 years (2019: range between 5.7 and 9.9 years),

Reconciliation of outstanding awards

The number of awards in this program granted to key employees developed as follows:

	2019	2020
Outstanding at the beginning of the period	-	745,236
Granted during the period	745,236	267,822
Forfeited during the period	-	106,462
Outstanding at the end of the period	745,236	906,595
Thereof vested	175,397	420,595

As of December 31, 2019, none of the awards were exercisable because an exit event or capital market transaction had not occurred. With the defined exit event "financing round" before the IPO the awards became exercisable, but none of them were exercised. As the IPO had taken place on August 14, 2020, shortly after the "financing event" before the IPO, the awards became subject to the lock-up period, which is 180 days after the initial listing, i. e. on February 10, 2021. Hence, as of December 31, 2020 none of the awards were exercisable. Before these financial statements were authorized for issue, 55,932 options were exercised on February 11, 2021, at an average share price of 114.17 USD (94.15 EUR). These exercises have led to employer taxes in the amount of USD 127k which have to be paid by CureVac and have been provided for as of December 31, 2020.

Expense recognized in the statement of operations and other comprehensive income (loss)

The expense recognized for employee services received during the years ended December
31, 2020 and 2019 is shown in the following table:

	2019	2020
	EUR k	**EUR k**
Research and development expenses	(258)	(1,421)
Selling and distribution expenses	(743)	(296)
General and administrative expenses	(79)	(47)
Total	(1,080)	(1,764)

In the amounts in fiscal 2020 included above, EUR 1,052k refers to employer taxes to be payable by CureVac in the case of exercise of the options which have been provided for in 2020.

Long-Term Incentive Plan (LTIP)

On November 16, 2020, CureVac granted 266,155 options to the Chief Scientific Officer (CSO). Furthermore, on December 1, 2020, CureVac granted 266,156 options (in 3 tranches) to the company`s Chief Business Officer (CBO) and Chief Commercial Officer (CCO). All grants were made at no cost under the terms of a new long-term incentive plan put in place by Curevac N.V. Options will be settled in shares of Curevac N.V.

Options granted to the CSO have, an exercise Price: EUR 10.04 per share option and an Expiration Date: July 14, 2030. The exercise price was based on value of the shares at entry date of the CSO. They vest in installments over a period of four year, subject to a stock price increase of +20% over the period of time, based on the 10 days VWAP at time of exercise This performance condition is considered a market condition.

Options granted to the CBO / CCO are granted in tranches vesting over 1 to 3 years, with exercise prices applicable to future tranches being estimated. The exercise price of the first tranche is EUR 43.87 (USD 52.96). The exercise prices for future installments, 2021 and 2022, were estimated to be EUR 81.48 and 81.65. The tranches have a term of 10 years. Exercise of all three tranches are contingent on a share price increasing of more than 10 % over the relevant period, based on a 10-day VWAP at the time of exercise

For the grants to the CSO and CBO/CCO, a Monte Carlo simulation has been used to measure the fair value at the relevant grant dates. The inputs used in the measurement of the fair value at grant date were as follows:

- For the grant to the CSO

Weighted average fair value per option	EUR 57.40
Weighted average share price (10-days VWAP before grant date)	EUR 50.01
Exercise price (USD 11.90)	EUR 10.04
Expected volatility (%)	62.06%
Expected life (years)	1.82
Risk-free interest rate (%)	0.07-1.48%

- For the grant to the CBO/CCO

First tranche:

Weighted average fair value per option	EUR 48.27
Weighted average share price (actual 10-days VWAP before grant date, USD 81.03)	EUR 67.12
Exercise price (USD 52.96)	EUR 43.87
Expected volatility (%)	62.27%
Expected life (years)	1.78
Risk-free interest rate (%)	0.07-1.50%

Second tranche:

Weighted average fair value per option	EUR 24.36
Weighted average share price (estimated by Monte Carlo simulation to be USD 98.36)	EUR 81.48
Exercise price (estimated by Monte Carlo simulation to be USD 98.36)	EUR 81.48
Expected volatility (%)	62.27%
Expected life (years)	2.23
Risk-free interest rate (%)	0.07-1.50%

Third tranche:

Weighted average fair value per option	EUR 20.01
Weighted average share price (estimated by Monte Carlo simulation to be USD 98.57)	EUR 81.65
Exercise price (estimated by Monte Carlo simulation to be USD 98.57)	EUR 81.65
Expected volatility (%)	62.27%
Expected life (years)	2.66
Risk-free interest rate (%)	0.07-1.50%

At December 31, 2020, none of the totals of 532,311 options granted to the CSO and CBO/CCO under the LTIP were vested and hence, not exercisable yet.

The expense recognized for employee services received under the LTIP during the years ended December 31, 2020, is in an amount of EUR 4,736k is included in selling and distribution expenses.

Grant to Former Chief Executive Officer

In 2019, CureVac granted 3,866,309 options to Dan Menichella, then Chief Executive Officer (CEO) of CureVac from June 20, 2018, to March 10, 2020, with an exercise price of USD 8.28 per share option.

2,819,120 of these options vested in 2019 and the remainder in 2020. Except for 100.000 options, all options were exercised in 2020, when a qualifying financing round occurred and were settled after the IPO against the issuance of 3,195,276 common shares of CureVac NV for no cash consideration. The weighted average share price at the date of exercises was USD 55.22 (EUR 46.72). The remaining life of the outstanding 100,000 share options as of December 31, 2020, is 7.69 years. The intrinsic value of one option is 59,60 EUR.

An advanced Black-Scholes Model (Enhanced American Stock Option Model) has been used to measure the fair value at the grant date of October 14, 2019. The inputs used in the measurement of the fair value at grant date were as follows:

Weighted average fair value	EUR3.87
Weighted average share price	EUR9.19
Exercise price (USD 8.28)	EUR7.50
Expected volatility (%)	50.0%
Expected life (years)	4.77
Risk-free interest rate (%)	1.71%

In FY 2020, EUR 2,551k (2019: EUR 12,409k) were recognized as expense in general and administrative expenses. In addition, the Group recorded and an additional amount of EUR 2,033k for employer taxes paid or payable upon exercise under US regulations.

Legacy plan

Under the terms of a legacy plan, at January 1, 2018, five members of (former) management held 1,188,651 of share options outstanding and exercisable. These share options grant the holder the right to acquire shares of CureVac AG at nominal value and are classified as equity-settled share-based payments. In 2018, 485,734 of these options expired and the remaining 702,917 options held by three (former) members of management will expire on December 31, 2021.

Due to the corporate reorganization described in Note 1.1, the parties to the shareholders' agreement amended the existing agreements in February 2021 and, therefore, CureVac N.V. is required to settle the existing entitlements.

No expenses have been recognized during the years ended December 31, 2020, December 31, 2019, and December 31, 2018, under this program.

10. Trade and other payables

Trade payables and other payables are all due within one year and include the following:

	2019	2020
	EUR k	EUR k
Trade payables	5,331	17,623
License fees payable	537	537
Miscellaneous liabilities	607	3,525
Total	**6,475**	**21,685**

There is no concentration of risk. Miscellaneous liabilities consist mainly of payroll-related and withholding taxes of EUR 223k (2019: EUR 104k) and of other payroll taxes and social liabilities of EUR 1,178k (2019: EUR 504k).

11. Other liabilities

Other current liabilities include the following:

	2019	2020
	EUR k	EUR k
Personnel provisions (e.g. bonus, vacation)	3,257	5,871
Grants from government agencies and similar bodies	4,148	36,063
Outstanding invoices	3,478	7,577
Professional fees	578	511
VAT and other taxes (real estate transfer taxes)	-	12,268
Other	554	2,036
Total	**12,015**	64,326

In fiscal 2020, EUR 23,736k (2019: EUR 5,385k) of the grants from government agencies and similar bodies were recognized as other operating income. The other taxes consist of real estate taxes in the amount of EUR 924k (2019: nil).

12. Loans

As of December 31, 2019, CureVac had been granted two convertible loan facilities (i.e., First Loan and Second Loan) by Dietmar Hopp. On June 26, 2020, CureVac drew down the second tranche of the Second Loan in the amount of USD 26,800k (EUR 24,860k). On July 24, 2020, the First Loan and Second Loan were terminated and on August 7, 2020, the total principal of EUR 94,749k and total accrued interest of EUR 5,641k were repaid in full. During the year ended December 31, 2020, EUR 11,008k of interest expense, inclusive of EUR 5,194k which resulted from the early termination of the First Loan and Second Loan (December 31, 2019: EUR 11,960k), was recognized.

On June 27, 2020, CureVac signed a financing arrangement with the European Investment Bank, or EIB, under which EIB agreed to provide the Company with a line of credit in an amount of up to EUR 75 million for the partial financing of CureVac´s clinical developments and large-scale production of the infectious diseases vaccine candidates including a vaccine against SARS-CoV-2, or the Investment, provided that the amount of financing does not exceed 50% of the cost of the Investment. The EIB financing is available in three tranches of at least EUR 15 million and up to EUR 25 million upon completion of pre-defined milestones. These pre-defined milestones are tied to evidence of successful progress in the development and large-scale production of CureVac´s vaccine candidate against SARS-CoV-2. In addition, the disbursements of the second and third tranches are contingent upon the occurrence of the disbursement of the first and second tranches, respectively. Each tranche is due 7 years from the disbursement date. The EIB loan requires fixed remuneration at an interest at a rate of 0.5% per annum. Additionally, the loan agreement requires CureVac to pay variable remuneration depending on the output produced in the Company's GMP IV manufacturing facilities, which is EUR 200k per batch, up to an aggregate remuneration cap of EUR 75 million, on batches produced during the "Remuneration Period" beginning the earlier of the first financial year when CureVac AG has a positive EBITDA or in 2025 and extending for a period of 12 years thereafter. Payment of the variable remuneration is due on the first March 31st of the Remuneration Period and then each following March 31st, thereafter, in the Remuneration Period. The loan agreement provides CureVac an option to buy-out the variable remuneration by paying an amount equal to the higher of €5 million and 150-190% of the outstanding principal of the loan, depending on the number of years following the initial disbursement under the loan, but in any case limited to an aggregate remuneration cap of EUR 75 million.

CureVac is subject to several restrictive covenants on its business activities as described in the financing agreement, including limitations on certain merger and acquisition transactions, disposition of certain assets, and mandatory maintenance of assets related to the Investment. In November 2020, a land charge (lien) amounting to EUR 75 million was registered in favor of the EIB to secure the loan. The EIB may demand, without prior notice, the immediate repayment of outstanding principal together with any accrued interest upon certain events including, among others, the Company's failure to continue the development of its Investment following a grace period.

As of December 31, 2020, CureVac had drawn the first of the three tranches and, thus, EUR 25 million (plus accrued interest of EUR 189k) was outstanding on the loan as of that date.

13. Income tax

The Group has tax losses in Germany that are available indefinitely for offsetting against future taxable profits of the companies in which the losses arose. Under German tax law, taxable profits in a given year can be offset with tax loss carryforwards up to an amount of EUR 1,000k. 60% of taxable profit in excess of this amount can be offset with any remaining tax loss carryforwards. As a result, 40% of the taxable profits in excess of EUR 1,000k are subject to taxation.

With the exception of CureVac Inc., which is U.S.-based company, all other entities within the Group are considered Germany entities for tax purposes.

Tax loss carryforwards are examined by the German taxation authorities and may be adjusted. Furthermore, significant changes in the shareholder and company structure can lead to a reduction in the loss carryforwards under the current provisions of German tax law, which can be used to calculate the annual amount for offsetting against the future taxable income.

In fiscal 2020, 2019 and 2018, the Group recorded a consolidated income tax benefit and expense of EUR 726k, EUR 252k and EUR -110k, respectively. The income tax benefit in fiscal 2020 results from current income tax expenses from CureVac Inc. of EUR 403k (2019: EUR 203k and 2018: EUR 243k) and deferred tax income (2019 and 2018: expenses) on taxable temporary differences of EUR 2,843k (2019: EUR 656k and 2018: EUR 472K), which were offset by deferred tax expenses (prior years: benefits) of EUR 1,716k (2019: EUR 1,111k and 2018: EUR 605K) recognized from net operating loss carryforwards. In fiscal 2020, the Group further recorded deferred tax liabilities of EUR 39k (2019: EUR 2,212k and 2018: EUR nil) related to taxable temporary differences on the equity component of the convertible loans recognized in capital reserve. In fiscal 2020, the Group recognized deferred tax assets related taxable temporary differences arising from share-based payments of EUR 1,012k in equity. For outside basis differences of EUR 972k (2019: EUR 770k and 2018: EUR 397k), which are indefinitely reinvested and associated with investments in subsidiaries, deferred tax liabilities have not been recognized.

The significant components of income tax for the years ending December 31, 2019 and 2018 were as follows:

Tax reconciliation:

	2018	2019	2020
	EUR k	EUR k	EUR k
Loss before tax	(71,131)	(100,125)	(129,848)
Expected tax benefit (based on statutory tax rate of 29.13% in 2020, 2019 and 2018)	20,744	29,162	37,818
Adjustments in respect of current income tax of previous years	42	-	18
Adjustments in respect of deferred income tax of previous years			160
Effects from Recognition or Non-Recognition of DTA through Equity			(1,012)
Effects of (Non-) Recognition of tax loss carryforwards recognized in prior years			(1,716)
Effects from differences between Group and local tax rates	10	8	8
Effects resulting from non-recognition of tax loss carryforwards	(22,428)	(22,836)	(30,168)
Effects resulting from non-recognition of DTA/DTL	-	-	(179)
Non-recognition of DTA for deductible temporary differences from SBP this year	430	-	(2,946)

Non-deductible expenses for tax purposes			
- Effects from non-deductible share-based-payments	1,209	(5,698)	-
- Effects from (additions / deductions) for local trade taxes	(65)	(191)	(63)
- Other non-deductible expenses / including "Zinsschranke"	(53)	(78)	(1,154)
Other effects	-	(114)	(39)
Effective tax benefit / (expense)	(110)	252	726

Deferred taxes

Deferred taxes relate to the following:

	December 31, 2019 EUR k	December 31, 2020 EUR k
Intangible assets	(4)	(4)
Property, plant and equipment	(694)	(1,075)
Right of use-assets	(3,01)	(8,458)
Other assets	(281)	(303)
Inventories	115	44
Trade Receivables	-	19
Contract assets	(426)	(235)
Other financial assets	2	-
Other current assets	-	(286)
Cash and cash equivalents	(283)	2,091
Assets	**(5,473)**	**(8,207)**
Share-based payments	56	-
Lease liabilities (non-current portion)	3,472	7,774
Financial liabilities / Convertible Loan	(1,987)	-
Other Non-current financial liabilities	-	53
Other non-current liabilities	25	(43)
Trade and other payables	9	434
Lease liabilities (current portion)	576	934
Other liabilities	(14)	(320)
Liabilities	**2,136**	**8,830**
Deferred Taxes on temporary differences	**(3,337)**	**624**
Non-Recognition of Deferred Tax Assets (DTA) on temporary differences	-	**(1,391)**
DTA on deductible temporary differences Share-based Payment	-	**1,212**
Deferred Taxes on loss carryforwards	**1,716**	-
Deferred Taxes Total	**(1,621)**	**445**

The following unused tax losses for which no deferred tax asset is recognized in the statement of financial position had been carried forward as of the end of the reporting periods:

Tax loss carryforwards	2018	2019	2020
	EUR k	EUR k	EUR k
Unused tax losses for corporate income tax	330,753	407,434	775,956
Unused tax losses for trade tax	329,210	405,123	773,165
Unused interest carryforward ("Zinsschranke")	-	-	3,627

The main reasons for the increase in the unused tax loss carryforwards for corporate income and trade tax can be explained as follows:

Due to the corporate restructuring and the exit event triggered by the IPO for the several share-based payments becoming exercisable in 2020 (or later), as described in detail in Note 9 share-based payments, at the first time in fiscal 2020, CureVac recognized expenses in the amount of approximately EUR 245.3 million in its financial statements according to local GAAP and German income tax purposes. From this amount, only approx. EUR 18.9 million were recognized cumulatively through profit or loss in the consolidated financial statements according to IFRS until fiscal year-end 2020, by which about EUR 4.3 million refer to the reporting period 2020 and EUR 14.6 million to prior periods. The difference of EUR 226.4 million has and will not affect profit or loss in the consolidated financial statements according to IFRS. In the case of recognition of a deferred tax asset arising from this part of the tax loss carryforward, this amount would be credited against equity according to IAS 12.68A-C. Furthermore, in fiscal 2020 another EUR 18.9 million in transaction costs in respect of the capital increases were debited to capital reserves. These amounts were tax-deductible according to German income tax regulations. In the case of recognition of a deferred tax asset arising from this part of the tax loss carryforward, this amount would be credited against capital reserves.

The following deductible temporary differences for which no deferred tax asset is recognized in the statement of financial position had been carried forward as of the end of the reporting periods:

Deductible temporary differences	2018	2019	2020
	EUR k	EUR k	EUR k
Not recognized over P&L	-	-	109,272
Not recognized over equity	-	-	415,018

The amounts disclosed above (in respect of the development of deductible temporary differences not recognized) also result mainly from share-based payments as described in Note 9 share-based payments. These programs will become tax-deductible according to German income tax regulations upon exercise. The reported amount "Not recognized over P&L" is the amount that has been cumulatively expensed in CureVac`s consolidated financial statements according to IFRS until December 31, 2020, for these programs (less the amounts for which deferred tax assets have been recognized) with EUR 10.1 million relating to fiscal 2020 and the remainder to prior periods. The reported amount "Not recognized over equity" represents the amount that would be credited against equity according to IAS 12.68A-C (less the amounts for which deferred tax assets have been recognized).

The reported amount of „Not recognized over equity" may significantly fluctuate depending on the share price of CureVac which itself would lead to another allocation of the deferred tax asset recognized through profit or loss or equity. The same considerations apply to the deferred tax asset recognized for unused tax loss carryforwards. Hence, there might be significant changes in the allocation of deferred tax assets to be recognized through profit or loss or equity in the future which might lead to significant volatilities in the P&L line item income taxes solely due to the changes in the share price of CureVac.

Due to the enacted increases in the trade tax levy rate by the city council of Tuebingen as of April 13, 2021, in the case of the full recognition of deferred tax assets and deductible temporary differences not recognized as of December 31, 2020, the effects on deferred tax assets would be approximately EUR 4.6 million, which would be credited by 51% to equity and 49% to profit or loss.

Deferred tax assets on tax loss carryforwards and deductible temporary differences in excess of taxable temporary differences have not been recognized as management concluded that there is not sufficient probability as per IAS 12 that there will be future taxable profits available in the foreseeable future against which the unused tax losses can be utilized. The accumulated unused tax losses relate entirely to Germany.

14. Earnings per share

Amounts in this Note reflect the retrospective effect of the share split resulting from the corporate reorganization described in Note 1.

Earnings per share is calculated by dividing the consolidated net loss of CureVac N.V. by the weighted average number of shares outstanding in the fiscal period.

There were no share issuances in fiscal 2018 and 2019 and, therefore, the weighted average number of shares outstanding was 96,693,265 in both of these periods. The weighted average number of shares outstanding in fiscal 2020 was 132,195,792. This has led to basic loss per share of EUR 0.74, EUR 1.03, and EUR 0.98 for fiscal 2018, 2019 and 2020, respectively.

The 180,460,565, 96,693,265 and 96,693,265 share options outstanding at December 31, 2020, 2019 and 2018, respectively, are potential ordinary shares for the purpose of calculating diluted earnings per share for 2020. Since the conversion of the options to ordinary shares and the issue of the new shares at the beginning of fiscal would decrease loss per share in fiscal 2020, 2019 and 2018, they are considered antidilutive. Therefore, the diluted earnings per share equals basic earnings per share in fiscal 2020, 2019 and 2018.

15. Disclosure of financial instruments and management of financial risks

General information

CureVac is exposed to certain financial risks with respect to its assets and liabilities and the transactions associated with its business model. These risks generally relate to credit risks, liquidity risks and market risks (including currency risk, interest rate risk and price risk).

The aim of risk management is to limit the potential negative impact on expected cash flows and take advantage of any opportunities that arise. As a result, the management of CureVac assesses at least once a year whether risks have changed and whether the measures in place to limit risk are still sufficient.

Credit risk

Credit risk is managed by CureVac's finance department. Credit risk arises from cash and cash equivalents and other financial assets, including deposits with banks and financial institutions, as well as credit exposures to customers, including outstanding receivables and contract assets. Cash deposits and investments are placed only with reputable financial institutions with a credit rating of not less than A- (Standard & Poor's), A3 (Moody's) or A- (Fitch).

CureVac is exposed to bank default and concentration risk as its cash is concentrated at few financial institutions. The high cash inflow in Q4 2020 and the high cash total as of December 31, 2020 led to concentration risk. Management therefore decided to pool 75% of the cash at Germany's largest private bank and 21% at a major German Landesbank. The focused cash management structure with few banks allows enhanced bank risk supervision. The market capitalization of all listed banks is regularly reviewed. Credit risk is further limited by investing only in liquid instruments.

CureVac is also exposed to a credit risk for all receivables and contract assets. Counterparty credit limits are reviewed by CureVac's Management Board on an annual basis and may be updated throughout the year. The limits are set to minimize the concentration of risks and therefore mitigate financial loss through a counterparty's potential failure to make payments. The Group manages its credit risk with customers by closely monitoring its receivables. The risk of default is considered to be low because the structure of customers consists of reputable collaborating parties and government grantors. Receivables management and financial accounting incorporates monitoring of payments received and any overdue receivables.

The carrying amount of other financial assets recognized determines the maximum theoretical credit risk. As of the end of fiscal 2019, available funds are deposited at two reputable financial institutions.

In connection with cash and cash equivalents, (other) financial assets, trade receivables and contract assets, CureVac uses the simplified approach under IFRS 9 in determining the loss allowance at an amount equal to the lifetime expected credit losses. As of December 31, 2020, the loss allowance for the "expected credit losses" totaled to EUR 183k (2019: EUR 76k), resulting in an effect recognized in profit and loss in the consolidated statement of operations and other comprehensive expense in fiscal 2020 of EUR -106k (2019: EUR 371k).

Liquidity risk / Capital management

For the purpose of CureVac's capital management, capital includes share capital and all other equity reserves attributable to the equity holders. The primary objective of CureVac's capital management is to maximize the shareholder value through investment in the development activities of the Group.

Based on its business as an active research group, CureVac has historically relied almost exclusively on debt and equity funding by its shareholders and lenders as a means of financing itself prior to successful development and sales of a marketable product. In 2020, as a result of the BMBF and EC APA agreements (see Notes 3.1., respectively) the Company has received significant advance payments with contribute to its financing of its operations. Such funds are primarily being invested in CureVac's COVID-19 vaccine candidate research and development.

The Group's finance department reviews the total amount of cash of the Group on a weekly basis. As part of this review, the committee considers the total cash and cash equivalents, the cash outflow, currency translation differences and refinancing activities. The Group monitors cash using a burn rate. The cash burn rate is defined as the average monthly net cash flow from operating and investing activities during a financial year.

In meeting its financing objectives, the Group negotiates and enters into research cooperation agreements. In general, the aim is to maximize the financial resources available for further research and development projects.

CureVac is not subject to externally imposed capital requirements. However, certain grant funds received may be required to be returned if qualifying costs are not incurred or are not incurred in accordance with the grant terms. Additionally, while the Company is subject to certain loan covenants under the EIB loan, such covenants do not impose minimum capital requirements but does provide the right to the EIB to call for repayment of the loan in the occurrence of certain events (refer to Note 12 for additional information). The objectives of CureVac's capital management were achieved in the reporting year.

No changes were made in the objectives, policies or processes for managing cash during the years ended December 31, 2020 and 2019.

In order to safeguard liquidity, the Group invests funds not required immediately for operating purposes in short-term investments at banks with high standing and call-deposit accounts with maturity up to three months. Liquidity risks are therefore expected to be low. The Group does not enter into trading of financial instruments and monitors its risk of a shortage of funds using a liquidity planning tool.

Historically, CureVac has relied on financing from shareholders and collaborators in order to ensure sufficient liquidity. Lack of external financial support could pose a risk of going concern. The

liquidity management of CureVac ensures the availability of cash and cash equivalents for operational activities and further investments through appropriate budget planning.

Ultimately, the responsibility for liquidity risk management lies with management, who has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. CureVac manages liquidity risks by holding appropriate reserves, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities.

The table below summarizes the maturity profile of the Group`s financial liabilities based on contractual undiscounted payments:

2020

	less than 3 months EUR k	**3 to 12 months EUR k**	**1 to 5 years EUR k**	**> 5 years EUR k**	**Total EUR k**
Contractual commitments	-	(97,151)	-	-	(97,151)
Lease liabilities (Note 4.2)	(728)	(2,233)	(15,805)	(11,322)	(30,087)
Other liabilities (Note 11)	(52,637)	0	(8,423)	(138)	(61,199)
Trade and other payables (Note 10)	(21,004)	(682)		-	(21,685)
EIB loan (Note 12)	-	-	-	(25,875)	(25,875)
Total	**(74,368)**	**(100,066)**	**(24,228)**	**(37,335)**	**(235,997)**

2019	**less than 3 months EUR k**	**3 to 12 months EUR k**	**1 to 5 years EUR k**	**> 5 years EUR k**	**Total EUR k**
Convertible loans (Note 12)	—	—	(83,940)	—	(83,940)
Lease liabilities (Note 4.2)	(732)	(1,985)	(9,192)	(5,086)	(16,995)
Other liabilities (Note 11)	—	(12,015)	(362)	(167)	(12,544)
Trade and other payables (Note 10)	(5,938)	(537)	—	—	(6,475)
Total	**(6,670)**	**(14,537)**	**(93,494)**	**(5,253)**	**(119,954)**

Foreign currency risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. CureVac's exposure to the risk of changes in foreign exchange rates relates primarily to the Group's operating activities (when revenue or expense is denominated in a foreign currency) and the amounts held as cash and cash equivalents.

CureVac N.V.'s, CureVac AG's and CureVac Real Estate GmbH's functional currency is the Euro. The functional currency of CureVac Inc. is the USD. CureVac AG's exposure in foreign currency at the end of fiscal 2020 and 2019 is as follows:

	2020 (in thousands)			
Cash and cash equivalents	84,798	EUR	104,055	USD
Trade and other receivables	76	EUR	93	USD
Total monetary assets in foreign currency	84,874	EUR	104,148	USD
Trade and other payables	3,761	EUR	4,615	USD
Trade and other payables	65	EUR	58	GBP
Trade and other payables	3	EUR	3	CHF
Total monetary liabilities in foreign currency	3,828	EUR		

	2019 (in thousands)			
Cash and cash equivalents	22,608	EUR	25,398	USD
Trade and other receivables	9,458	EUR	10,585	USD
Other receivables	105	EUR	93	GBP
Other receivables	84	EUR	92	CHF
Other receivables	81	EUR	91	USD
Monetary assets in foreign currency	32,336	EUR		
Trade and other payables	505	EUR	567	USD
Trade and other payables	219	EUR	186	GBP
Trade and other payables	10	EUR	11	CHF
Monetary liabilities in foreign currency	734	EUR		

As shown in the tables above, CureVac N.V. is exposed to a significant currency risk only in relation to the USD. Therefore, a foreign currency sensitivity analysis is only presented in respect to the net exposure in USD at fiscal year ends. CureVac's net exposure in USD is the difference between monetary assets in USD and monetary liabilities in USD and developed as follows:

Net exposure in USD

2019 (1 EUR = 1.1234 USD)
EUR 30,656k from USD 34,400k

2020 (1 EUR = 1.2271 USD)
EUR 77,669k from USD 95,311k

At December 31, 2020, if the EUR had weakened 10 per cent against the US dollar with all other variables held constant, pre-tax loss for the year would have been EUR 8,630k (2019: EUR 3,406k) lower and post-tax loss would have been EUR 6,116k (2019: EUR 2,414k). Conversely, if the EUR had strengthened 10 per cent against the US dollar with all other variables held constant, pre-tax loss would have been EUR 7,061 (2019: EUR 2,787k) higher and post-tax loss would have been EUR 5,004k (2019: EUR 1,975k) higher. The effects on pre- and post-tax loss and (accumulated) other comprehensive income due to fact that CureVac Inc's functional currency is the USD would still have been immaterial at December 31, 2020.

CureVac did not have derivatives in fiscal 2020 and 2019.

Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. CureVac's exposure to the risk of changes in market interest rates relates primarily to the CureVac`s cash and cash equivalents with floating interest rates. Due to persistent low-interest-rates CureVac might be exposed to the risk of being charged negative interest rates on its bank deposits.
If interest rates as of December 31, 2020 had been 1% higher while all other variables had remained the same, the net loss for the year (before and after tax) would have been EUR 13,226k (2019: EUR 307k) lower because the higher interest income would have been generated from floating rates on invested cash and cash equivalents. Because interest rates on cash and cash equivalents as of December 31, 2020 and 2019 had been almost near zero, lower interest rates would have had an

immaterial effect on the net loss for the year (before and after tax) and on other comprehensive income.

Fair value measurement

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized with the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — Inputs use quoted prices in active markets for identical assets or liabilities
- Level 2 — Inputs are inputs, other than quoted prices included in Level 1, which are directly or indirectly observable
- Level 3 — Inputs are unobservable and have values estimated by management based on market participant assumptions which are reasonably available

All financial instruments are measured at amortized cost at December 31, 2020 and December 31, 2019. Apart from this, liabilities from licenses agreements (i.e., acquired intangible assets) of EUR 821k (2019: EUR 848k), are classified as financial liabilities at fair value through profit or loss under the Level 2 input factors. Management assessed that the fair values of cash and cash equivalents, short-term investments, trade receivables and other financial assets, trade payables and other current liabilities as well as liabilities from licensing agreement approximate their carrying amounts. Moreover, management assessed that the potential differences between carrying amounts and fair value of liabilities to banks, (finance) lease liabilities and the liabilities for licensing agreements should be immaterial.

16. Notes to the consolidated statements of cash flows

Changes in liabilities arising from financing activities

EUR k	January 1, 2020	Cash flows	Reclassification	Disposals	New Leases	Accrued interest	Paid Interest	Foreign Exchange Movements	December 31, 2020
Convertible loans (Note 12)	65,018	(69,889)	(126)	—	—	10,637	(5,640)	—	—
EIB loan (Note 12)	—	25,000	—	—	—	189	—	—	25,189
Lease Liabilities (Note 4.2)	14,13	(2,996)	—	(43)	19,310	—	—	(316)	30,086
Total liabilities from financing activities	**79,148**	**(47,885)**	**(126)**	**(43)**	**19,310**	**10,826**	**(5,640)**	**(316)**	**55,275**

in EUR k	January 1, 2019	Cash flows	Reclassification	New leases	Accrued interest	Foreign Exchange Movements	December 31, 2019
Convertible loans (Note 12)	—	69,889	(7,604)	—	2,733	—	65,018
Lease liabilities (Note 2)	15,810	(1,910)	—	153	—	77	14,130
Total liabilities from financing activities	**15,810**	**67,979**	**(7,604)**	**153**	**2,733**	**77**	**79,148**

The reclassification of €7,604k results from an amount recorded as a component of equity.

17. Commitments and contingencies

In the course of its ordinary activities, no major claims have been made against the Company. For contractual commitments, refer to Note 15.

18. Remuneration of the Company's key management personnel

Total remuneration of key management personnel

Remuneration of the Company's key management personnel was as follows in fiscal 2020:

Remuneration of key management in 2020	Management Board	Supervisory Board
	EUR k	EUR k
Short-term benefits	3,840	557
Share-based payments	7,287	
Total	11,127	557

Remuneration of the Company's key management personnel was as follows in fiscal 2019:

Remuneration of key management in 2019	Management Board	Supervisory Board
	EUR k	EUR k
Short-term benefits	3,166	521
Share-based payments	18,483	—
Total	**21,649**	**521**

The amounts disclosed in the table are the amounts recognized as an expense during the reporting period related to key management personnel.

19. Other related party disclosures

dievini Hopp BioTech holding GmbH & Co. KG

As disclosed in Note 1, dievini Hopp BioTech holding GmbH & Co. KG (dievini) is the largest holder of the share capital of the Company, is the controlling shareholder and is the ultimate parent of the Group.

Other related party transactions

Molecular Health GmbH

Molecular Health GmbH (Molecular Health) is a wholly owned subsidiary of dievini. In December 2017 CureVac concluded a contract with Molecular Health, according to which Molecular Health provides services in conjunction with the Modeling of the biological and clinical effects of Toll-like receptor 7 and 8 agonists in cancer and immune cells. In fiscal 2020, the Group incurred EUR 0k (2019: 0k, 2018: 30k) in research and development expenses in connection with this contract.

Rittershaus Rechtsanwaelte

Since December 15, 2005, a consultant agreement is in place for an indefinite term with Rittershaus. The agreement can be terminated without notice by CureVac and with notice of three months to the end of the quarter by Rittershaus. In fiscal 2020, consulting fees of EUR 990k (2019: EUR 208k, 2018: EUR 145k) were paid to the Rittershaus. Prof. Dr. Christof Hettich is a managing director of Rittershaus and dievini as well.

Dr. Ingmar Hoerr

Since June 2018, an advisory agreement between CureVac and Mr. Hoerr was in place. This contract was terminated in March 2020 after the transition of Dr. Hoerr from CureVac's Supervisory Board to its Management Board on March 10, 2020. In fiscal 2020, advisory fees of EUR 45k (2019: EUR 240k, 2018: EUR 144k) were paid to Dr. Hoerr.

Dietmar Hopp

During 2019, Dietmar Hopp, principal of dievini Hopp BioTech holding GmbH & Co. KG (dievini), the largest shareholder of the Group, granted two convertible loans to the Group which were terminated in July 2020 and fully repaid in August 2020; see note 12 for further information. Additionally he made a further equity investment in the Company as described in Note 8.

BePharBel Manufacturing S.A.

In December 2020, CureVac Real Estate GmbH and BePharBel Manufacturing S.A., entered into a commercial supply agreement to develop and manufacture the diluent that is expected to be used to dilute the Group's concentrated COVID-19 vaccine candidate, CVnCoV, to the amount specified by each dose level. Pursuant to the terms of the agreement, BePharBel Manufacturing will manufacture and deliver to CureVac Real Estate GmbH a low seven figure amount of commercial batches of diluent per year, in 2021 and 2022. CureVac Real Estate GmbH paid EUR 1 million at the signing of the agreement to cover the estimated capex financing. The total payments pursuant to the agreement, including the EUR 1 million, will be approximately in the range of EUR 5.96 million and EUR 6.83 million. CureVac Real Estate GmbH may terminate the agreement, without notice, prior to December 2022, if CureVac does not obtain marketing authorization for CVnCoV, but will be required to pay a termination fee of EUR 591k and reimburse all artwork, primary, secondary and tertiary packing that BePharBel Manufacturing has in stock or ordered up to the date of the receipt of the notice of termination. Baron Jean Stéphenne, our supervisory board member, holds directly and indirectly 15.61% of BePharBel Manufacturing's equity and is a director of BePharBel Manufacturing, and Baron Jean Stéphenne's son, Vincent Stéphenne, holds 1.43% of BePharBel Manufacturing's equity and is a managing director of BePharBel Manufacturing.

Indemnification Agreements

Our articles of association require us to indemnify our current and former managing directors and supervisory directors to the fullest extent permitted by law, subject to certain exceptions. We entered into indemnification agreements with all our managing directors and supervisory directors.

20. Subsequent events

In January 2021, the Company entered into a collaboration with Bayer where Bayer will support the further development, supply and key territory operations of the Company's COVID-19 vaccine candidate, CVnCoV. Bayer is to contribute its expertise and established infrastructure in areas such as clinical operations, regulatory affairs, pharmacovigilance, medical information, supply chain performance as well as support in selected countries. CureVac will be the Marketing Authorization Holder, while Bayer will support CureVac with country operations within the European Union (EU) and selected additional markets. Bayer holds further options to become Marketing Authorization Holder in other markets outside of Europe.

In February 2021, the Company closed a public offering by which it sold 5,750,000 common shares, inclusive of shares issued upon exercise by the underwriters of an overallotment option, for aggregate gross proceeds to the Company of approximately $517.5 million (EUR 428.6 million) before deducting underwriting discounts and commissions and offering expenses payable by the Company.

In February 2021, GlaxoSmithKline plc and the Company announced a new €150m collaboration, building on their existing relationship, to jointly develop next generation mRNA vaccines for COVID-19 with the potential for a multi-valent approach to address multiple emerging variants in one vaccine. Through this new exclusive co-development agreement, GSK and CureVac will contribute resources and expertise to research, develop, and manufacture a number of novel mRNA vaccine candidates, including multi-valent and monovalent approaches. Under the terms of the new collaboration agreement, GSK will be the marketing authorization holder for the next generation vaccine, except in Switzerland, and will have exclusive rights to develop, manufacture, and commercialize the next generation COVID-19 vaccine in all countries with the exception of Germany, Austria and Switzerland. GSK will be required to make an upfront payment of €75 million

and a further milestone payment of €75 million, conditioned on the achievement of specific milestones. Additionally, pursuant to a preliminary agreement regarding the secondary manufacturing of CureVac's first generation COVID-19 vaccine candidate, CVnCoV, we entered into with GSK, GSK will also support the secondary manufacturing of up to 100 million doses of CVnCoV in 2021.

In February 2021, the Company announced initiation of a rolling submission with the European Medicines Agency (EMA) for CVnCoV, the company's mRNA-based COVID-19 vaccine candidate, currently in late-stage clinical testing. The process was initiated when the first data package consisting of CVnCoV pre-clinical data was submitted to EMA and passed the technical validation. The rolling submission represents a time-optimized route to provide and review all necessary data needed for a potential market authorization during a public health emergency. Over the course of the rolling submission process, EMA will assess CVnCoV's compliance with standards for vaccine efficacy, safety, and pharmaceutical quality on the basis of individually submitted data packages as a prerequisite for a formal market authorization application.

In April 2021, CureVac initiated a rolling submission to Swissmedic, the Swiss regulator for therapeutic products including vaccines, of CVnCoV for use in Switzerland.

21. Exemption provision in Section 264 (3) of the German Commercial Code (HGB)

The following companies domiciled in Germany have made use of the exemption provision in Section 264 (3) of the German Commercial Code (HGB) and have waived the filing of the 2020 annual financial statements and the preparation of a management report:

- CureVac AG, Tübingen
- CureVac Real Estate GmbH, Tübingen

10. Company Financial Statement

CureVac N.V.

Company Financial Statements

for the Year ended
December 31, 2020

CureVac N.V.

Company Statements of Operations and Other Comprehensive Income (Loss)

(in EURk)		April 7, 2020 - December 31, 2020
General and administrative expenses	3.1	(2.961)
Operating loss		**(2.961)**
Finance income	3.2	1.900
Finance expenses	3.2	(7.402)
Loss before income tax		**(8.463)**
Share of losses in subsidiaries after tax	3.3	(73.012)
Net loss for the period		**(81.475)**
Total comprehensive loss for the period		**(81.475)**

CureVac N.V.

Company Statements of Financial Position

(after appropriation of result)

(in EURk)		2020
Assets	**Notes**	
Non-current assets		
Investments in subsidiaries	**4.**	377.871
Total non-current assets		**377.871**
Current assets		
Intercompany loan receivable	**5.**	149.524
Prepaid expenses and other assets	**5.**	3.597
Cash and cash equivalents	**6.**	182.887
Total current assets		**336.008**
Total assets		**713.879**
Equity and liabilities		
Equity	**7.**	
Issued capital		21.655
Capital reserve		1.334.704
Accumulated deficit		(645.069)
Currency translation reserve		57
Total equity		**711.347**
Current liabilities		
Trade and other payables	**9.**	402
Other liabilities	**8.**	2.130
Total current liabilities		**2.532**
Total liabilities		**2.532**
Total equity and liabilities		**713.879**

1. Corporate Information

CureVac N.V. ("CureVac" or "CV" or the "Company") is the parent company of CureVac Group ("Group") and, along with its subsidiaries, is a global biopharmaceutical company developing a new class of transformative medicines based on the messenger ribonucleic acid (mRNA) that has the potential to improve the lives of people.

The Company is incorporated in the Netherlands and is registered in the commercial register at the Netherlands Chamber of Commerce under RSIN 861149336. The Company's registered headquarters is Friedrich-Miescher-Strasse 15, 72076 Tuebingen, Germany. The major shareholder and ultimate parent company of the Group is dievini Hopp BioTech holding GmbH & Co. KG (dievini), which is an investment company dedicated to the support of companies in health and life sciences.

On August 14, 2020, the Company completed an initial public offering (IPO) on the Nasdaq Global Market; in connection with the IPO, the Company underwent a corporate reorganization by which CureVac N.V. became the parent holding company with 100% interest in CureVac AG. Prior to the reorganization, CureVac AG was the parent holding company of the Group; as part of the reorganization, CureVac B.V. was formed on April 7, 2020, and existing shareholders of CureVac AG subscribed for new common shares in CureVac B.V. and agreed to transfer their respective shares in CureVac AG to CureVac B.V. as a contribution in kind against issuance of the common shares in CureVac B.V. shares (share split) on a 1-to-133,0778 basis. As a result, CureVac B.V. became the holding company of CureVac AG, while the existing shareholders had a 100% shareholding in CureVac B.V. Effective with the IPO, CureVac B.V. changed its legal form and became CureVac N.V. and the common shares of CureVac B.V. were converted to common shares of CureVac N.V.

Basis of preparation

The description of the activities and the structure of CureVac N.V. ("CureVac" or "CV" or the "Company") as included in the notes to the consolidated financial statements also apply to the Company Financial Statements.

The financial statements of CureVac N.V. included in this section are prepared in accordance with Part 9 of Book 2 of the Dutch Civil Code. Section 2:362 (8) of the Dutch Civil Code, allows companies that apply IFRS as endorsed by the European Union in their consolidated financial statements to use the same measurement principles in their company financial statements. The Company has prepared these Company financial statements using this provision.

The accounting policies are described in the Summary of significant accounting policies of the consolidated financial statements and are deemed incorporated and repeated herein by reference.

In case single balance sheet line items and profit and loss accounts are not further disclosed in the company financial statements, we refer to the disclosure to the consolidated financial statements.

Functional currency

The functional currency is the Euro, which is the reporting currency of CureVac

Going Concern

These financial statements have been prepared on the basis of the going concern assumption.

2. Significant accounting policies

The accounting policies as included in the notes to the consolidated financial statements also apply to the company financial statements.

Investment in subsidiaries

Investments in subsidiaries refers to contractual and non-contractual involvement that exposes an entity to variability of returns from the performance of the other entity. An investment in subsidiaries can be evidenced by but is not Iimited to, the holding of equity or debt instruments as well as other forms of involvement such as the provision of funding, liquidity support, credit enhancement, and guarantees. It includes the means by which an entity has control or joint control of, or significant influence over, another entity. An entity does not necessarily have an interest in another entity solely because of a typical customer-supplier relationship.

Investments in subsidiaries are accounted at equity method.

For an overview of subsidiaries, refer to the consolidated financial statements.

Expected credit loss

Expected credit losses on intercompany receivables are offset against the intercompany receivables themselves.

Foreign currency translation

The functional currency is the Euro, which is the reporting currency of CureVac. Monetary assets and liabilities in a foreign currency are recognized at the exchange rate in effect on the date of the transaction and later at the rate in effect on the reporting date. Differences resulting from foreign currency translation are recognized in Finance income and expenses in the Company Statements of Operations and Other Comprehensive Income (Loss)

3. Notes to the Company financial statements

3.1 General and administrative expenses

General and administrative expenses include the following

	2020
	EURk
Legal and other professional services	(1.865)
Other	(1.096)
Total	**(2.961)**

Legal and other professional services mainly consist of insurance expenses of EURk 1.288 and legal, tax and accounting services EURk 576. Other mainly consists of the real estate transfer taxes of EURk 930.

3.2 Financial income and expenses

Finance income and expenses include the following:

	2020
	EURk
Finance income	1.900
Finance expenses	(7.403)
Total	**(5.503)**

Finance income mainly includes the gain from the foreign currency of EURk 1.648 and interest from the intercompany loan of EURk 214. Finance expenses mainly include the foreign currency loss of EURk 7.330.

4. Non-current assets

Non-current assets consist of the Company's investment in wholly-owned subsidiaries CureVac AG (Tuebingen, Germany), CureVac RealEstate GmbH (Tuebingen, Germany), and CureVac Inc. (Boston, USA) of EURk 377.871.

As of December 31, 2020, CureVac N.V. holds the following direct participating interests in subsidiaries.

Name, location		**Interest in %**
Fully consolidated		
CureVac AG	Germany	100
CureVac RealEstate GmbH	Germany	100
CureVac Inc.	USA	100

CureVac N.V. operated and controls all of the business and affairs of the subsidiary and its respective subsidiaries.

Investments in subsidiaries 2020	
At 18. August 2020	**EURk**
Net book value	491.291
Movements in book value 2020	
Capital contribution to Curevac AG	100.000
Share result from subsidiaries	(73.012)
Settlement of share-based payments on behalf of Curevac AG	(149.310)
Share-based-payments	7.738
Others	1.164
Total	**377.871**

5. Intercompany loan receivables and prepaid expenses

Current assets consist of the intercompany loan of EURk 149.524 to CureVac AG and prepaid expenses of EURk 3.597. For the intercompany loan receivables, refer to Note 14.

6. Cash and cash equivalents

Cash and cash equivalents amounted to EURk 182.887. The development and application of cash and cash equivalents are in the consolidated statement of cash flows. All cash at banks is available for immediate use by the group, without any restrictions.

7. Equity

According to CureVac NV`s articles of association, which are effective as of August 14, 2020, the company`s authorized share capital amount to EUR 92.700.000. It is divided into 386.250.000 common shares and 386.250.000 preferred shares, each having a nominal value of EUR 0,12. As of December 31, 2020, no preferred shares had been issued and all issued common shares issued and outstanding were fully paid.

The development of equity is shown in the following table.

-	**Issued capital**	**Capital reserve**	**Accumulated deficit**	**Currency translation reserve**	**Total equity**
(in EURk)					
Balance as of April 7, 2020	**-**	**-**	**-**	**-**	**-**
Contribution in kind of CureVac AG shares	18.547	1.036.315	(563.594)	23	491.291
Issuance of share capital IPO	1.840	190.899	-	-	192.739
Issuance of share capital post IPO	885	99.005	-	-	99.890
Share-based payment	383	7.354	-	-	7.737
Net loss	-	-	(81.475)	-	(81.475)
Others	-	1.131		34	1.165
Balance as of December 31, 2020	**21.655**	**1.334.704**	**(645.069)**	**57**	**711.347**

The main changes can be summarized as follows:

Contribution in kind of CureVac AG shares: The existing shareholders of CureVac AG subscribed for new common shares in CureVac B.V. as a contribution in kind (share split) on a 1-to-133,0778 basis. The difference to the

issued capital of CureVac AG at that time (EURk 1.161) was debited to capital reserve. On August 14, 2020, the Company completed an initial public offering (IPO) on the Nasdaq Global Market. In connection with the IPO, the Company underwent a corporate reorganization by which CureVac N.V. became the parent holding company with 100% interest in CureVac AG. Capital reserves at that time include the share premiums received in the capital increases in February 2020 (EURk 20.000) and July 2020 (EURk 559.280) before the IPO net of transaction costs of EURk 4.200. Accumulated deficit includes the net 2020 loss (EURk 47.646) of CureVac AG and its subsidiaries until August 13, 2020. Currency translation reserve was substantially unchanged as of the contribution date compared to December 31, 2019.

Issuance of share capital at IPO and post IPO reflect the amounts raised at the NASDAQ IPO as of August 14, 2020, and the concurrent private placement as of August 18, 2020 net of transaction costs of EURk 14.730.

Share-based payments reflect the total share-based payment expense recognized and described in note 9 in the consolidated financial statements that can be allocated to the period after the corporate reorganization until December 31, 2020. For a description of the effects of the share-based payments in total, as well as the man characteristics of the plans, reference is made to Note 9 of the consolidated financial statements.

Others: Other changes in equity relate mainly to the recognized deferred tax assets directly through equity on the level of CureVac AG and CureVac RealEstate GmbH (EURk 1.012).

Besides the minimum amount of share capital to be held under Dutch law and the currency translation reserve, there are no distribution restrictions applicable to equity of the Company. However, in certain events, Bill & Melinda Gates Foundation (BMGF) has the right to require the Company to redeem or facilitate the purchase by a third-party of all common shares it holds and Genmab has the right to subscribe once for common shares at a certain price under an anti-dilution and down round-protection clause effective through February 2022. For more details, we refer to the consolidated financial statements.

Net loss of EURk 81.475 reflects the portion of the total net loss of EURk 129.122 from the consolidated financial statements that can be attributed to the period from August 14, 2020, until December 31, 2020. The General Meeting will be proposed to carry forward the loss after tax for 2020 and deduct EURk 81.475 from the other accumulated deficit.

8. Trade and other payables

Trade payables and other payables are all due within one year and include the following:

	2020
	EURk
Payables third parties	208
Payables related parties	115
Other payables	79
Total	**402**

9. Other liabilities

Other current liabilities include the following:

	2020
	EURk
Accruals for audit	240
Accruals for invoices to be received	967
Accruals for other taxes	923
Total	**2.130**

10. Auditors´ Fees

Ernst & Young Accountants LLP billed us approximately EUR 0.1 million for local statutory audit services for fiscal 2020.

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft billed us approximately EUR 1.4 million and EUR 0.3 million for audit services for fiscal 2020 and 2019, respectively, including fees associated with the annual audit, consultations on various accounting issues, performance of local statutory audits and comfort letters, and review of offering documents filed with the SEC.

Audit-Related Fees

Ernst & Young Accountants LLP and/or Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft did not bill us for audit-related services for fiscal 2020 and 2019.

Tax Fees

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft billed us approximately EUR 0.1 million and EUR 0.2 million for tax fees, including fees associated with tax compliance, tax advice, and tax planning services for fiscal 2020 and 2019, respectively.

All Other Fees

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft billed us approximately EUR 0.5 million for services other than those categorized in Audit Fees, Audit-Related Fees, and Tax Fees described above for fiscal 2020. Ernst & Young did not bill us for anything other than Audit Fees, Audit-Related Fees, and Tax Fees described above for fiscal 2019.

11. Income tax

CureVac NV is considered a German-based entity for income tax purposes. In fiscal 2020, as a newly founded company, it has suffered tax losses in the amount of EURk 18.411 for corporate income tax and trade tax purposes by which EURk 14.730 relate to equity transaction costs that were debited directly to equity in the IFRS financial statements. Under German tax law, these tax loss carryforwards are available indefinitely for offsetting against future taxable income. Tax profits in a given year can be offset against tax loss carryforwards up to an amount of EURk 1.000. 60% of tax profit in excess of this amount can be offset against any remaining tax loss carryforwards. As a result, 40% of the profits in excess of EURk 1.000 are subject to taxation.

Tax loss carryforwards are examined by the German tax authorities and may be adjusted. Furthermore, significant changes in the shareholder and company structure can lead to a reduction in the loss carryforwards under the current provisions of German tax law, which can be used to calculate the annual amount for offsetting against the future taxable income.

In fiscal 2020, CureVac NV recorded no current income tax. Deferred tax assets on tax loss carryforwards (EURk 5.362) and deductible temporary differences (EURk 1.676) in excess of deferred tax liabilities (EURk 286) for taxable temporary differences have not been capitalized as management concluded that there is not sufficient probability as per IAS 12 that there will be future taxable profits available in the foreseeable future against which the unused tax losses can be utilized.

12. Remuneration

The emolument as referred to in Section 2:383(1) of the Netherlands Civil Code, charged in the financial period to the company can be detailed as follows.

Remuneration and Other Benefits to Supervisory and Managing Directors as of December 31, 2020

Our compensation policy authorizes our supervisory board to determine the amount, level, and structure of the compensation packages of our managing directors at the recommendation of our compensation committee. These compensation packages may consist of a mix of fixed and variable compensation components, including base salary, short-term incentives, long-term incentives, fringe benefits, severance pay, and pension arrangements, as determined by our supervisory board.

Supervisory Board

Compensation of Supervisory Directors

For the year ended December 31, 2020, the aggregate compensation accrued or paid to our supervisory directors for services in all capacities was EUR 557.192. The following table sets forth the aggregate compensation and benefits provided to our supervisory board members in the year ended December 31, 2020.

Name	Fixed Compensation (€)	Attendance Fees (€)	Total Compensation (€)
Baron Jean Stéphenne	102.747	0	102.747
Ralf Clemens	55.000	27.500	82.500
Mathias Hothum	55.000	27.500	82.500
Hans Christoph Tanner	55.000	27.500	82.500
Friedrich von Bohlen und Halbach	55.000	0	55.000
Ingmar Hoerr	21.301	0	21.301
Timothy M. Wright	55.000	0	55.000
Craig A. Tooman	55.000	0	55.000
Dr. Viola Bronsema (1)	20.644	0	20.644
	474.692	**82.500**	**557.192**

(1) Dr. Bronsema became a supervisory director in August 2020.

The supervisory board members did not receive any share-based payment compensation in fiscal 2020.

Management Board

Compensation of Managing Directors

For the year ended December 31, 2020, the aggregate compensation accrued or paid to our managing directors for services in all capacities was € 12.359.364 (including an approximate conversion of Mr. Menichella's and Mr. Splawski's compensation from USD). The following table sets forth the compensation and benefits provided to our management board in the year ended December 31, 2020.

Compensation of Managing Directors

Name*	Salary (€)	Bonus(1) (€)	Share-based payment expense (€)	All Other Compensation(2) (€)	Total Compensation(3) (€)
Daniel L. Menichella(4)(5)	129.843	318.218	4.583.935	651.025	(6) 5.683.021
Florian von der Mulbe	258.533	235.375	0	25.482	519.390
Mariola Fotin-Mleczek	226.866	221.875	0	19.492	468.233
Franz-Werner Haas	264.866	312.150	0	24.865	601.881
Pierre Kemula	250.199	235.375	0	99.928	585.502
Igor Splawski(7)(8)	146.883	0	4.280.300	74.154	4.501.337
	1.277.190	**1.322.993**	**8.864.235**	**894.946**	**12.359.364**

(1) This amount represents the annual variable payment received based on a percentage of yearly gross remuneration for reaching certain targets agreed upon with the supervisory board.

(2) All other compensation includes other monetary benefits and contributions to social security insurance if any.

(3) This column does not include the virtual shares held by certain of the management board members, as described in the virtual share chart below.

(4) On March 10, 2020, the service agreement with Daniel Menichella (the former CEO) was discontinued. He was succeeded on the management board by Dr. Hoerr on that same day. Dr. Hoerr was a managing director of CureVac AG at the time of the Corporate Reorganization but is no longer a managing director of CureVac AG and is not a managing director of CureVac N.V.

(5) Mr. Menichella also held 29.053 options, which were exchanged for 3.866.309 options for common shares in CureVac N.V. in connection with the Corporate Reorganization, out of which he exercised 3.766.309 options between August 2020 and December 2020. See note 9 to our consolidated financial statements, contained elsewhere in this Annual Report, for further information on Mr. Menichella's options. During this period, he was paid in USD. The table reflects an approximate conversion of Mr. Menichella's compensation in EUR.

(6) This amount includes the $750.000 severance payment Mr. Menichella received in connection with the discontinuation of his service agreement. The table reflects an approximate conversion of Mr. Menichella's severance payment in EUR.

(7) Dr. Splawski became a managing director on July 15, 2020.

(8) Compensation is expressed in EUR. Dr. Splawski was based in Boston and paid by CureVac Inc. from July 15, 2020, until August 31, 2020. During this period, he was paid in USD. Dr. Splawski moved to Tübingen and was paid by CureVac AG

beginning on September 1, 2020. During this period, he was paid in EUR. The table reflects an approximate conversion of Dr. Splawski's compensation in EUR.

We did not provide pension, retirement, or similar benefits to our managing directors and supervisory directors board in the year ended December 31, 2020. Neither did we pay any dividends to our managing directors and supervisory directors board.

Bonus Plan

We maintain and implement a management bonus plan for the members of our management. Under the management bonus plan, we provide a variable bonus payment as a component of management compensation that ranges from 45% to 55% of the individual's annual base salary, depending on management level. We agree upon the respective individual amount of the target bonus with each employee on an individual contractual basis. The annual performance review is used to measure the achievement of objectives. In the individual's annual performance review, we measure the achievement of objectives for the past year and define the objectives for the coming year. The calculation of the respective bonus payment is based on the individual degree of target achievement, which is then calculated as a percentage of the annual base salary and is usually paid out in March of the following year. The bonus is calculated on a pro-rata basis if the individual joins or leaves CureVac during the year.

Equity Incentive Plans

Certain members of our management received share-based compensation under the legacy management stock option plan, or Legacy Management Stock Option Plan, in the form of share option awards. These options grant the holder the right to purchase series A shares of CureVac AG for a purchase price of €1 per share. All of the outstanding options have vested and will expire on December 31, 2021. From the time of our Corporate Reorganization until December 31, 2021, the option holders will have the option to convert these options into option awards exercisable for common shares of CureVac N.V. on a 1 to 133,0778 basis. Following this conversion, subject to the vesting, exercise, and expiration terms discussed above, these option awards will be governed by the new equity incentive plan, or the Plan, that was established in connection with the completion of our Corporate Reorganization.

In addition to the management share option awards described above, we maintain a virtual share plan for members of the management board and other key employees of CureVac, or Prior VSOP. As of December 31, 2020, 7.964.573 awards are outstanding and 43.383 awards available for issuance under the Prior VSOP. Ten percent (10%) of each award under the Prior VSOP became exercisable upon expiry of the 180 days lock-up period following the closing of CureVac's initial public offering, which occurred at the end of February 9, 2021. The remaining part of each award may be exercised (in whole or in part) upon the occurrence of certain defined triggering events, including, but not limited to, drug approval, or the sale by a majority shareholder of 5% of our outstanding shares, in each case subject to the conditions of the Prior VSOP. The rights under the Prior VSOP will terminate after the expiry of the ninth calendar year after the listing of our common shares on Nasdaq. The Prior VSOP was restructured upon the completion of our Corporate Reorganization. Following this restructuring, upon vesting of virtual shares, the holder will be able to exchange his or her virtual shares (in whole or in part) for cash or common shares of CureVac N.V. (instead of shares of CureVac AG) on a 1 to 133,0778 basis.

Due to the increase in value of CureVac prior to our Corporate Reorganization, we modified our incentive program to allow members of the management board and other employees to participate in the value-increased business based on CureVac's valuation at the time of its reorganization and conditional upon the occurrence of certain enumerated exercise cases reflecting such value-increase, or New VSOP. Each virtual share tracked one underlying series A share of CureVac AG. The New VSOP provided a cash-claim against CureVac in the amount of the positive difference between the value of CureVac per virtual share at the grant date (as determined by CureVac when the New VSOP was established) and the value per virtual share at the time of exercise of such virtual share (such value to be derived from the valuation of CureVac in the relevant triggering event) and gave CureVac discretion to provide tradable shares against payment of the value of CureVac per virtual share at the grant date. Such awards provided under the New VSOP had a term of ten years from the date of grant and vest over four years, where 25% vest after the first anniversary of the hire date and the remainder vests monthly with vesting on the last day of the month. These virtual shares were assumed by CureVac N.V. upon the completion of our Corporate Reorganization. At this time, the virtual shares were converted into options, exercisable for common shares of CureVac N.V. on a 1 to 133,0778 basis. Following this conversion, subject to the vesting, exercise, and expiration terms discussed above, these option awards are governed by the Plan.

In connection with our initial public offering, we established the Plan pursuant to which we may grant options, restricted stock, restricted stock units, share appreciation rights and other equity and equity-based awards. As of December 31, 2020, 13.917.808 awards are outstanding and 13.256.713 awards available for issuance under the Plan. The maximum number of common shares underlying awards granted pursuant to the Plan, including the awards granted in connection with the conversion of awards under the Legacy Management Stock Option Plan and the New VSOP, as discussed above, plus the common shares underlying awards under the Prior VSOP to the extent such awards have not yet been exercised or settled, will in total not exceed an equivalent of 15% of our issued share capital from time to time. The Plan is administered by our management board and supervisory board, where appropriate, on the basis of a recommendation of our compensation committee (the body administering the Plan, the, or Committee. Awards under the Plan may be granted to our employees, our managing directors and supervisory directors, consultants, or other advisors. Awards under the Plan may be conditioned upon the achievement or satisfaction of performance criteria. The vesting conditions for awards under the Plan will be determined by the Committee and will be set forth in the applicable award documentation. The Plan provides for special provisions for good leavers and bad leavers as well as for a change in control of our company.

The development of the share options and virtual shares outstanding and granted to the individual board members can be summarized as follows;

Name	Program	outstanding at the beginning of the period	granted during the period	forfeited during the period	exercised during the period	expired during the period	outstanding at the end of the period	exercisable at the end of the period	Exercise price of outstanding options (EUR)	Remaining term of outstanding options
Supervisory Board										
Ingmar Hoerr	Prior VSOP	2.070.291 *	0	0	0	0	2.070.291	0	0,00	8,6
	Legacy plan	369.423	0	0	0	0	369.423	0	0,00751	1,0

Name	Program	outstanding at the beginning of the period	granted during the period	forfeited during the period	exercised during the period	expired during the period	outstanding at the end of the period	exercisable at the end of the period	Exercise price of outstanding options (EUR)	Remaining term of outstanding options
Management Board										
Daniel L. Menichella	Grant former CEO	3.866.309	0	0	(3.766.309)	0	100.000	100.000	8,28 ***	
Florian von der Mulbe	Prior VSOP	1.679.708 **	0	0	0	0	1.679.708	0	0,00	8,6
	Legacy plan	268.417	0	0	0	0	268.417	0	0,00751	1,0
Mariola Fotin-Mleczek	Prior VSOP	451.533	0	0	0	0	451.533	0	0,00	8,6
Franz-Werner Haas	Prior VSOP	867.933	0	0	0	0	867.933	0	0,00	8,6
Pierre Kemula	Prior VSOP	665.389	0	0	0	0	665.389	0	0,00	8,6
Igor Splawski	LTIP	0	266.155	0	0	0	266.155	0	10,04	9,5

* Ingmar Hoerr has an obligation to deliver up to 104.998 common shares of CureVac NV as an existing shareholder 2015 to settle this program.
** Florian von der Muelbe has an obligation to deliver up to 76.254 commonshares of CureVac NV as an existing shareholder 2015 to settle this program.
*** in USD

No options were exercisable and exercised at the beginning of the year. For any details in respect of the terms and conditions of the grants during the year refer to note 9 of the consolidated financial statements.

The share options exercised by Dan Menichella after the IPO were settled against the issuance of 3.195.276 common shares of CureVac NV for no cash consideration.
The weighted average share price at the date of exercises was USD 55,22 (EUR 46,72). The intrinsic value of one outstanding option as of December 31, 2020 is 72,79 USD (59,60 EUR).
The share price of one CureVac NV common share as of December 31, 2020 was 81,07 USD (66,38 EUR)

13. Employees

There were no employees in 2020.

14. Related Party transactions

Transactions with the CureVac Group companies

In December 2020, CureVac N.V. granted to CureVac AG a loan of EURk 149.310 at the rate of 0.50% p.a. repayable on or before June 30th, 2021.

15. Share-based payment

The summary of the different programs at CureVac is as follows:

Reconciliation of outstanding options/virtual shares:

The number of options in these programs developed as follows:

	Prior VSOP	New VSOP	LTIP	Grant former CEO	Legacy plan	Total
outstanding at the beginning of the period	**7.305.838**	**745.236**	-	**3.866.309**	**702.917**	**12.620.300**
granted during the period	658.735	267.822	532.311	-	-	1.458.868
forfeited during the period	-	(106.462)	-	-	-	(106.462)
exercised during the period	-	-	-	(3.766.309)	-	(3.766.309)
expired during the period	(13.308)	-	-	-	-	(13.308)
outstanding at the end of the period	**7.951.265**	**906.595**	**532.311**	**100.000**	**702.917**	**10.193.088**
exercisable at the end of the period	-	-	-	100.000	-	100.000

	Prior VSOP	New VSOP	LTIP*	Grant former CEO	Legacy plan
	EUR	USD	EUR	USD	EUR
Exercise price of outstanding options	0,00	6,21	10,04 - 81,65	8,28	0,00751

Prior VSOP and Legacy plans are denominated in EUR, New VSEP and Grant former CEO are denominated in USD.

* LTIP Grant to CSO is denominated in EUR at a fixed strike price of EUR 10,04.
LTIP Grant to CBO/CCO ranges between EUR 43,87 and EUR 81,65.
The weighted average exercise price of all LTIP grants is EUR 36,38.
For details in respect of this range refer to note 9 of the consolidated financial statements.

	Prior VSOP	New VSOP**	LTIP***	Grant former CEO	Legacy plan
	years	years	years	years	years
Remaining term of outstanding options	8,6	8,0	10,1	7,5	1,0

** Weighted average for the range of 4,7 to 9,1 years.
*** Weighted average for the range of 9,5 to 11,9 years.

Regarding details of the individual plans, we refer to note 9. of the consolidated financial statements.

16. Contingent liabilities

CureVac NV represents and undertakes to procure that CureVac AG will receive adequate financial funding to ensure that CureVac AG is financially and capital-wise equipped in such a way that it is at all times in a position to meet all its payment obligations towards its creditors.

Signed by the Board of Directors,

Place:

Date:

Signature page to the Dutch statutory board report and financial statements of CureVac N.V. for the fiscal year ended December 31, 2020

Management Board

/s/ F.W. Haas

Name: F.W. Haas
Title : CEO & COO

/s/ P.T.V. Kemula

Name: P.T.V. Kemula
Title : CFO

/s/ F. von der Mülbe

Name: F. von der Mülbe
Title : CPO

/s/ M.W. Fotin-Mleczek

Name: M.W. Fotin-Mleczek
Title : CTO

/s/ I. Splawski

Name: I. Splawski
Title : CSO

Supervisory Board

/s/ Baron J.R.G. Stéphenne

Name: Baron J.R.G. Stéphenne
Title : Supervisory Board Member

/s/ R.L. Clemens

Name: R.L. Clemens
Title : Supervisory Board Member

/s/ M.P. Hothum

Name: M.P. Hothum
Title : Supervisory Board Member

/s/ H.C. Tanner

Name: H.C. Tanner
Title : Supervisory Board Member

/s/ F.H. von Bohlen und Halbach

Name: F.H. von Bohlen und Halbach
Title : Supervisory Board Member

/s/ T. Wright

Name: T. Wright
Title : Supervisory Board Member

/s/ C.A. Tooman

Name: C.A. Tooman
Title : Supervisory Board Member

/s/ V. Bronsema

Name: V. Bronsema
Title : Supervisory Board Member

Other information

1.1 Independent Auditor's Report

Independent auditor's report

To: the shareholders and supervisory board of CureVac N.V.

Report on the audit of the financial statements 2020 included in the annual report

Our opinion

We have audited the financial statements 2020 of CureVac N.V. based in Amsterdam. The financial statements comprise the consolidated and company financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of CureVac N.V. as at 31 December 2020 and of its result and its cash flows for 2020 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code
- The accompanying company financial statements give a true and fair view of the financial position of CureVac N.V. as at 31 December 2020 and of its result for 2020 in accordance with Part 9 of Book 2 of the Dutch Civil Code

The consolidated financial statements comprise:

- The consolidated statement of financial position as at 31 December 2020
- The following statements for 2020: the consolidated statements of operations and other comprehensive income (loss), changes in Shareholders' equity and cash flows
- The notes comprising a summary of the significant accounting policies and other explanatory information

The company financial statements comprise:

- The company statement of financial position as at 31 December 2020
- The company statement of operations and other comprehensive income (loss) for 2020
- The notes comprising a summary of the accounting policies and other explanatory information

Basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the Our responsibilities for the audit of the financial statements section of our report.

We are independent of CureVac N.V. in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the "Wet toezicht accountantsorganisaties" (Wta, Audit firms supervision act), the "Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten" (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore we have complied with the "Verordening gedrags- en beroepsregels accountants" (VGBA, Dutch Code of Ethics).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our audit approach

Our understanding of the business

CureVac N.V. is a global biopharmaceutical company developing transformative medicines based on messenger ribonucleic acid (mRNA). The group is structured in components and we tailored our group audit approach accordingly. We paid specific attention in our audit to a number of areas driven by the operations of the group and our risk assessment.

We start by determining materiality and identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud, non-compliance with laws and regulations or error in order to design audit procedures responsive to those risks and to obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

In 2020 we were forced to perform our procedures to a greater extent remotely due to the COVID-19 measures. This limits our observation and increases the risk of missing certain signals. In order to compensate for the limitations related to physical contact and direct observation, we performed alternative procedures, such as an intensified contact through use of video conferencing and remote reviews, to obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.

Materiality

Materiality	€7.0 million
Benchmark applied	4% of operating expenses
Explanation	CureVac N.V. is a clinical-stage biopharmaceutical Group that does not yet generate product revenues. Operating expenses is the key activity-based measure that is relevant for the users of the financial statements as the company is currently in its research and development phase.

We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

We agreed with the supervisory board that misstatements in excess of €348,500, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

Scope of the group audit

CureVac N.V. is the parent of a group of entities. The financial information of this group is included in the consolidated financial statements of CureVac N.V. In August 2020 the Group completed an initial public offering and in connection with the IPO the company underwent a corporate reorganization and transferred its registered office from Germany to The Netherlands and simultaneously transformed the company from an Aktiengesellschaft (AG) to a Naamloze Vennootschap (N.V.) governed by Dutch law. As a result of this transfer the audit mandate transferred from EY Germany and started as a first year audit by EY Accountants LLP (the Netherlands). During the audit we have had regular meetings with management and EY Germany and assessed key audit matters at an early stage.

Because we are ultimately responsible for the opinion, we are also responsible for directing and supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. On this basis, we selected group entities for which group audit and/or review procedures had to be carried out on the complete set of financial information or specific items.

Our audit mainly focused on significant group components. The group consists of 4 components.
Of these 4 components, we identified 3 as significant components and we performed full-scope audit procedures on these components. These components are significant in size and likelihood of material misstatements. For the remaining component, we performed review procedures on aggregated level. This component is insignificant in size and likelihood of material misstatements.

In total these procedures represent 100% of the group's total assets, operating expenses and loss for the period.

Because of the (international) travel restrictions and social distancing due to the COVID-19 pandemic, we needed to restrict or have been unable to visit management and/or component auditors to discuss, among others, the business activities and the identified significant risks or to review and evaluate relevant parts of the component auditor's audit documentation and to discuss significant matters arising from that evaluation on site. In these extraordinary circumstances we predominantly used digital communication and collaboration technology in order to obtain sufficient and appropriate audit evidence.

By performing the procedures mentioned above at group entities, together with additional procedures at group level we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion about the consolidated financial statements.

Teaming and use of specialists
We ensured that the audit team included the appropriate skills and competences which are needed for the audit of a listed client in this industry. We included specialists in the areas of IT audit, forensics, income tax and have made use of our own experts in evaluating compliance with IFRS with respect to accounting for share based payment instruments. Considering the nature of the company, we also included an EY Biotech expert to the team.

Our focus on fraud and non-compliance with laws and regulations

Our responsibility
Although we are not responsible for preventing fraud or non-compliance and cannot be expected to detect non-compliance with all laws and regulations, it is our responsibility to obtain reasonable assurance that the financial statements, taken as a whole, are free from material misstatement, whether caused by fraud or error.

Non-compliance with laws and regulations may result in fines, litigation or other consequences for the company that may have a material effect on the financial statements.

Our audit response related to fraud risks
In order to identify and assess the risks of material misstatements of the financial statements due to fraud, we obtained an understanding of the entity and its environment, including the entity's internal control relevant to the audit and in order to design audit procedures that are appropriate in the circumstances. As in all of our audits, we addressed the risk of management override of internal control. We do not audit internal control per se for the purpose of expressing an opinion on the effectiveness of the company's internal control.

We considered available information and made enquiries of relevant executives, directors and the supervisory board. As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption in close co-operation with our forensic specialists.

In our process of identifying fraud risks, we considered whether the COVID-19 pandemic gives rise to specific fraud risk factors resulting from a dilution in the effectiveness of controls as a result of the general disruption associated with remote working, pressure to make emergency procurements, management overrides and workarounds becoming the norm and manual payments.

We evaluated the design and the implementation of internal controls that mitigate fraud risks. In addition, we performed procedures to evaluate key accounting estimates for management bias in particular relating to important judgment areas and significant accounting estimates as disclosed in Note 2 to the financial statements. We have also used data analysis to identify and address high-risk journal entries. Our audit procedures to address the assessed fraud risks did not result in a key audit matter.

We incorporated elements of unpredictability in our audit. We considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance. If so, we reevaluate our assessment of fraud risk and its resulting impact on our audit procedures.

Our audit response related to risks of non-compliance with laws and regulations
We assessed factors related to the risks of non-compliance with laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general industry experience, through discussions with the executive directors, reading minutes, inspection of compliance reports, and performing substantive tests of details of classes of transactions, account balances or disclosures.

We also inspected lawyers' letters and correspondence with regulatory authorities and remained alert to any indication of (suspected) non-compliance throughout the audit. Finally we obtained written representations that all known instances of non-compliance with laws and regulations have been disclosed to us.

Going concern

We performed the following procedures in order to identify and assess the risks of going concern and to conclude on the appropriateness of management's use of the going concern basis of accounting.
We discussed and evaluated the risk with management, exercising professional judgment and maintaining professional skepticism, and specifically focusing on management bias that could represent a risk, the impact of current events (including the COVID-19 pandemic) and conditions that have an impact on the company's operations and forecasted cash flows, with a focus on whether the company will have sufficient liquidity to continue to meet its obligations as they fall due.

We consider based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion.

Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern.

General audit procedures

Our audit further included among others:

- Performing audit procedures responsive to the risks identified, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures
- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation

Our key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. We have communicated the key audit matters to the supervisory board. The key audit matters are not a comprehensive reflection of all matters discussed.

These matters were addressed in the context of our audit of the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Recognition of the BMBF grant income and revenues (Reference is made to Note 3.1 of the consolidated financial statements)	
Risk	In August 2020, as a result of its COVID-19 vaccine research, CureVac N.V. received a government grant from the German Ministry of Education & Research (Bundesministeriums für Bildung und Forschung, BMBF) to develop and produce a COVID-19 vaccine in Germany and Europe. The arrangement contains a performance obligation as well as a grant component. The allocation between the two categories requires (management) judgement. Considering the significance of the amount in the financial statements and the level of judgement in the assessment we assessed this matter as a Key audit matter.

Recognition of the BMBF grant income and revenues (Reference is made to Note 3.1 of the consolidated financial statements)	
Our audit approach	In order to address the identified risk, we obtained an understanding of the grant agreement and obtained an understanding of the process for aggregating/evaluating eligible costs and preparing fund request submissions. We also obtained an understanding of the design of internal controls implemented in this process. We performed the following substantive audit procedures: • We evaluated the accounting policies applied for the grant. • We evaluated the reasonableness of the allocation of the grant to performance obligations and government grant income. • We obtained an understanding of the restrictions and eligibility for reimbursement and tested expenses submitted for reimbursement. Key items above a set threshold were selected for testing together with and additional representative sample. • With the help of an EY internal biotech expert, we evaluated whether the invoices relate to programs which are reasonable for use in COVID-19 vaccine development including an assessment if they match the current stage of development. This included inquiries of the company's scientific personnel involved in the development program. • We performed fraud inquiries with individuals in the controlling department responsible for grant request submissions. • We obtained account payable confirmations from the CROs (contract research organizations) and other service organizations involved in the costs submitted. • We performed cut- off procedures around year-end. • We assessed the appropriateness of the disclosures of the grant.
Key observations	We concur with the company's accounting for the BMBF grant and consider the related disclosures to be appropriate.

Valuation of share-based compensation instruments (Reference is made to Note 9 of the consolidated financial statements)	
Risk	During 2020 CureVac N.V. operated multiple share-based payment plans for members of management and other key employees of the group. Considering the involvement of a relatively complex valuation model for the multiple share-based payment plans, including various input assumptions which require management judgement, we assessed this matter as a Key audit matter.
Our audit approach	In order to address the identified risk, we obtained an understanding of the different share-based compensation plans and obtained an understanding of the estimation process, including the process to establish assumptions included in the valuation of share-based compensation instruments and the design of internal controls implemented in this process. We performed the following substantive audit procedures. • We reviewed the accounting for the different plans, involving an IFRS technical expert to ensure the accounting meets the requirements of IFRS 2.

Valuation of share-based compensation instruments (Reference is made to Note 9 of the consolidated financial statements)	
	• For all options granted, we obtained the signed grant notices to validate appropriate grant terms are utilized in the fair value calculation. • We inspected the terms of the grants to validate that grants were appropriately established. • We obtained the valuation model and assessed reasonableness of assumptions utilized in the model including volatility and vesting conditions, and involved an EY valuation specialist to review the valuation model. • We recalculated the share-based payment expenses. • We assessed the appropriateness of the disclosures of the share based compensation instruments.
Key observations	We concur with the company's accounting for share-based compensation instruments and consider the related disclosures to be appropriate.

Research and development expenses (Reference is made to Note 3.4 of the consolidated financial statements)	
Risk	During the fiscal year, significant research and development expenses were recorded as a result of increased focus on research and development activities, primarily related to the COVID-19 study. Significant parts of the COVID-19 research and development activities are performed by CROs on behalf of CureVac N.V. Contractual billing schedules may vary from the actual rendering of services. As such, the company must estimate the liability to accrue for these services by estimating the degree of fulfillment of the contracted activities. Considering this estimation involves management judgement, we assessed this matter as a Key audit matter.
Our audit approach	In order to address the identified risk, we obtained an understanding of the different contracts with CROs and obtained an understanding of the research and development process, including the accrual estimation process and the design of internal controls implemented in this process. We performed the following substantive audit procedures. • We evaluated the accounting policies applied for the research and development projects. • We have read new clinical research agreements and other third-party agreements related to the COVID-19 research and performed inquiries with the research and development director as well as the COVID-19 project lead about the key terms of material agreements with third party research organizations. • We performed substantive testing procedures of CRO invoices received and tested the appropriate accounting for these invoices. • We inspected the year-end cut-off documentation prepared by the company and performed extended cut-off procedures, focusing on the moment to recognize prepaid CRO expenses and the completeness of accrued expenses. • We have sent out confirmations to CRO vendors to confirm the balance of research and development expenses to be paid as of year-end. • We performed plausibility checks for the progress of each study at year-end and the resulting expenses recorded.

Research and development expenses (Reference is made to Note 3.4 of the consolidated financial statements)	
Key observations	We concur with the company's accounting for the research and development expenses. We consider the research and development expenses and related accruals to be fairly stated and consider the disclosures to be appropriate.

Capital structure and corporate reorganization (Reference is made to Note 1 and Note 8 of the consolidated financial statements and to Note 4 and Note 6 of the company-only financial statements)	
Risk	The company completed multiple capital transactions during the year. On 7 April 2020, CureVac B.V. was incorporated under the laws of the Netherlands and became the holding company of CureVac AG in connection with the initial public offering on 14 August 2020. As part of the corporate reorganization, the legal form of CureVac B.V. was converted from a Dutch private company with limited liability to a Dutch public company. Considering the capital transactions, corporate reorganization and initial public offering resulted in significant, complex equity transactions, we assessed this matter as a Key audit matter.
Our audit approach	In order to address the identified risk, we obtained an understanding of the capital transactions, corporate reorganization and the impact on the financial statements. In addition, we obtained an understanding of the company's process for the preparation of the company-only financial statements. We performed the following substantive audit procedures. • We evaluated the appropriateness of the accounting for the capital transactions. • We obtained evidence of the cash receipt from the capital transactions and traced this (net of transaction costs) to the recorded capital reserves. • We audited the company's detail of the transaction costs and traced this to the recorded capital reserves. • We inspected the underlying agreements supporting the transfer of shares of CureVac AG to CureVac N.V. and recalculated the equity impact of the share split. • We tested the company-only equity schedule and movement schedule of the investment in associates, including the opening equity representing the investment in CureVac AG upon the transfer and the equity transactions recorded after the transfer. • We assessed the appropriateness of the disclosures of the capital transactions and corporate reorganization.
Key observations	We concur with the company's accounting for the capital transactions and corporate reorganization and consider the related disclosures to be appropriate.

Report on other information included in the annual report

In addition to the financial statements and our auditor's report thereon, the annual report contains other information that consists of:

- The Dutch statutory board report
- Other information as required by Part 9 of Book 2 of the Dutch Civil Code

Based on the following procedures performed, we conclude that the other information:

- Is consistent with the financial statements and does not contain material misstatements
- Contains the information as required by Part 9 of Book 2 of the Dutch Civil Code

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements. By performing these procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

The management board is responsible for the preparation of the other information, including the Dutch statutory board report in accordance with Part 9 of Book 2 of the Dutch Civil Code and other information required by Part 9 of Book 2 of the Dutch Civil Code.

Description of responsibilities for the financial statements

Responsibilities of the management board and the supervisory board for the financial statements

The management board is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, the management board is responsible for such internal control as it determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, the management board is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, the management board should prepare the financial statements using the going concern basis of accounting unless the management board either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so. The management board should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The supervisory board is responsible for overseeing the company's financial reporting process.

Our responsibilities for the audit of the financial statements

Our objective is to plan and perform the audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgment and have maintained professional skepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. The Our audit approach section above includes an informative summary of our responsibilities and the work performed as the basis for our opinion.

Communication

We communicate with the supervisory board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identify during our audit.

We provide the supervisory board with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the supervisory board, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

Eindhoven, 31 May 2021

Ernst & Young Accountants LLP

signed by R. Frentz

1.2 Profit appropriation

In accordance with Article 35 of the Articles of Association, a distribution can only be made to the extent that the Company's equity exceeds the amount of the paid up and called up part of its capital plus the reserves which must be maintained by law.

Pursuant to the Company's articles of association, any profits shown in the adopted statutory annual accounts of the Company shall be appropriated as follows, and in the following order of priority:

a. to the extent that any preferred shares have been cancelled without full repayment as described in the articles of association and without such deficit subsequently having been paid in full, an amount equal to any such (remaining) deficit shall first be distributed to those who held those preferred shares at the moment of such cancellation becoming effective;

b. if preferred shares are issued and outstanding and to the extent that the mandatory annual distribution on the preferred shares (i.e., an amount equal to the applicable interest rate calculated over the aggregate amount paid up on those preferred shares, calculated in accordance with the relevant provisions of the articles of association), or part thereof, in relation to previous financial years has not yet been paid in full, an amount equal to any such (remaining) deficit shall be distributed on the preferred shares;

c. if preferred shares are issued and outstanding, the mandatory annual distribution (as described above under b.) payable on preferred shares shall then be distributed on the preferred shares;

d. following those distributions, the Management Board shall determine which part of the remaining profits shall be added to the Company's reserves; and

e. subject to a proposal by the Management Board to that effect, the remaining profits shall be at the disposal of the General Meeting for distribution on the ordinary shares.

See note 7 in the Notes to the Company Financial Statements (section 10) for the appropriation of profits realized during the financial year to which this report pertains.

1.3 Special rights of control under our articles

See sections 4.3, 5.1, 5.8.5 and 8 of this report for the special rights of KfW and dievini in relation to the Company pursuant to our articles of association. There are no other parties with special rights of control in relation to the Company pursuant to our articles of association.

1.4 Non-voting shares and shares carrying limited economic entitlement

The Company has not issued non-voting shares. The preferred shares in the Company's capital carry a limited entitlement to the Company's profit and reserves. As at December 31, 2020, no preferred shares in the Company's capital were issued.

1.5 Other establishments

The Company has no branch offices.