As confidentially submitted with the Securities and Exchange Commission on April 29, 2020.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CureVac B.V.*

(Exact name of Registrant as specified in Its charter)

(*) We intend to convert the legal form of our company under Dutch law from a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a public company (*naamloze vennootschap*) and to change our name from CureVac B.V. to CureVac N.V. prior to the closing of this offering.

Not Applicable

(Translation of Registrant's name into English)

The Netherlands		**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Friedrich-Miescher-Strasse 15, 72076
Tübingen,
Germany
+49 7071 9883 0

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

CureVac Inc.
250 Summer St. 3rd Fl.
Boston, Massachusetts 02210
+1-617-377-4044

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Richard D. Truesdell, Jr. **Leo Borchardt** **Davis Polk & Wardwell LLP** **450 Lexington Avenue** **New York, New York 10017** **+1 (212) 450-4000**	**Paul van der Bijl** **NautaDutilh N.V.** **Beethovenstraat 400** **1082 PR Amsterdam** **The Netherlands** **+31 (20) 717-1000**	**Nathan Ajiashvili** **Oliver Seiler** **Latham & Watkins LLP** **885 Third Avenue** **New York, New York 10022** **+1 (212) 906-1200**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ _____

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ _____

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ _____

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[(1)]	Amount of registration fee
Common shares, par value €0.12 per share	$	$

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of additional shares that the underwriters have the option to purchase.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

Subject to Completion
Preliminary Prospectus dated , 2020

P R O S P E C T U S

Shares

Common Shares

CureVac B.V.

to be converted and renamed

CureVac N.V.

(incorporated in the Netherlands)

This is CureVac B.V.'s initial public offering. We are selling common shares, €0.12 par value per share.

We expect the public offering price to be between $ and $ per common share. This is our initial public offering and no public market currently exists for our common shares. We intend to apply to list our common shares on The Nasdaq Global Market under the symbol "CVAC."

We are both an "emerging growth company" and a "foreign private issuer" as defined under the U.S. federal securities laws and, as such, will be subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company" and "— Implications of Being a Foreign Private Issuer."

Investing in our common shares involves risks. See "Risk Factors" beginning on page 12 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discounts (1)	$	$
Proceeds, before expenses, to us	$	$

(1) We refer you to "Underwriting" beginning on page 240 of this prospectus for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional common shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The common shares will be ready for delivery on or about , 2020.

BofA Securities **Jefferies** **Credit Suisse**

The date of this prospectus is , 2020.

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We and the underwriters have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, common shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common shares.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus or any free writing prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common shares and the distribution of this prospectus and any free writing prospectus outside the United States.

ABOUT THIS PROSPECTUS

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to "CureVac" or the "Company," "we," "our," "ours," "ourselves," "us" or similar terms refer to (i) CureVac AG, together with its subsidiaries, prior to the completion of the contribution and transfer to CureVac B.V. of all of the outstanding shares of CureVac AG in a capital increase in exchange for newly issued common shares of CureVac B.V., (ii) CureVac B.V., together with its subsidiaries, as of the completion of the contribution and transfer to CureVac B.V. of all of the outstanding shares of CureVac AG in a capital increase in exchange for newly issued common shares of CureVac B.V. and (iii) CureVac N.V., together with its subsidiaries, after giving effect to the conversion of CureVac B.V. into CureVac N.V. See "Corporate Reorganization."

We are incorporated in the Netherlands, and a majority of our outstanding securities are owned by non U.S. residents. Under the rules of the U.S. Securities and Exchange Commission, or the SEC, we are currently eligible for treatment as a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

We have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we may have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters have not authorized any other person to provide you with different or additional information. Neither we nor the underwriters are making an offer to sell the common shares in any jurisdiction where the offer or sale is not permitted. This offering is being made in the United States and elsewhere solely on the basis of the information contained in this prospectus. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of the common shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

PRESENTATION OF FINANCIAL INFORMATION

We report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

Our financial statements included in this prospectus are presented in euro and, unless otherwise specified, all monetary amounts are in euro. All references in this prospectus to "$," "U.S. dollars" and "dollars" means U.S. dollars and all references to "€" and "euro" mean euro, unless otherwise noted.

In this prospectus, unless otherwise indicated, some euro amounts have been translated into U.S. dollars at the rate of $1.00 to € , the official exchange rate quoted as of , 2020 by the Federal Reserve Bank of New York.

This prospectus contains the historical financial statements and other financial information of CureVac AG, which is expected to be acquired by CureVac B.V. as a consequence of a capital increase of CureVac B.V. in the context of which the shareholders of CureVac AG will contribute and transfer their shares in CureVac AG as contribution in kind to CureVac B.V. prior to the closing of this offering. CureVac B.V.'s common shares are being offered hereby. CureVac B.V. is a newly incorporated holding company incorporated for the purpose of effecting the offering and has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. CureVac B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Following the corporate reorganization, CureVac N.V. will become the holding company of CureVac AG and the historical consolidated financial statements of CureVac AG included in this prospectus will become the historical consolidated financial statements of CureVac N.V. See "Corporate Reorganization."

TRADEMARKS

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 prospectus 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 prospectus 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.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry, including our general expectations and market position, market opportunity and market size estimates, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this prospectus is generally reliable and is based on reasonable assumptions, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the heading "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements."

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire prospectus carefully, including the "Risk Factors," "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections and our audited consolidated financial statements and notes to those statements, included elsewhere in this prospectus, before deciding to invest in our common shares.

Our Company

We are a leading global clinical-stage 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 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 oncology, prophylactic vaccines and protein therapy. Our lead clinical programs, CV8102 for the treatment of four types of solid tumors and CV7202 for potential vaccination against rabies, have generated promising early efficacy and safety results in clinical trials. We are rapidly advancing our mRNA vaccine against coronavirus (SARS-CoV-2) through preclinical studies and expect to initiate the first Phase 1/2a clinical trial in .

mRNA-based medicines represent a foundational class of medicine that have the potential to address limitations of conventional treatment modalities. We are leveraging the inherent advantages of mRNA-based medicines in the development of our 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:*** increasing 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 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 continuously improve our technology platform and maintain flexibility in clinical development. We control the critical steps of manufacturing in-house, which allows us to drive innovation and to maintain flexibility, which allows us to pivot quickly in clinical development and potential commercialization. We currently operate three GMP-certified suites, with the capacity to supply our clinical programs and potential early commercialization activities. We are in the process of building a fourth GMP facility that will support our future commercial launches. Based on the doses and efficacy seen in our CV7202 study, we believe our fourth GMP facility could potentially supply materials for billions of doses of our vaccine product candidates. In addition to our GMP manufacturing facilities, we are developing a novel downsized and automated process for producing our mRNA, which we refer to as the RNA Printer.

Our approach seeks to mitigate clinical and developmental risk across multiple levels to advance and expand our broad product portfolio 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 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.

We are exploring a range of potential approaches in oncology 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 the toll like receptors 7, or TLR7, TLR8 and retinoic acid-inducible gene I, or RIG-I pathways using an intratumoral approach. CV8102 is currently being evaluated in a Phase 1/2 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 2019, we have enrolled 32 patients (21 in the single agent cohort and 11 in the combination cohort with anti-PD-1) in the Phase 1 dose-escalation portion of the study. As of October 2019, in the single agent cohort, we have observed a complete response in a stage IIIc melanoma patient and two additional patients have shown a stabilization of their disease, including shrinkage of non-injected lesions. Overall, six out of 21 patients treated with single agent CV8102 remained free of progression for at least six months. Based on the results from the Phase 1 clinical trial, we plan to determine the recommended dose for the Phase 2 expansion portion of the trial.

Our mRNA technology platform has shown potential in the development and production of prophylactic vaccines against infectious diseases. Our lead 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 Phase 1 clinical trial, evaluating safety, including reactogenicity, and immunogenicity. In January 2020, we reported preliminary data from our Phase 1 trial of CV7202 in rabies. CV7202 induced adaptive immune response as shown by rabies-specific virus-neutralizing antibody titers, or VNTs, above the World Health Organization, or WHO, thresholds considered to be protective, 28 days 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 plan to report follow up data from our Phase 1 clinical trial in and initiate a Phase 2 clinical trial in .

In response to the global pandemic due to novel coronavirus 2019 disease, or COVID-19, we have rapidly advanced our mRNA vaccine program against SARS-CoV-2. Upon publication of the sequence of the novel coronavirus disease (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. We have selected two constructs for further evaluation that encode for stabilized S-protein, which are currently undergoing preclinical testing. Exploratory data on these constructs indicated high immunogenicity and titers of S specific binding and neutralizing antibodies in mice after a single vaccination. We intend to initiate the first Phase 1/2a clinical trial in healthy volunteers in , with initial results expected in . We are working closely with many organizations, including the Coalition for Epidemic Preparedness Innovations, or CEPI, on the development of this vaccine.

Our development efforts for protein therapy are based on delivering optimized mRNAs to trigger production of antibodies or therapeutic proteins. 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. Our protein therapy platform has the potential to be used as a treatment against infectious diseases and toxins and to be applied in many disease indications including cancer, cardiovascular 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 therapeutic levels in the blood stream. We are also currently advancing multiple undisclosed programs in preclinical studies across liver and rare diseases, eye disorders, lung diseases as well as delivering therapeutic antibodies.

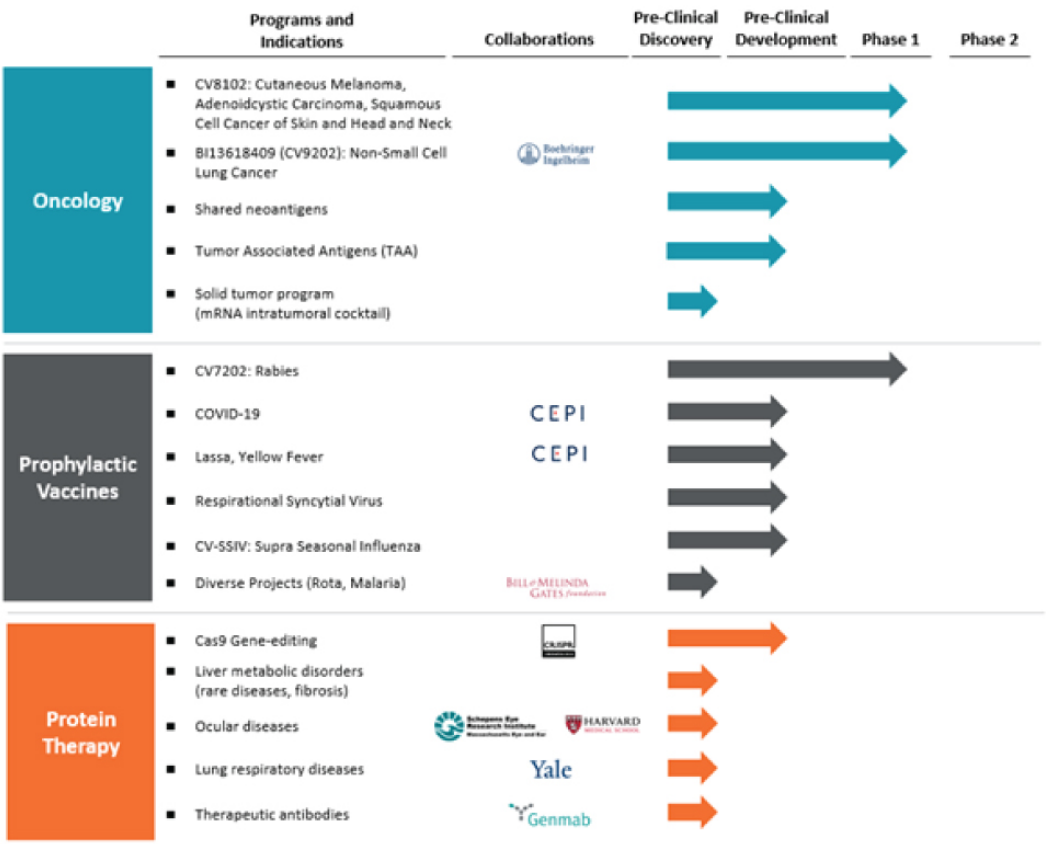
We have built an intellectual property portfolio in the United States, Europe and other major geographies. Our patent portfolio includes claims relating to our RNA technology platform, our CVCM delivery system and our CV8102, CV7202, CV-SSIV and SARS-CoV-2 product candidates. We retain the worldwide development and commercialization rights for our lead product candidates.

We have a history of partnering with leading biopharmaceutical companies such as Boehringer Ingelheim GmbH, or Boehringer Ingelheim, CRISPR Therapeutics AG, or CRISPR Therapeutics, and Genmab B.V., or Genmab. We also have received research grants from the Bill & Melinda Gates Foundation and CEPI for the development of several prophylactic vaccines. In addition, we have collaborations with the Schepens Eye Research Institute, Harvard Medical School and the Massachusetts Eye and Ear Infirmary, collectively SERI, as well as Yale University. 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.

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. We currently have over 450 employees, including over 116 employees with advanced scientific degrees. Since our founding in 2000, we have raised approximately €451 million in gross proceeds from a combination of equity and convertible debt financings with an additional €44 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 oncology, infectious diseases and protein therapy.



Our Strengths

We are developing a broad portfolio of product candidates 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.
- We have a broad portfolio of mRNA-based medicines designed for efficacy, safety and protein expression at relatively low doses.
- We have the ability to target different tissue types based on our delivery systems.
- 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 entered into strategic partnerships with leading biopharmaceutical companies and research and non-profit institutions to expand the applications of our technology platform.
- We have built an intellectual property portfolio in a variety of markets for our platform and product candidates.
- We have a long history of mRNA research and development and are led by an experienced management team.

Our Strategy

Our goal is to continue 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.
- Utilize a rational disease selection approach to minimize clinical and commercial risk for our programs and broader platform.
- Rapidly advance our lead product candidates through clinical development and regulatory approval.
- Continue to invest in our manufacturing capabilities to further add scale and flexibility for potential commercialization.
- Selectively seek strategic partners to develop and commercialize product candidates in certain therapeutic areas and geographies.
- Seek strategic acquisitions or in-licenses of technology or assets that are complementary to our programs and technology platform.
- Strengthen and expand our intellectual property portfolio to protect our scientific and technical know-how.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

- the adequacy of our capital resources to successfully complete the development and commercialization of our product candidates, and a failure to obtain additional capital;
- our history of operating losses and our need for additional funding before we can expect to become profitable from the sales of our products;
- we rely on existing strategic partnerships for the funding, research, development and commercialization of our platform and certain of our product candidates, including with Genmab, Arcturus Therapeutics, Inc., or Arcturus, Acuitas Therapeutics Inc., or Acuitas, CRISPR Therapeutics, Boehringer Ingelheim, the Bill & Melinda Gates Foundation, CEPI, and Tesla Grohmann Automation GmbH, or Tesla Grohmann, among others; if our partners are unsuccessful in their efforts or chose to terminate their agreements with us, our business will be materially harmed;
- our approach to the discovery and development of product candidates based on mRNA technology is unproven, and we do not know whether we will be able to successfully develop any products;
- clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes;
- 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;
- to date, no product that utilizes mRNA as a therapeutic or prophylactic vaccine has been approved in the United States or Europe and 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 U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed;
- some of our product candidates are classified as gene therapies by the FDA and the EMA. 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;

- the manufacture of mRNA-based medicines is complex and manufacturers often encounter difficulties in production;
- the timing, receipt, and amount of sales of, or royalties or milestones on, our future products, if any;
- our ability to obtain, maintain, protect and defend our intellectual property, which is difficult and costly;
- concentration of ownership by our principal shareholder may conflict with your interest and may prevent you from influencing significant corporate decisions;
- our ability to develop and commercialize our product candidates without infringing, misappropriating or otherwise violating the intellectual property of third parties; and
- the recent outbreak of the COVID-19, which may cause business disruptions and could have a material adverse effect on our business plan or clinical trials.

A change in the outcome of any of these variables with respect to the development of any product candidate that we may develop could mean a significant change in the costs and timing associated with the development of such product candidate.

Corporate Reorganization

We were incorporated pursuant to the laws of the Netherlands as CureVac B.V. on April 7, 2020 to become a holding company for CureVac AG. Pursuant to the terms of a corporate reorganization that will be completed prior to the closing of this offering, all of the outstanding shares in CureVac AG will be contributed and transferred to CureVac B.V. in a capital increase in exchange for newly issued common shares of CureVac B.V. and, as a result, CureVac AG will become a wholly owned subsidiary of CureVac B.V. and the current shareholders of CureVac AG will become the shareholders of CureVac B.V. Prior to the closing of this offering, we intend to convert from CureVac B.V. into CureVac N.V. See “Corporate Reorganization.”

Corporate Information

Our principal executive offices are located at Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany. Our telephone number at this address is +49 7071 9883 0. Investors should contact us for any inquiries through the address and telephone number of our principal executive office. Our principal website is www.curevac.com. The information contained on our website is not part of this prospectus.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to have only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. 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. We may choose to take advantage of some but not all of these reduced burdens. We cannot predict if investors will find our common shares less attractive because we will 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.

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.

Implications of Being a Foreign Private Issuer

We are also considered a "foreign private issuer." In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our managing directors, supervisory directors and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our common shares. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of the managing directors or supervisory directors are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies.

THE OFFERING

Issuer	CureVac B.V., to be converted into and renamed CureVac N.V. prior to the closing of this offering.
Common shares offered	We are offering common shares.
Underwriters' option to purchase additional common shares	We have granted the underwriters the right to purchase up to an additional common shares from us within 30 days of the date of this prospectus.
Common shares to be outstanding after this offering	common shares (common shares if the underwriters' option to purchase additional common shares is exercised in full).
Voting rights	Our common shares have one vote per share.
Listing	We intend to apply to list our common shares on The Nasdaq Global Market, or Nasdaq, under the symbol "CVAC."
Use of proceeds	We estimate that the net proceeds to us from the offering will be approximately $ ($ if the underwriters' option to purchase additional common shares is exercised in full), assuming an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus. We intend to use the net proceeds from the offering, together with cash and cash equivalents on hand to advance the development of our preclinical and clinical programs, invest in further development of our mRNA technology platform, fund the expansion of our manufacturing capabilities, and the remainder for working capital and general corporate purposes. See "Use of Proceeds."
Dividend policy	We have never paid or declared any cash dividends on our common shares and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. As of the completion of our corporate reorganization, under Dutch law, we may only pay dividends to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-in and called-up share capital plus the reserves required to be maintained by Dutch law or by our articles of association and (if it concerns a distribution of profits) after adoption of the annual accounts by the general meeting from which it appears that such dividend distribution is allowed. Subject to such restrictions, any future determination to pay dividends will be at the discretion of our management board with the approval of our supervisory board and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our management board and supervisory board deem relevant.

Lock-up agreements	We have agreed with the underwriters, subject to certain exceptions, not to offer, sell or dispose of any shares of our share capital or securities convertible into or exchangeable or exercisable for any shares of our share capital during the 180-day period following the date of this prospectus. Our managing directors and our supervisory directors, as well as substantially all of our existing shareholders, have agreed to substantially similar lock-up provisions, subject to certain exceptions.
Risk factors	See “Risk Factors” and the other information included in this prospectus for a discussion of factors you should consider before deciding to invest in our common shares.

The number of common shares to be outstanding after this offering is based on common shares outstanding as of , 2020.

Unless otherwise indicated, all information contained in this prospectus assumes:

- the completion, prior to the closing of this offering, of our corporate reorganization, as further described under the section titled “Corporate Reorganization”;
- an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus; and
- no exercise of the option granted to the underwriters to purchase up to additional common shares in connection with the offering.

SUMMARY CONSOLIDATED FINANCIAL INFORMATION

The following summary consolidated statement of financial position as of December 31, 2019 and the consolidated statement of operations and comprehensive income (loss) for the years ended December 31, 2018 and 2019 of CureVac AG are derived from the consolidated financial statements included elsewhere in this prospectus, which have been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, or Ernst & Young.

We maintain our books and records in euros, and we prepare our financial statements under IFRS as issued by the IASB.

CureVac B.V. is a newly formed holding company formed for the purpose of effecting the offering and has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. CureVac B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Accordingly, summary financial information for CureVac B.V. is not presented. CureVac AG's financial statements, including the notes thereto, are included elsewhere in this prospectus. See "Corporate Reorganization."

This financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, including the notes thereto, included elsewhere in this prospectus.

	For the Years Ended December 31,	
	2018	2019
	(in thousands of euros, except per share amounts)	
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)**

	As of December 31, 2019		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
	(in thousands of euros)		
Statement of Financial Position Data:			
Cash and cash equivalents	30,684		
Total assets	130,620		
Total liabilities	173,422		
Total equity	(42,802)		

(1) Pro forma to give effect to our corporate reorganization.

(2) Pro forma as adjusted to give further effect to the issuance and sale of common shares in this offering at the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming no exercise of the underwriters' option to purchase additional common shares. The as adjusted information presented above is illustrative only and will vary based on the actual public offering price, the actual number of common shares offered by us and the other terms of the offering determined at pricing.

(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, total assets and total equity by $ million, assuming the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of common shares we are offering. Each increase (decrease) of 1.0 million in the number of common shares offered by us would increase (decrease) each of cash and cash equivalents, total assets, share capital and total equity by approximately $ million, assuming no change in the assumed initial public offering price and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this prospectus before making an investment in our common shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common shares could decline and you could lose all or part of your investment.

This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including the risks facing our company.

Risks Related to Our Financial Position and Need for Additional Capital

We cannot assure you of the adequacy of our capital resources, including the proceeds from this offering, 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, 2019, we had cash and cash equivalents amounting to €30.7 million. 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:

- our ability to successfully complete this offering;
- 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 end-points;
- 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 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 year ended December 31, 2019 was €99.9 million. As of December 31, 2019, our accumulated deficit was €515.9 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 shareholders' deficit and 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 you to lose all or part of your investment.

Even if we consummate this offering, we will require substantial additional financing, which may not be available on acceptable terms, or at all. Raising additional capital may cause dilution to our shareholders, including purchasers of common shares in this offering, restrict our operations or require us to relinquish rights to our technology or product candidates.

We expect our expenses to increase in connection with our planned operations and as we become and operate as a public company. To the extent that we raise additional capital through the sale of common shares, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common shareholder. 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 additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. 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 additional 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 additional 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 additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of 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 Genmab, Arcturus, Acuitas, CRISPR Therapeutics, Boehringer Ingelheim, the Bill & Melinda Gates Foundation, CEPI and Tesla Grohmann,

among others. For certain of these programs, 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. 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 Genmab, Arcturus, Acuitas, Boehringer Ingelheim, the Bill & Melinda Gates Foundation, CRISPR Therapeutics and CEPI, 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 “Business — 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 Genmab, CRISPR Therapeutics and Boehringer Ingelheim, 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. 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 prospectus 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 “Business — 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. As of the date of this prospectus, we are not aware of any product that utilizes mRNA as a therapeutic or prophylactic vaccine being approved in the United States or Europe. We have not yet succeeded and may not succeed in demonstrating the efficacy and safety of any of our product candidates in clinical trials or in obtaining marketing approval thereafter. We have completed an interim analysis of safety and immunogenicity in an ongoing Phase 1 clinical trial for our CV7202 (Rabies vaccine) product candidate and have ongoing Phase 1/2a clinical trials for our CV8102 (cMEL, ACC, SCC and HNSCC) and BI 1361849 (former CV9202)

(Non-Small-Cell Lung Cancer, or NSCLC) product candidates. 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. While we have assessed the results and this trial has informed our approach going forward, we can provide no assurance that future clinical trials will not 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. 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 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. We also rely on contract manufacturing organizations, or CMOs, to manufacture and supply our product candidates. 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 completed clinical trials sufficient for obtaining marketing approvals for any of our product candidates. Our CV7202 (Rabies), BI 1361849 (former CV9202) (NSCLC) and CV8102 (Melanoma, Adenoidcystic Carcinoma, Squamous Cell Cancer of Skin and Head and Neck) product candidates are in clinical development and all other of our product candidates 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 after this offering.

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 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 pre-existing 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 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 recent COVID-19 pandemic. As a result of measures imposed by the governments in affected regions, businesses and schools have been suspended due to quarantines intended to contain the pandemic. The rapid spread of COVID-19 from China to other countries (including the United States and Europe) has resulted in the Director General of the World Health Organization declaring the COVID-19 pandemic as a Public Health Emergency of International Concern, based on the advice of the Emergency Committee under the International Health Regulations (2005), and the Centers for Disease Control and Prevention in the U.S. issued a warning on February 25, 2020 regarding the spread of COVID-19 to the U.S. The president of the United States declared the COVID-19 a national emergency and many states and municipalities in the United States have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing “shelter-in-place” orders which direct individuals to shelter at their places of residence (subject to limited exceptions).

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. Some of our clinical trial sites are located in countries, such as Spain and Italy, 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.

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 implementing a work-from-home policy for employees except for those related to our laboratory operations, and these arrangements may cause reduced productivity of our employees and/or disruptions of our business operations. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to COVID-19, 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.

All of 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.

All of our proprietary product candidates are still in preclinical or early 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. 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, you 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.

No mRNA product has been approved, and none may ever be approved. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of medicines.

As a potential new category of therapeutics, to our knowledge, no mRNA immunotherapies have been approved by the FDA, EMA or other regulatory agency. Successful discovery and development 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, or fail to reach 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. In addition, because no mRNA-based product has been approved, the regulatory pathway 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. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these 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 pre-specified 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 pre-specified 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.

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.

The United Kingdom withdrew from the European Union effective as of January 31, 2020, and is now in a period of transition until the end of 2020. The transition period maintains all existing trading arrangements. During the transition period, the United Kingdom and the European Union will negotiate future trading arrangements. Until a final agreement has been reached, an exit without a trade agreement in place, which would result in the United Kingdom losing access to free trade agreements for goods and services with the European Union and other countries, continues to be a risk. An exit by the United Kingdom from the European Union without an agreement in place would likely lead to legal uncertainty and potentially divergent laws and regulations between the United Kingdom and the European Union. We cannot predict whether or not the United Kingdom will significantly alter its current laws and regulations in respect of the pharmaceutical industry and, if so, what impact any such alteration 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 foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. 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. 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 on-going 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 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 nonexclusive 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 nonexclusive, 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 SARS-CoV-2 vaccine 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 SARS-CoV-2 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 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 nonexclusive 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 of 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 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 “Business — 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 Genmab, Arcturus, Acuitas, Boehringer Ingelheim, the Bill & Melinda Gates Foundation, CRISPR

Therapeutics and CEPI, 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 re-examination, 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 patents relating to mRNA formulation, mRNA-based vaccination of specific patient populations, combination of mRNA-based vaccination and inhibition of the PD-1 pathway, methods for RNA analysis and intratumoral (m)RNA treatment 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 antigens in LNPs and LNP-formulated RNA that may be construed to cover the LNP-formulated RNA technology used in our vaccines and protein therapies. 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 nonexclusive, 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 results 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 of our 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 nonexclusive. 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, health care 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 health care 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 health care 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 health care 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, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace 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 2029, unless additional congressional action is taken. These reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. 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 have 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. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "blueprint" to lower prescription drug prices and out-of-pocket costs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative 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. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. If these 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 of 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 health care.

Cyber-attacks 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 cyber-attacks 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 cyber-attacks 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 cyber-attack 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 cyber-attacks 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. 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 and the United Kingdom, 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 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. In particular, the United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR taking effect in January 2021 (after the end of the transitional period) which could expose us to two parallel regimes each of which potentially authorizes fines for certain violations up to the greater of either 4% of the total global annual turnover of the preceding financial year or €20 million.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 approval 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. 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, including purchasers of common shares in this offering, 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, health care 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 and the Offering

There is no existing market for our common shares, and we do not know whether one will develop to provide you with adequate liquidity. If our share price fluctuates after this offering, you could lose a significant part of your investment, and you may not be able to sell your common shares at or above the initial public offering price.

Prior to this offering, there has not been a public market for our common shares. If an active trading market does not develop, you may have difficulty selling any of our common shares that you buy. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on The Nasdaq Global Market, or otherwise, or how liquid that market might become. The initial public offering price for the common shares will be determined by negotiations between us and the underwriters and may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell our common shares at prices equal to or greater than the price paid by you in this offering. 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 cover our common shares after this offering 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. Under our articles of association as they will read upon the closing of this offering, we will be authorized to issue up to common shares, of which common shares will be outstanding following this offering. We have agreed with the underwriters, subject to certain exceptions, not to offer, sell, or dispose of any shares of our share capital or securities convertible into or exchangeable or exercisable for any shares of our share

capital during the 180-day period following the date of this prospectus. Our managing directors and our supervisory directors, as well as certain of our existing shareholders, have agreed to substantially similar lock-up provisions, subject to certain exceptions. Following the expiration of the lock-up period, our existing shareholders may determine to sell their common shares, subject to certain restrictions. See "Description of Share Capital and Articles of Association." 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.

The trading price of our common shares may in the future be highly volatile, which could result in substantial losses for purchasers of our common shares in this offering, and a decline in our share price and invite securities litigation against our company or our management.

Our share price is likely to be highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common shares at or above the public offering price and you may lose some or all of your investment. The market price for our common shares may be influenced by many factors, including:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the timing, enrollment and results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- any delay in our development or regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- unanticipated serious safety concerns related to the use of our product candidates;
- our failure to commercialize our product candidates;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- successful manufacturing of our products;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- our cash position;

- trading volume of our common shares;
- announcement or expectation of additional financing efforts;
- sales of our common shares by us, our insiders or other shareholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in accounting practices or the ineffectiveness of our internal controls;
- changes in estimates or recommendations by securities analysts, if any, that cover our shares, or the withdrawal of research coverage by securities analysts;
- significant lawsuits, including patent or shareholder litigation;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors specifically;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been brought against a company and its management following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant share price volatility in recent years. Such litigation, if instituted against us, could cause us or members of our management to incur substantial costs and divert management's attention and resources from our business.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

We have broad discretion in the use of the net proceeds received by us from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return on your investment.

Although we currently intend to use the net proceeds received by us from this offering in the manner described in the section titled "Use of Proceeds" in this prospectus, our management has broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common shares. For example, we intend to use the net proceeds received by us from this offering, together with cash and cash equivalents on hand, to pursue the approval of our product candidates for a number of indications, some of which may never reach approval, as well as for general corporate purposes. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering. 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 their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Concentration of ownership by our principal shareholder may conflict with your interest and may prevent you from influencing significant corporate decisions.

Upon the completion of this offering, our principal shareholder dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, or dievini, will beneficially own approximately % of our common shares, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same (or % if the underwriters exercise in full their option to purchase additional shares).

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. The concentration of ownership could deprive you of an opportunity to receive a premium for your 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 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.

Transformation into a public company may increase our costs and disrupt the regular operations of our business.

This offering will have a significant transformative effect on us. Our business historically has operated as a privately owned company, and we expect to incur significant additional legal, accounting, reporting and other expenses as a result of having publicly traded common shares. We will also incur costs which we have not incurred previously, 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 incur 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 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 accounting 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. See "Prospectus Summary — Implications of Being an Emerging Growth Company." Furthermore, after the date we are no longer an emerging growth company, our independent registered public accounting 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 accounting firm may still decline to attest to our management's assessment or 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 revenue, 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, you 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 will 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 will vary 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)(2), which requires an issuer to have a majority of independent directors on its board. We will 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 of the effectiveness of the registration statement of which this prospectus forms a part. 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. For an overview of our corporate governance principles, see "Description of Share Capital and Articles of Association." Accordingly, you 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 2019 taxable year, we have not yet determined our expected PFIC status for the current taxable year or any future taxable year. 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 current taxable year. However, under recently proposed Treasury regulations (the preamble to which specifies that a taxpayer may generally choose to apply them in their entirety prior to their finalization provided that the taxpayer consistently applies them), or the Proposed 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. Although no assurances may be given in this regard, we expect that we would be eligible in our 2020 taxable year to use the fair market value of our assets for purposes of the asset test, and U.S. investors are urged to consult their tax advisers whether they could apply the Proposed Regulations for purposes of the asset test. The remainder of this discussion assumes that U.S. Holders will choose to apply the Proposed Regulations in their entirety.

Based on the composition of our income and assets during 2019, we do not believe that we were a PFIC for our 2019 taxable year. However, PFIC status is a fact-intensive determination made on an annual basis after the end of each taxable year, and we have not yet determined our expected PFIC status for the current taxable year or any future taxable year. Whether we will be a PFIC in 2020 or any future year is uncertain because, among other things, (i) we currently own, and will own after the closing of this offering, 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 2020 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. See "Taxation — Material U.S. Federal Income Tax Considerations to U.S. Holders."

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 complete this 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 will continue to have substantial control over us after this offering and could limit your ability to influence the outcome of key transactions, including a change of control.

Our principal shareholders, managing directors, supervisory directors and executive officers and entities affiliated with them will own approximately % of the outstanding common shares after the closing of this offering. 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 yours 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 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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not

currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our common shares would likely be negatively impacted. In the event securities or industry analysts initiate coverage, 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 your 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 "Risk Factors — 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 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 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 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, 2019, there are NOLs of CureVac AG and CureVac Real Estate GmbH for German corporate tax purposes of approximately €413,325,000 (€398,322,000 for CureVac AG and €15,003,000 for CureVac Real Estate GmbH) and for German trade tax purposes of approximately €411,014,000 (€396,342,000 for CureVac AG and €14,672,000 for CureVac Real Estate GmbH) available. The intended contribution of 100% of CureVac AG's shares into CureVac B.V. qualifies 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.

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.

Investors purchasing common shares in this offering will experience immediate and substantial dilution as a result of this offering and any future equity issuances.

The initial public offering price of our common shares is substantially higher than the pro forma net tangible book value per common share. Dilution is the difference between the initial public offering price per common share and the pro forma net tangible book value per common share after this offering. If you purchase common shares in this offering, you will incur immediate and substantial dilution in the amount of $ per common share. We also have approximately outstanding share options to purchase common shares with exercise prices that are below the assumed initial public offering price of the common shares. To the extent that these options are exercised, there will be further dilution. See "Dilution."

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. Prior to the closing of this offering, our management board, subject to approval of our supervisory board, will be 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.

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 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. 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 prospectus.

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.

Upon the closing of this offering, we will be a Dutch public company. 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.

Upon the closing of this offering, we will be a public company (*naamloze vennootschap*) organized under the laws of the Netherlands. Our corporate affairs are governed by our articles of association 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, your interests as a shareholder.

For more information on relevant provisions of Dutch corporation law and of our articles of association, see “Description of Share Capital and Articles of Association” and “Comparison of Dutch Corporate Law and U.S. Corporate Law.”

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, 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 prepared by our supervisory board which can only be overruled by a two-thirds majority of votes cast representing more than 50% 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 in which case a simple majority of the votes would be sufficient);
- a provision allowing, among other matters, the former chairman of our supervisory board or our former CEO, as applicable, to manage our affairs if all of our managing directors and supervisory directors are removed from office and to appoint others to be charged with the management and supervision of our affairs, until new managing directors and supervisory directors are appointed by the general meeting on the basis of a binding nomination discussed above; 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.

We are not obligated to, and do not, comply with all best practice provisions of the Dutch Corporate Governance Code.

Upon the closing of this offering, we will be 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 “Description of Share Capital and Articles of Association.” This may affect your rights as a shareholder and you 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 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.

Prior to this offering, we have been 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 accountants identified a material

weakness in our internal control over financial reporting. 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 consistent application of 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 capitalization of tangible and intangible assets. Additionally, certain of our documentation was insufficient for assessment of critical accounting guidance for complex or judgmental areas, including share-based compensation. 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 related to this offering and expect to continue to do so while we remediate this material weakness.

We have initiated a remediation plan to address this material weakness; however, our control environment can still be improved, and as a result, we may be exposed to errors. We plan to take additional steps to remediate the material weakness and improve our accounting function, including hiring of additional senior level and staff accountants to support the timely completion of financial close procedures, implement robust processes, and provide additional needed technical expertise, and in the interim, continuing 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 intend to develop and implement consistent accounting policies, internal control procedures and provide additional training to our accounting and finance staff.

While we are working to remediate the weakness as quickly and efficiently as possible, we cannot at this time, provide an estimate of the timeframe 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 result of becoming a public company, we will be 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 accountants as to our internal control over financial reporting for the foreseeable future.

When we become a public company following this initial public offering, we will be 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 following the completion of this offering. The process of designing and implementing internal control over financial reporting required to comply with this requirement will be 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 "—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." 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 accounting 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 accounting 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 later of the filing of our second annual report following the completion of this offering or the date we are no longer an "emerging growth company," as defined in the JOBS Act. Accordingly, you will 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 accounting 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.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this prospectus 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 prospectus 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 prospectus. 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;
- 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 use of proceeds from this offering;
- 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 “Risk Factors.”

You should read this prospectus 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 prospectus 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.

USE OF PROCEEDS

We estimate that the net proceeds to us from the offering will be approximately $, assuming an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our net proceeds, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and offering expenses, by $ million. If the underwriters exercise in full their option to purchase additional shares, we estimate that the net proceeds from this offering will be approximately $ million.

We intend to use the net proceeds from this offering, together with cash and cash equivalents on hand, as follows:

- to advance the development of our preclinical and clinical programs;
- to invest in further development of our mRNA technology platform;
- to fund the expansion of our manufacturing capabilities; and
- the remainder for working capital and general corporate purposes.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors. As a result, our management will have broad discretion in the application of the net proceeds of this offering, and investors will be relying on our judgment regarding the application of the net proceeds.

Pending their use, we plan to invest the net proceeds of this offering in short- and intermediate-term interest-bearing investments.

We believe that the anticipated net proceeds from this offering, together with 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 through . 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. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Contractual Obligations and Commitments — Future Capital Requirements” and “Risk Factors — Risks Related to Our Financial Position and Need for Additional Capital — We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability” and “— Even if we consummate this offering, we will require substantial additional financing, which may not be available on acceptable terms, or at all. Raising additional capital may cause dilution to our shareholders, including purchasers of common shares in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.”

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common shares, and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. As of the completion of our corporate reorganization, under Dutch law, we may only pay dividends to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-in and called-up share capital plus the reserves required to be maintained by Dutch law or by our articles of association and (if it concerns a distribution of profits) after adoption of the annual accounts by the general meeting from which it appears that such dividend distribution is allowed. Subject to such restrictions, any future determination to pay dividends will be at the discretion of our management board with the approval of our supervisory board and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our management board and supervisory board deem relevant.

Under our articles of association, our management board may decide that all or part of the profits are added to our reserves. After reservation of any profit, the remaining profit will be at the disposal of the general meeting for distribution, subject to restrictions of Dutch law and approval by our supervisory board. Our management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting, but only with the approval of the supervisory board. Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

CORPORATE REORGANIZATION

Introduction

CureVac B.V. is a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) that was incorporated for the purpose of making this offering. Upon the incorporation of CureVac B.V., Mr. Franz-Werner Haas, our chief operating officer, became the sole director and the sole shareholder of CureVac B.V., holding one common share in the capital of CureVac B.V., the nominal value of which (in the amount of €0.12) has not been paid-in. CureVac B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. As part of the corporate reorganization, all of the interests in CureVac AG will be exchanged for new common shares of CureVac B.V. to be issued to the existing security holders of CureVac AG in the course of such exchange in the course of a capital increase of CureVac B.V., and as a result, CureVac AG will become a wholly owned subsidiary of CureVac B.V., while the current shareholders of CureVac AG will become the shareholders of CureVac B.V. In connection with such exchange, the common share in CureVac B.V. held by Mr. Franz-Werner Haas will be cancelled (*ingetrokken*). Subsequently, CureVac B.V. will convert into a Dutch public company (*naamloze vennootschap*) and change its name to CureVac N.V. Therefore, investors in this offering will only acquire, and this prospectus only describes the offering of, common shares of CureVac N.V. We refer to the reorganization described above as our "corporate reorganization."

The corporate reorganization will take place in several steps as described below.

Exchange of CureVac AG Securities for CureVac B.V. Common Shares

Immediately following the pricing of this offering, the existing shareholders of CureVac AG will each become a party to a separate notarial deed of issue under Dutch law, the existing shareholders will (i) subscribe for new common shares in CureVac B.V. and (ii) agree to transfer their respective shares in CureVac AG to CureVac B.V. as a contribution in kind against issuance of the aforementioned common shares in CureVac B.V. in the course of a capital increase of CureVac B.V. Immediately thereafter, the existing shareholders of CureVac AG will effect such transfer of their respective shares in CureVac AG to CureVac B.V.. As a result of the issuance of common shares in CureVac B.V. to the shareholders of CureVac AG as consideration for the contribution and transfer of their respective shares in CureVac AG to CureVac B.V., CureVac B.V. will become the sole shareholder of CureVac AG.

Shares of CureVac B.V. to be Outstanding After the Corporate Reorganization

Shares of CureVac AG will be exchanged for common shares of CureVac B.V. on a -to- basis as provided for in each notarial deed of issue.

Upon completion of this share exchange (and prior to the closing of this offering), the current shareholders of CureVac AG will hold an aggregate of common shares of CureVac B.V.

Conversion of CureVac B.V. into CureVac N.V.

As part of the corporate reorganization, the legal form of CureVac B.V. will be 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. will become effective. Such final step will take place by means of the execution of a notarial deed of conversion and amendment, which will take place prior to the listing of our common shares on Nasdaq. This deed of conversion and amendment shall be executed following the delivery of a Dutch auditor's statement confirming that, on a day within five months prior to the conversion, our shareholders' equity was at least equal to the paid-in part of our issued share capital as set forth in the deed of conversion and amendment. The conversion will result in a name change from CureVac B.V. to CureVac N.V. Our articles of association, as they will read upon the closing of this offering, are further described in the section "Description of Share Capital and Articles of Association" and are filed (as an English translation of the official Dutch version) as an exhibit to the registration statement of which this prospectus forms a part.

CAPITALIZATION

The table below sets forth our cash and cash equivalents and capitalization (defined as long-term debt and shareholders' equity) as of December 31, 2019 derived from our audited consolidated financial statements prepared in accordance with IFRS as issued by the IASB:

- on an actual basis;
- on a pro forma basis to give effect to our corporate reorganization; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of common shares in this offering, assuming an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

This table should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Corporate Reorganization," "Certain Relationships and Related Party Transactions" and the consolidated financial statements and notes thereto appearing elsewhere in this prospectus.

	December 31, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted[1]
	(in thousands of euros)		
Cash and cash equivalents	30,684		
Convertible loans	65,018		
Equity:			
Issued capital	727		
Capital reserve	472,396[2]		
Accumulated deficit	(515,947)		
Other comprehensive income	22		
Total shareholders' equity	(42,802)		
Total capitalization	**22,216**		

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $ million, assuming the assumed initial public offering price remains the same. The actual net proceeds payable to us will adjust based on the actual number of common shares sold by us, the actual public offering price and other terms of the offering determined at pricing. U.S. dollar amounts have been translated into euros at a rate of USD to €1.00, the official exchange rate quoted as of , 2020 by the Federal Reserve Bank of New York. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of euros at the dates indicated.

(2) Includes €7,604,000 equity component of outstanding convertible loans.

DILUTION

If you invest in our common shares in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share and the as adjusted net tangible book value per common share after this offering.

At December 31, 2019, we had a pro forma net tangible book value of $ million (€ million), corresponding to a pro forma net tangible book value of $ per common share (€ per common share). Pro forma net tangible book value represents the amount of our total assets less our total liabilities, excluding intangible assets, divided by , the number of common shares issued and outstanding, after giving effect to the corporate reorganization.

After giving further effect to the sale of the common shares offered by us in the offering at an assumed initial public offering price of $ per common share (€ per common share), which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value estimated at December 31, 2019 would have been approximately $ (€), representing $ per common share (€ per common share). This represents an immediate increase in pro forma net tangible book value of $ per common share (€ per common share) to existing shareholders and an immediate dilution in net tangible book value of $ per common share (€ per common share) to new investors purchasing common shares in this offering. Dilution for this purpose represents the difference between the price per common shares paid by these purchasers and net tangible book value per common share immediately after the completion of the offering.

The following table illustrates this dilution to new investors purchasing common shares in the offering.

	$	€
Assumed initial public offering price per common share		
Pro forma net tangible book value per common share at December 31, 2019 after giving effect to the corporate reorganization		
Increase in net tangible book value per common share attributable to new investors		
Pro forma as adjusted net tangible book value per common share at December 31, 2019 after giving effect to the corporate reorganization and the offering		
Dilution per common share to new investors		
Percentage of dilution per common share to new investors		

Each $1.00 increase (decrease) in the offering price per common share, respectively, would increase (decrease) the pro forma as adjusted net tangible book value after this offering by $ per common share (€ per common share) and the dilution to new investors purchasing common shares in the offering by $ per common share (€ per common share). Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the pro forma as adjusted net tangible book value after this offering by $ per common share (€ per common share) and the dilution to new investors purchasing common shares in the offering by $ per common share (€ per common share).

If the underwriters were to fully exercise their option to purchase additional shares, the pro forma as adjusted net tangible book value per common share after the offering would be $ per common share (€ per common share), and the dilution per common share to new investors would be $ per common share (€ per common share), in each case at the initial public offering price of $ per common share (€ per common share).

SELECTED CONSOLIDATED FINANCIAL INFORMATION

The following selected consolidated statement of financial position as of December 31, 2018 and 2019 and the consolidated statement of operations and comprehensive income (loss) for the years ended December 31, 2018 and 2019 of CureVac AG are derived from the consolidated financial statements included elsewhere in this prospectus, which have been audited by Ernst & Young.

We maintain our books and records in euros, and we prepare our financial statements under IFRS as issued by the IASB.

CureVac B.V. is a newly formed holding company formed for the purpose of effecting the offering and has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. CureVac B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Accordingly, summary financial information for CureVac B.V. is not presented. CureVac AG's financial statements, including the notes thereto, are included elsewhere in this prospectus.

This financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, including the notes thereto, included elsewhere in this prospectus.

	For the Years Ended December 31,	
(in thousands of euros, except per share amounts)	**2018**	**2019**
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)	**(98.05)**	**(137.45)**

	As of December 31,	
	2018	**2019**
	(in thousands of euros)	
Statement of Financial Position Data:		
Cash and cash equivalents	21,380	30,684
Total assets	125,659	130,620
Total liabilities	93,576	173,422
Total equity	32,083	(42,802)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with CureVac AG's audited consolidated financial statements as of and for the years ended December 31, 2018 and 2019 and the notes thereto, included elsewhere in this prospectus, as well as the information presented under "Selected Consolidated Financial Information." 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 "Risk Factors" and elsewhere in this prospectus.

On April 7, 2020, CureVac B.V. was incorporated under the laws of the Netherlands to become the holding company for CureVac AG in connection with this offering pursuant to the corporate reorganization. See "Corporate Reorganization." CureVac B.V. has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. CureVac B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Accordingly, financial information for CureVac B.V. and a discussion and analysis of its results of operations and financial condition for the period of its operations prior to the corporate reorganization would not be meaningful and are not presented. Following the corporate reorganization, CureVac N.V. will become the holding company of CureVac AG and the historical consolidated financial statements of CureVac AG included in this Registration Statement will become part of the historical consolidated financial statements of CureVac N.V.

Overview

We are a leading global clinical-stage 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 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 oncology, prophylactic vaccines and protein therapy. Our lead clinical programs, CV8102 for the treatment of four types of solid tumors and CV7202 for potential vaccination against rabies, have generated promising early efficacy and safety results in clinical trials. In addition, we are rapidly advancing our mRNA vaccine against SARS-CoV-2 through preclinical studies and expect to initiate the first Phase 1/2a clinical trial in .

As of December 31, 2019, we had cash and cash equivalents amounting to €30.7 million. We have incurred significant losses since our inception. Our consolidated net loss for the year ended December 31, 2019 was €99.9 million. As of December 31, 2019, our accumulated deficit was €515.9 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. 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.

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 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.

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 oncology, infectious diseases and protein delivery.

For more information on our proprietary technology and clinical development pipeline, see "Business — 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.

We have historically been able to fund the research and development expenses primarily through 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.

The net proceeds to us from this offering will also be an important source of funds for our research and development. For more information on the nature of the intended uses for the proceeds from this offering, see "Use of Proceeds."

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 complete 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 "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.

Our Collaborations and Related License 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. 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. As part of our business development strategy, we aim to increase the number of our strategic collaborations in order to derive further value from our platform and more fully exploit their potential.

Certain key terms of our current material collaboration and license agreements are summarized below. For further details on our collaboration agreements, see “Business — Collaborations.”

Genmab

In December 2019, we entered into a Collaboration and License Agreement, which we refer to as 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 agreed to pay us a $10 million upfront fee and made a €20 million equity investment in March 2020. Genmab will be obligated to pay us fees upon the selection of each additional product concept for development under the Genmab Agreement, upon selection of a product targeting Genmab’s proprietary antibody for further development and commercialization and upon each exercise of its option to obtain a commercial license. 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 and we would be eligible to receive up to between $275 million and $368 million in development, regulatory and commercial milestones for each product, depending on the specific product concept. In addition, we are eligible to receive tiered royalties in the range from mid single digits up to low double digits on net sales of licensed products on a per product basis. 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.

Arcturus

In January 2018, we entered into a Development and Option Agreement, which we refer to as 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 agreed to pay Arcturus an upfront fee of $5 million and are required to reimburse Arcturus for certain costs incurred in connection with development activities and to pay additional fees upon each acceptance of an irrevocable offer to obtain a license for

further development and commercialization with respect to a selected target. We will additionally be required to make certain royalty payments on net sales of licensed products and certain milestone payments under the license agreements to be entered into upon each acceptance of such irrevocable offer with respect to each target. As of December 31, 2019, we have not accepted such offer with respect to any targets.

Acuitas

In April 2016, we entered into a Development and Option Agreement, which we refer to as 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 an annual target reservation and maintenance fee for each target we reserve under the Acuitas Agreement and to reimburse Acuitas for certain costs incurred in connection with development activities. We are additionally required to pay an option exercise fee upon each exercise of our option to obtain a license for further development and commercialization with respect to a selected target. As of December 31, 2019 we have exercised our option to obtain a nonexclusive license to nine targets.

For each option that we have exercised under the Acuitas Agreement, we have entered into a nonexclusive 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 milestone payments under each Acuitas License Agreement and we must pay Acuitas annual fees for any additional protein targeted by a vaccine product licensed under each Acuitas License Agreement. We additionally are obligated to pay Acuitas a royalty on net sales of licensed products. As of December 31, 2019, we have made a milestone payment to Acuitas with respect to the license agreement relating to Rabies RAV-G and have not made any royalty payments.

CRISPR Therapeutics

In November 2017, we entered into a Development and License Agreement, which we refer to as 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.

We are eligible to receive up to a low nine-figure amount in development and 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.

Boehringer Ingelheim

In August 2014, we entered into an Exclusive Collaboration and License Agreement, which we refer to as 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 (former CV9202).

We received an upfront payment of €30 million, as well as, an option fee payment of €5 million. As of December 31, 2019, we have received an additional €7 million in milestone payments. We are eligible to receive up to an additional mid nine-figure amount in development, regulatory and commercial milestones as well as royalties in the low teens on net sales of licensed products.

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 for up to a low seven-figure amount. 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 a high six-figure amount in funding from the Bill & Melinda Gates Foundation for the development of a vaccine for picornaviruses. In November 2017, we were awarded two additional grants each for up to a low seven-figure amount in funding from the Bill & Melinda Gates Foundation for the development of a universal influenza and a malaria vaccine respectively.

Coalition for Epidemic Preparedness Innovations

In February 2019, we entered into a framework partnership agreement, which we refer to as 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 a SARS-CoV-2 vaccine. CEPI agreed to contribute up to approximately $34 million in funding for projects undertaken under the CEPI Agreement and an additional $8.3 million in connection with development of the SARS-CoV-2 vaccine.

Tesla Grohmann

In November 2015, we entered into a development and intellectual property agreement, which we refer to as 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 additional commercial milestone payments of up to an aggregate mid eight-figure amount in commercial milestone payments as well as certain development costs under each associated work order.

Results of Operations

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 prospectus, as well as the information presented under “Selected Financial Information.”

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.

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

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

(in thousands of EUR, except per share data)	For the Years Ended December 31, 2018	2019
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)	**(98.05)**	**(137.45)**

Revenue

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. Certain of these payments are initially recorded on our statement of financial position and are subsequently recognized as revenue in accordance with our accounting policy as described further in "Critical Accounting Policies and Estimates" and note 2 to our consolidated financial statements included elsewhere in this prospectus.

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 higher product sales in 2019 under our collaboration agreements.

Cost of sales

Cost of sales consists primarily of personnel costs, costs for materials and third-party services, as well as maintenance and lease costs (for 2018), and depreciation and amortization.

Cost of sales was €28.0 million for 2019, representing an increase of €10.3, or 58%, from €17.7 million for 2018. The increase was primarily attributable to higher third-party laboratory services expenses, cost of materials related to higher product sales under our collaboration agreements and personnel costs.

	For the years ended December 31,	
	2018	2019
	(in thousands of euros)	
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 primarily consist of personnel expenses which include salary and salary-related expenses and expenses from share-based compensation.

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 thousands of euros)	
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 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.

We also have partnered programs as further described under “Business — Collaborations,” 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.

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 thousands of euros)	
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)**

We expect that our total research and development expenses in 2020 will be significantly higher compared to our expenses in 2018 and 2019. Such increased research and development expenses primarily relate to the following key programs:

- Our lead oncology program, CV8102, which is currently in a Phase 1/2 dose escalating clinical trial for four types of solid tumors as a monotherapy and in combination with anti-PD-1.
- Our lead vaccine program, CV7202, which is currently in a Phase 1 clinical trial as a vaccine candidate for rabies.
- Our mRNA vaccine program against SARS-CoV-2, which we are advancing in response to the global pandemic due to COVID-19.

General and administrative expenses

General and administrative expenses generally include wages and salaries, share-based compensation, fringe benefits and other personnel costs of our senior management and administrative personnel, costs for professional services, including legal, audit and consulting services and costs of facilities and office expenses. We expect that our general and administrative costs will increase as a result of a greater level of support for our increasing research and development activities, potential commercialization of our product candidates and costs associated with being a public company in the United States.

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 thousands of euros)	
Personnel	(10,084)	(31,645)
Maintenance and lease costs	(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

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.

Overview

Since inception, we have incurred significant operating losses. For the years ended December 31, 2018 and 2019, we incurred net losses of €71.2 million and €99.9 million, respectively. To date, we have financed our operations primarily through 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, 2018 and 2019 were at €21.4 million and €30.7 million, respectively. Our primary cash needs are for working capital requirements, capital expenditures and to fund our non-clinical and clinical development programs.

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 (“Convertible Loan I”). On October 24, 2019, we entered into an additional convertible loan agreement with Mr. Hopp, 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, if our cash balance falls below €15 million (“Convertible Loan II,” and together with Convertible Loan I, the “Loans”). The Loans bear an interest rate

of 8.00% per annum. As of December 31, 2019, the outstanding principal amount is €69.9 million. Upon consummation of this offering the amount outstanding, including accrued interest under the Loans, could be converted into shares of CureVac AG that will be contributed and transferred to CureVac B.V. in a capital increase in exchange for newly issued common shares of CureVac B.V. as part of our corporate reorganization. See note 12 to our financial statements contained elsewhere in this prospectus for further information on the Loans and "Corporate Reorganization" for further information on our corporate reorganization.

Comparative Cash Flows

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 thousands of euros)	
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.

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.

Contractual Obligations and Commitments

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019 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	2020	2021	2022	2023	2024	Thereafter
	(in thousands of Euros)						
Convertible loans	(83,940)[1]	—	—	(83,940)	—	—	—
Lease liabilities	(17,121)	(2,843)	(2,298)	(2,298)	(2,298)	(2,298)	(5,086)
Total	**(101,061)**	**(2,843)**	**(2,298)**	**(86,238)**	**(2,298)**	**(2,298)**	**(5,086)**

(1) Upon consummation of this offering, based on the terms of the Loans, the amount outstanding, including accrued interest, could convert into shares of CureVac AG that will be contributed and transferred to CureVac B.V. in a capital increase in exchange for newly issued common shares of CureVac B.V. as part of our corporate reorganization.

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.

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.

Future Capital Requirements

We expect our expenses to increase in connection with our ongoing activities. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase if, and as, we:

- advance the development of our clinical programs;
- leverage our programs to advance our other product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to discover and develop additional product candidates;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, quality control and scientific personnel;
- expand and/or build out the manufacturing capacities and production volume of our GMP I/II and GMP III facilities, continue construction of our GMP IV facility, and construct or operate additional facilities;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- advance the testing, process development and operation of the RNA Printer™ prototypes;
- secure, maintain, expand, enforce and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

We believe that the anticipated net proceeds from this offering, together with 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 through . 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.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development

of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties and grants from organizations and foundations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that may adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts or to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Quantitative and Qualitative Disclosures About Market Risk

In the ordinary course of our business activities, we are exposed to various market risks that are beyond our control, including fluctuations in foreign exchange rates, which may have an adverse effect on the value of our financial assets and liabilities, future cash flows and profit. As a result of these market risks, we could suffer a loss due to adverse changes in foreign exchange rates in the countries in which we operate. Our policy with respect to these market risks is to assess the potential of experiencing losses and the consolidated impact thereof and to mitigate these market risks. We are not currently exposed to significant interest rate risk because we do not currently hold long-term debt that is exposed to market rates. See note 15 to our financial statements contained elsewhere in this prospectus for further information on our risk management policies and exposure to market risks.

Credit Risk

Our credit risk arises primarily 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. These financial instruments approximate fair value due to short-term maturities. We maintain our cash and cash equivalents and short-term investments with high credit quality financial institutions. We believe that our credit policies reflect normal industry terms and business risk.

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. Our exposure to the risk of changes in foreign exchange rates relates primarily to our operating activities (when revenue or expense is denominated in a foreign currency) and the amounts held as cash and cash equivalents. Our consolidated financial statements are reported in euros. We generate a significant portion of our revenue and incur a significant portion of our expenditures in certain non-euro currencies, principally U.S. dollars. We are exposed to fluctuations in foreign currency exchange rates primarily on revenue generated from sales in these foreign currencies. Our results of operations can be affected if the U.S. dollar appreciates or depreciates against the euro. As of December 31, 2019, if the euro had weakened 10% against the U.S. dollar with all other variables held constant, pre-tax loss for the year would have been €3.4 million (2018: €1.2 million) lower and post-tax loss would have been €2.4 million lower (2018: €0.8 million). Conversely, if the euro had strengthened 10% against the U.S. dollar with all other variables held constant, pre- tax loss would have been €2.8 million (2018: €1.0 million) higher and post-tax loss would have been €2.0 million (2018: €0.7 million) higher. The effects

on pre- and post-tax loss and (accumulated) other comprehensive income due to fact that our subsidiary CureVac Inc.'s functional currency is the U.S. dollar would still have been immaterial at December 31, 2019.

To the extent that we need to convert U.S. dollars we receive from this offering into foreign currencies for our operations, appreciation of such foreign currencies against the U.S. dollar would adversely affect the amount of such foreign currencies we receive from the conversion. Sensitivity analysis is used as a primary tool in evaluating the effects of changes in foreign currency exchange rates on our business operations. The analysis quantifies the impact of potential changes in these rates on our earnings, cash flows and fair values of assets and liabilities during the forecast period, most commonly within a one-year period. The ranges of changes used for the purpose of this analysis reflect our view of changes that are reasonably possible over the forecast period. Fair values are the present value of projected future cash flows based on market rates and chosen prices.

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. Our exposure to the risk of changes in market interest rates relates primarily to our cash and cash equivalents with floating interest rates. Due to persistent low-interest-rates we may be exposed to the risk of being charged negative interest rates on our bank deposits. If interest rates as of December 31, 2018 and 2019 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 €0.3 million (2018: €0.2 million) 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, 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 other comprehensive income.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. 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 judgments, estimates and assumptions" and "note 9 — Share-based payments" to our consolidated financial statements included elsewhere in this prospectus.

Recent Accounting Pronouncements

We have applied, in our consolidated financial statements for the year 2019, new standards and amendments as issued by IASB and that are mandatory as of January 1, 2019. See note 2 to our consolidated financial statements included elsewhere in this prospectus for further information these new standards and amendments.

The new standards and interpretations applicable on a mandatory basis for fiscal years beginning on or after January 1, 2019, as disclosed in note 2 to our financial statements, mainly relate to IFRS 16 Leases. IFRS 16 supersedes IAS 17 Leases, IFRIC 4 (Determining whether an Arrangement contains a Lease), SIC-15 (Operating Leases-Incentives) and SIC-27 (Evaluating the Substance of Transactions Involving the Legal Form of a Lease). The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model.

We adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of January 1, 2019. Under this method, the standard is applied retrospectively with the cumulative

effect of initially applying the standard recognized at the date of initial application. We elected to use certain transition practical expedients, including applying the standard only to contracts that were previously identified as leases applying IAS 17 and IFRIC 4 at the date of initial application.

The following several other amendments and interpretations apply for the first time in 2019:

- IFRIC Interpretation 23: Uncertainty over Income Tax Treatment
- Amendments to IFRS 9: Prepayment Features with Negative Compensation
- Amendments to IAS 19: Plan Amendment, Curtailment or Settlement
- Amendments to IAS 28: Long-term interests in associates and joint ventures
- Annual Improvements 2015-2017 Cycle
    - IFRS 3 Business Combinations
    - IFRS 11 Joint Arrangements
    - IAS 12 Income Taxes
    - IAS 23 Borrowing Costs

These standards did not have a material impact on our consolidated financial statements. We have not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

Internal Control Over Financial Reporting

Historically, we have been a private company and did not maintain the internal accounting and financial reporting resources necessary to comply with the obligations of a public reporting company, including maintaining effective internal control over financial reporting. We and our independent registered public accountants identified a material weakness primarily related to (i) a lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training and (ii) a lack of consistent application of our accounting processes and procedures. As a result of the material weakness, management failed to identify adjustments in various areas, including but not limited to grants from government agencies and similar bodies and capitalization of tangible and intangible assets.

We have initiated a remediation plan to address this material weakness; however, our control environment can still be improved, and as a result, we may be exposed to errors. Our remediation plan includes 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, and in the interim, continuing 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 intend to develop and implement consistent accounting policies and internal control procedures. In addition, we will provide additional training to our accounting and finance staff. While we are working to remediate the weakness as quickly and efficiently as possible, we cannot at this time, provide an estimate of the timeframe we expect in connection with implementing our plan to remediate this material weakness.

JOBS Act Exemptions and Foreign Private Issuer Status

JOBS Act

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management’s discussion and analysis of financial condition and results of operations in this prospectus;

- exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal controls over financial reporting; and
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions for up to five years or until such earlier time that we are no longer an emerging growth company. We will 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.

We may choose to take advantage of some but not all of these reduced burdens. For example, we have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus, and intend to take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F. To the extent that we take advantage of these reduced burdens, the information that we provide shareholders may be different than you might obtain from other public companies in which you hold equity interests.

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.

Foreign Private Issuer

We are also considered a "foreign private issuer." In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our managing directors, supervisory directors and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our common shares. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our managing directors or supervisory directors are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies.

BUSINESS

Overview

We are a leading global clinical-stage 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 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 oncology, prophylactic vaccines and protein therapy. Our lead clinical programs, CV8102 for the treatment of four types of solid tumors and CV7202 for potential vaccination against rabies have generated promising early efficacy and safety results in clinical trials. We are rapidly advancing our mRNA vaccine against SARS-CoV-2 through preclinical studies and expect to initiate the first Phase 1/2a clinical trial in .

mRNA-based medicines represent a foundational class of medicine that have the potential to address limitations of 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:*** increasing 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 continuously improve our technology platform and maintain flexibility in clinical development. We control the critical steps of manufacturing in-house, which allows us to drive innovation and to maintain flexibility, which allows us to pivot quickly in clinical development and potential commercialization. We currently operate three GMP-certified suites, with the capacity to supply our clinical programs and potential early commercialization activities. We are in the process of building a fourth GMP facility that will support our future commercial launches. Based on the doses and efficacy seen in our CV7202 study, we believe the fourth GMP facility could potentially supply materials for billions of doses of our vaccine product candidates. In addition to our GMP manufacturing facilities, we are developing a novel downsized and automated process for producing our mRNA, 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 first 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 rapid advances in de-risking our RNAoptimizer 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 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.

We are exploring a range of potential approaches in oncology including intratumoral therapy and novel cancer vaccines targeting neoepitopes and tumor associated antigens. mRNA-based medicines offer a versatile platform for cancer vaccine development, allowing us to encode a wide range of antigens from full length tumor associated antigens to neoepitopes. Our lead oncology candidate, CV8102, is a complex of single stranded non-coding RNA which has been optimized to maximize activation of the toll like receptors 7, or TLR7, TLR8 and retinoic acid-inducible gene I, or RIG-I pathways using an intratumoral approach. CV8102 is currently being evaluated in a Phase 1/2 clinical trial for the 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 2019, we have enrolled 32 patients (21 in the single agent cohort and 11 in the combination cohort with anti-PD-1) in the Phase 1 dose-escalation portion of the study. As of October 2019, in the single-agent cohort, we have observed a complete response in a stage IIIc melanoma patient and two additional patients have shown a stabilization of their disease, including shrinkage of non-injected lesions. Overall, six out of 21 patients treated with single agent CV8102 remained free of progression for at least six months. Based on the results from the Phase 1 clinical trial, we plan to determine the recommended dose for the Phase 2 expansion portion of the trial.

Our mRNA technology platform has shown potential in the development and production of prophylactic vaccines against infectious diseases. mRNA-based vaccines can encode for specific protein antigens of choice, including combinations of multiple antigens, offering potential for the development of prophylactic vaccines against multiple known and as yet unidentified pathogenic threats. mRNA vaccines are also generally expected to be safer than live or attenuated vaccines since no living virus is injected. Our lead 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 Phase 1 clinical trial, evaluating safety, including reactogenicity, and immunogenicity. In January 2020, we reported preliminary data from our Phase 1 trial of CV7202 in rabies. CV7202 induced adaptive immune response as shown by rabies-specific virus-neutralizing antibody titers, or VNTs, above the World Health Organization, or WHO, thresholds considered to be protective, 28 days 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 plan to report follow up data from our Phase 1 clinical trial in and initiate a Phase 2 clinical trial in .

In response to the global pandemic due to COVID-19, we have rapidly advanced our mRNA vaccine program against SARS-CoV-2. Upon publication of the sequence of the novel coronavirus disease (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. We have selected two constructs for further evaluation that encode for stabilized S-protein, which are currently undergoing preclinical testing. Exploratory data on these constructs indicated high immunogenicity and titers of S specific binding and

neutralizing antibodies in mice after a single vaccination. We intend to initiate the first Phase 1/2a clinical trial in healthy volunteers in , with initial results expected in . We are working closely with many organizations, including CEPI, on the development of this vaccine.

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. Our protein therapy platform has the potential to be used as a treatment against infectious diseases and toxins and to be applied in many disease indications including cancer, cardiovascular 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 therapeutic levels in the blood stream. We are also currently advancing multiple undisclosed programs in preclinical studies across liver and rare diseases, eye disorders, lung diseases as well as delivering therapeutic antibodies.

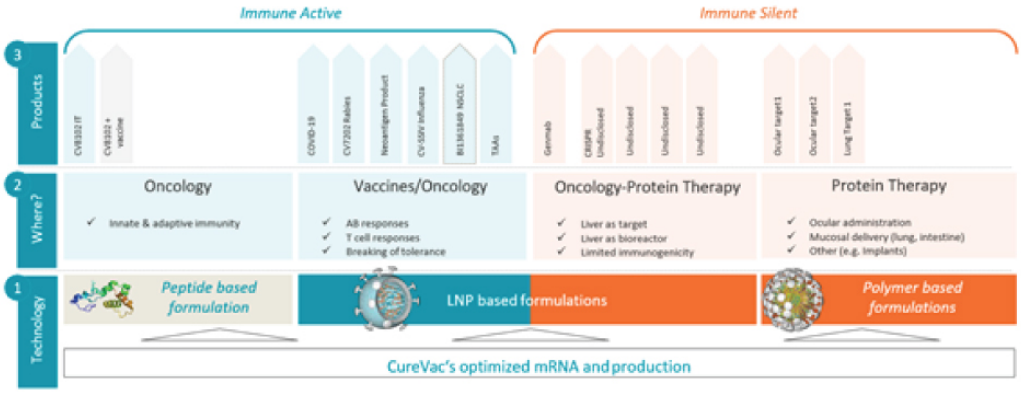
We have built an intellectual property portfolio in the United States, Europe and other major geographies. As of April 17, 2020, we own approximately 233 issued patents worldwide, including 47 issued U.S. patents, 50 issued European patents, and 136 issued patents in other foreign countries, 120 pending U.S. patent applications, 81 pending European patent applications and 312 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 SARS-CoV-2 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. We currently have over 450 employees, including 116 employees with advanced scientific degrees. Since our founding, we have raised approximately €451 million in gross proceeds from a combination of equity and convertible debt financings, with an additional €44 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 oncology, infectious diseases 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. Our approach is initially focused on RNA or mRNA-based medicines that trigger an immune response such as oncology and prophylactic vaccines. Based on the proof of concept clinical data from our prophylactic vaccine programs, we have expanded our product portfolio to include mRNA therapies based on the expression of therapeutic proteins (including liver, ocular and mucosal applications).



Our lead proprietary programs include:

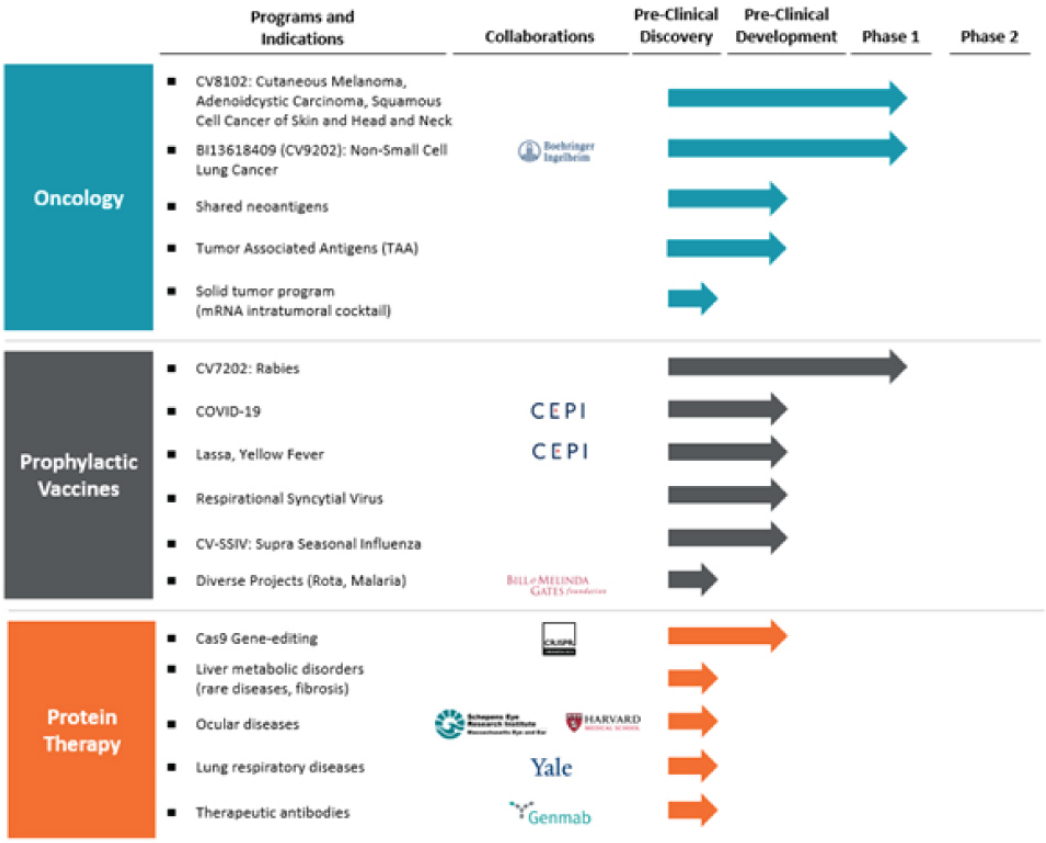
- Our lead oncology program, CV8102, is currently in a Phase 1/2 dose escalating clinical trial for four types of cancers as a monotherapy and in combination with anti-PD-1. Based on the results from the Phase 1 trial, we plan to determine the recommended dose for Phase 2 expansion portion of the trial.
- Our lead vaccine program, CV7202, is currently in a Phase 1 clinical trial as a vaccine candidate against rabies. We plan to report follow up data from our Phase 1 clinical trial in and to initiate a Phase 2 clinical trial in .
- In response to the global pandemic due to COVID-19, we have rapidly advanced our mRNA vaccine program against SARS-CoV-2. We are continuing to advance this program through preclinical testing in various animal models and intend to initiate a Phase 1/2a study in healthy volunteers in , with results expected in .

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 the development of several vaccine projects including programs against SARS-CoV-2, 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.



Our Strengths

We are developing a broad portfolio of product candidates that we believe position us at the forefront of targeted immune active and immune silent mRNA-based 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 advantages of the mRNA-based medicines over existing treatment modalities, 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 designed for efficacy, safety and protein expression at relatively low doses.** Our technology optimized for immune activation has shown promising results in multiple clinical studies. 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 efficacy with shrinkage of non-treated lesions, with limited treatment emergent adverse events. Our most clinically advanced vaccine product candidate, CV7202, for prophylactic vaccination against rabies, induced protective antibody titers above the WHO threshold in a Phase 1 study, following two doses as low as 1µg of mRNA. In addition, we have

rapidly advanced our mRNA vaccine program against SARS-CoV-2 in response to the COVID-19 global pandemic. We are continuing to advance this program through preclinical testing in various animal models and intend to initiate the first Phase 1/2a clinical trial in healthy volunteers in , with initial results expected in . We are working closely with many organizations, including CEPI, on the development of this vaccine. 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. 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 currently have three certified GMP suites, with the ability to produce mRNA material for our late stage clinical studies and early commercialization activities. In December 2019, our GMP III facility was certified by the EMA, allowing us to achieve additional scale. We are currently constructing our GMP IV facility which will allow us to scale up even further and provide supplies for our future commercialization efforts. Based on the doses and efficacy seen in our CV7202 study, we believe our fourth GMP facility could potentially supply materials for billions of doses of our vaccine product candidates.

- **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 Boehringer Ingelheim, CRISPR Therapeutics and Genmab. 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 April 17, 2020, we owned approximately 233 issued patents worldwide, including 47 issued U.S. patents, 50 issued European patents, and 136 issued patents in other foreign countries, 120 pending U.S. patent applications, 81 pending European patent applications and 312 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, Ipsen, LION Bioscience, Pharmacia (Pfizer), Pixium Vision, Sirona Dental Systems, Sygnis Pharma AG and other companies. Our broader team includes over 115 individuals with advanced scientific degrees working on advancing our mRNA platform.

Our Strategy

Our goal is to continue 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 while taking a de-risked 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 lead oncology candidate, CV8102, is currently being evaluated in a Phase 1/2 clinical trial for the treatment of four types of solid tumors — cMEL, ACC, SCC and HNSCC. Based on the results from the Phase 1 clinical trial, we plan to determine the recommended dose for the Phase 2 expansion portion of the trial. Similarly, our most clinically advanced vaccine candidate, CV7202, is currently in development for the prophylactic vaccination of rabies. We intend to report results from our Phase 1 clinical trial in and initiate a Phase 2 clinical trial in .

  Additionally, we have rapidly advanced our mRNA vaccines against SARS-CoV-2 through preclinical testing. We intend to initiate a Phase 1/2a study in healthy volunteers in , with results expected in , and the goal of quickly proceeding to late stage clinical development. Given the urgency of the need for an effective vaccine for COVID-19, we intend to pursue an accelerated clinical development pathway.

  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 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. We are currently building our GMP IV facility which would allow us to further scale up, reduce manufacturing time and reduce production costs. In addition, we are developing a new automated

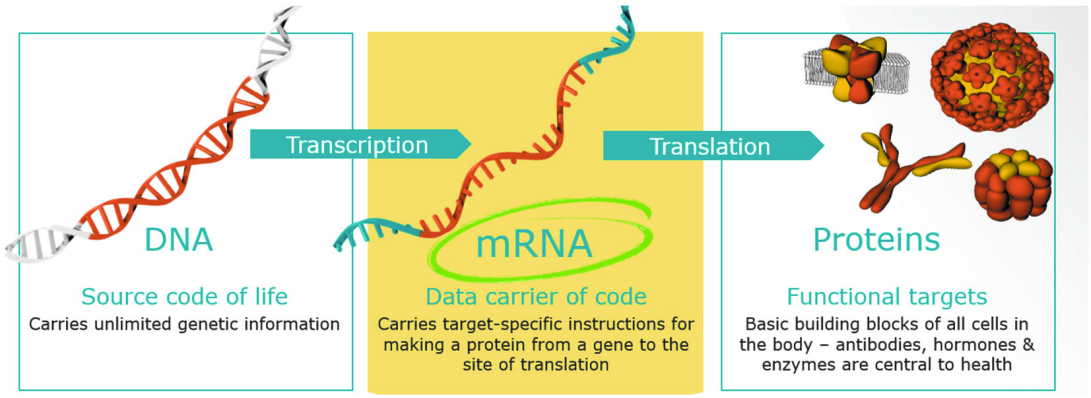
production concept, the RNA Printer, which would enable downscaling of the production of mRNA material, allowing us to be more flexible and respond rapidly to manufacturing needs. We have successfully manufactured a demonstration batch with the first RNA Printer prototype and are currently developing a second generation prototype.

- **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.


Transcription
Translation
DNA
Source code of life
Carries unlimited genetic information
mRNA
Data carrier of code
Carries target-specific instructions for making a protein from a gene to the site of translation
Proteins
Functional targets
Basic building blocks of all cells in the body – antibodies, hormones & enzymes are central to health

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.

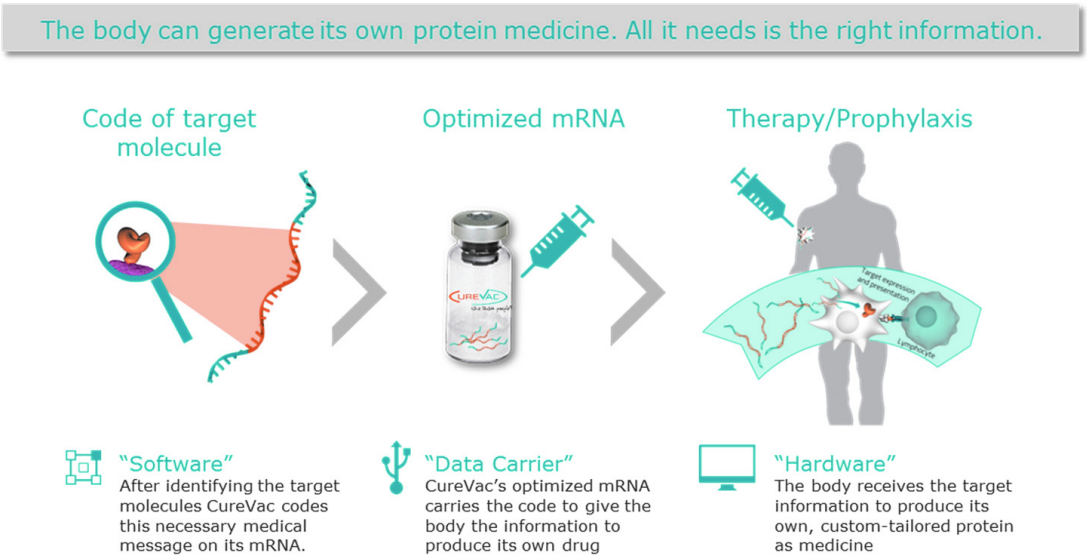
Small Molecule: While small molecules offer advantages over other treatment modalities in terms of biodistribution, tolerability, and delivery, they do not directly address specific gene defects and have a high potential to cause off-target toxicities.

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 advantages of mRNA therapies that could position it as a foundation 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.

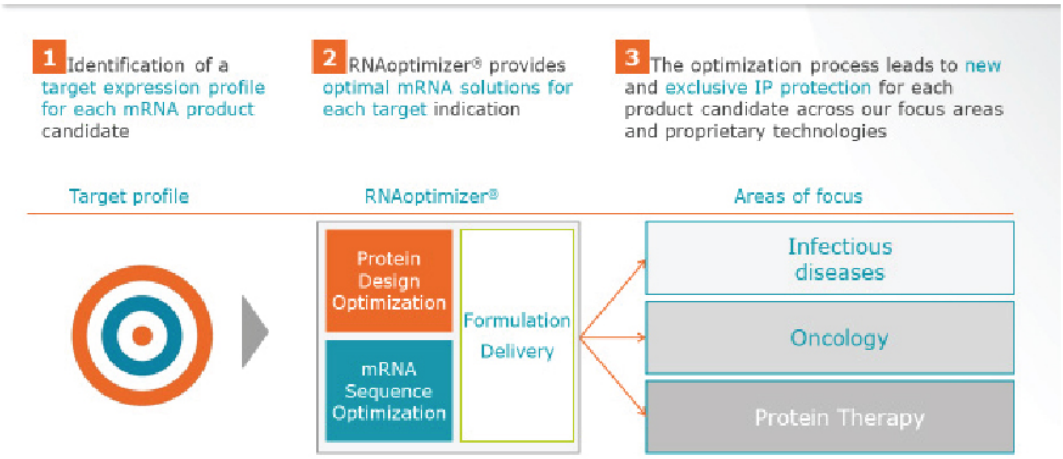
Our Proprietary Technology Platform

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 millions 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.

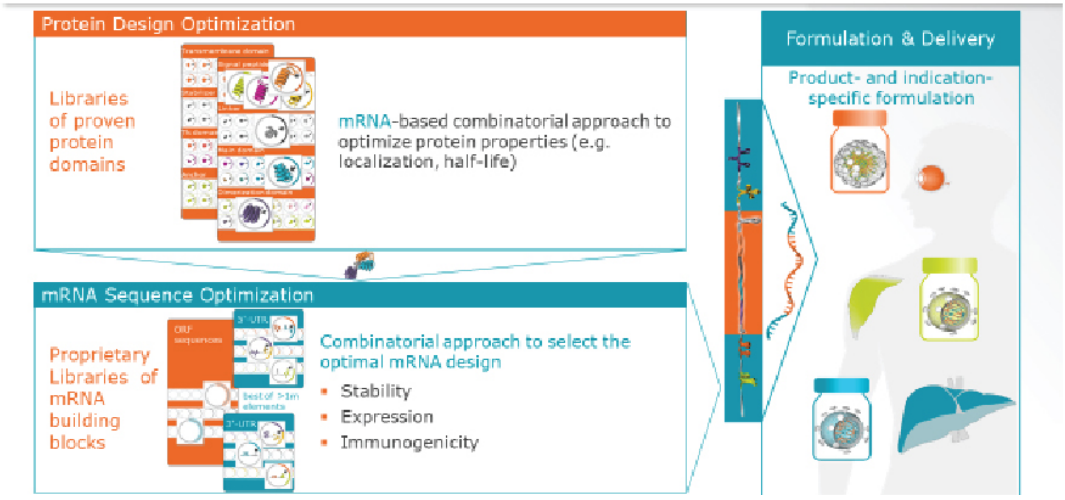
We have a long track record of performing clinical trials with multiple product candidates since 2008. The data generated in these clinical trials has allowed us to better understand the biology of mRNA and to further accelerate development in new therapeutic areas and approaches. We were the first company 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.


Protein Design Optimization
Libraries of proven protein domains
mRNA-based combinatorial approach to optimize protein properties (e.g. localization, half-life)
mRNA Sequence Optimization
Proprietary Libraries of mRNA building blocks
Combinatorial approach to select the optimal mRNA design
Stability
Expression
Immunogenicity
Formulation & Delivery
Product- and indication-specific formulation

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 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.

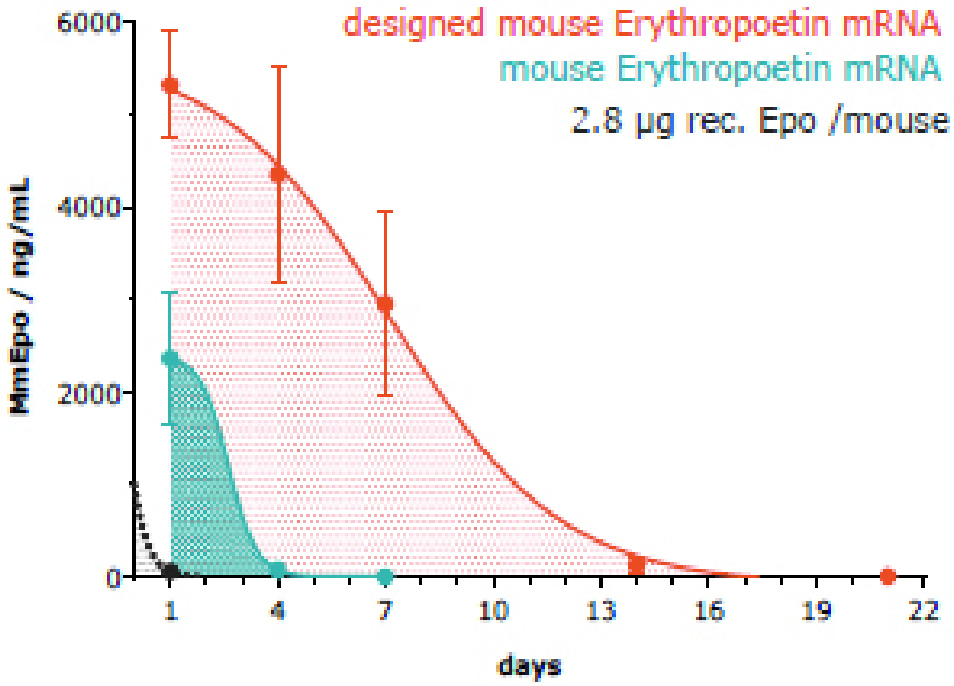
Protein design always depends on the function of the individual protein of interest. The protein can serve as a therapeutic protein without any activation of the immune system or the protein can serve as an antigen with the goal of inducing strong immune responses against it. We employ different optimization 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.

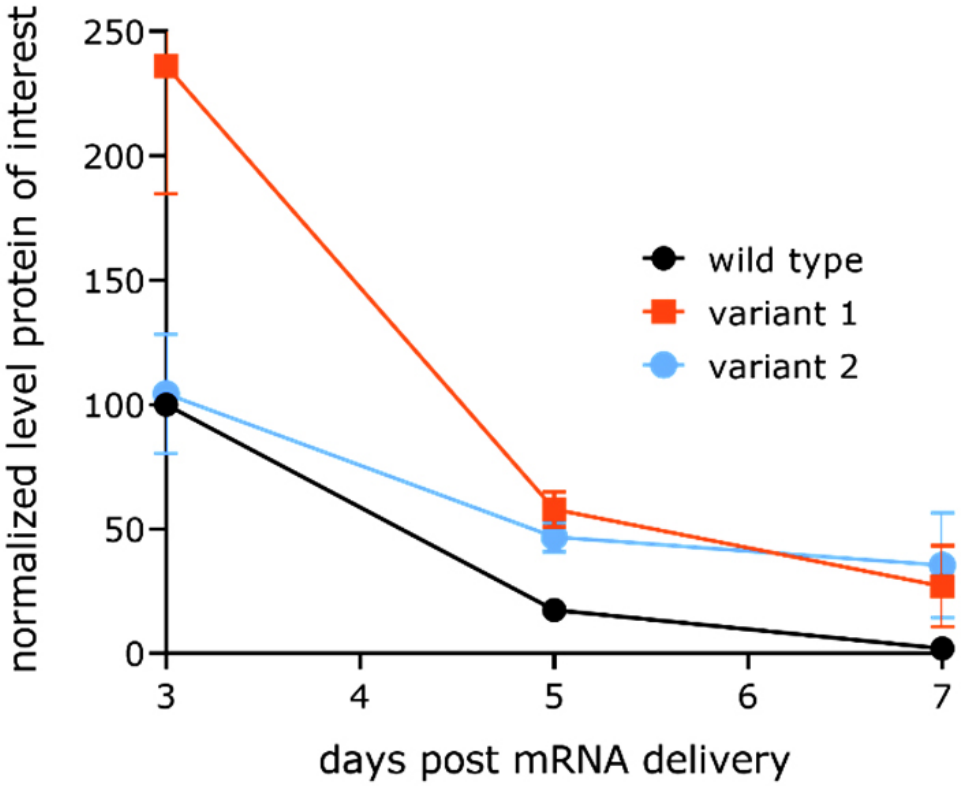
For example, wild type erythropoietin (Epo) is a protein that has a very short half-life of three to four hours in the bloodstream. In a preclinical model, mice were dosed with mouse Epo and protein engineered mouse Epo, both encoded with our optimized mRNA. Dosing with the engineered mouse Epo protein 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

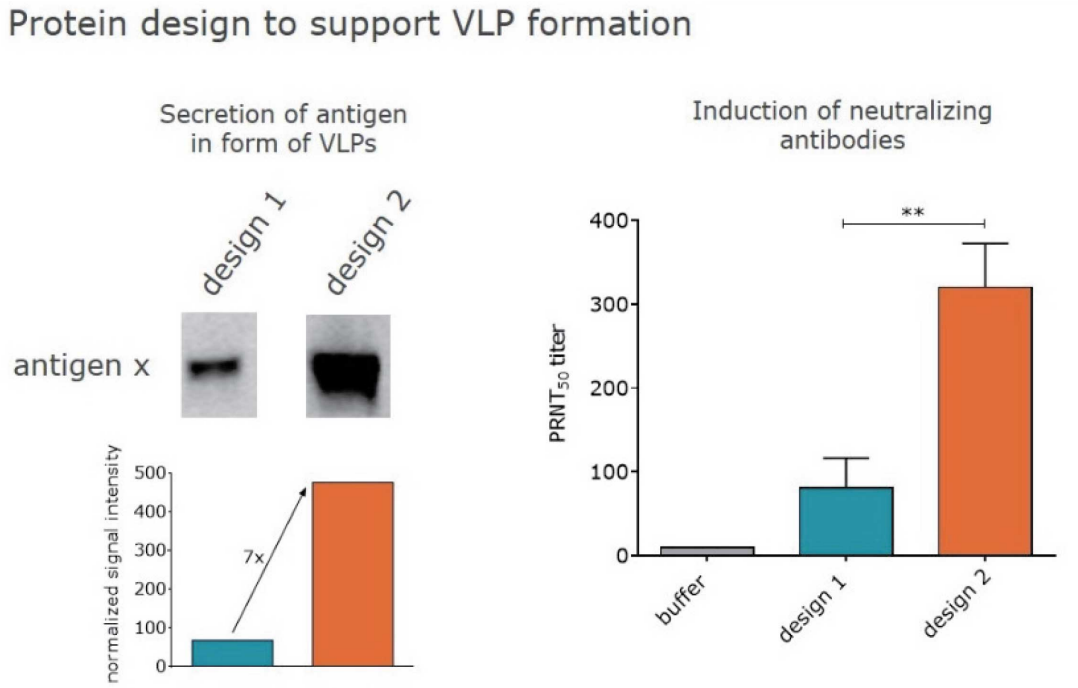
Similar approaches can also be applied to intracellular proteins, promoting the half-life of functional target proteins. In the example below, protein variant 1 represents the fusion of a protein of interest with a selected protein domain, while variant 2 represents a construct with a single point mutation 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. Notably, variant 1 and 2 had no deleterious effect on protein function.



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.

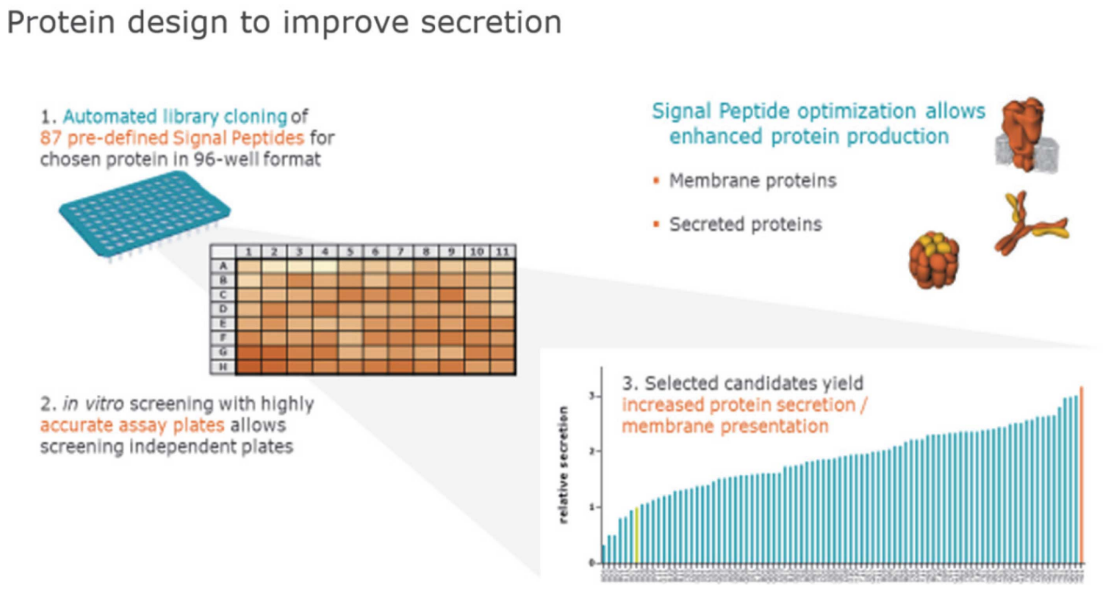


Protein sequence of viral antigen was optimized (design 2) by adding an element promoting secretion and clustering of antigen. In the left-hand side of the graphic, secretion of antigen in form of clusters was confirmed by Western Blot analysis of supernatants from transfected human cells. In the right-hand 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.

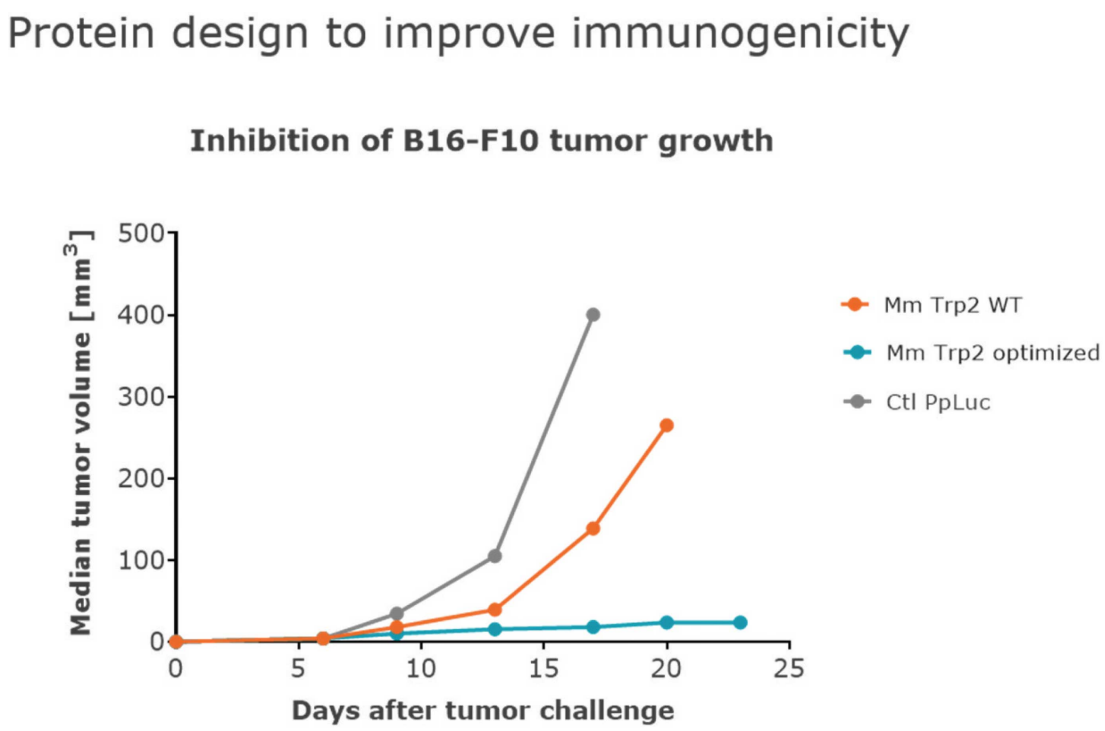
For example, we selected a set of 87 verified signal peptides to maximize secretion. These were combined with the novel target protein via automated cloning to enable facile screening and selection of the most potent product candidate. In the figure below, the top hit from this screen increased the secreted 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.


5`
Cap
5` UTR
Start
Stop
3`
Poly-A tail
Coding Sequence (CDS)
3` UTR

In addition to the coding sequence, mRNAs contain the following elements:

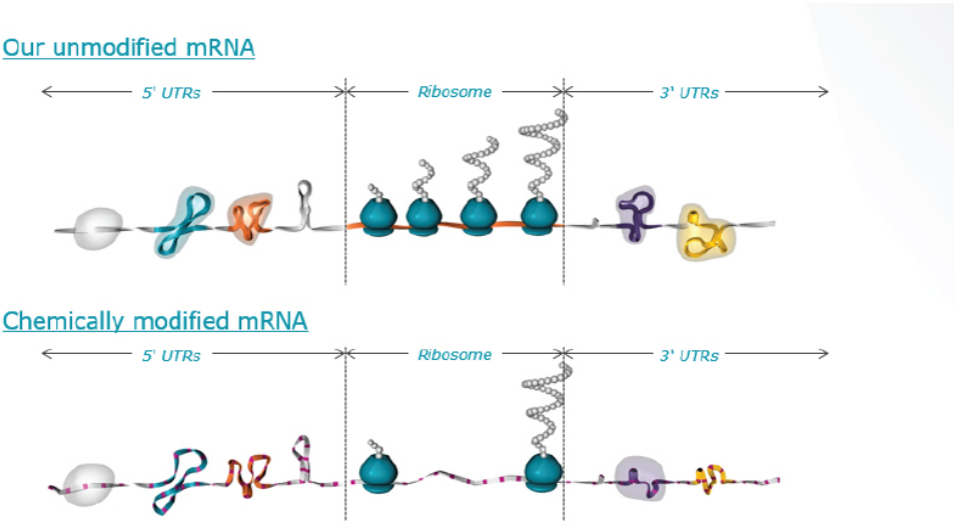
- Untranslated regions, or UTRs — UTRs are sequences that are not translated into protein. The 5' UTR precedes the start codon, the 3' UTR follows the stop codon. These regions play important roles in gene expression including mRNA stability, mRNA localization and translational efficiency via protein-RNA 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 efficacy of the mRNA construct. These elements include 5' cap, 5' UTR, ORF, 3' UTR, and 3' poly-A tail and 3' end.

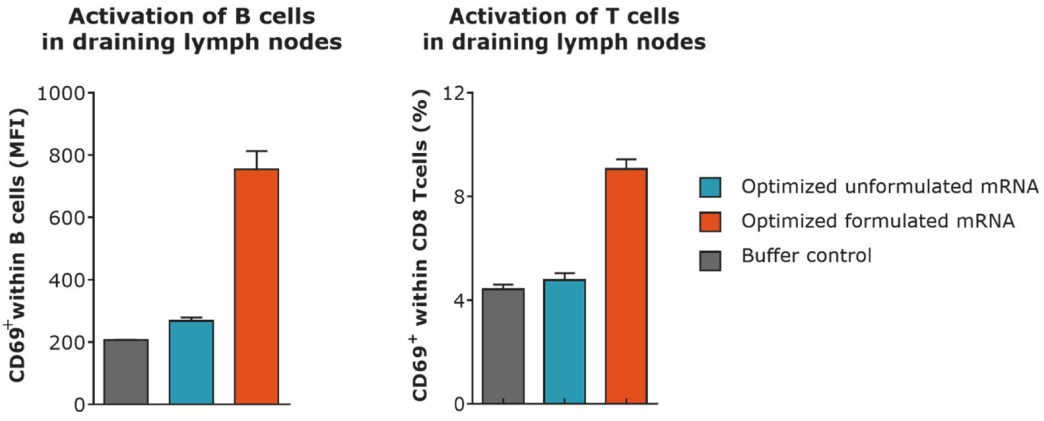
Depending on the target and indication, the required pharmacokinetics of protein expression might be different. Some applications may require the highest possible protein expression but only for a limited time, as is the case for gene editing approaches. For other applications, for example some protein 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 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.



With unmodified mRNA, we do not require additional structural optimization to restore protein-RNA interactions. It is an inherent feature of our natural building blocks.

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 shut down 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.

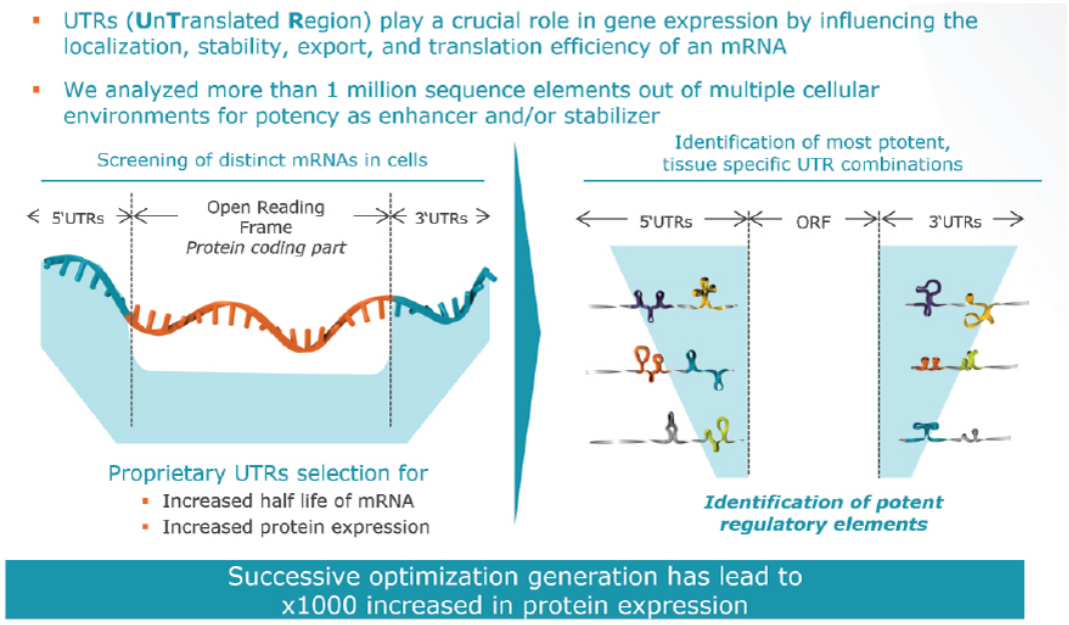
Cap structure

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

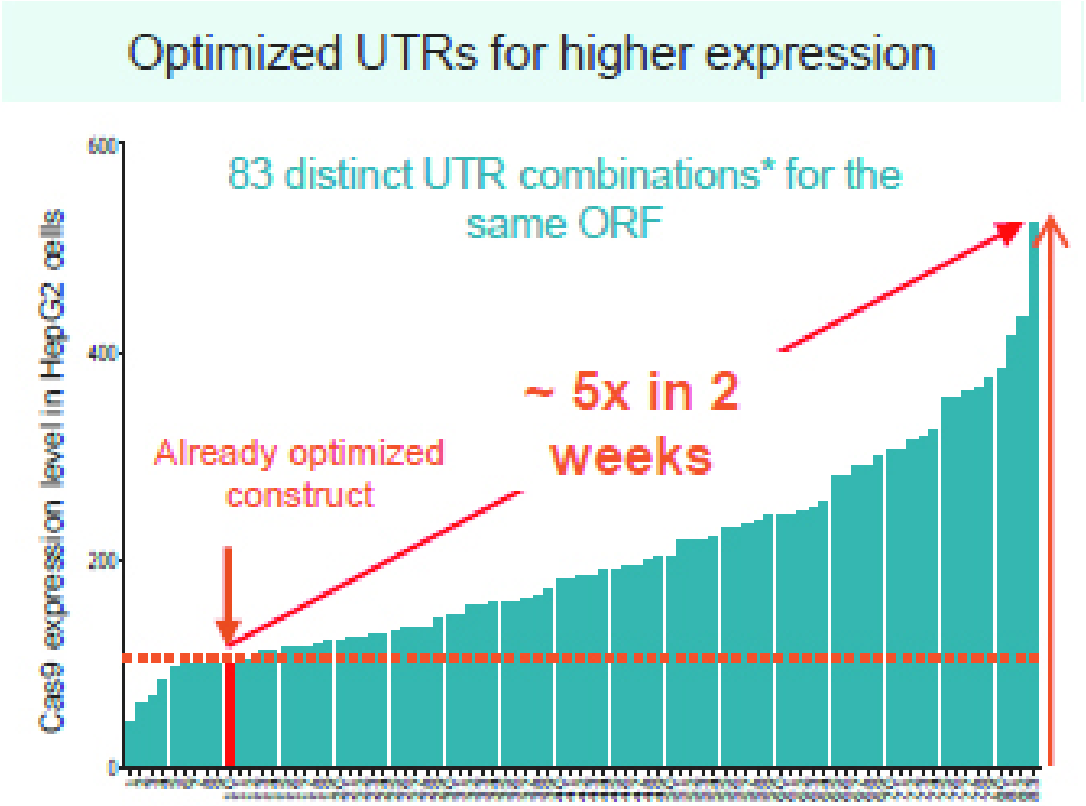
is recognized by yet other sensors of the innate immune system. Accordingly, there is great potential to improve protein expression and immunosilence in mRNA by optimizing the cap structure. We have access to several cap structures, including those we have developed and commercially available ones.

5' and 3' UTRs

We have identified over six million 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 within several weeks.

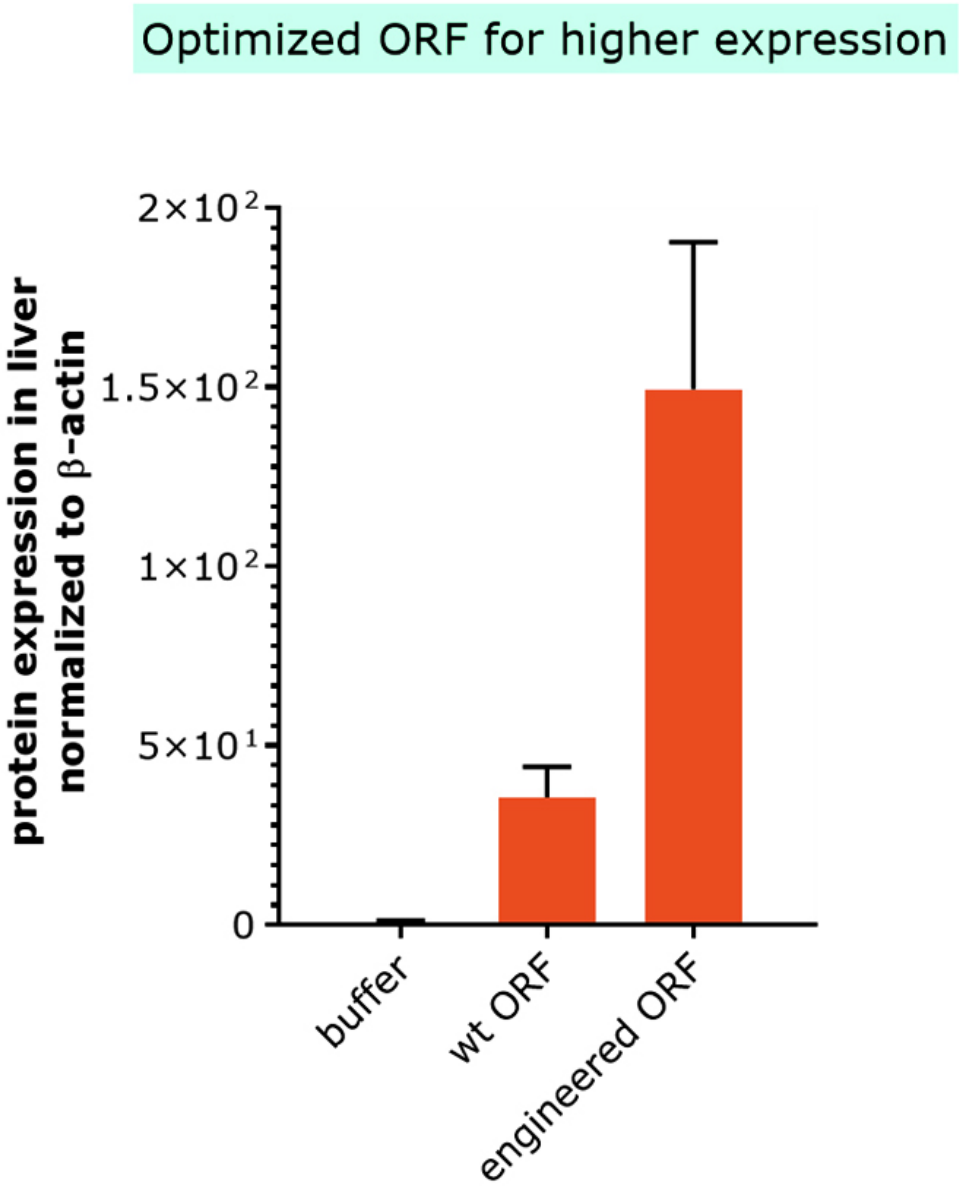


To maximize expression of the target protein a set of 83 combinations of untranslated regions (UTR) was selected from screens identifying stable or highly translated endogenous transcripts. These UTR combinations were combined with the target open reading frame (ORF) via automated cloning to enable facile 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.

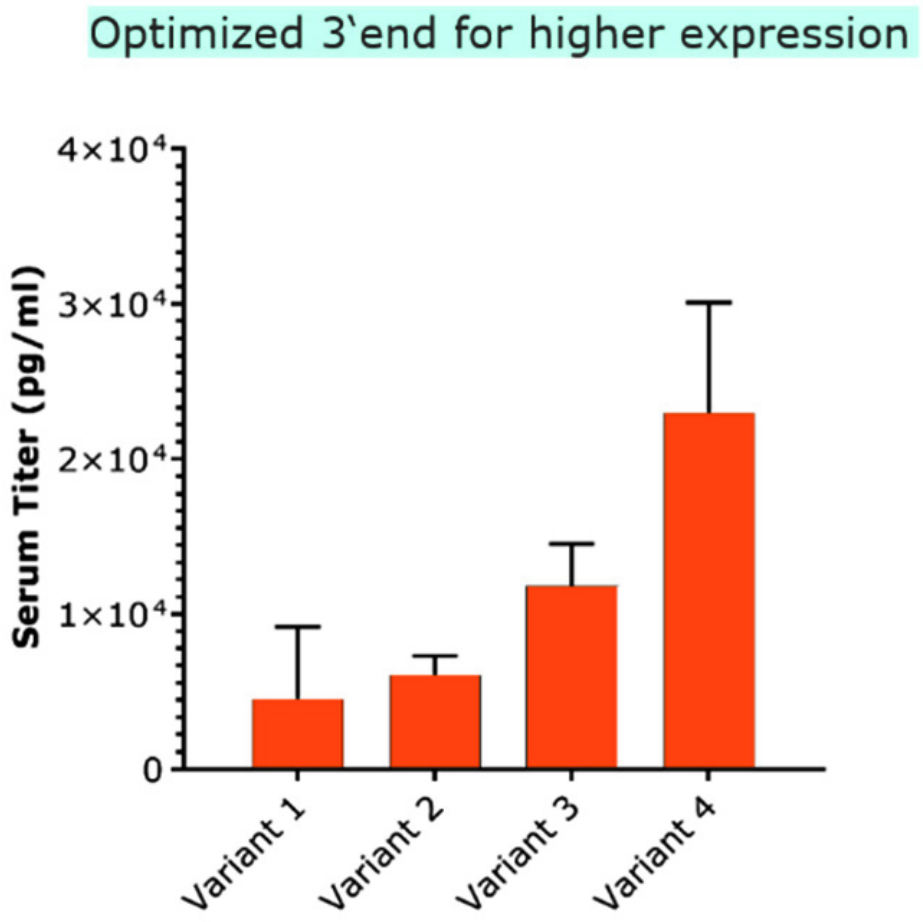
In the following example, protein expressed from our mRNA containing a wild type coding sequence was abundant in the livers of mice injected intravenously with LNP-encapsulated mRNA. However, protein levels were higher from our mRNA containing a coding sequence engineered for maximal protein expression.



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

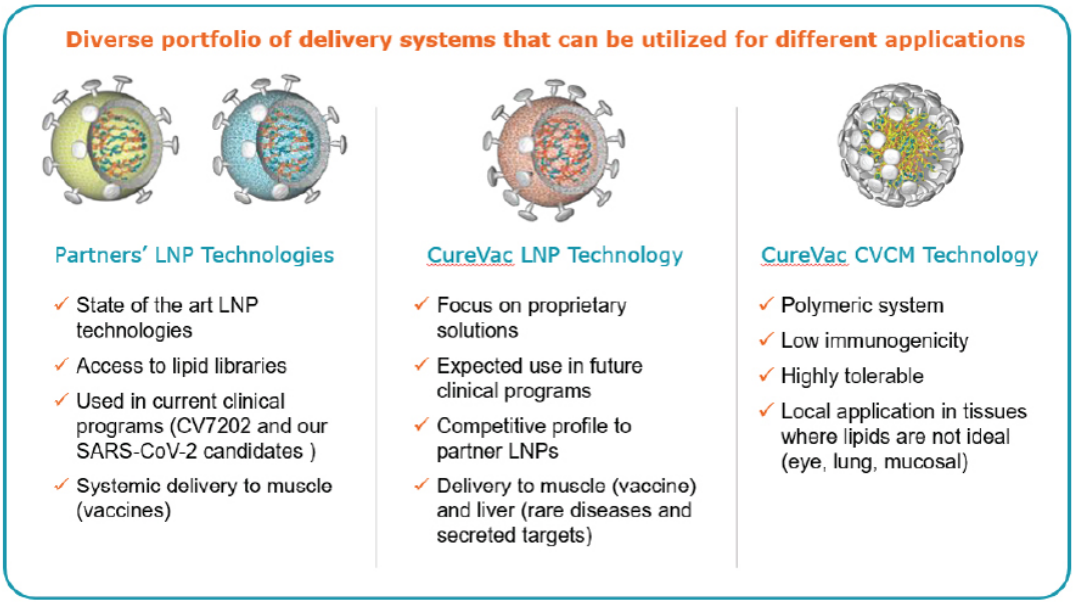
The potency of the administered mRNA drug product is the combination of the efficacy of the mRNA that encodes the protein and the delivery system that transports the mRNA to the cells. Protein levels are highly correlated with the number of transfected cells which requires optimized delivery systems. 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 (LNPs) to deliver our mRNA-based prophylactic and cancer vaccines locally. For rare disease and antibody therapeutic candidates, we apply LNP-formulated mRNA systemically and deliver mRNA to the liver. 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 (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)

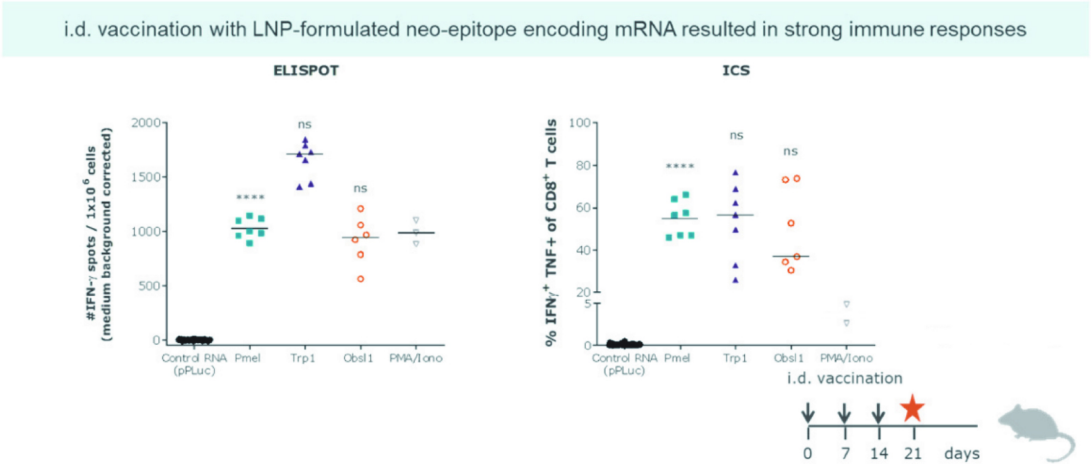
A variety of nanoparticles have been developed over the years for use in drug delivery. LNPs represent the most clinically advanced non-viral delivery systems. Encapsulation of the mRNA within

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

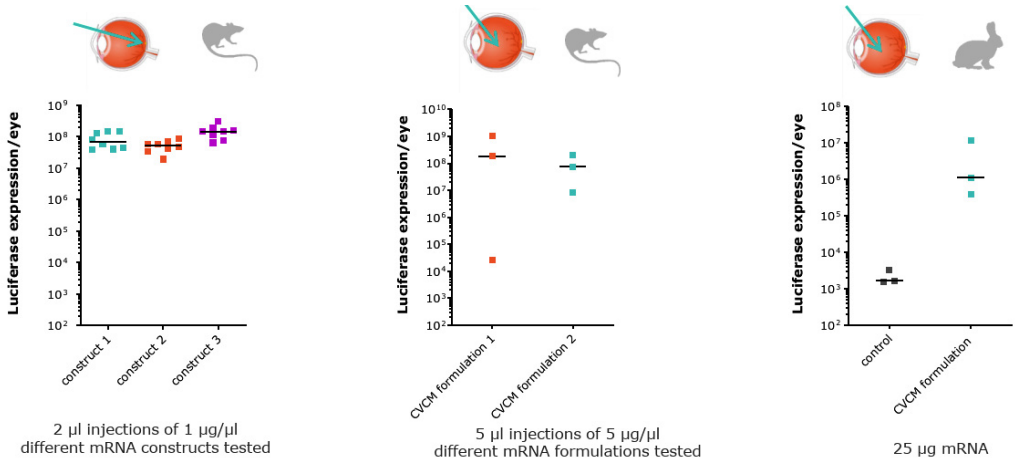
Our proprietary CVCM delivery technology is a polymer based approach for local delivery of mRNA medicines to selected tissues. CVCMs are uptaken via endocytosis and at lower pH during the trafficking, the core peptide and the lipids get protonated. The lipids are then released from the CVCM particles 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 showed high delivery efficacy in eye after intravitreal or sub-retinal administration.



Picture: CVCM nanoparticles delivery efficacy 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.

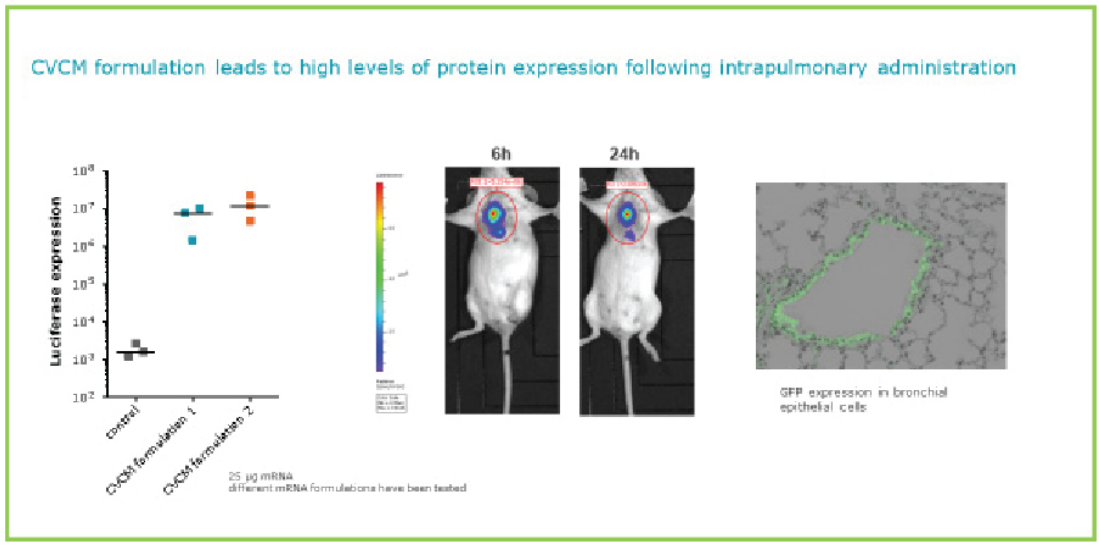


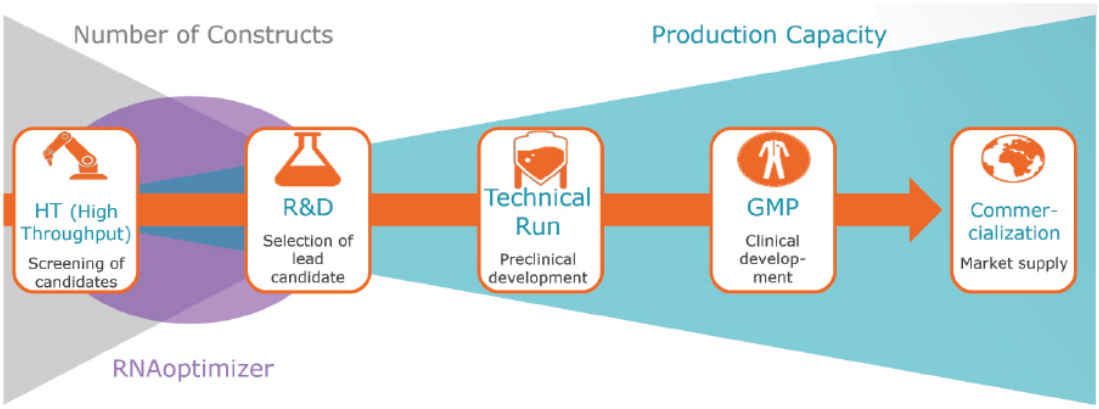
Figure legend: CVCM formulated mRNA, encoding Luciferase was delivered, intratracheal using penncentury device.

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, which allows 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 pre-clinical 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 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 to support our future commercial launches, as shown in the picture below.

GMP IV facility

The RNA Printer

In addition to our GMP manufacturing facilities, we are currently developing a new automated 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 a demonstration batch with the first RNA Printer prototype and are developing a second generation prototype. 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.

Our Approach to Disease Selection

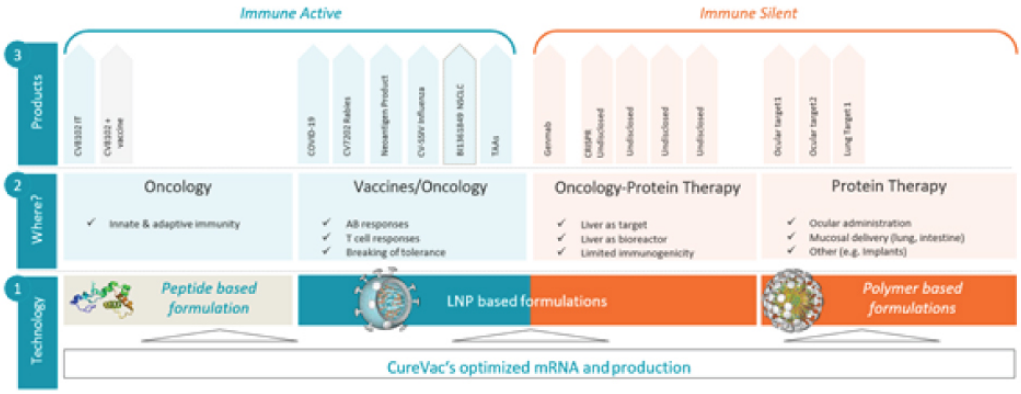
Our approach seeks to mitigate risk across multiple levels to advance and expand our broad product portfolio. While mRNA is still an emerging treatment modality, we believe that we have made rapid advances towards de-risking our technology platform through rational disease selection. Our approach for 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 platform technology 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 a mRNA based medicine that triggers an immune response, or that is immune active, or a 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 in clinical 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 immuno-silent 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 1/2 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 achieve optimal therapeutic efficacy 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 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 humoral 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 advantages over existing vaccine technologies, including:

- mRNA vaccines mimic several aspects of a natural viral infection and may 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 to either provide a broader efficacy by including additional target pathogens, or to strengthen 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:

- **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.
- **SARS-CoV-2 vaccine:** Our mRNA vaccine program against SARS-CoV-2 is currently in preclinical studies in various animal models. Initial exploratory data on these constructs indicated high immunogenicity and titers of S specific binding and neutralizing antibody in mice after a single vaccination.
- **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.

Our current approach to the development of protein therapies is focused on:

- **Liver and Rare diseases:** We are currently developing multiple undisclosed programs focused on liver-specific metabolic disorders. The goal of these programs 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. We have shown initial proof of concept in a knockout mice model for hereditary spastic paraplegia type 5 (SPG5), where we demonstrated a significant reduction in oxysterols in serum, liver and brain. We are applying this approach for delivery of liver-specific protein factors, which we believe can resolve liver fibrosis, a key pathological feature of NAFLD, NASH, cirrhosis and hepatocellular carcinoma. In addition, we have conducted preclinical studies in undisclosed lysosomal storage disorder using liver as a bioreactor.
- **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 fomulations, 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

CV8102

CV8102 is the first compound we are developing for treatment of various solid tumors using an intratumoral approach. CV8102 was shown to activate TLR7, TLR8, and RIG-I pathways. These molecules activate the innate immune system upon detection of RNA molecules. 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 innate immune system. CV8102 was initially developed as a vaccine adjuvant and was shown to enhance the induction of multifunctional CD8 T cell responses and therapeutic efficacy of peptide vaccines against cancer in preclinical models.

CV8102 is currently in a Phase 1/2 clinical trial for the intratumoral treatment of four types of solid tumors — cMEL, ACC, SCC and HNSCC. As of October 2019, we have enrolled 32 patients (21 in the single agent cohort and 11 in the combination cohort) in the Phase 1 dose-escalation portion of the study. In the single agent cohort, we have observed a complete response in a stage IIIc melanoma patient. Two additional patients have shown a stabilization of their disease, including shrinkage of non-injected lesions.

Based on encouraging clinical data from the ongoing Phase 1 portion of the trial, further clinical development of CV8102 will continue after selection of a recommended Phase 2 dose. We plan to further investigate safety, biological effects and clinical efficacy of this dose in a Phase 2a expansion part of the trial.

Currently, expansion cohorts of 20 to 40 patients per indication are planned and will include combination with anti-PD-1 antibodies in PD-1 naïve and refractory patient populations. In selected sub-cohorts assessment of mandatory tumor biopsies is planned to elucidate the mechanism of action help to predict which patients may be more responsive to the treatment.

Mechanism of Action

CV8102 activates different cells of the innate immune system via toll-like receptors, or TLR7 and TLR8 as well as RIG-I resulting in activation of a set of genes that are also induced by virus infections. CV8102 recruits and activates antigen-presenting cells at the site of injection to present tumor antigens in dying tumor cells to T cells in the draining lymph node. This results in activation of tumor specific T cells, which can migrate to the injected tumor but also to distant non-injected tumor lesions / metastases, that kill tumor cells and thereby, control tumor growth. Activation of natural killer, or NK, cells at the site of injection may also contribute to the antitumor effect.

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 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 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;
    - failed approved standard therapies or for whom no standard therapy is available; and
    - at least 1 line of anti-cancer therapy for advanced disease (except adenoid cystic carcinoma).
- Patients enrolled 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 8 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 toxicities to grade ≤ 1.
- ECOG PS 0 or 1, 18 years of age or older.

Key Exclusion Criteria:

- Rapidly progressing multi-focal 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 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 study drug.

Primary Endpoints:

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

Secondary Endpoints:

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

Exploratory Endpoints:

- Effects on immune parameters and other biomarkers of interest in the peripheral blood.
- 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 2019, 32 patients were enrolled in the clinical trial: 21 in the single agent cohort and 11 in the combination cohort with anti-PD-1 antibodies. In single agent cohorts, 48% of patients were pre-treated with anti-PD-1 antibodies and 5% with anti CTLA-4 antibodies. In the combination cohort, 91% were pre-treated with anti PD-1 antibodies and 45% with anti CTLA-4 antibodies. 56% of patients enrolled in the trial had cMEL, 22% ACC, 16 % HNSCC and 6% SCC.

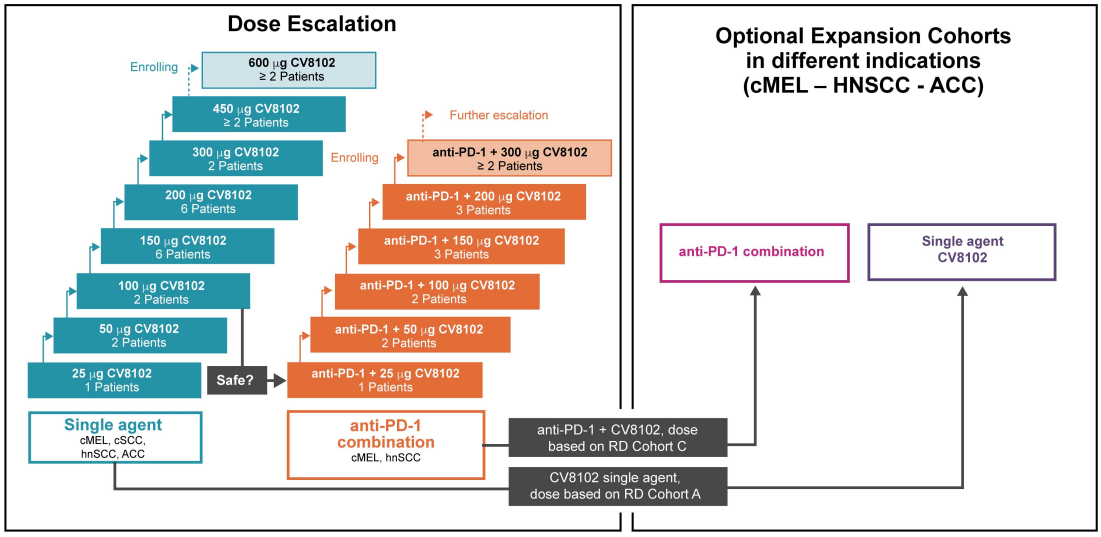
	Number of patients (%)		
Characteristics	**Single Agent Cohort A (n=21)**	**Combination Cohort C (n=11)**	**All (n=32)**
Age range (yrs)	35-91	36-86	35-91
Gender			
Male	8 (38)	3 (27)	11 (34)
Female	13 (62)	8 (73)	21 (66)
cMEL			
Stage IIIB	1 (5)	0 (0)	1 (3)
State IIIC	3 (14)	1 (9)	4 (13)
Stage IV	5 (24)	8 (73)	13 (41)
HNSCC			
Stage IV	3 (14)	2 (18)	5 (16)
SCC			
Stage IV	2 (10)	0 (0)	2 (6)
ACC			
Stage IV	7 (33)	0 (0)	7 (22)
ECOG PS			
0	11 (52)	7 (64)	18 (56)
1	10 (48)	4 (36)	14 (44)
Pre-treatment anti-PD-1	10 (48)	10 (91)	20 (63)
Pre-treatment anti-CTLA-4	1 (5)	5 (45)	6 (19)

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 enrolment. 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 Enrolment Status as of October 2019



As of October 2019, the clinical trial has not yet encountered a MTD and there has been no evidence of dose limiting toxicities (DLTs). We presented a Phase 1 trial update at the SITC conference in November 2019.

Preliminary Safety Data

Preliminary safety data: Treatment emergent AEs occurring in ≥ 10% of patients as of October 2019

	Number of subjects with 21 TEAE (%)		
AE Preferred term	**Single Agent G1/2 (n=21)**	**anti-PD-1 combination G1/2 (n=11)**	**All G1/2 (n=32)**
Any Adverse Event	21 (100)	11 (100)	32 (100)
Fatigue	10 (48)	4 (36)	14 (44)
Pyrexia	8 (38)	3 (27)	11 (34)
Chills	4 (19)	6 (55)	10 (31)
Headache	7 (33)	3 (27)	10 (31)
Influenza like illness	7 (33)	2 (18)	9 (28)
Injection site pain	5 (24)	2 (18)	7 (22)
Pain in extremity	4 (19)	3 (27)	7 (22)
Arthraigia	4 (19)	2 (18)	6 (19)
C-reactive protein increased	4 (19)	2 (18)	6 (19)
Urinary tract infection	2 (10)	4 (36)	6 (19)

Nausea	3 (14)	2 (18)	5 (16)
Decreased appetite	1 (5)	3 (27)	4 (13)
Injection site reaction	2 (10)	2 (18)	4 (13)

As of October 2019, CV8102 was generally well tolerated, with mostly mild to moderate adverse events to date. Grade 3 AEs considered related to CV8102 were self-limiting or manageable with supportive treatment and did not show a clear dose dependency. A maximum tolerated dose has not been reached to date.

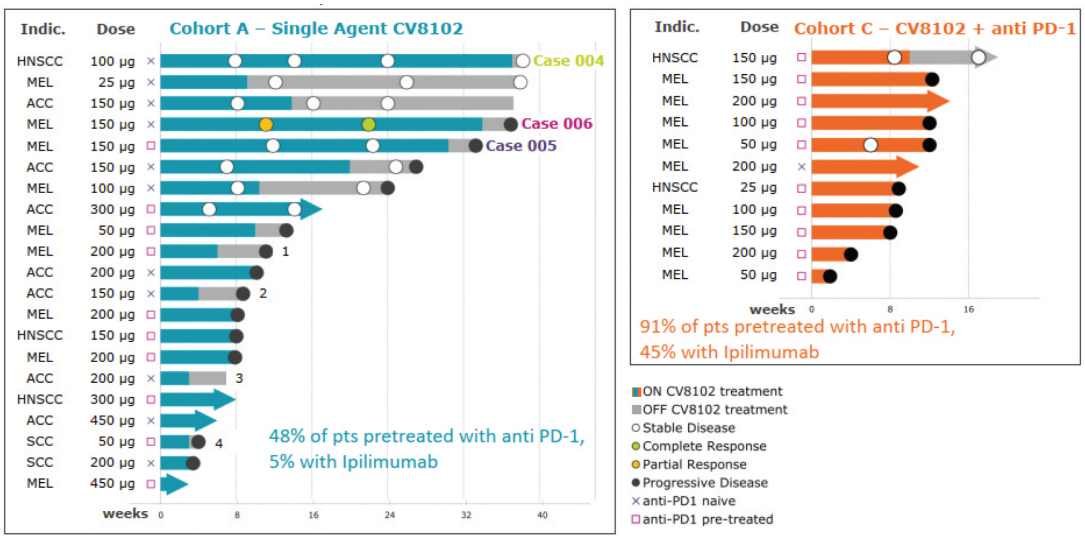
As of October 2019:

- The most frequently reported adverse events occurring in more than 20% of patients were mild to moderate fatigue, fever, chills, headache, influenza like illness, pain at the injection site and pain at an extremity.
- 10 (31%) patients experienced treatment emergent ≥ G3 AEs and 6 (19%) pts experienced G3 AEs considered treatment related per investigator's judgement (none of the events fulfilled criteria for dose limiting toxicities per protocol). There were no G4/5 AEs considered related to study treatment.
- In the single agent CV8102 cohort, 3 patients (1 at 150 µg dose level, 2 at 200 µg dose level) experienced transient self-limiting G3 elevations of liver enzymes. 1 patient (150 µg dose level) experienced a G3 abscess of the injected tumor lesion 3 months after the last administration of CV8102. Prior to the event, a necrosis of the injected tumor lesion was observed. The abscess resolved after antibiotic and surgical treatment. In view of the long latency between last injection of CV8102 and abscess formation the event was considered a potential secondary effect of tissue damage and inflammation induced by CV8102. In the combination cohort of CV8102 with anti PD-1 antibodies, 1 patient (100 µg dose level) experienced G3 hypertension, mild chills and tachycardia on day of administration of CV8102 and anti-PD-1 requiring inpatient observation and transient asymptomatic G3 elevation of serum lipase. 1 patient (100 µg dose level) experienced transient asymptomatic G3 elevation of serum amylase.
- Further Grade 3 or higher AEs assessed by investigators to be unrelated to treatment included: one patient with laryngeal obstruction and one patient with progressive disease in CV8102 single agent cohort; one patient with paraparesis and disease progression, one patient with disease progression, one patient with neuropathic pain, one patient with tumor bleeding and one patient with anemia in the CV8102 and anti-PD-1 combination cohort.

Preliminary Efficacy Data

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 2019



Preliminary efficacy data single agent CV8102

As of October 2019, the Phase 1 study has observed one patient with a complete response after single agent CV8102 and two further patients experiencing stable disease, with shrinkage of noninjected

lesions, according to RECIST 1.1 criteria. Overall six of 21 patients treated with single agent CV8102 remained free of progression for at least six months.

Preliminary efficacy in combination with PD-1 antibodies

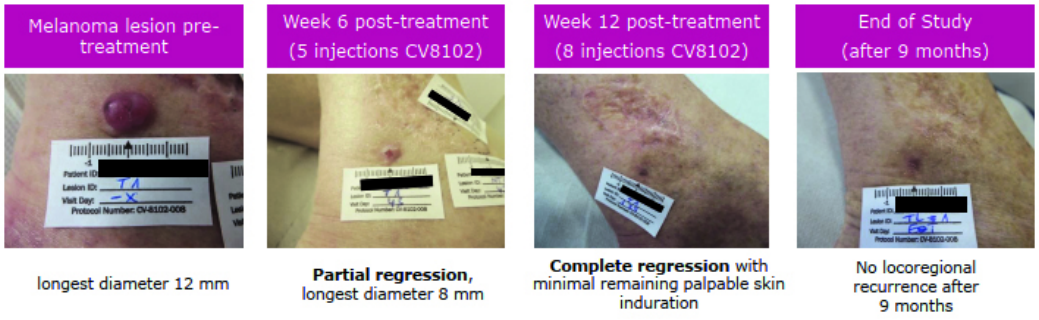
As of October 2019, no objective responses or cases of SD with tumor shrinkage have been observed in the PD-1 combination cohort. Out of 11 patients enrolled, one PD-1 refractory patient with HNSCC and one PD-1 refractory melanoma patient experienced stable disease at the first tumor assessment.

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 (91% vs. 45 % were pretreated with anti-PD-1 antibodies and 48% vs. 5% with anti CTLA4 antibody).

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.



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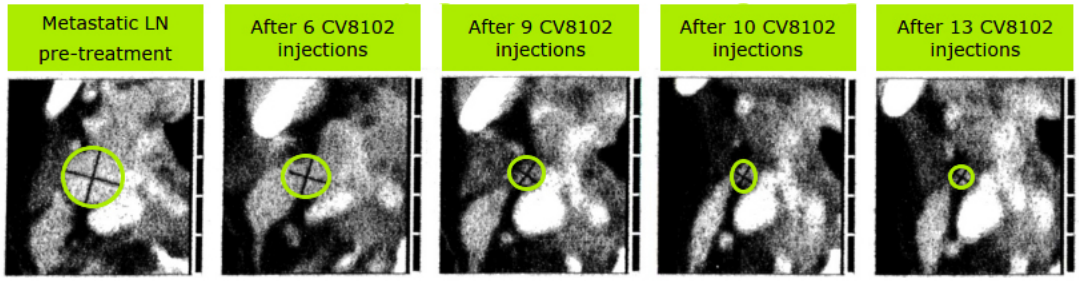
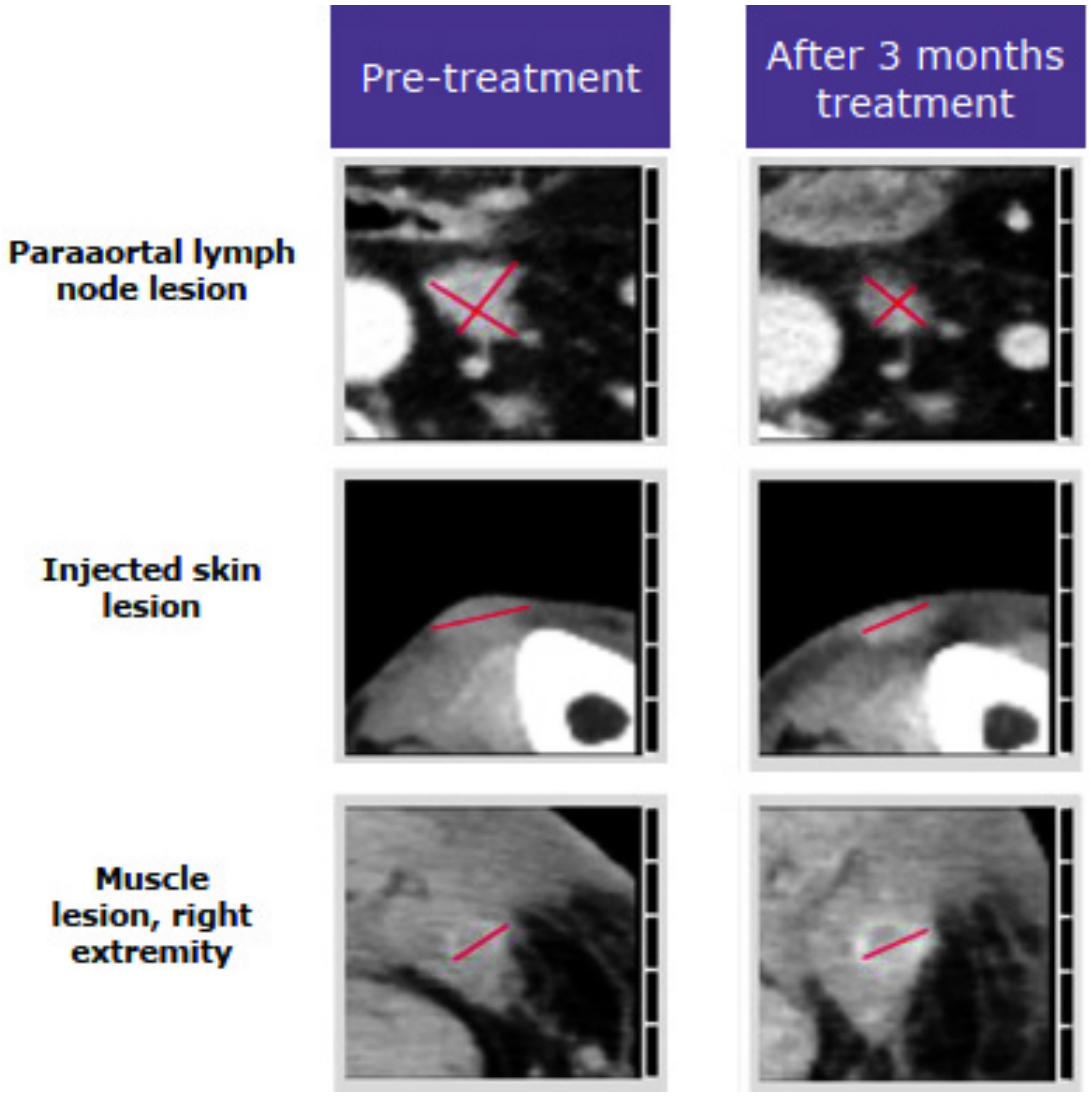
A 91-year-old male patient with Stage IV SCCHN with large buccal and small lip lesion and a contralateral metastatic cervical lymph node was treated with single agent CV8102 (100 µg) after pretreatments with cetuximab, external beam radiation, and multiple surgeries. The patient experienced prolonged 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.



CV8102 with Rabies Vaccine

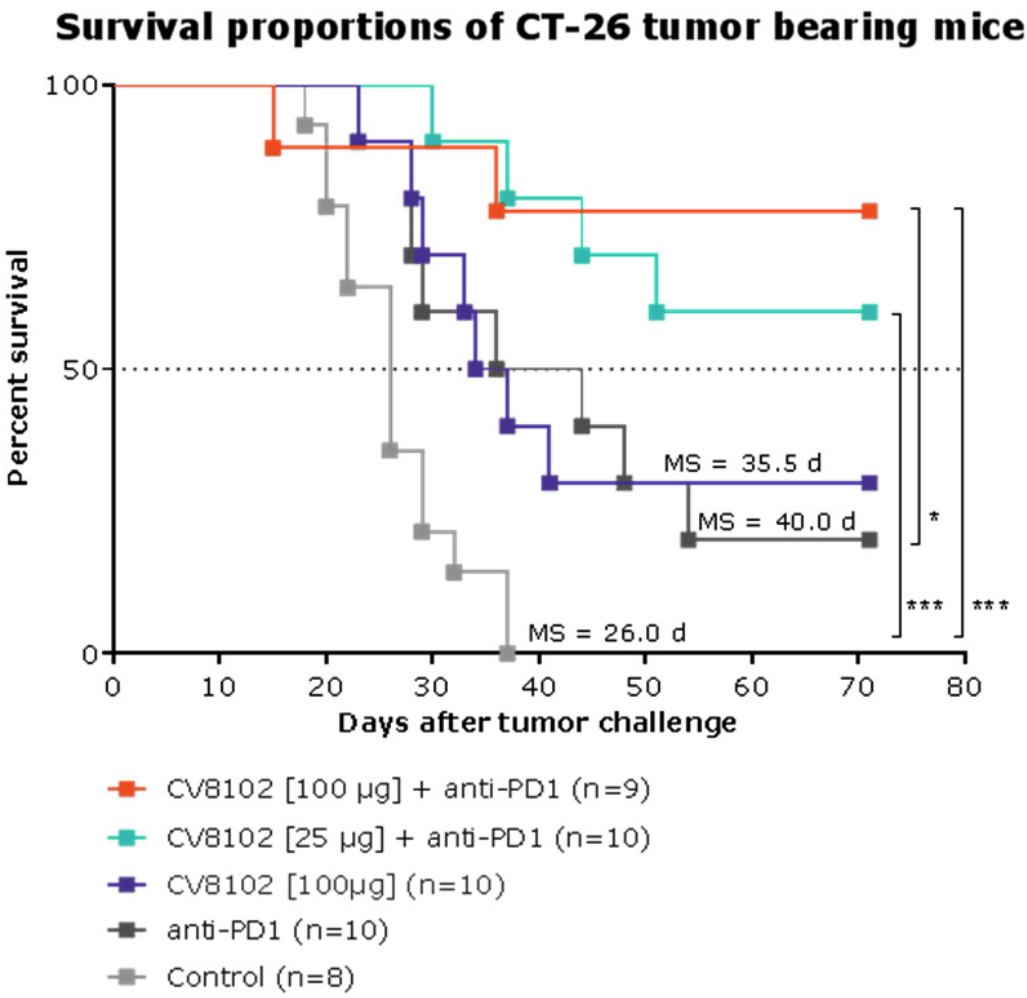
We completed a Phase 1 clinical trial to investigate the safety and tolerability of intramuscular administered CV8102 and an intramuscular administered combination of CV8102 and rabies vaccine in humans. CV8102 was injected intramuscularly on days 0 and 21 either alone or mixed with fractional doses of the licensed rabies vaccine (Rabipur) as model antigen. The primary objective 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 objective 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 models, CV8102 showed dose dependent antitumor activity as single agent and synergistic efficacy in combination with systemic anti-PD-1 antibodies. This included therapeutic activity in

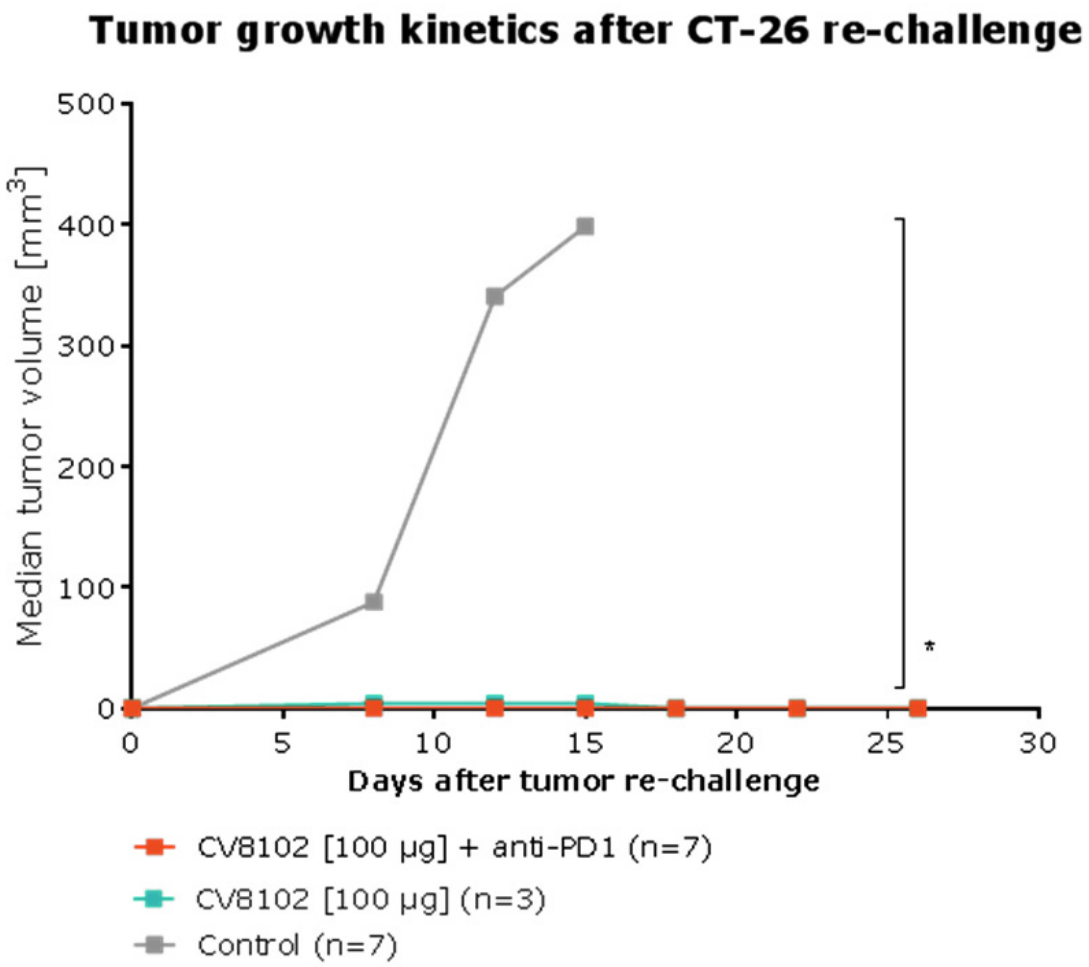
the A20 tumor model that did not respond to systemic anti-PD-1 antibody therapy alone.

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



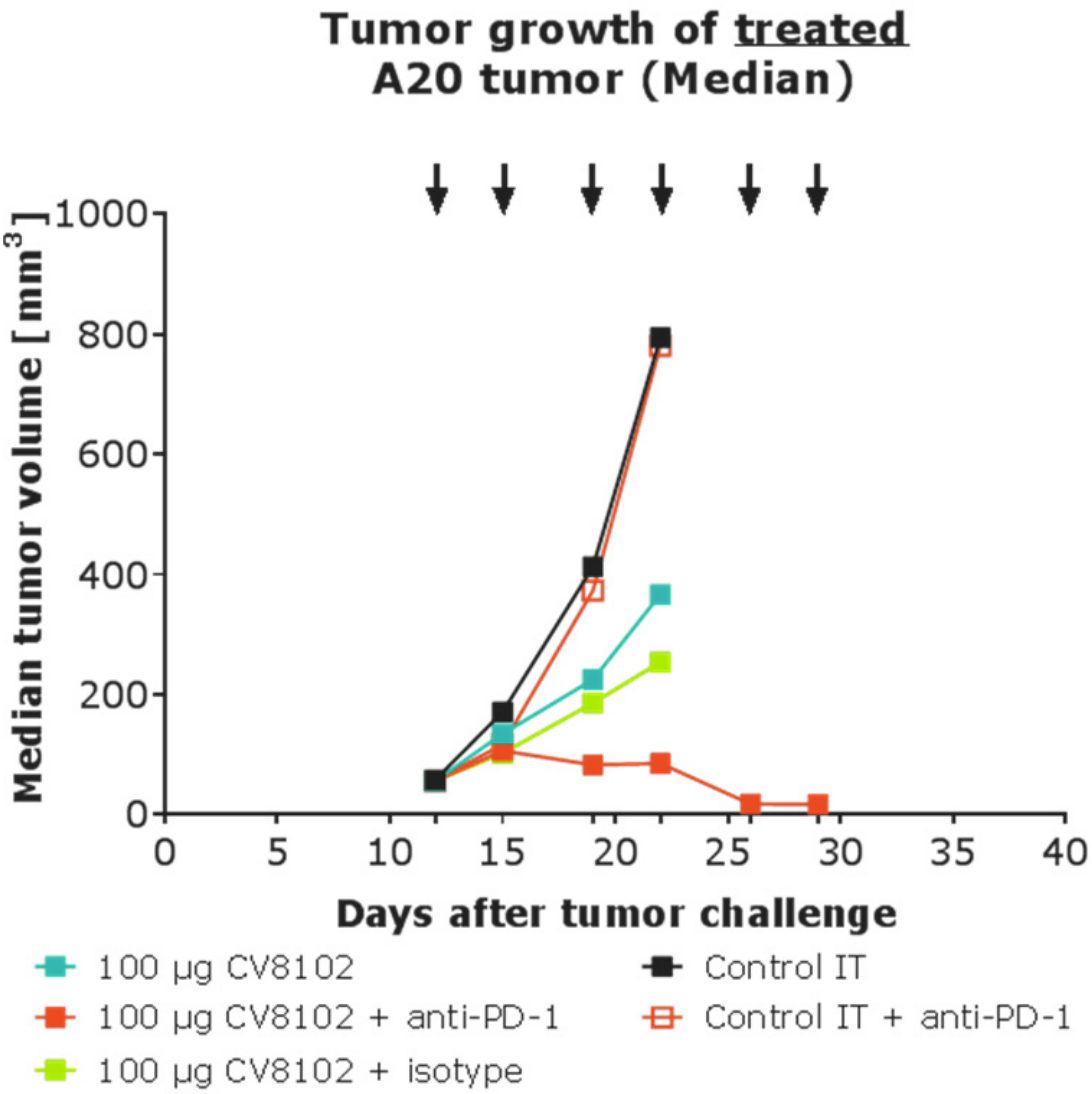
In a Kaplan-Meier curve, the graph above demonstrates the effect of monotherapy CV8102 treatment and combination of CV8102 with anti-PD-1 treatment. In the murine CT26 tumor model, an established colon carcinoma model, treatment led to an increased survival time, an increased proportion of animals surviving, 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 exhibited only modest efficacy whereas the combination of CV8102 and anti PD-1 resulted in a significant prolongation of survival times.

CV8102 + anti-PD-1 treatment confers protective immunity against tumor re-challenge



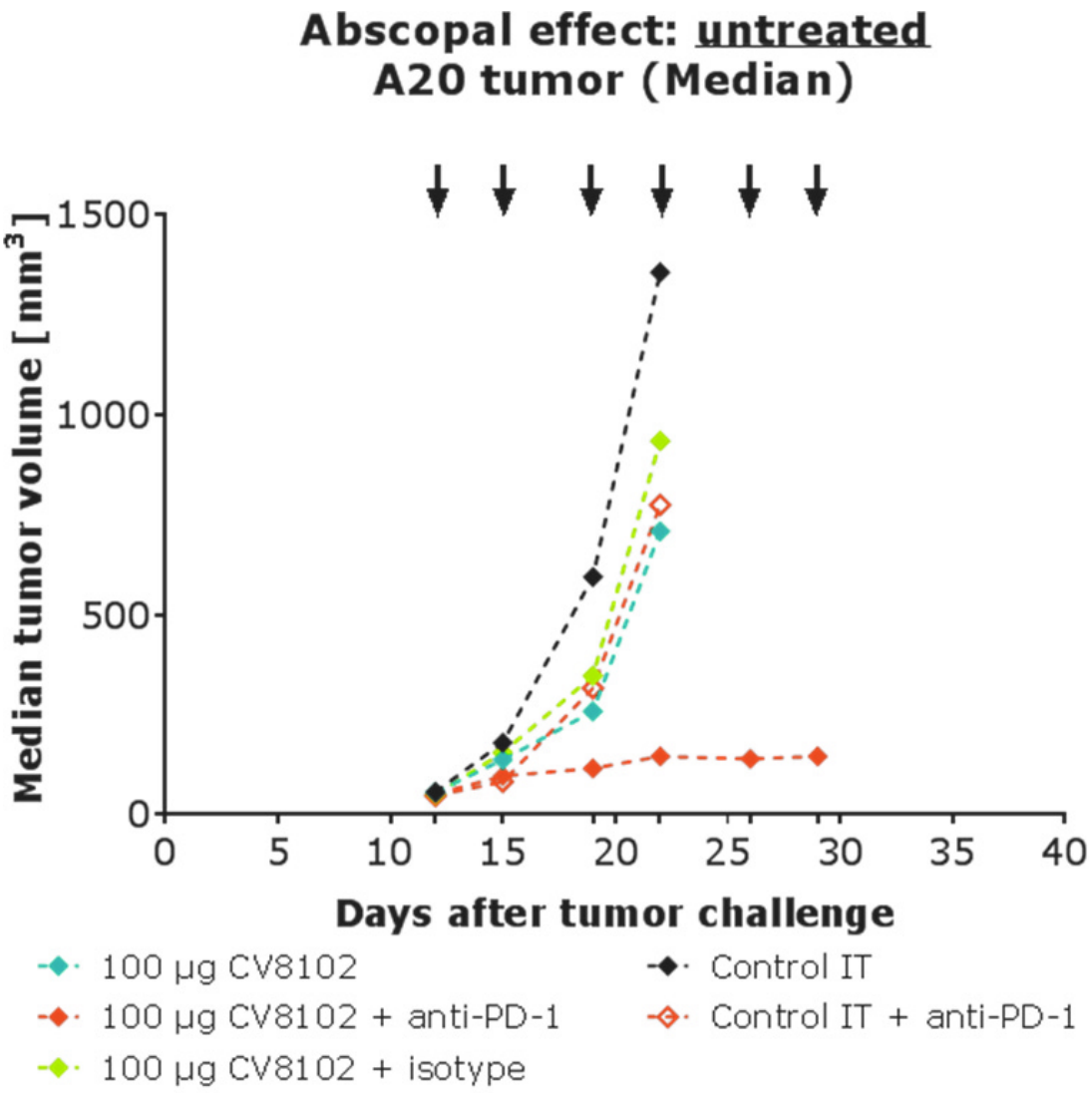
The graph above takes those animals from the previously described experiment that survived and were cured either with CV8102 alone or with combination therapy. The control arm represents animals that did not have any pretreatment. Animals treated with prior CV8102 and CV8102 treatment in combination 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 leads 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 a complete remission of the tumor in 50% of the animals.

CV8102 + anti-PD-1 treatment leads to complete remission of abscopal untreated tumors



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 efficacy, and the combination of CV8102 and anti-PD-1 results in complete remission in four out of 10 animals.

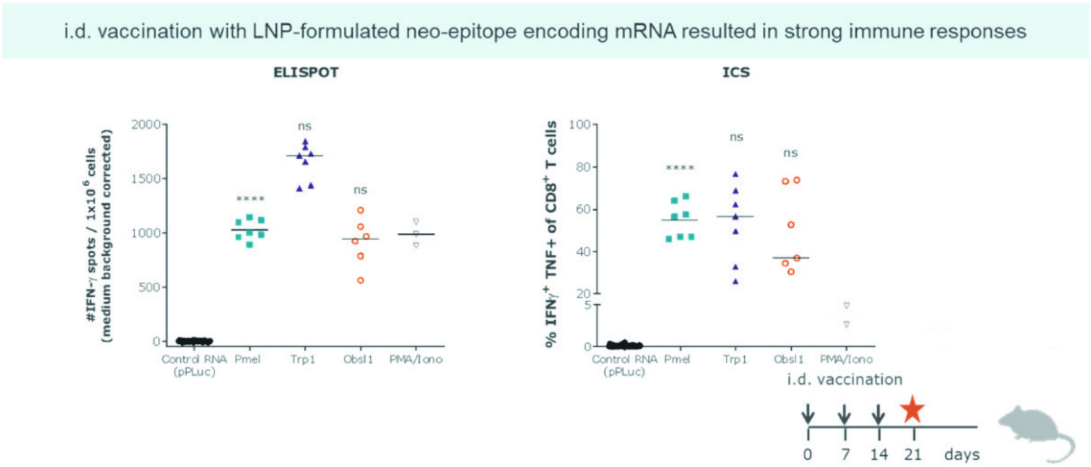
Discovery of mRNA candidates for intratumoral treatments

We are currently investigating combinations of mRNA encoding different immunostimulatory proteins (e.g. cytokines) with the aim to identify combinations with high therapeutic efficacy in anti-PD-1

refractory preclinical tumor models. We are also working to optimize mRNA design and formulation to optimize protein expression in the tumor tissue. These mRNA treatments are intended for the treatment of PD-1 low responsive or refractory tumors with accessible tumor lesions.

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 (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 (former 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 partial response (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 ≥ 4cycles 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 objectives 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
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)

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

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 1 and 2 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 objective 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:

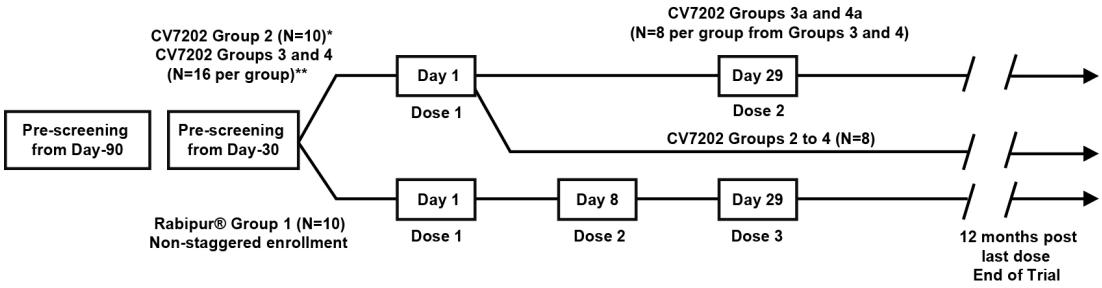
Subjects must satisfy the following criteria at trial entry:

- Healthy male and female subjects aged 18 to 40 years; and
- Physical examination and laboratory results without clinically significant findings and Body Mass Index (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 4 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 enrolment 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 3 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 December 2019, we have 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 2 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

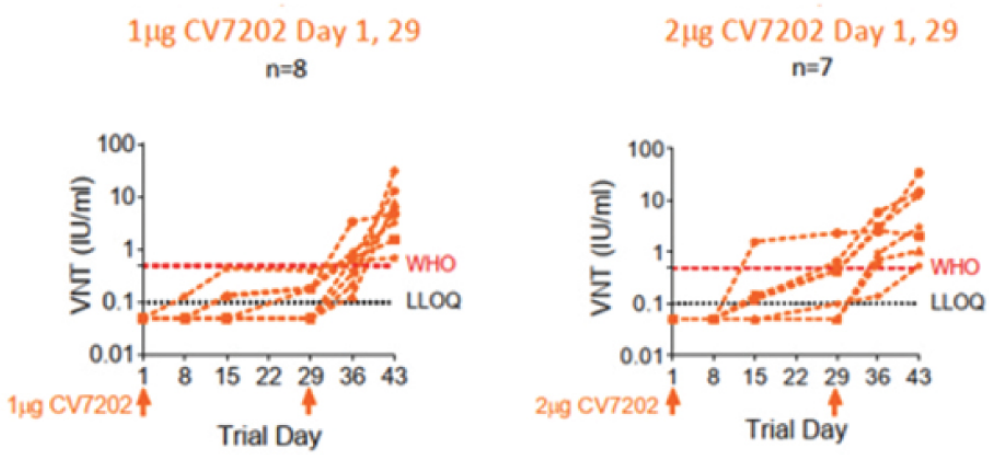
enrolled in the Rabipur group received, 10 subjects received the licensed 3-dose primary vaccination schedule on Days 1, 8 and 29, respectively.

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 7 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 6/10 (60%) subjects in the CV7202 5µg group.

Preliminary immunogenicity results:

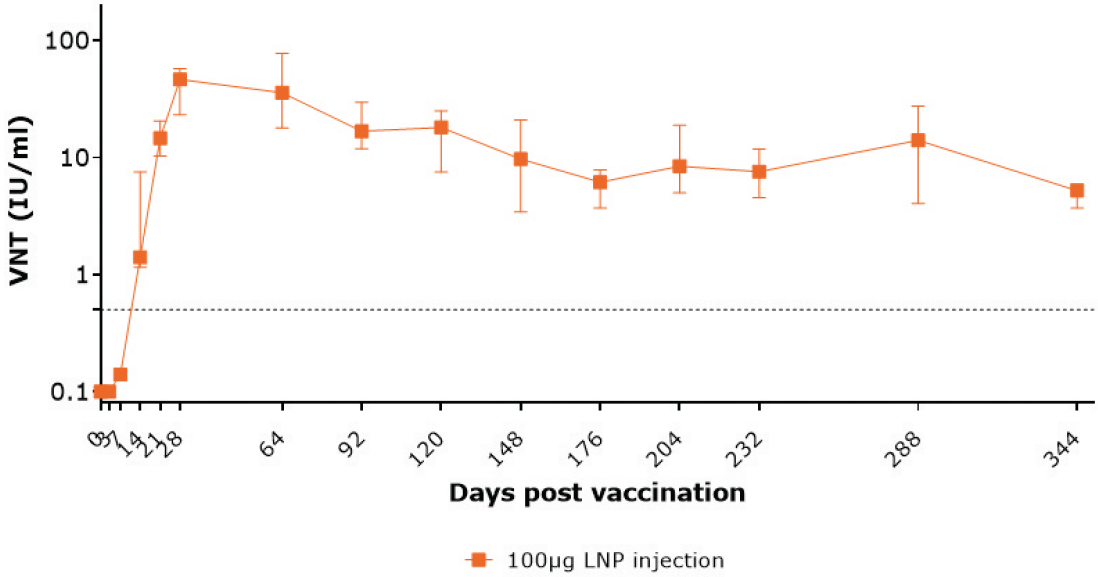
Based on our preliminary data as of January 2020, after two doses of 1µg or 2µg CV7202, 28 days apart, all evaluable subjects had virus neutralizing titers, or VNTs, above the ≥0.5IU/mL level considered protective 14 days after Dose 2 (Day 43). Subjects in the CV7202 5 µg group did not receive a second 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 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



COVID-19 Vaccines Program

Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (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 2 million people around the world. More than 150,000 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 is currently undergoing preclinical testing. Exploratory data on these constructs indicated high immunogenicity and titers of S specific binding antibody in mice after a single vaccination.

We have been working closely with the European regulatory authorities to advance our program into clinical testing. We expect to initiate the first Phase 1/2a study in humans in . We are collaborating with CEPI on the development of a vaccine against SARS-CoV-2. CEPI is funding our preparatory work and early clinical studies.

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 health care provider for their illness, 490,600 hospitalizations, and 34,200 deaths from influenza in the United States. a 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 advantages of our approach to traditional seasonal vaccines include:

- Commercial seasonal vaccines usually contain three to four strains of the virus offering limited efficacy as the virus mutates. Adding more strains or further antigens, which can increase or broaden the level of efficacy 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 a 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 a 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 pre-requisites.

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 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

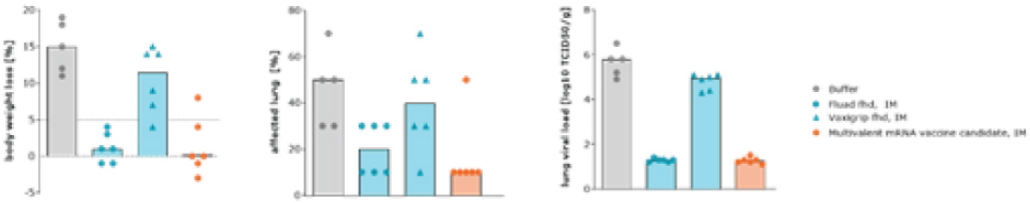
As part of our influenza program, we have evaluated mRNA-based influenza vaccines starting with a monovalent influenza vaccine followed by several seasonal multivalent influenza vaccines. Our preclinical experiments have shown that we can encode for multiple targets in our cocktail mRNA vaccines without 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 and NHPs. 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 and NHPs, 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 candidates 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 28 (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 performed equivalent to the vaccine efficacy for Fluad.

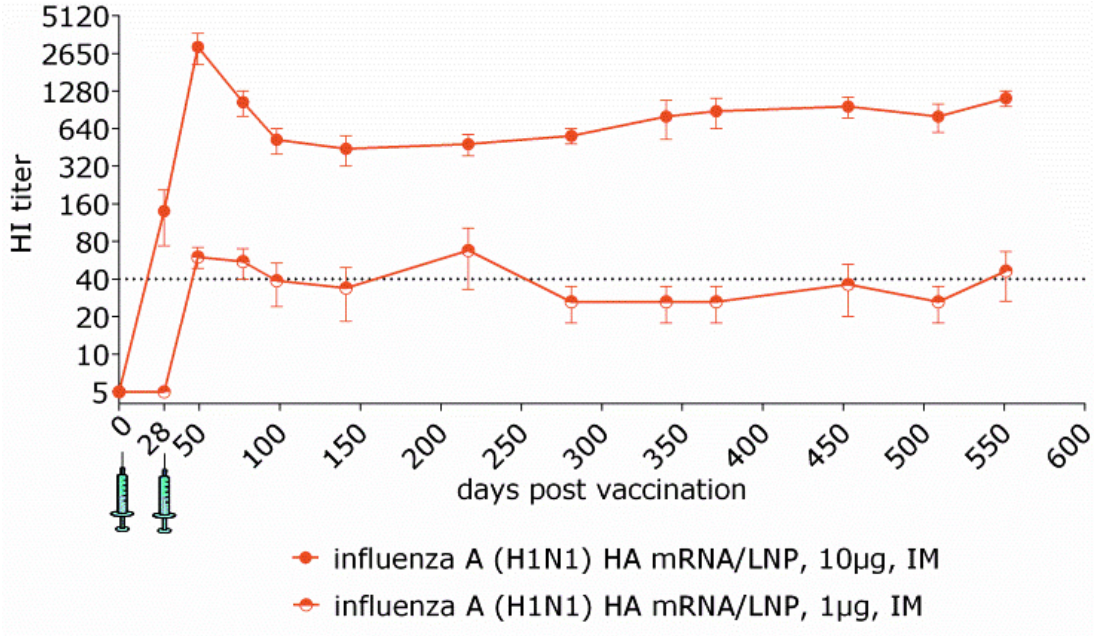
mRNA vaccination protects from weight loss and viral replication comparable to the adjuvanted Influenza vaccine Fluad in ferrets



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 (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.

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 (G) and the fusion glycoprotein (F). Deletion of RSV G leads to a viable but attenuated virus, indicating that RSV G is not

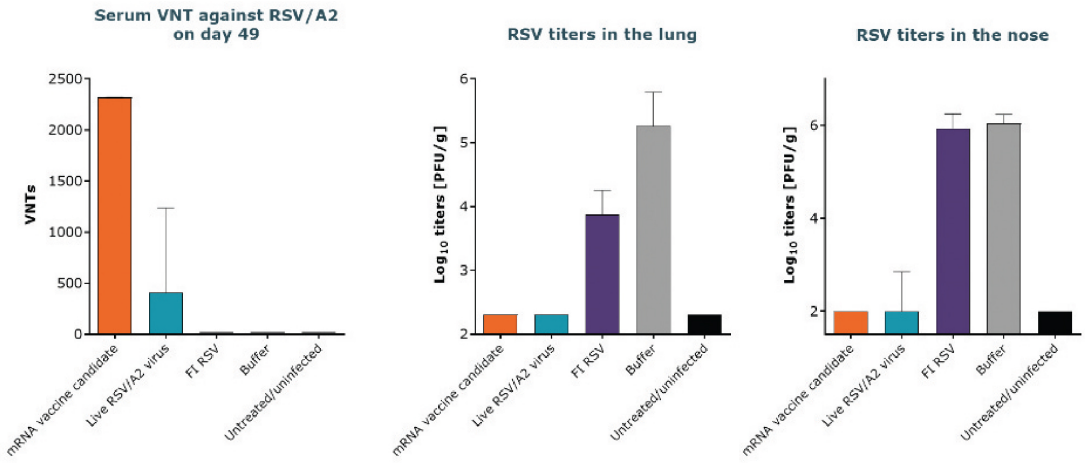
essential for viral entry. In contrast, the RSV F protein is essential to the viral replication process, as it facilitates pH-independent fusion of the viral membrane with the host-cell plasma membrane, leading to infection of the host cell. Expression of RSV F on the surface of cells can also cause 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.

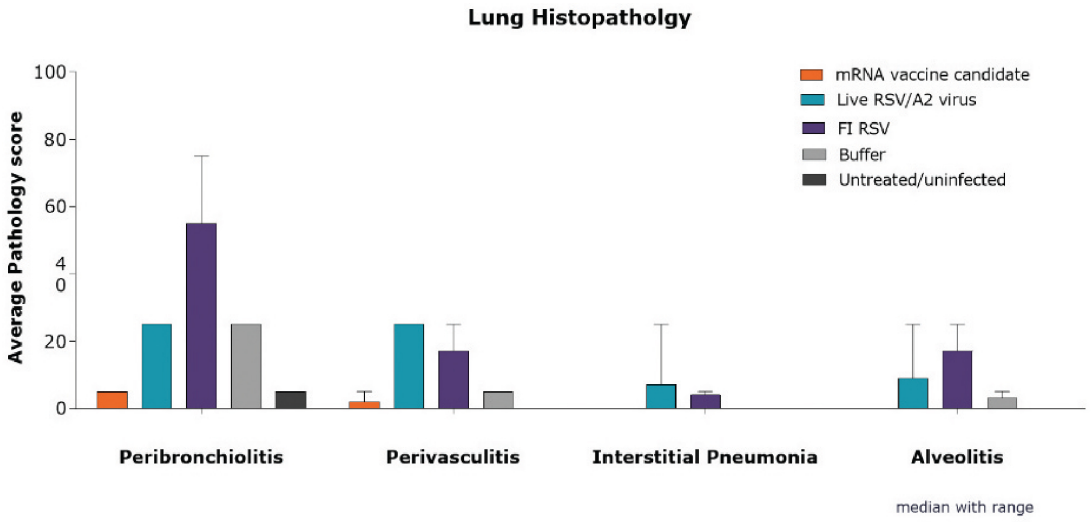
Our approach for the RSV program is based on delivering mRNAs encoding for the RSV F (fusion) protein. This is considered as an advantage over vaccines consisting of the glycoprotein G. Glycoprotein G determines the RSV subtypes and hence, vaccines that aims to protect against all RSV subtypes would 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 Th_2-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 5 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.


Serum VNT against RSV/A2
on day 49
VNTs
2500
2000
1500
1000
500
0
mRNA vaccine candidate
Live RSV/A2 virus
FI RSV
Buffer
Untreated/uninfected
RSV titers in the lung
Log10 titers [PFU/g]
6
5
4
3
2
mRNA vaccine candidate
Live RSV/A2 virus
FI RSV
Buffer
Untreated/uninfected
RSV titers in the nose
Log10 titers [PFU/g]
6
4
2
mRNA vaccine candidate
Live RSV/A2 virus
FI RSV
Buffer
Untreated/uninfected



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 5 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.

Protein Delivery

Liver and Rare Diseases

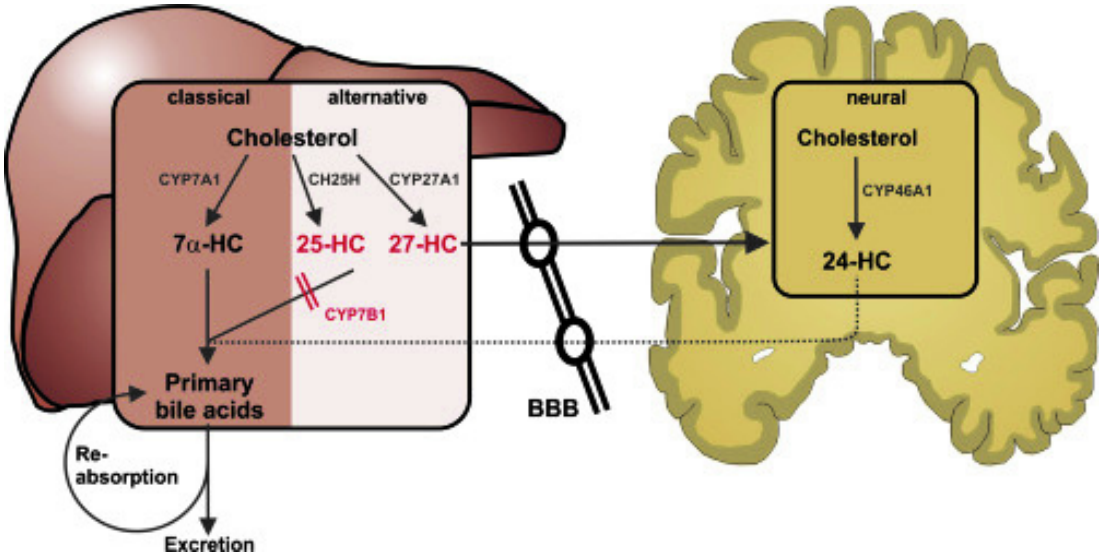
mRNA-based protein supplementation offers a therapeutic approach to compensate for lack of proteins in monogenetic diseases caused by loss-of function mutations. It offers a potentially curative

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 treatment of hereditary spastic paraplegia, or HSP.

Hereditary Spastic Paraplegia

HSP is a group of inherited disorder that are characterized by progressive weakness and spasticity of the legs due to axonal degeneration of the corticospinal tract. Hereditary spastic paraplegia type 5 (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 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.

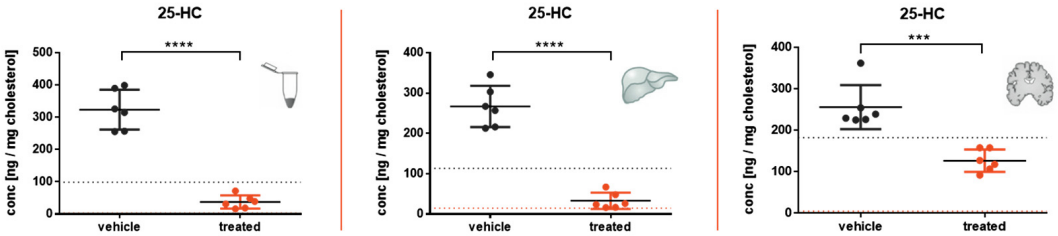


Our approach is based on replacement of CYP7B1 by administration of mRNA. We have studied the intravenous application of formulated CYP7B1 mRNA in mice lacking the endogenous *Cyp7b1* gene. Comparable to the human situation in SPG5 patients, a drastic increase of these oxysterols was detected in all 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 5 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 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.

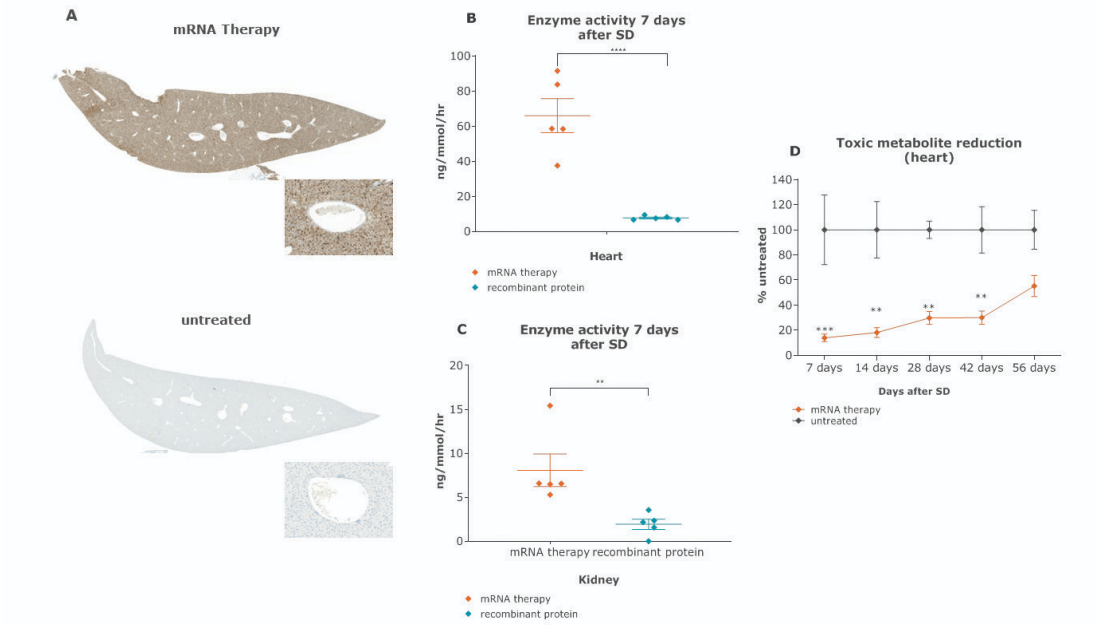


Lysosomal Storage Disorders

We continue to leverage our expertise in liver delivery technology by focusing on inherited rare diseases associated with metabolic disorders of the liver and lysosomal storage diseases. As a group, these 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, leading 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).



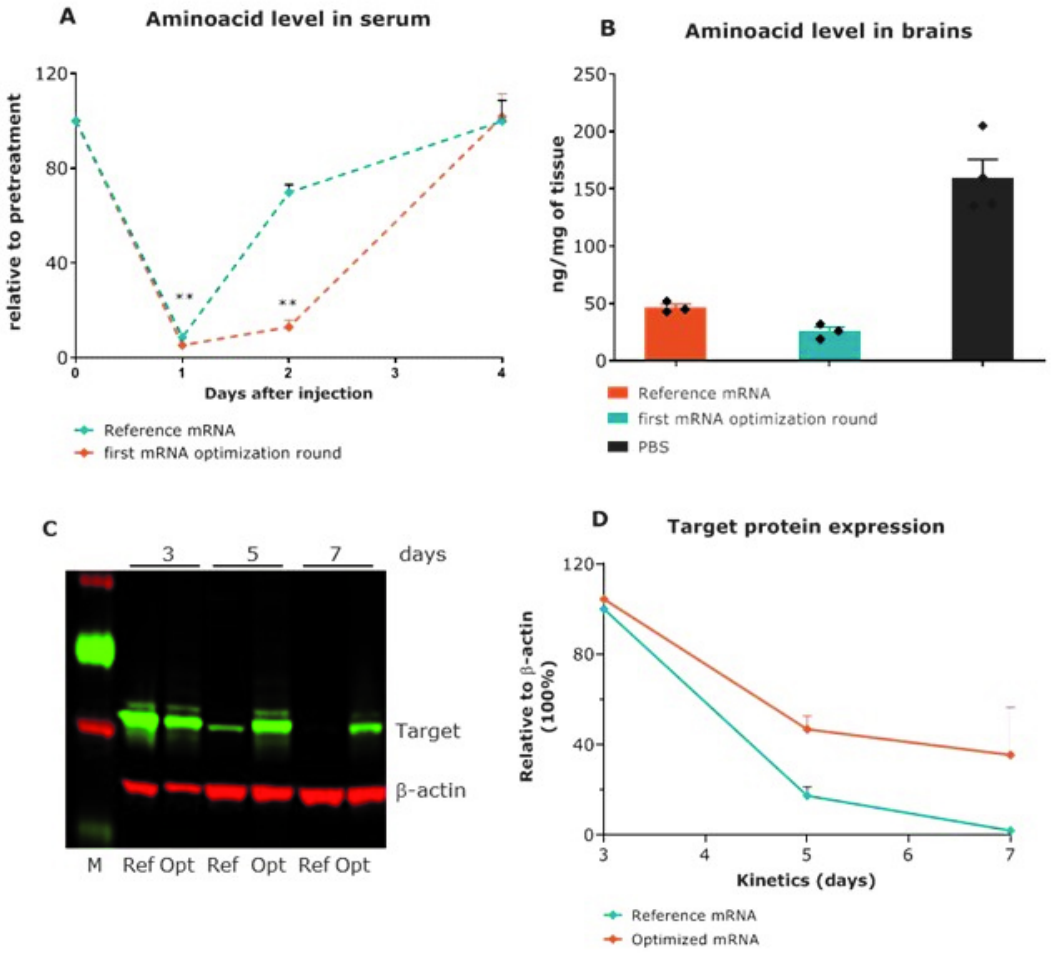
Liver-Specific Metabolic Diseases

We are applying a similar approach to multiple undisclosed programs focused on inherited liver-specific metabolic disorders of amino acids, nitrogen, and essential nutrients. The goal of these rare disease programs 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 therapy 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). To maximize the therapeutic window to reach the desired target product profile, 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 before entering into further development.

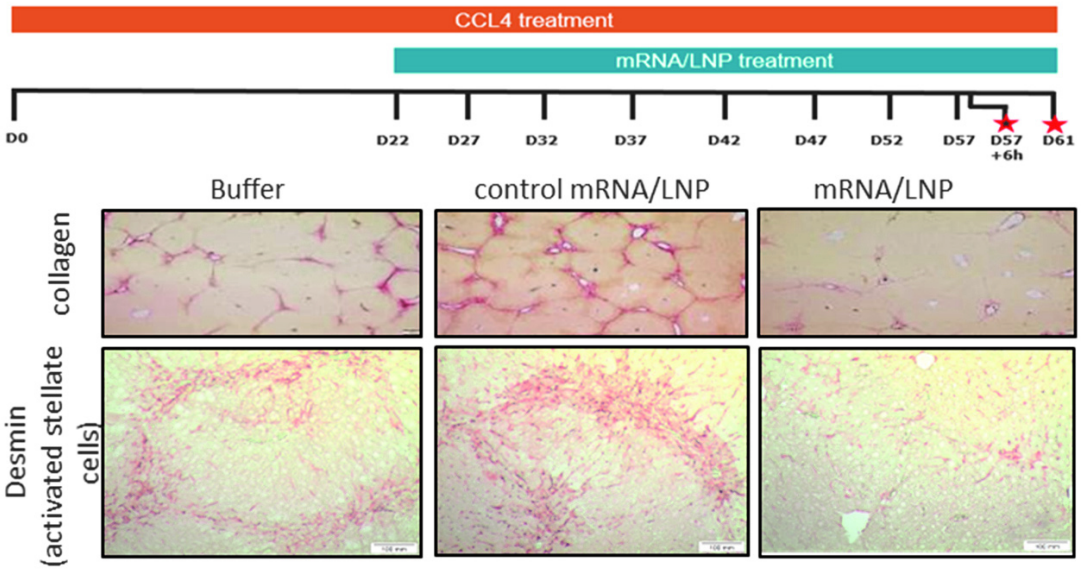


Fibrotic Liver Diseases

Leveraging efficient liver delivery technology, we are developing our programs focused on treating liver diseases. 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 5 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.

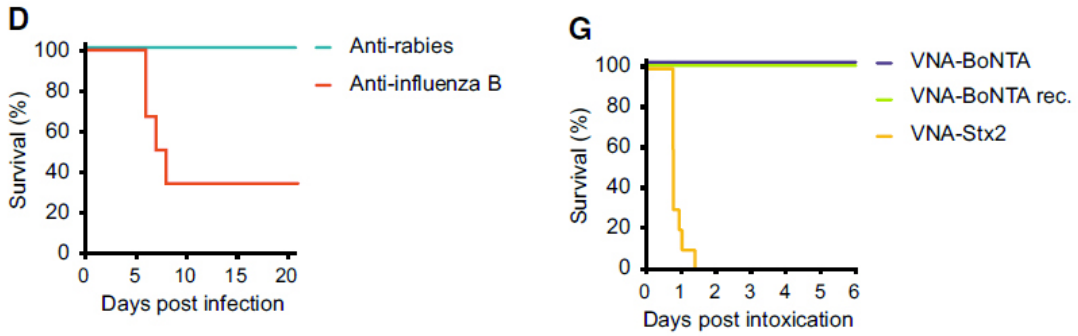


Therapeutic Antibodies

mRNA has 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.

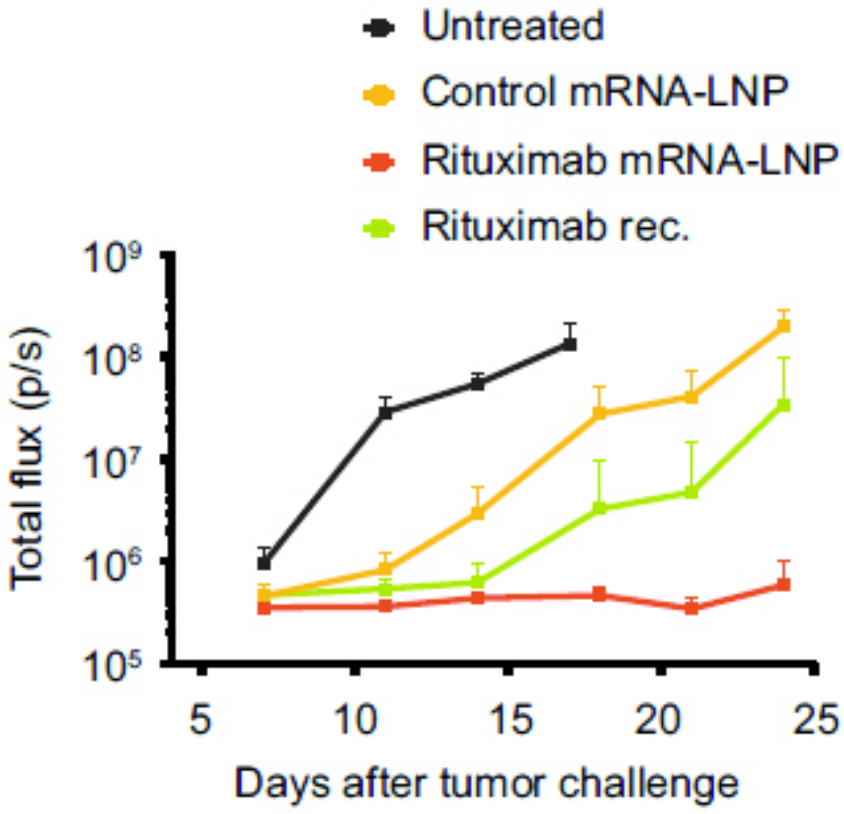
We evaluated the use of mRNA for passive immunization in two indications, rabies and botulism, that can be considered prototypes for anti-pathogen and anti-toxin therapies, respectively. Single injections of mRNA-LNPs were sufficient to establish rapid, strong, and long-lasting serum antibody titers *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 a few 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.

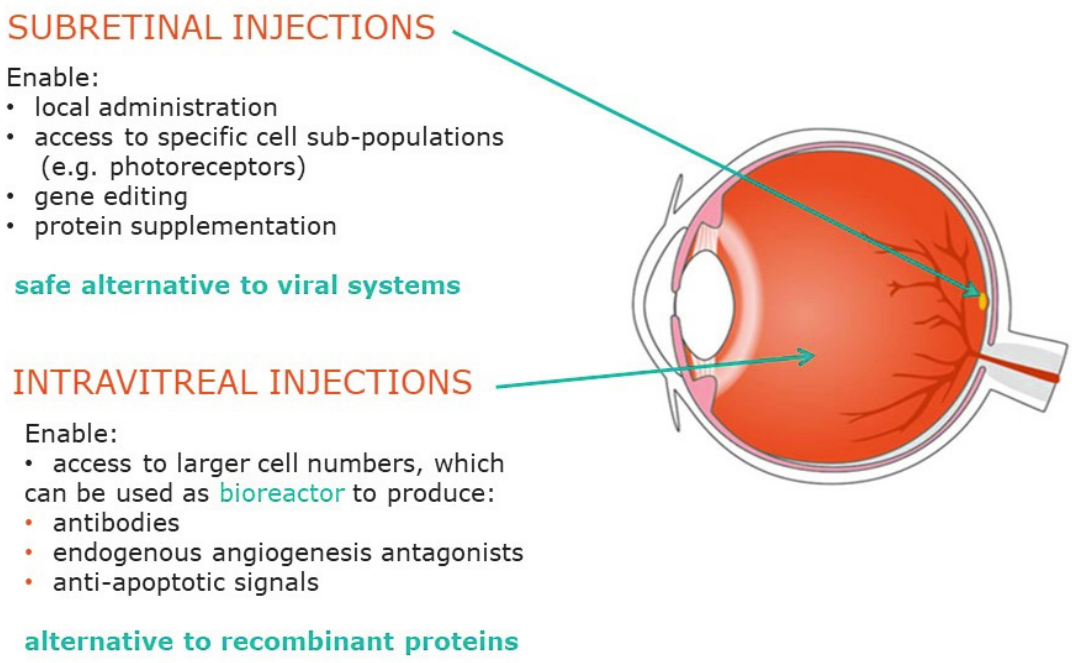


Eye Diseases

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:

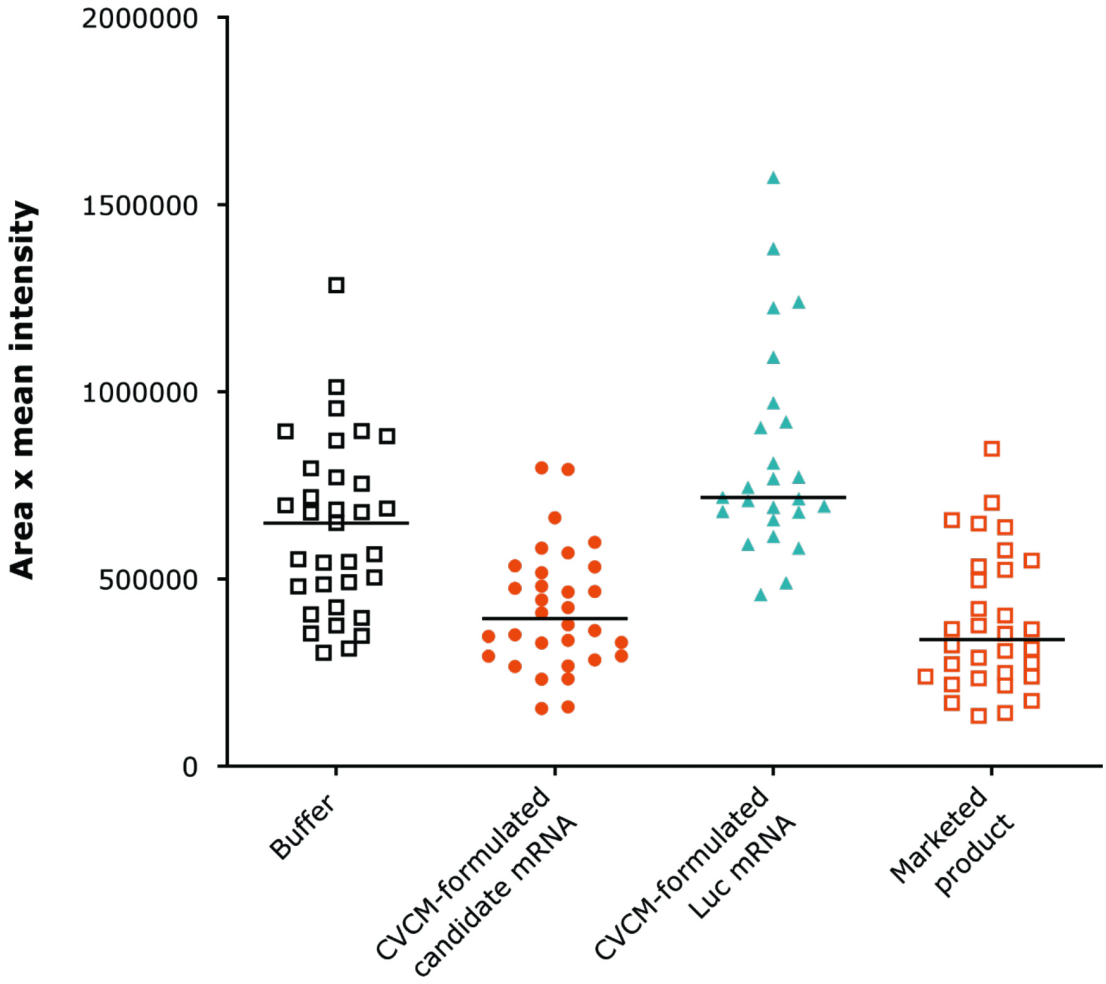
- Therapeutic protein can be produced directly and locally within the target tissue;
- Local treatment in the eye requires lower mRNA doses, thereby minimizing systemic exposure;
- Enables production of endogenous proteins to stop or prevent pathological processes locally in the eye, such as neo-vascularization 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, include 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.

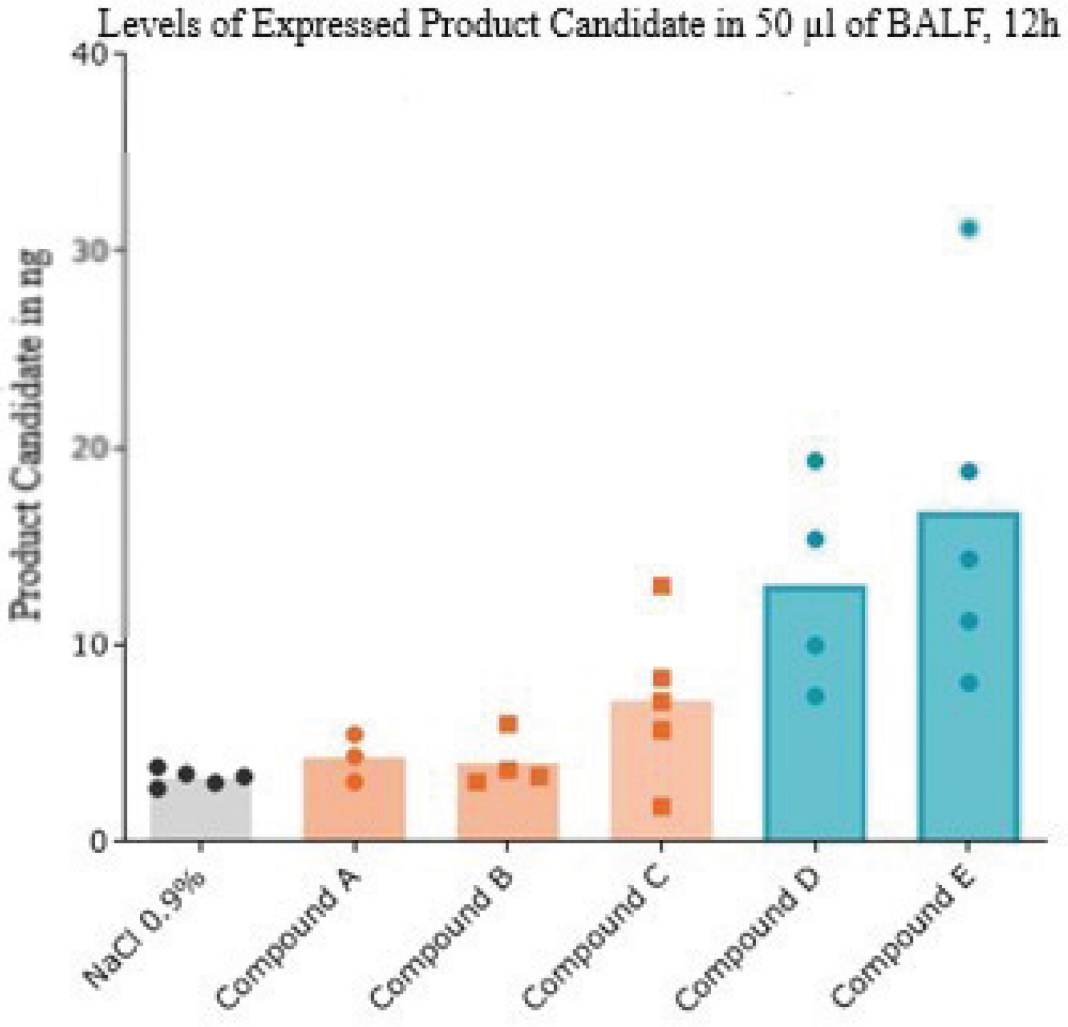
To further optimize the CVCM delivery system for ocular administration, formulations containing mRNA encoding product candidates were tested in a rat model. The animal model has been used in the development of therapeutics to treat retinal diseases. Multiple intravitreal injections of the CVCM-based 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.


Area x mean intensity
2000000
1500000
1000000
500000
0
Buffer
CVCM-formulated candidate mRNA
CVCM-formulated Luc mRNA
Marketed product

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 (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 of 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.

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 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, Moderna, eTheRNA Immunotherapies, Translate Bio, GlaxoSmithKline Sanofi, AstraZeneca and Merck & Co. and those with preclinical programs include Arcturus Therapeutics, Ethris and Genevant Sciences. Specifically, 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.

Collaborations

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

Genmab Collaboration and License Agreement

In December 2019, we entered into 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.

In partial consideration for entering into the Genmab Agreement, Genmab was required to pay us an upfront fee of $10 million and made a €20 million equity investment. Genmab additionally will be obligated to pay us fees upon the selection of each additional product concept for development, upon

selection of a product from the Genmab First Program for further development and commercialization and upon each exercise of its option to obtain a commercial license. 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 $275 million and $368 million in development, regulatory and commercial milestone payments for each product, depending on the specific product concept. In addition, we are eligible to receive tiered royalties in the range from mid single digits up to low double digits on aggregate net sales of licensed products, on a per product basis 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 a certain period from the date of the first commercial sale of such product. 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. 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.

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 nonexclusive. 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 Genmab's termination for convenience, the licenses granted to Genmab will automatically terminate. Additionally, at our request, Genmab will grant us a nonexclusive, 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 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, 2019, 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. We will reimburse Arcturus for certain costs incurred in connection with development activities.

We agreed to pay Arcturus an upfront fee of $5 million in connection with the Arcturus Agreement and are required to pay an additional acceptance fee upon accepting the irrevocable offer with regard to each target under the Arcturus Agreement. We are additionally required to make certain royalty and milestone payments under the license agreements to be entered into in connection with our selection of targets.

Under the Arcturus Agreement, Arcturus granted us a worldwide, nonexclusive license under its LNP technology for research and preclinical development. We granted Arcturus a worldwide, nonexclusive

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. 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 or for Arcturus's change of control, 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 the Acuitas Agreement pursuant to which Acuitas granted us the right to reserve a certain number of 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. As of December 31, 2019 we have exercised our option to obtain a nonexclusive license to nine targets.

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. We will reimburse Acuitas for certain costs incurred in connection with development activities.

We are required to pay Acuitas an annual target reservation and maintenance fee for each target we reserve under the Acuitas Agreement. We are additionally required to pay an option exercise fee upon each exercise of our option under the Acuitas Agreement. We are additionally required to make certain royalty and milestone payments under the license agreements to be entered into upon each exercise of our option.

Under the Acuitas Agreement, Acuitas granted us a worldwide, nonexclusive license under its LNP technology for us to perform development activities and we granted Acuitas a worldwide, nonexclusive 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 2021 unless earlier terminated or extended. Both parties have the right to terminate the Acuitas 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 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. 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.

Acuitas Nonexclusive License Agreements

For each option we have exercised under the Acuitas Agreement, we have entered into a nonexclusive 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 nonexclusive, 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 nonexclusive licenses to exclusive licenses subject to certain additional financial obligations.

We must pay Acuitas milestone payments under each Acuitas License Agreement upon the occurrence of certain milestone events. We additionally are obligated to pay Acuitas annual fees for any additional protein targeted by a vaccine product licensed under an Acuitas License Agreement. We are further required to pay Acuitas a 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 a certain period following the first commercial sale of such product in such country. As of December 31, 2019, we have made a milestone payment to Acuitas with respect to the license agreement relating to Rabies RAV-G 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' 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 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.

We are eligible to receive up to a low nine-figure amount in development and 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 a certain period 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.

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.

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 (iii) by either party in the event of the other party's material breach following a cure period 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 the Boehringer Agreement with Boehringer Ingelheim 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 (former 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 (former CV9202) for all uses for cancer in humans, which option right expires in August 2024. As of December 31, 2019, Boehringer Ingelheim has not yet 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 (former 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 (former CV9202) is currently in Phase 1/2 of clinical investigation in combination with two checkpoint blocking antibodies, Durvalumab, a PD-L1 antibody, and Tremelimumab, an 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 (former CV9202). We are required to use commercially reasonable efforts to progress certain research and development activities in respect of the manufacturing of BI 1361849 (former CV9202). We are required to provide all BI 1361849 (former 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 (former 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. To date, we have received €7 million in milestone payments and can further achieve development, regulatory and commercial milestone payments of up to a mid nine-figure amount. 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 a certain period following the date of first commercial sale of such licensed product in such 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 (former CV9202) manufacturing technology. Boehringer Ingelheim is responsible for all other development and commercialization costs.

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 (former 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 (former 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 (former CV9202), as well as any intellectual property that is directed to the development or manufacture of BI 1361849 (former 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 (former CV9202), the exploitation of any product other than BI 1361849 (former CV9202) and for any use other than uses for cancer in humans. We grant Boehringer Ingelheim a cost-free, fully paid-up, nonexclusive, 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 (former 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 (former CV9202), the exploitation of any product other than BI 1361849 (former 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 nonexclusive 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 (former CV9202). 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 (former CV9202) for a certain period. In the event of termination for 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.

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, the Bill & Melinda Gates Foundation will provide up to a low seven-figure amount in funding and we are required to perform certain activities specified in a project collaboration plan. 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 nonexclusive, 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.

In November 2016 in connection with and subject to the terms of the Global Access Agreement, we were awarded a grant for up to a high six-figure amount in funding from the Bill & Melinda Gates Foundation for the development of a vaccine for picornaviruses. We granted the Bill & Melinda Gates Foundation a nonexclusive, 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 2021; 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, each for up to a low seven-figure amount in funding, from the Bill & Melinda Gates Foundation for the development of a universal influenza vaccine and a malaria vaccine respectively. 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 influenza grant agreement until June 2020, 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 or 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.

Coalition for Epidemic Preparedness Innovations Framework Partnering Agreement

In February 2019, we entered into 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 a SARS-CoV-2 vaccine.

We are required to use reasonable efforts to achieve certain development milestones and are 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 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.

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 $8.3 million in connection with development of the SARS-CoV-2 vaccine. In the event of our commercial use of the pharmaceutical products developed under the CEPI Agreement, we must notify CEPI and agree in good faith how such commercial benefits are to be equitably managed between the parties.

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 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 are unable to achieve certain milestones or in certain additional scenarios. 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. 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 to our financial statements contained elsewhere in this prospectus 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 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 a mid eight-figure sum in commercial milestone payments as well as certain development costs under each associated work order.

The parties jointly own any intellectual property developed under the Tesla Grohmann Agreement and Tesla Grohmann granted us a nonexclusive, 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 nonexclusive), 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 nonexclusive, 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 nonexclusive, 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 a certain period 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, Tesla Grohmann must grant us a nonexclusive, fully paid-up, world-wide, 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, we must pay Tesla Grohmann a termination fee and grant Tesla Grohmann a nonexclusive, 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.

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 all costs incurred in connection with research activities conducted 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 a low seven-figure amount in milestone payments per licensed product, an annual maintenance fee per licensed product and a low single-digit percentage royalty on net sales. Yale additionally granted us an exclusive option to negotiate an exclusive or nonexclusive 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 nonexclusive 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 low five-figure upfront payment, up to a low seven figure amount in milestone payments, and a low single-digit percentage royalty on net sales subject to certain minimum annual payments. We are required to provide a low seven-figure amount in funding to SERI in multiple payments during the term of 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 March 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. 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 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.

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 U.S. 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 April 17, 2020, we own approximately 47 issued U.S. patents, 120 pending U.S. patent applications, 186 issued foreign patents, 393 pending foreign patent applications and 14 pending Patent Cooperation Treaty, or PCT, patent applications, including two pending U.S. patent applications, sixteen 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 (former CV9202), CV7202, CV-SSIV, our SARS-CoV-2 vaccine and our CVCM delivery system, as described further below.

RNAoptimizer

As of April 17, 2020 we own 16 issued U.S. patents, 17 pending U.S. patent applications, 68 issued foreign patents, including in Europe, Canada, China, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 131 pending foreign patent applications and one PCT patent application 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 (former CV9202), CV7202, CV-SSIV and SARS-CoV-2 product candidates. 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 2039, excluding any additional term for patent term adjustments or patent term extensions.

CV8102

As of April 17, 2020 we own four issued U.S. patents, three pending U.S. patent applications, 31 issued foreign patents, including in Europe, Canada, China, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 29 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 (former CV9202)

As of April 17, 2020 we own ten issued U.S. patents, ten pending U.S. patent applications, 56 issued foreign patents, including in Europe, Canada, China, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 71 pending foreign patent applications relating to our BI 1361849 (former 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 April 17, 2020 we own four issued U.S. patents, five pending U.S. patent applications, 17 issued foreign patents, including in Europe, Canada, China, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 30 pending foreign patent applications relating to our CV7202 product candidate. The issued patents are expected to expire between 2022 and 2031, 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 April 17, 2020 we own five issued U.S. patents, ten pending U.S. patent applications, 22 issued foreign patents, including in Europe, Canada, China, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, 29 pending foreign patent applications and one PCT patent application 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.

SARS-CoV-2 vaccine

As of April 17, 2020 we own four issued U.S. patents, four pending U.S. patent applications, 17 issued foreign patents, including in Europe, Canada, China, Japan, the Republic of Korea, Singapore, Russia, Mexico and Australia, and 23 pending foreign patent applications and one PCT patent application relating to our SARS-CoV-2 product candidate. The issued patents are expected to expire between 2022 and 2031, 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 2040, excluding any additional term for patent term adjustments or patent term extensions.

CVCM delivery system

As of April 17, 2020 we own three issued U.S. patents, two pending U.S. patent applications, 11 issued foreign patents, including in Europe, Canada, China, Japan, the Republic of Korea, Singapore,

Russia, Mexico and Australia, and 12 pending foreign patent applications relating to our proprietary CVCM delivery system. The issued patents are expected to expire in 2029, 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 U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the U.S., 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 "Business — 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 "Risk Factors — Risks Related to Our Intellectual Property Rights."

Trademarks

As of April 17, 2020, we own trademark registrations or registration applications for CureVac, and the CureVac logo in the U.S. 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 "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 "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 postapproval 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 Trials 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 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 European Commission. The Clinical Trials Regulation will only become applicable six months after the European Commission confirms the full functionality of CTIS. Such a confirmation will only occur once CTIS is audited. The CTIS audit is currently planned for December 2020.

Marketing Authorization

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

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or 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 European Commission 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 European Commission 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 European Commission 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 health care 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 health care 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 attorney's 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. 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 and the United Kingdom, 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 or the United Kingdom, security breach notifications, and other requirements concerning the security and confidentiality of personal data. 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, in so far 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 and the United Kingdom to the U.S. The general transfer of personal data outside of the European Union and the United Kingdom 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 U.S. 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 U.S. 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 or United Kingdom. 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. In particular, the United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR taking effect in January 2021 (after the end of the transitional period) which could expose us to two parallel regimes each of which potentially authorizes fines for certain violations up to the greater of either 4% of the total global annual turnover of the preceeding financial year or €20 million. For more information regarding the risks related to data security and privacy, see “Risk Factors — Risks Related to Our Business and Industry.”

Our Employees

As of December 31, 2019, we had 454 total employees worldwide, 360 of whom were full-time, 116 of whom hold Ph.D. or M.D. degrees, 147 of whom were engaged directly or indirectly in production, 214 of whom were engaged in research and development activities, 29 of whom were engaged in clinical and regulatory activities, 9 of whom were engaged in marketing and sales activities, and 55 of whom were engaged in management, business development or marketing, finance, human resources or administrative support. Of our 454 total employees, 439 work in Germany and 15 work in the United States. We consider our relationship with our employees to be good. We are not subject to collective bargaining agreements or similar labor contracts and do not have a workers’ council.

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 sub-lease 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 sub-lease 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 (Phase 1 and 2 of clinical trials). In addition, we have established a third in-house production suit (GMP III) with an up-scaled manufacturing process, which was certified in March 2020. 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 above mentioned sub-lease agreements entered into with CureVac Real Estate GmbH.

We are also constructing a new manufacturing facility, designed for the development of a GMP production process on a large industrial scale 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 July 2022.

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.

Legal Proceedings

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this prospectus, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Unless otherwise noted, this section presents information about our management upon the consummation of the offering and after giving effect to the corporate reorganization. See "Corporate Reorganization."

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.

Management Board

Our management board is expected to be composed of six members, who we refer to as our managing directors (and who are also our executive officers). Following the closing of this offering, each managing director of CureVac N.V. will hold office for the term set by our general meeting (as set forth in the table below), except in the case of his or her earlier death, resignation or removal. Our managing directors do not have a retirement age requirement under our articles of association. The current members of the management board of CureVac AG are expected to be appointed as managing directors of CureVac N.V. prior to the closing of this offering.

Our managing directors are responsible for the management and representation of our company. We have a strong centralized management team led by Dr. Ingmar Hoerr, our CEO and co-founder. 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.

The following table lists our current managing directors — all of whom we consider executive officers — as well as their ages, term served, the year of expiration of their term as managing directors of CureVac N.V. and position:

Name	Age	Term Served	Year in which Term Expires	Position
Ingmar Hoerr, PhD, MBA	51	3/2020 – Present	2021	Chief Executive Officer
Florian von der Mülbe, PhD, MBA	47	9/2015 – Present	2021	Chief Production Officer
Mariola Fotin-Mleczek, PhD	53	9/2015 – Present	2021	Chief Technology Officer
Franz-Werner Haas, LLD, LLM	50	9/2015 – Present	2021	Chief Operating Officer
Pierre Kemula, B.Sc.	46	11/2016 – Present	2021	Chief Financial Officer
Bernd Winterhalter, MD, PhD[(1)]	61	6/2018 – Present	Not Defined	Chief Development Officer (Interim)

(1) 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. 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.

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 business addresses for each managing director is Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany.

Ingmar Hoerr, PhD, MBA is our chief executive officer since 2020. Dr. Hoerr founded CureVac in 2000 together with Florian von der Mülbe and other colleagues in Tübingen. He was elected in 2018 as our chairman of the supervisory board, a position in which he served until his transition to the management board in March 2020, and initially served as our CEO and head of business development from 2000 until 2018. He currently advises the European Commission as member of the High Level Group of Innovators in developing a European Innovation Council and is juror of the founder prize WEconomy. He recently

served on the Founding Board of Agency of Disruptive Innovations initiated by the German ministers Karliczek and Altmaier and is a member of the Board of Trustees of the Max Planck Institute for Biological Cybernetics, Developmental Biology and the Friedrich Miescher Laboratory in Tuebingen. Dr. Hoerr received his PhD from the University of Tübingen and his MBA from Danube University, Krems, Austria.

Florian von der Mülbe, PhD, 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, PhD, 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: oncology, infectious diseases and protein therapy. 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.

Franz-Werner Haas, LLD, LLM is our chief operating officer since 2018. Mr. Haas was our chief corporate officer from 2012 until 2018. He is responsible for our HR, IP, and Legal and Operations functions. 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.

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 (LSE) in the United Kingdom.

Bernd Winterhalter, MD, PhD is our interim chief development officer since December 2019. He has served as a consultant and interim manager of CureVac since June 2018. Previously, Dr. Winterhalter was the executive medical director of Bristol-Myers Squibb for European Markets, Turkey and Russia from 2012 until 2018 and executive medical director for Germany from 2004 until 2011, where he successfully contributed to the clinical development and market introduction of 15 new products in multiple therapeutic areas, as well as Vice President Medical and Science and Health Economics at Pharmacia (Pfizer) in Germany from 1997 to 2003. Earlier in his career, Dr. Winterhalter worked as ward physician at the department of internal medicine I (medical oncology and hematology) at the university hospital Albert Ludwigs University Freiburg. He is a board certified specialist of internal medicine since 1993 and holds a Ph.D. and an MD degree from Albert Ludwigs University in Freiburg.

Supervisory Board

We are currently reviewing the composition of our supervisory board and our corporate governance practices in light of this offering and applicable requirements of the DCGC, SEC and Nasdaq. In subsequent filings with the SEC, we will update any relevant disclosure herein as appropriate.

Our supervisory board is expected to be composed of at least seven members. Following the closing of this offering, each supervisory director will hold office for the term set by our general meeting (as set forth in the table below), except in the case of his earlier death, resignation or removal. Our supervisory directors do not have a retirement age requirement under our articles of association. The current members of the supervisory board of CureVac AG are expected to be appointed as supervisory directors of CureVac N.V. prior to the closing of this offering.

The following table sets forth the names and functions of our current supervisory directors, their ages, term served and the year of expiration of their term as supervisory directors of CureVac N.V.:

Name	Age	Term Served	Year in which Term Expires	Functions
Baron Jean Stéphenne, MSc, MBA	70	8/2015 – Present	2020	Chairman
Ralf Clemens, MD, PhD	67	8/2015 – Present	2020	Supervisory Director
Mathias Hothum, PhD	53	8/2015 – Present	2020	Supervisory Director
Hans Christoph Tanner, PhD	68	8/2015 – Present	2020	Supervisory Director
Friedrich von Bohlen und Halbach, PhD	58	8/2015 – Present	2020	Supervisory Director
Timothy M. Wright, MD	64	6/2019 – Present	2024	Supervisory Director
Craig A. Tooman, MBA	54	6/2019 – Present	2024	Supervisory Director

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 the our supervisory directors is Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany.

Baron Jean Stéphenne, MSc, MBA has served as a supervisory director since 2016. 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, PhD has served as a supervisory director since 2016. Dr. Clemens is 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 led the global vaccine development at Novartis from 2006 until 2012. Prior to this position, Dr. Clemens 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 and as 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. He is a member of the Selection Committee of GHIT Tokyo, Japan and a member of the Scientific Committee of CEPI, Oslo, Norway. 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, PhD has served as a supervisory director since 2016. 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, PhD has served as a supervisory director since 2016. Since 2015 Dr. Tanner is the chief financial officer and head of investor relations of Cassiopea S.p.A. 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. Dr. Tanner is also a member of the supervisory board or advisory board (Beirat) of DKSH AG, Paion AG since 2017, Qvanteq AG since 2011, and Joimax GmbH since 2003. He received his Ph.D. in economics and a diploma as an economist from the University of St. Gallen. 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.

Friedrich von Bohlen und Halbach, PhD has served as a supervisory director since 2016. 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 AC Immune SA, CureVac AG, immatics biotechnologies GmbH, 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 postdoctoral 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 September of 2019, Mr. Tooman has 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.

Committees

Audit Committee

The audit committee, which is expected to consist of , and , will assist the supervisory board in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee will be responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our supervisory board has determined that satisfies 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 intend to rely 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 independence standard for audit committee membership within one year of the effectiveness of the registration statement of which this prospectus forms a part. The audit committee will be governed by a charter that complies with applicable Nasdaq rules, which charter will be posted on our website prior to the listing of our common shares on Nasdaq.

Compensation Committee

The compensation committee is expected to consist of and . The compensation committee will assist the supervisory board in determining compensation for our executive officers and our managing directors and supervisory directors. The composition of our compensation committee is consistent with the best practice provisions of the DCGC.

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 will opt out of Nasdaq Listing Rule 5605(d), which requires that a compensation committee consist entirely of independent supervisory directors. The compensation committee will be governed by a charter that will be posted on our website prior to the listing of our common shares on Nasdaq.

Nomination and Corporate Governance Committee

The nomination and corporate governance committee is expected to consist of and . The nomination and corporate governance committee will assist 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 is consistent with the best practice provisions of the DCGC.

As permitted by the listing requirements of Nasdaq, we will opt out of Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations. The nominating and corporate governance committee will be governed by a charter that will be posted on our website prior to the listing of our common shares on Nasdaq.

Remuneration and Other Benefits to Supervisory and Managing Directors for the Year Ended December 31, 2019

As a foreign private issuer, in accordance with Nasdaq listing requirements, we will comply with home country compensation requirements and certain exemptions thereunder rather than complying with Nasdaq compensation requirements. Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to our managing directors or supervisory directors, provided that such compensation is consistent with our compensation policy. Such compensation policy requires approval by our general meeting. The supervisory board determines the remuneration of individual managing directors with due observance of the compensation policy. A proposal with respect to remuneration schemes in the

form of shares or rights to shares in which managing directors may participate is subject to approval by our general meeting. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the managing directors and the criteria for granting or amendment. The compensation for our supervisory directors is set by the general meeting.

Our compensation policy will authorize 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, 2019, the aggregate compensation accrued or paid to our supervisory directors for services in all capacities was €510,276. The following table sets forth the aggregate compensation and benefits provided to our supervisory board members in the year ended December 31, 2019.

Name	Fixed Compensation (€)	Attendance Fees (€)	Total Compensation (€)
Baron Jean Stéphenne	82,500		82,500
Ralf Clemens	55,000	27,500	82,500
Mathias Hothum	55,000		55,000
Hans Cristoph Tanner	55,000	27,500	82,500
Friedrich von Bohlen und Halbach	55,000		55,000
Ingmar Hoerr[1]	110,000		110,000
Timothy M. Wright	21,389		21,388
Craig A. Tooman	21,389		21,388

(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.

Share Ownership of Supervisory Directors

The following table sets forth the share ownership of our supervisory directors as of December 31, 2019.

Name	Number of Shares	Percentage of Shares Outstanding	Voting Rights
Baron Jean Stéphenne	—	—	—
Ralf Clemens	—	—	—
Mathias Hothum	—	—	—
Hans Cristoph Tanner	1,414	0.20%	[2]
Friedrich von Bohlen und Halbach	1,818	0.24%	[3]
Ingmar Hoerr[1]	8,485	1.14%	[4]
Timothy M. Wright	—	—	—
Craig A. Tooman	—	—	—

(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. Of his 8,485 shares, 85 are Series A shares and 8,400 are Series C shares.

(2) Dr. Tanner holds Series A shares, each of which carries one vote per share.

(3) Dr. Halbach holds Series A shares, each of which carries one vote per share.

(4) Dr. Hoerr holds Series A shares and Series C shares, each of which carries one vote per share.

Option Ownership of Supervisory Directors

The following table sets forth the option ownership of our supervisory directors as of December 31, 2019.

Name	Number of Options	Title	Amount of Securities (€)	Exercise Price (€)	Purchase Price (€)	Expiration Date
Baron Jean Stéphenne	—	—	—	—	—	—
Ralf Clemens	—	—	—	—	—	—
Mathias Hothum	—	—	—	—	—	—
Hans Cristoph Tanner	—	—	—	—	—	—
Friedrich von Bohlen und Halbach	—	—	—	—	—	—
Ingmar Hoerr[1]	2,776	Share Option Awards	2,776	1.00	2,776	12/31/2021
Timothy M. Wright	—	—	—	—	—	—
Craig A. Tooman	—	—	—	—	—	—

(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.

Management Board

Compensation of Managing Directors

For the year ended December 31, 2019, the aggregate compensation accrued or paid to our managing directors for services in all capacities was €3,314,153 (including an approximate conversion of Mr. Menichella's and Mr. Voliotis's compensation from USD to euros and excluding the severance payment to Mr. Voliotis) . The following table sets forth the compensation and benefits provided to our management board in the year ended December 31, 2019.

Name	Salary (€)	Bonus (€)[3]	All Other Compensation[4] (€)	Total Compensation (€)
Daniel L. Menichella[1][2]	508,455[3]	206,250	37,098	751,803
Florian von der Mülbe	250,000	84,375	25,634	360,009
Mariola Fotin-Mleczek	210,000	70,875	12,977	293,852
Franz-Werner Haas	247,000	111,150	25,442	383,592
Pierre Kemula[5]	250,000	84,375	146,103	480,478
Bernd Winterhalter[6]	—	—	333,601	333,601
Dimitris Voliotis[7][2]	425,208	168,760	—	593,958
Ulrike Gnad-Vogt[8]	187,500	63,281	9,732	260,513

(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.

(2) Compensation is expressed in USD. Mr. Menichella also holds 29,053 options. See note 9.4 to our consolidated financial statements, contained elsewhere in this prospectus, for further information on Mr. Menichella's New Plan.

(3) 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.

(4) All other compensation includes other monetary benefits and contributions to social security insurance, if any.

(5) Mr. Kemula also holds 5,000 Beteiligungspunkte (virtual shares). See note 9.2 to our consolidated financial statements, contained elsewhere in this prospectus, for further information on Mr. Kemula's award.

(6) 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. He serves as our interim chief development officer under a consulting agreement dated as of December 14, 2019 that specifies his service is indefinite and may be terminated by either party with four weeks' notice. 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. The amount shown as bonus payment does not include the severance payment made to him in 2020.

(8) Ms. Gnad-Vogt resigned from our management board effective September 30, 2019.

We did not provide pension, retirement or similar benefits to our managing directors and supervisory directors board in the year ended December 31, 2019.

Share Ownership of Managing Directors

The following table sets forth the share ownership of our managing directors as of December 31, 2019.

Name	Number of Shares	Percentage of Shares Outstanding	Voting Rights
Daniel L. Menichella[1]	—	—	—
Florian von der Mülbe	6,162[2]	0.83%	[3]
Mariola Fotin-Mleczek	—	—	—
Franz-Werner Haas	—	—	—
Pierre Kemula	—	—	—
Bernd Winterhalter[4]	—	—	—
Dimitris Voliotis	—	—	—
Ulrike Gnad-Vogt	—	—	—

(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.

(2) Of such shares, 62 are Series A shares and 6,100 are Series C shares.

(3) Mr. Mülbe holds both Series A and Series C shares, each of which carries one vote per share.

(4) 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. He serves as our interim chief development officer under a consulting agreement dated as of December 14, 2019 that specifies his service is indefinite and may be terminated by either party with four weeks' notice. Amount included in his total compensation column includes reimbursement for travel and out of pocket expenses.

Option Ownership of Managing Directors

The following table sets forth the option ownership of our managing directors as of December 31, 2019.

Name	Number of Options	Title	Amount of Securities (€)	Exercise Price (€)	Purchase Price (€)	Expiration Date
Daniel Menichella[1]	—	—	—	—	—	—
Florian von der Mülbe	2,017	Share Option Awards	2,017	1.00	2,017	12/31/2021
Mariola Fotin-Mleczek	—	—	—	—	—	—
Franz-Werner Haas	—	—	—	—	—	—
Pierre Kemula	—	—	—	—	—	—
Bernd Winterhalter[2]	—	—	—	—	—	—
Dimitris Voliotis	—	—	—	—	—	—
Ulrike Gnad-Vogt	—	—	—	—	—	—

(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. Under the terms of the Menichella Employment Agreement, Mr. Menichella is entitled to receive up to 29,053 options. See note 9.4 to our consolidated financial statements, contained elsewhere in this prospectus, for further information on Mr. Menichella's New Plan.

(2) 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. 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.

Virtual Point ("VAP") Ownership of Management Board Members from VSOP Programs

Management Board VAP Status as of December 31, 2019

Name	Program	VAP Points Granted	Max Vested Points	Start of Vesting Period (Only for New Participants)	Grant date (Date of Allocation Letter)	Vesting Period	VSOP Plan	Valid until
Florian von der Mülbe	VAP	778	778		01.01.2009	36	VAP Old	31.12.2025
Florian von der Mülbe	VAP	3,486	3,486		01.01.2011	36	VAP Old	31.12.2025
Florian von der Mülbe	VAP	736	736		01.01.2013	36	VAP Old	31.12.2025
Florian von der Mülbe	VAP	1,522	1,522		01.01.2015	12	VAP Old	31.12.2025
Florian von der Mülbe	VAP	6,100	6,100		11.12.2015	12	VAP Old IPO only	31.12.2025
Mariola Fotin-Mleczek	VAP	316	316		01.01.2009	60	VAP Old	31.12.2025
Mariola Fotin-Mleczek	VAP	250	250		01.01.2013	36	VAP Old	31.12.2025
Mariola Fotin-Mleczek	VAP	250	250		01.01.2014	36	VAP Old	31.12.2025
Mariola Fotin-Mleczek	VAP	250	250		01.01.2015	36	VAP Old	31.12.2025
Mariola Fotin-Mleczek	VAP	2,327	2,327		01.01.2015	12	VAP Old	31.12.2025
Ulrike Gnad-Vogt	VAP	682	682		01.07.2011	60	VAP Old	31.12.2025
Ulrike Gnad-Vogt	VAP	250	250		01.01.2013	36	VAP Old	31.12.2025
Ulrike Gnad-Vogt	VAP	250	250		01.01.2014	36	VAP Old	31.12.2025
Ulrike Gnad-Vogt	VAP	250	250		01.01.2015	36	VAP Old	31.12.2025
Ulrike Gnad-Vogt	VAP	1,961	1,961		01.01.2015	12	VAP Old	31.12.2025
Franz-Werner Haas	VAP	1,400	1,400		01.06.2012	36	VAP Old	31.12.2025
Franz-Werner Haas	VAP	3,600	3,600		01.01.2013	36	VAP Old	31.12.2025
Franz-Werner Haas	VAP	1,522	1,522		01.01.2015	12	VAP Old	31.12.2025
Pierre Kemula	VAP	5,000	5,000	01.10.2016	18.04.2019	36	VAP Old	31.12.2025
Daniel Menichella*	*	29,053	29,053	08.01.2017	14.10.2019	48	*	08.01.2027

* Daniel Menichella: New Plan – Kick in price at a valuation of USD 800 million. See note 9.4 to our consolidated financial statements, contained elsewhere in this prospectus, for further information on Mr. Menichella's New Plan.

Service Agreements

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 (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.

Management Board Service Contracts

We entered into a Management Board Services Contract with the following managing directors: Mr. Hoerr, Mr. Mülbe, Ms. Fotin-Mleczek, Mr. Haas, and Mr. Kemula ("Management Contracts"). The Management Contracts generally provide for a term of either three 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.

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.

Employment Agreements with Daniel Menichella

In January 2017, we entered into an employment agreement with Daniel Menichella which provided that Mr. Menichella will serve as the Chief Executive Officer ("CEO") of CureVac Inc (the "Prior Menichella Agreement"). In June 2018, we entered into an employment agreement with Mr. Menichella ("Menichella Employment Agreement"), which terminated and replaced the Prior Menichella Agreement, under which Mr. Menichella became the CEO of CureVac AG in addition to CureVac Inc. Under the Menichella Employment Agreement, Mr. Menichella is entitled to receive an initial base salary of $500,000 and is eligible to receive a discretionary bonus in a target amount of up to 55% of his base salary conditioned upon our financial performance and Mr. Menichella meeting certain agreed upon performance goals established jointly with our Management and our Board of Directors. Mr. Menichella is also entitled to the specified allowances and perquisites under the Menichella Employment Agreement, including reimbursement of certain expenses (i.e., moving expenses) and commuting, housing and vehicle allowances.

Under the terms of the Menichella Employment Agreement, Mr. Menichella is also entitled to receive up to 29,053 options, which provide Mr. Menichella with a cash claim against CureVac AG, which can 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 expire on January 8, 2027.

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 health care 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 by Dr. Hoerr on that same day.

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 with him in 2015, which is substantially similar to the management board service 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 (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 "Related Party Transactions."

On March 10, 2020, Dr. Hoerr succeeded Mr. Menichella as a managing director on the management board.

Consulting Agreement with Bernd Winterhalter

We entered into a consulting agreement with Dr. Winterhalter in June 2018 (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.

Offer Letter with Pierre Kemula

We entered into an offer letter with Pierre Kemula in April 2019 (the "Kemula Offer Letter") to prolong his service on the management board pursuant to the Management Board Service 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, 5,000 Beteiligungspunkte (virtual shares). See note 9.2 to our consolidated financial statements, contained elsewhere in this prospectus, for further information on Mr. Kemula's award.

Employment Agreement and Separation Agreement with Dimitris Voliotis

We entered into an employment agreement with Dimitris Voliotis in January 2019 whereby Mr. Voliotis agreed to serve as the Chief Development Officer of CureVac. The agreement provides for a base salary, discretionary bonus, equity opportunities and additional allowances. The agreement provides Mr. Violiotis with severance in the event we terminate him for convenience or without cause equal to nine months of his base salary and a pro rata portion of his discretionary bonus. The agreement contains restrictive covenants, including covenants related to confidentiality and proprietary information, and a non-competition and non-solicit of customers and employees for nine months after termination.

We subsequently entered into a separation agreement with Mr. Voliotis in January 2020 under which Mr. Violiotis resigned from his employment and received separation pay equal to nine months of his base salary and his discretionary bonus less half of the signing bonus received in connection with his employment agreement

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 receive share-based compensation under the legacy management stock option plan (''Legacy Management Stock Option Plan'') in the form of share option awards. As of December 31, 2019 there were a total of 8,932 option awards outstanding and exercisable out of the Legacy Management Stock Option Plan. 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, with 3,650 of these options expired pursuant to the terms of the Plan on December 31, 2018 and another 5,282 options will expire on December 31, 2021.

In addition to the management share option awards described above, we have a virtual share plan for members of the management board and other key employees of CureVac ("Prior VSOP") under which a total of up to 60,175 Beteiligungspunkte (virtual shares) may be issued. As of December 31, 2019, there were 54,899 virtual shares issued and 5,276 outstanding under the Prior VSOP. The economic burden of the Prior VSOP will be borne exclusively by those shareholders already invested in CureVac AG as of October 1, 2015. The holders of the virtual shares do not hold a direct interest in CureVac AG. A holder is able to exchange his or her virtual shares (in whole or partly) for cash or shares of CureVac upon the occurrence of certain defined triggering events, which means (1) a merger, (2) a sale or (3) an IPO of CureVac combined with the satisfaction of one condition from the list of enumerated conditions listed in the Prior VSOP. This offering will constitute an IPO under the Prior VSOP; however, one of the enumerated conditions must also be satisfied in order for the holders to be eligible up to 10% of their virtual shares for the exchange of shares. If no triggering event or conversion occurs within the term of the Prior VSOP, which extends until December 31, 2025, all rights under the Prior VSOP will be forfeited. Following this offering, the rights under the Prior VSOP terminate after the expiry of the ninth calendar year after the first listing.

Due to the increase in value of CureVac, 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 current valuation and conditional upon certain enumerated exercise cases (such as an asset, share, or merger deal, equity financing, or IPO) reflecting such value-increase ("New VSOP"). As of December 31, 2019, there were 21,888 virtual shares outstanding under the New VSOP. The New VSOP provides a cash-claim against CureVac in the amount of the positive difference between the value of CureVac per virtual share at the grant date and the value per virtual share at the time of exercise of such virtual share and gives CureVac discretion to provide newly listed shares against payment of the value of CureVac per virtual share at the grant date. Such options provided under the New VSOP have a term of ten years 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.

In connection with this offering, we intend to establish a new equity incentive plan (the "Plan") pursuant to which we may grant options, restricted stock, restricted stock units, share appreciation rights and other equity and equity-based awards. The maximum number of common shares underlying awards granted pursuant to the Plan, the Prior VSOP and the New VSOP shall in total not exceed an equivalent of 15% of our issued share capital immediately following the closing of this offering. The Plan will be 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 "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 will provide for special provisions for good leaver and bad leaver as well as for a change in control of our company.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics, or code of conduct, which outlines the principles of legal and ethical business conduct under which we do business. The code of conduct applies to all of our management board and supervisory directors and employees. Upon the closing of this offering, the full text of the code of conduct will be available on our website at www.curevac.com. The information and other content appearing on our website are not part of this prospectus.

In addition, we have implemented a compliance management policy which describes the compliance management system implemented at CureVac AG, which is designed to ensure compliance with all legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the management board, which reports regularly to the audit committee. In the performance of its compliance responsibilities, the management board has delegated the corresponding tasks to various functions at CureVac AG.

PRINCIPAL SHAREHOLDERS

As of the date of this prospectus, our authorized share capital is € , consisting of common shares, par value €0.12 per share. Each of our common shares entitles its holder to one vote. The following table presents information relating to the beneficial ownership of our common shares as of , 2020 and after giving effect to our corporate reorganization by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding common shares;
- each managing director and supervisory director; and
- all managing directors and supervisory directors as a group.

Subsequent to the pricing of this offering and as the initial step of our corporate reorganization, all of the outstanding shares in CureVac AG will be contributed and transferred to CureVac B.V. in a capital increase in exchange for common shares of CureVac B.V. on a -to- basis. Following the completion of this offering and the corporate reorganization, we will have only one class of shares issued and outstanding, and all outstanding common shares will carry the same voting rights. See "Corporate Reorganization."

The number of common shares beneficially owned by each entity, person, supervisory director or managing director is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any common shares over which the individual has sole or shared voting power or investment power as well as any common shares that the individual has the right to acquire within 60 days of , 2020 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all common shares held by that person.

The percentage of outstanding common shares is computed on the basis of common shares outstanding as of , 2020. Common shares that a person has the right to acquire within 60 days of , 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all members of the supervisory board and management board as a group. Unless otherwise indicated below, the address for each beneficial owner is CureVac AG, Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany.

	Common shares beneficially owned prior to the corporate reorganization and the Offering		Common shares beneficially owned after giving effect to the corporate reorganization and the Offering		
			No exercise of underwriter's option		Full exercise of underwriter's option
Shareholder	Number	Percentage	Number	Percentage	Percentage
5% Shareholders:					
dievini Hopp BioTech holding GmbH & Co. KG		%		%	%
Mr. Dietmar Hopp		%		%	%
Managing Directors:					
Ingmar Hoerr, PhD, MBA		%		%	%
Florian von der Mülbe, PhD, MBA		%		%	%
Mariola Fotin-Mleczek, PhD		%		%	%
Franz-Werner Haas, LLD, LLM		%		%	%
Pierre Kemula, B.Sc.		%		%	%

	Common shares beneficially owned prior to the corporate reorganization and the Offering		Common shares beneficially owned after giving effect to the corporate reorganization and the Offering		
			No exercise of underwriter's option		Full exercise of underwriter's option
Shareholder	**Number**	**Percentage**	**Number**	**Percentage**	**Percentage**
Supervisory Directors:					
Ralf Clemens, MD, PhD		%		%	%
Mathias Hothum, PhD		%		%	%
Baron Jean Stéphenne, MSc, MBA		%		%	%
Hans Cristoph Tanner, PhD		%		%	%
Friedrich von Bohlen und Halbach, PhD		%		%	%
Timothy M. Wright, MD		%		%	%
Craig A. Tooman, MBA		%		%	%
All Managing Directors and Supervisory Directors as a Group:		**%**		**%**	**%**

* Represents beneficial ownership of less than 1%.

As of , 2020, after giving effect to our corporate reorganization, common shares, representing % of our issued and outstanding common shares, were held by U.S. record holders.

Following the completion of this offering and the corporate reorganization, each of our shareholders is entitled to one vote per common share. None of the holders of our shares will have different voting rights from other holders of shares after the closing of this offering. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into since January 1, 2017 with any of our management and supervisory directors and the holders of more than 5% of our common shares.

dievini Hopp BioTech holding GmbH & Co. KG, Walldorf

Dievini holds the majority of our capital stock and is the controlling shareholder. Molecular Health GmbH (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 2017, 2018 and 2019, payments to Molecular Health with respect to research and development amounted to €60,000, €30,000 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 ("Convertible Loan I"). On October 24, 2019, we entered into an additional convertible loan agreement with Mr. Hopp, 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, if our cash balance falls below €15,000,000 ("Convertible Loan II," and together with Convertible Loan I, the "Loans"). The Loans bear an interest rate of 8.00% per annum. As of December 31, 2019, the outstanding principal amount is €69,889,000. Prior to the consummation of this offering, the amount outstanding under the Loans could be converted into shares of CureVac AG and subsequently exchanged for common shares in CureVac N.V. in connection with our corporate reorganization. See note 12 to our financial statements contained elsewhere in this prospectus for further information on the Loans and "Corporate Reorganization" for further information on our corporate reorganization.

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 2017, 2018 and 2019, consulting fees of €67,500, €144,900 and €208,000 were paid to Rittershaus. Prof. Dr. Christof Hettich, one of the managing directors of dievini is a partner of Rittershaus.

Dr. Ingmar Hörr

From June 2018 until March 2020 an advisory agreement was in place between Dr. Ingmar Hoerr and CureVac. Dr. Hoerr, our CEO since March 10, 2020, received €144,000 and €240,000 for consulting services in fiscal years 2018 and 2019, respectively.

Investment and Shareholders Agreement

We and the shareholders who subscribed for our Series A, B and C shares entered into a shareholders agreement, dated December 18, 2019 (the "Shareholders Agreement"). The Shareholders Agreement provides for certain particular shareholders' rights and also envisages restrictions on the shareholders party thereto, including restrictions on transfer, as well as certain tag along rights, drag along rights, demand rights, rights of first offer and rights of first refusal. The Shareholders Agreement will be terminated as a result of the corporate reorganization.

Indemnification Agreements

Our articles of association, as they will be effective upon closing of the offering, will 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 intend to enter into indemnification agreements with all our managing directors and supervisory directors, effective upon the closing of this offering.

Employment Agreements

Certain of our managing directors and supervisory directors have entered into service agreements with us as discussed in more detail within the “Management Board Service Contracts” and “Supervisory Board Service Contracts” sections above.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

We were incorporated pursuant to the laws of the Netherlands as CureVac B.V. on April 7, 2020 to become a holding company for CureVac AG prior to the closing of this offering. Pursuant to the terms of a corporate reorganization that will be completed prior to the closing of this offering, all of the outstanding shares in CureVac AG will be contributed and transferred to CureVac B.V. in a capital increase in exchange for common shares of CureVac B.V. and, as a result, CureVac AG will become a wholly owned subsidiary of CureVac B.V. Immediately following such exchange, and prior to the listing of our common shares on Nasdaq, we intend to convert into a public company (*naamloze vennootschap*) under Dutch law pursuant to a Dutch notarial deed of amendment and conversion, following which our legal name will be CureVac N.V. See "Corporate Reorganization." Our affairs are governed by the provisions of our articles of association and internal rules, regulations and policies, as amended and restated from time to time, and by the provisions of applicable Dutch law.

As provided in our articles of association, subject to Dutch law, we have full capacity to carry on or undertake any business or activity, do any act or enter into any transaction consistent with the objects specified in our articles of association, and, for such purposes, full rights, powers and privileges. Our registered office is Friedrich-Miescher-Strasse 15, 72076, Tübingen, Germany.

As of the execution of our deed of conversion and amendment as part of the corporate reorganization (see "Corporate Reorganization"), our authorized share capital will amount to € , divided into common shares, each with a nominal value of €0.12, and our issued share capital will amount to € . Upon the closing of this offering, our issued share capital will amount to € . We intend to apply to list our common shares on Nasdaq under the symbol "CVAC."

Initial settlement of our common shares will take place on the closing date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities. Each person owning common shares held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the common shares. Persons wishing to obtain certificates for their common shares must make arrangements with DTC.

The following is a summary of relevant information concerning our share capital and our articles of association as they will read upon the closing of this offering. This summary does not constitute legal advice regarding those matters and should not be regarded as such.

Common Shares

The following summarizes the main rights of holders of our common shares:

- each holder of common shares is entitled to one vote per share on all matters to be voted on by shareholders generally, including the appointment of managing directors and supervisory directors;
- there are no cumulative voting rights;
- the holders of our common shares are entitled to dividends and other distributions as may be declared from time to time by us out of funds legally available for that purpose, if any;
- upon our liquidation, dissolution or winding-up, the holders of common shares will be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities; and
- the holders of common shares have preemptive rights in case of share issuances or the grant or rights to subscribe for shares, except if such rights are limited or excluded by the corporate body authorized to do so and except in such cases as provided by Dutch law and our articles of association.

Shareholders' Register

Pursuant to Dutch law and our articles of association, we must keep our shareholders' register accurate and current. The management board keeps our shareholders' register and records names and addresses of all holders of shares, showing the date on which the shares were acquired, the date of the

acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a right of use and enjoyment (*vruchtgebruik*) in shares belonging to another or a pledge (*pandrecht*) in respect of such shares. The common shares offered in this offering will be held through DTC, therefore DTC or its nominee will be recorded in the shareholders' register as the holder of those common shares. The shares are in registered form (*op naam*). We may issue share certificates (*aandeelbewijzen*) for registered shares in such form as may be approved by our management board.

Corporate Objectives

Pursuant to our articles of association, our main corporate objectives are:

- to develop, license, manufacture and commercialize pharmaceutical and related products;
- to incorporate, to participate in, to finance, to hold any other interest in and to conduct the management or supervision of other entities, companies, partnerships and businesses;
- to acquire, to manage, to invest, to exploit, to encumber and to dispose of assets and liabilities;
- to furnish guarantees, to provide security, to warrant performance in any other way and to assume liability, whether jointly and severally or otherwise, in respect of obligations of group companies or other parties; and
- to do anything which, in the widest sense, is connected with or may be conducive to the objects described above.

Limitations on the Rights to Own Securities

Our common shares may be issued to individuals, corporations, trusts, estates of deceased individuals, partnerships and unincorporated associations of persons. Our articles of association contain no limitation on the rights to own our shares and no limitation on the rights of nonresidents of the Netherlands or foreign shareholders to hold or exercise voting rights.

Limitation on Liability and Indemnification Matters

Under Dutch law, managing directors and supervisory directors may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to the company and to third parties for infringement of the articles of association or of certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Subject to certain exceptions, our articles of association provide for indemnification of our current and former managing directors and supervisory directors (and other current and former officers and employees as designated by our management board). No indemnification shall be given to an indemnified person:

(a) if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);

(b) to the extent that his or her financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);

(c) in relation to proceedings brought by such indemnified person against the company, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and the company which has been approved by the management board or pursuant to insurance taken out by the company for the benefit of such indemnified person; and

(d) for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without the company's prior consent.

Under our articles of association, our management board may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

Shareholders' Meetings

General meetings may be held in Amsterdam, Arnhem, Assen, The Hague, Haarlem, Hertogenbosch, Groningen, Leeuwarden, Lelystad, Maastricht, Middelburg, Rotterdam, Schiphol (Haarlemmermeer), Utrecht or Zwolle, all in the Netherlands. The annual general meeting must be held within six months of the end of each financial year. Additional extraordinary general meetings may also be held, whenever considered appropriate by the management board or the supervisory board and shall be held within three months after our management board has considered it to be likely that our equity has decreased to an amount equal to or lower than half of its paid-in and called up share capital, in order to discuss the measures to be taken if so required.

Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law who jointly represent at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party/parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting. The court shall disallow the application if it does not appear that the applicants have previously requested our management board and our supervisory board to convene a general meeting and neither our management board nor our supervisory board has taken the necessary steps so that the general meeting could be held within six weeks after the request.

General meetings must be convened by an announcement published in a Dutch daily newspaper with national distribution. The notice must state the agenda, the time and place of the meeting, the record date (if any), the procedure for participating in the general meeting by proxy, as well as other information as required by Dutch law. The notice must be given at least 15 days prior to the day of the meeting. The agenda for the annual general meeting shall include, among other things, the adoption of the annual accounts, appropriation of our profits and proposals relating to the composition of the management board and supervisory board, including the filling of any vacancies in such bodies. In addition, the agenda shall include such items as have been included therein by the management board or the supervisory board. The agenda shall also include such items requested by one or more shareholders, or others with meeting rights under Dutch law, representing at least 3% of the issued share capital. Requests must be made in writing or by electronic means and received by us at least 60 days before the day of the meeting. No resolutions shall be adopted on items other than those that have been included in the agenda.

In accordance with the DCGC and our articles of association, shareholders having the right to put an item on the agenda under the rules described above shall exercise such right only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy (for example, the removal of managing directors or supervisory directors), the management board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, the management board must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the management board shall report on this consultation and the exploration of alternatives to the general meeting. This shall be supervised by our supervisory board. The response period may be invoked only once for any given general meeting and shall not apply: (a) in respect of a matter for which a response period has been previously invoked; or (b) if a shareholder holds at least 75% of the company's issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting be convened, as described above.

The general meeting is presided over by the chairman of the supervisory board. If no chairman has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by another supervisory director present at the meeting. If no supervisory director is present, the meeting shall be presided over by our CEO. If no CEO has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by another managing director present at the meeting. If no managing director is present at the meeting, the general meeting shall be presided over by any other person appointed by the general meeting. In each case, the person who should chair the general meeting pursuant to the rules described above may appoint another person to chair the general meeting instead. Managing directors and supervisory directors may always attend a general meeting. In these meetings, they have an advisory vote. The chairman of the meeting may decide at his or her discretion to admit other persons to the meeting.

All shareholders and others with meeting rights under Dutch law are authorized to attend the general meeting, to address the meeting and, in so far as they have such right, to vote pro rata to his or her shareholding. Shareholders may exercise these rights, if they are the holders of shares on the record date, if any, as required by Dutch law, which is currently the 28th day before the day of the general meeting. Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

Each common share confers the right on the holder to cast one vote at the general meeting. Shareholders may vote by proxy. No votes may be cast at a general meeting on shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depository receipts. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use and enjoyment (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge (*pandrecht*). Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a general meeting.

Decisions of the general meeting are taken by a simple majority of votes cast, except where Dutch law or our articles of association provide for a qualified majority or unanimity.

Managing Directors and Supervisory Directors

Appointment of Managing Directors and Supervisory Directors

Under our articles of association, the managing directors and supervisory directors are appointed by the general meeting upon binding nomination by our supervisory board. However, the general meeting may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting overrules the binding nomination, the supervisory board shall make a new nomination.

Prior to the closing of this offering, our supervisory board shall adopt a diversity policy for the composition of our management board and our supervisory board, as well as a profile for the composition of the supervisory board. The supervisory board shall make any nomination for the appointment of a managing director or supervisory director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

At a general meeting, a resolution to appoint a managing director or supervisory director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that general meeting or in the explanatory notes thereto.

Under Dutch law, when nominating a person for appointment or reappointment as a supervisory director, the nomination must be supported by reasons (if it concerns a reappointment, past performance

must be taken into consideration) and the following information about such person must be provided: (i) age and profession; (ii) the aggregate nominal value of the shares held in the company's capital; (iii) present and past positions, to the extent relevant for the performance of the tasks of a supervisory director; and (iv) the name of each entity where such person already holds a position as supervisory director or non-executive director (in case of multiple entities within the same group, the name of the group shall suffice).

Duties and Liabilities of Managing Directors and Supervisory Directors

Under Dutch law, the management board is charged with the management of the company, subject to the restrictions contained in our articles of association, and 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 managing directors may divide their tasks among themselves in or pursuant to the internal rules applicable to the management board. Each managing director and supervisory director has a statutory duty to act in the corporate interest of the company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed. The supervisory board will also observe the corporate social responsibility issues that are relevant to us. Any resolution of the management board regarding a material change in our identity or character requires approval of the general meeting.

Our management board is entitled to represent the company. The power to represent the company also vests in the chief executive officer individually, as well as in any other two managing directors acting jointly.

Dividends and Other Distributions

Dividends

We may only make distributions, whether a distribution of profits or of freely distributable reserves, to our shareholders to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-in and called-up share capital plus any reserves required by Dutch law or by our articles of association. Under our articles of association, our management board with the approval of our supervisory board may decide that all or part of the profits are carried to reserves. After reservation of any profit, the remaining profit will be at the disposal of the general meeting for distribution, subject to restrictions of Dutch law and approval by our supervisory board.

We only make a distribution of dividends to our shareholders after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting, but only with the approval of the supervisory board.

Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

Exchange Controls

Under Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to European Union regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations and similar rules. There are no special restrictions in the articles of association or Dutch law that limit the right of shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

Squeeze-Out Procedures

Pursuant to Section 2:92a of the Dutch Civil Code, a shareholder who holds at least 95% of our issued share capital for his or her own account, alone or together with group companies, may initiate proceedings against the other shareholders jointly for the transfer of their shares to such shareholder. The proceedings are held before the Enterprise Chamber of the Amsterdam Court of Appeal, or the Enterprise Chamber (*Ondernemingskamer*), and can be instituted by means of a writ of summons served upon each of the other shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze-out in relation to the other shareholders and will determine the price to be paid for the shares, if necessary, after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the other shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

Dissolution and Liquidation

Under our articles of association, we may be dissolved by a resolution of the general meeting, subject to a proposal of the management board approved by our supervisory board. In the event of a dissolution, the liquidation shall be effected by the management board, under supervision of our supervisory board, unless the general meeting decides otherwise. During liquidation, the provisions of our articles of association will remain in force as far as possible. To the extent that any assets remain after payment of all debts, those assets shall be distributed to the holders of common shares in proportion of their number of shares.

Dutch Corporate Governance Code

As a listed Dutch public company (*naamloze vennootschap*), we will be subject to 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 statutory annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If they do not comply with these provisions (for example, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such noncompliance. See "Risk factors — we are not obligated to, and do not, comply with all best practice provisions of the Dutch Corporate Governance Code."

We do not comply with all principles and best practice provisions of the DCGC. As of the date of this prospectus, we deviate from the DCGC as summarized below, but cannot exclude the possibility of deviating from additional provisions of the DCGC, including after the date hereof in order to follow market practice or governance practices in the United States.

Under our articles of association, managing directors and supervisory directors are to be appointed on the basis of a binding nomination prepared by the supervisory board. This means that the nominee will be appointed, unless the general meeting overrules the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital (in which case a new nomination will be prepared for a subsequent general meeting). The DCGC recommends that the general meeting can pass such a resolution by simple majority, representing no more than one-third of the issued share capital.

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 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 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 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.

Dutch Financial Reporting Supervision Act

On the basis of the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*), or the FRSA, the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*), or AFM, supervises the application of financial reporting standards by Dutch companies whose securities are listed on a Dutch or foreign stock exchange.

Pursuant to the FRSA, the AFM has an independent right to (i) request an explanation from us regarding our application of the applicable financial reporting standards if, based on publicly known facts or circumstances, it has reason to doubt that the company's financial reporting meets such standards and (ii) recommend to us the making available of further explanations. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer*) order us to (i) make available further explanations as recommended by the AFM, (ii) provide an explanation of the way we have applied the applicable financial reporting standards to our financial reports or (iii) prepare or restate our financial reports in accordance with the Enterprise Chamber's orders.

Foreign Investment Legislation

Under existing laws of the Netherlands, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to European Union regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations and similar rules. There are no special restrictions in the articles of association or Dutch law that limit the right of shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

Listing

We will apply to list the common shares on Nasdaq under the symbol "CVAC."

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and registrar for the common shares will be .

COMPARISON OF DUTCH CORPORATE LAW AND U.S. CORPORATE LAW

The following comparison between Dutch corporate law, which applies to us, and Delaware corporation law, the law under which many publicly listed corporations in the United States are incorporated, discusses additional matters not otherwise described in this prospectus. Although we believe this summary is materially accurate, the summary is subject to Dutch law, including Book 2 of the Dutch Civil Code and the DCGC and Delaware corporation law, including the Delaware General Corporation Law.

Corporate Governance

Duties of Managing and Supervisory Directors

The Netherlands. In the Netherlands, a listed company typically has a two-tier board structure with a management board comprised of the managing directors (executive directors) and a supervisory board comprised of the supervisory directors (non-executive directors). We have a two-tier board structure consisting of our management board (*bestuur*) and a separate supervisory board (*raad van commissarissen*).

Under Dutch law, the management board is charged with the management of the company, subject to the restrictions contained in our articles of association, and 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 managing directors may divide their tasks among themselves in or pursuant to the internal rules applicable to the management board. Each managing director and supervisory director has a statutory duty to act in the corporate interest of the company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed. Any resolution of the management board regarding a material change in our identity or character requires approval of the general meeting.

The approval of our supervisory board is required for resolutions of the management board, including concerning the following matters: the making of certain proposals to the general meeting; the issue of shares or the granting of rights to subscribe for shares; the limitation or exclusion of pre-emption rights; the acquisition of shares by us in our own capital; the drawing up or amendment of our management board rules; the performance of legal acts relating to non-cash contributions on shares; material changes to the identity or the character of the company or its business; the charging of amounts to be paid up on shares against the company's reserves; the making of an interim distribution; and such other resolutions as the supervisory board shall have specified in a resolution to that effect and notified to the management board. The absence of the approval of the supervisory board shall result in the relevant resolution being null and void but shall not affect the powers of representation of the management board or of the managing directors.

Our management board is entitled to represent us. The power to represent us also vests in the chief executive officer individually, as well as in any other two managing directors acting jointly.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Director Terms

The Netherlands. The DCGC provides the following best practice recommendations on the terms for tenure of managing directors and supervisory directors:

- Managing directors should be appointed for a maximum period of four years, without limiting the number of consecutive terms managing directors may serve.
- Supervisory directors should be appointed for two consecutive periods of no more than four years. Thereafter, supervisory directors may be reappointed for a maximum of two consecutive periods of no more than two years, provided that any reappointment after an eight-year term of office should be disclosed in the company's annual report.

The general meeting shall at all times be entitled to suspend or dismiss a managing director or supervisory director. Under our articles of association, the general meeting may only adopt a resolution to suspend or dismiss such director by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital, unless the resolution is passed at the proposal of the supervisory board, in which case a simple majority of the votes cast is sufficient. In addition, the supervisory board may at any time suspend a managing director. A suspension by the supervisory board can at any time be lifted by the general meeting. If a managing director is suspended and the general meeting does not resolve to dismiss him or her within three months from the date of such suspension, the suspension shall lapse.

Delaware. The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Director Vacancies

The Netherlands. Under Dutch law, managing directors and supervisory directors of a company like ours are appointed and reappointed by the general meeting. Under our articles of association, managing directors and supervisory directors are appointed by the general meeting upon the binding nomination by our supervisory board. However, the general meeting may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital. If the general meeting overrules the binding nomination, the supervisory board shall make a new nomination.

Prior to the closing of this offering, our supervisory board shall adopt a diversity policy for the composition of our management board and our supervisory board, as well as a profile for the composition of the supervisory board. The supervisory board shall make any nomination for the appointment of a managing director or supervisory director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

Under Dutch law, when nominating a person for appointment or reappointment as a supervisory director, the nomination must be supported by reasons (if it concerns a reappointment, past performance must be taken into consideration) and the following information about such person must be provided: (i) age and profession; (ii) the aggregate nominal value of the shares held in the company's capital; (iii) present and past positions, to the extent relevant for the performance of the tasks of a supervisory director; and (iv) the name of each entity where such person already holds a position as supervisory director or non-executive director (in case of multiple entities within the same group, the name of the group shall suffice).

Delaware. The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-Interest Transactions

The Netherlands. Under Dutch law and our articles of association, our managing directors and supervisory directors shall not take part in any discussion or decision-making that involves a subject or transaction in relation to which he or she has a direct or indirect personal conflict of interest with us. Such a conflict of interest would generally arise if the managing director or supervisory director concerned is unable to serve our interests and the business connected with it with the required level of integrity and objectivity due to the existence of the conflicting personal interest. Our articles of association provide that if as a result of conflicts of interests no resolution of the management board can be adopted, the resolution may be passed by the supervisory board and that, if as a result of conflicts of interests no resolution of the supervisory board can be adopted, the resolution may nonetheless be adopted by the supervisory board as if none of the supervisory directors had a conflict of interest. In that case, each supervisory director is entitled to participate in the discussion and decision-making process and to cast a vote.

The DCGC provides the following best practice recommendations in relation to conflicts of interests in respect of managing directors or supervisory directors:

- A managing director should report any potential conflict of interest in a transaction that is of material significance to the company and/or to such person to the chairman of the supervisory board and to the other members of the management board without delay. The managing director should provide all relevant information in that regard, including the information relevant to the situation concerning his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree.
- A supervisory director should report any conflict of interest or potential conflict of interest in a transaction that is of material significance to the company and/or to such person to the chairman of the supervisory board without delay and should provide all relevant information in that regard, including the relevant information pertaining to his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree. If the chairman of the supervisory board has a conflict of interest or potential conflict of interest, he or she should report this to the vice-chairman of the supervisory board without delay.
- The supervisory board should decide, outside the presence of the managing director or supervisory director concerned, whether there is a conflict of interest.
- All transactions in which there are conflicts of interest with managing directors or supervisory directors should be agreed on terms that are customary in the market.
- Decisions to enter into transactions in which there are conflicts of interest with managing directors or supervisory directors that are of material significance to the company and/or to the relevant managing directors or supervisory directors should require the approval of the supervisory board. Such transactions should be published in the annual report, together with a description of the conflict of interest and a declaration that the relevant best practice provisions of the DCGC have been complied with.

Delaware. The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director’s relationship or interest are disclosed and a majority of disinterested directors consent;
- the material facts are disclosed as to the director’s relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

Proxy Voting by Directors

The Netherlands. An absent managing director may issue a proxy for a specific management board meeting but only to another managing director in writing or by electronic means. An absent supervisory

director may issue a proxy for a specific supervisory board meeting but only to another supervisory director in writing or by electronic means.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder Rights

Voting Rights

The Netherlands. In accordance with Dutch law and our articles of association, each issued common share confers the right to cast one vote at the general meeting. Each holder of shares may cast as many votes as it holds shares. No votes may be cast on shares that are held by us or our direct or indirect subsidiaries or on shares for which we or our subsidiaries hold depository receipts. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use and enjoyment (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge (*pandrecht*).

In accordance with our articles of association, for each general meeting, the management board may determine that a record date will be applied in order to establish which shareholders are entitled to attend and vote at the general meeting. Such record date shall be the 28th day prior to the day of the general meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting which must be published in a Dutch daily newspaper with national distribution at least 15 days prior to the meeting (and such notice may therefore be published after the record date for such meeting). Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

The Netherlands. Pursuant to our articles of association, extraordinary general meetings will be held whenever required under Dutch law or whenever our management board or supervisory board deems such to be appropriate or necessary. Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law representing at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party or parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting.

Also, the agenda for a general meeting shall include such items requested by one or more shareholders, and others entitled to attend general meetings, representing at least 3% of the issued share capital, except where the articles of association state a lower percentage. Our articles of association do not state such lower percentage. Requests must be made in writing or by electronic means and received by us at least 60 days before the day of the meeting.

In accordance with the DCGC and our articles of association, a shareholder shall exercise the right of putting an item on the agenda only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy (for example, the removal of managing directors or supervisory directors), the management board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, the management board must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the management board shall report on this consultation and the exploration of alternatives to the general meeting. This shall be supervised by our supervisory board. The response period may be invoked only once for any given general meeting and shall not apply: (a) in respect of a matter for which a response period has been previously invoked; or (b) if a shareholder holds at least 75% of the company's issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting be convened, as described above.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

The Netherlands. Under Dutch law, shareholders' resolutions may be adopted in writing without holding a meeting of shareholders, provided that (i) the articles of association allow such action by written consent, (ii) the company has not issued bearer shares or, with its cooperation, depository receipts for shares in its capital, and (iii) the resolution is adopted unanimously by all shareholders that are entitled to vote. Although our articles of association allow for shareholders' resolutions to be adopted in writing, the requirement of unanimity renders the adoption of shareholder resolutions without holding a meeting not feasible for us as a publicly traded company.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

The Netherlands. Subject to certain exceptions, Dutch law does not recognize the concept of appraisal or dissenters' rights. However, Dutch law does provide for squeeze-out procedures as described under "Dividends and Other Distributions — Squeeze-Out Procedures." Also, Dutch law provides for cash exit rights in certain situations for dissenting shareholders of a company organized under Dutch law entering into certain types of mergers. In those situations, a dissenting shareholder may file a claim with the Dutch company for compensation. Such compensation shall then be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the merger.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

The Netherlands. In the event a third-party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an

action on behalf of the company. Only in the event that the cause for the liability of a third-party to the company also constitutes a tortious act directly against a shareholder does that shareholder have an individual right of action against such third-party in its own name. Dutch law provides for the possibility to initiate such actions collectively, in which a foundation or an association can act as a class representative and has standing to commence proceedings and claim damages if certain criteria are met. The court will first determine if those criteria are met. If so, the case will go forward as a class action on the merits after a period allowing class members to opt out from the case has lapsed. All members of the class who are residents of the Netherlands and who did not opt-out will be bound to the outcome of the case. Residents of other countries must actively opt in in order to be able to benefit from the class action. The defendant is not required to file defenses on the merits prior to the merits phase having commenced. It is possible for the parties to reach a settlement during the merits phase. Such a settlement can be approved by the court, which approval will then bind the members of the class, subject to a second opt-out. This new regime applies to claims brought after January 1, 2020 and which relate to certain events that occurred prior to that date. For other matters, the old Dutch class actions regime will apply. Under the old regime, no monetary damages can be sought. Also, a judgment rendered under the old regime will not bind individual class members. Even though Dutch law does not provide for derivative suits, directors and officers can still be subject to liability under U.S. securities laws.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

The Netherlands. Under Dutch law, when issuing shares, a public company such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. A listed public company such as ours may acquire fully paid shares in its own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and its articles of association, such company may repurchase fully paid shares in its own capital if (i) the company's shareholders' equity less the payment required to make the acquisition does not fall below the sum of paid-in and called-up share capital plus any reserves required by Dutch law or its articles of association and (ii) the aggregate nominal value of shares of the company which the company acquires, holds or on which the company holds a pledge (*pandrecht*) or which are held by a subsidiary of the company, would not exceed 50% of its then-current issued share capital. Such company may only acquire its own shares if its general meeting has granted the management board the authority to effect such acquisitions.

An acquisition of common shares for a consideration must be authorized by our general meeting. Such authorization may be granted for a maximum period of 18 months and must specify the number of common shares that may be acquired, the manner in which common shares may be acquired and the price limits within which common shares may be acquired. The actual acquisition may only be effected pursuant to a resolution of our management board, with the approval of our supervisory board. Prior to the closing of this offering, our management board, subject to approval by our supervisory board, will be authorized, for a period of 18 months to cause the repurchase of common shares by us of up to 20% of our issued share capital, for a price per share not exceeding 110% of the average market price of our common shares on Nasdaq (such average market price being the average of the closing prices on each of the five consecutive trading days preceding the date the acquisition is agreed upon by us). These shares may be used to deliver shares underlying awards granted pursuant to our equity-based compensation plans.

No authorization of the general meeting is required if fully paid common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee share purchase plan.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-Takeover Provisions

The Netherlands. Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. In this respect, 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 provisions include:

- a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination prepared by our supervisory board which can only be overruled by a two-thirds majority of votes cast representing more than 50% 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 in which case a simple majority of the votes would be sufficient);
- a provision allowing, among other matters, the former chairman of our supervisory board or our former CEO, as applicable, to manage our affairs if all of our managing directors and supervisory directors are removed from office and to appoint others to be charged with the management and supervision of our affairs, until new managing directors and supervisory directors are appointed by the general meeting on the basis of a binding nomination discussed above; 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.

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.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits “business combinations,” including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation’s voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the

shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of Books and Records

The Netherlands. The management board and the supervisory board provide the general meeting, within a reasonable amount of time, all information that the shareholders require for the exercise of their powers, unless this would be contrary to an overriding interest of our company. If the management board or supervisory board invokes such an overriding interest, it must give reasons.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect for any proper purpose certain of the corporation's books and records during the corporation's usual hours of business.

Dismissal of Directors

The Netherlands. Under our articles of association, the general meeting shall at all times be entitled to dismiss a managing director or supervisory director. The general meeting may only adopt a resolution to suspend or dismiss a managing director or supervisory director by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital, unless the proposal was made by the supervisory board, in which latter case a simple majority is sufficient.

Delaware. Under the Delaware General Corporation Law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he or she is a part.

Issuance of Shares

The Netherlands. Under Dutch law, a company's general meeting is the corporate body authorized to resolve on the issuance of shares and the granting of rights to subscribe for shares. The general meeting can delegate such authority to another corporate body of the company, such as the management board, for a period not exceeding five years; this authorization may only be extended from time to time for a maximum period of five years. Prior to the closing of this offering, our management board, with the approval of our supervisory board, will be 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. We may not subscribe for our own shares on issue.

Delaware. All creation of shares require the board of directors to adopt a resolution or resolutions, pursuant to authority expressly vested in the board of directors by the provisions of the company's certificate of incorporation.

Preemptive Rights

The Netherlands. Under Dutch law, in the event of an issuance of common shares, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder (with the exception of common shares to be issued to employees or common shares issued against a contribution other than in cash or pursuant to the exercise of a previously acquired right to subscribe for shares). Under our articles of association, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting. Another corporate body, such as the management board, may restrict or exclude the preemptive rights in respect of newly issued common shares if it has been designated as the authorized body to do so by the general meeting. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting to restrict or exclude the preemptive rights or to designate another corporate body as the authorized body to do so

requires a majority of not less than two-thirds of the votes cast, if less than one-half of our issued share capital is represented at the meeting. Prior to the closing of this offering, our management board, with the approval of our supervisory board, will be authorized, for a period not exceeding five years to limit or exclude preemptive rights in relation to an issuance of shares or a grant of rights to subscribe for shares that the management board is authorized to resolve upon (see above under "Issuance of Shares").

Delaware. Under the Delaware General Corporation Law, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

The Netherlands. Dutch law provides that dividends (if it concerns a distribution of profits) may be distributed after adoption of the annual accounts by the general meeting from which it appears that such dividend distribution is allowed. Moreover, dividends may be distributed, whether as a distribution of profits or of freely distributable reserves, only to the extent the shareholders' equity exceeds the amount of the paid-in and called-up issued share capital and the reserves that must be maintained under the law or the articles of association. Interim dividends may be declared as provided in the articles of association and may be distributed to the extent that the shareholders' equity exceeds the amount of the paid-in and called-up issued share capital plus any reserves as described above as apparent from our interim financial statements prepared under Dutch law.

Under our articles of association, our management board, with the approval of our supervisory board, may decide that all or part of the profits are carried to reserves. After reservation of any profit, the remaining profit will be at the disposal of the general meeting for distribution, subject to restrictions of Dutch law and approval by our supervisory board. Our management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting, but only with the approval of the supervisory board. Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common stock, property or cash.

Shareholder Vote on Certain Reorganizations

The Netherlands. Under Dutch law, the general meeting must approve resolutions of the management board relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- a transfer of the business or virtually the entire business to a third-party;
- the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of a far-reaching significance for the company; and
- the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one-third of the amount of its assets according to its balance sheet and explanatory notes or, if the company prepares a consolidated balance

sheet, according to its consolidated balance sheet and explanatory notes in the last adopted annual accounts of the company.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Remuneration of Managing Directors and Supervisory Directors

The Netherlands.

The supervisory board determines the remuneration of individual managing directors with due observance of the compensation policy at the recommendation of our compensation committee. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which managing directors may participate is subject to approval by our general meeting. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the managing directors and the criteria for granting or amendment. The compensation for our supervisory directors is set by the general meeting.

Delaware. Under the Delaware General Corporation Law, the stockholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of the compensation policy may be subject to stockholder vote due to the provisions of U.S. federal securities and tax law.

COMMON SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common shares. Future sales of substantial amounts of our common shares in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of common shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common shares in the public market after such restrictions lapse. This may adversely affect the prevailing market price and our ability to raise equity capital in the future.

Upon completion of this offering, we will have common shares outstanding assuming the exercise in full of the underwriters' option to purchase additional common shares. Of these shares, common shares, or common shares if the underwriters exercise their option in full to purchase additional common shares, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any common shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining common shares existing are "restricted shares" as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act. As a result of the contractual 180-day lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

Rule 144

In general, a person who has beneficially owned our common shares that are restricted shares for at least six months would be entitled to sell such securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned our common shares that are restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of our common shares then outstanding, which will equal approximately common shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our common shares on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale; provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

Rule 701

In general, under Rule 701, any of our employees, managing directors, supervisory directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described below, beginning 90 days after the date of this prospectus, may be sold by persons other than "affiliates," as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by "affiliates" under Rule 144 without compliance with its one-year minimum holding period requirement.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

Lock-Up agreements

All of our managing directors and supervisory directors and the holders of substantially all of our common shares have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common shares or such other securities for a period of 180 days after the date of this prospectus, subject to certain exceptions, without the prior written consent of BofA Securities, Inc. and Jefferies LLC. See “Underwriting.”

TAXATION

The following summary contains a description of certain Dutch, German and U.S. federal income tax consequences of the acquisition, ownership and disposition of common shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase common shares. The summary is based upon the tax laws of the Netherlands and regulations thereunder, the tax laws of Germany and regulations thereunder and the tax laws of the United States and regulations thereunder as of the date hereof, which are subject to change. You should consult your tax advisor regarding the applicable tax consequences to you of investing in our common shares.

Material Dutch Tax Considerations

General

The following is a general summary of certain material Dutch tax consequences of the acquisition, ownership and disposal of our common shares. This summary does not purport to set forth all possible tax considerations or consequences that may be relevant to a holder or prospective holder or our common shares and does not purport to deal with the tax consequences applicable to all categories of investors, some of which (such as trusts or similar arrangements) may be subject to special rules. In view of its general nature, it should be treated with corresponding caution.

This summary is based on the tax laws of the Netherlands, published regulations thereunder and published authoritative case law, all as in effect on the date hereof, and all of which are subject to change, possibly with retroactive effect. Where the summary refers to "the Netherlands" or "Dutch" it refers only to the part of the Kingdom of the Netherlands located in Europe.

This discussion is for general information purposes and is not tax advice or a complete description of all Dutch tax consequences relating to the acquisition, ownership and disposal of our common shares. Holders or prospective holders of our common shares should consult their own tax advisor regarding the tax consequences relating to the acquisition, holding and disposal of our common shares in light of their particular circumstances.

Please note that this section does not set forth the tax considerations for:

- holders of common shares if such holders, and in the case of individuals, such holder's partner or certain relatives by blood or marriage in the direct line (including foster children), have a substantial interest (*aanmerkelijk belang*) or deemed substantial interest (*fictief aanmerkelijk belang*) in us within the meaning of chapter 4 of the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*). Generally, a holder of securities in a company is considered to hold a substantial interest in such company if such holder alone or, in the case of individuals, together with such holder's partner (as defined in the Dutch Income Tax Act 2001), directly or indirectly holds (i) an interest of 5% or more of the total issued and outstanding capital of that company or of 5% or more of the issued and outstanding capital of a certain class of shares of that company; or (ii) rights to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights in that company that relate to 5% or more of the company's annual profits and/or to 5% or more of the company's liquidation proceeds. A deemed substantial interest exists if a substantial interest (or part thereof) in a company has been disposed of, or is deemed to have been disposed of, on a non-recognition basis;
- holders of common shares that are not an individual and for which the common shares qualify or qualified as a participation (*deelneming*) for purposes of the participation exemption (*deelnemingsvrijstelling*) as defined in Section 13 of the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*). Generally, the common shares qualify as a participation as a result of which the participation exemption applies to the common shares if the holder of common shares is subject to Dutch corporate income tax and it, or a related entity, holds 5% or more in our nominal paid-in share capital (or, in certain cases, in voting rights);
- pension funds, investment institutions (*fiscale beleggingsinstellingen*), exempt investment institutions (*vrijgestelde beleggingsinstellingen*) (as defined in the Dutch Corporate Income Tax

Act 1969) and other entities that are, in whole or in part, not subject to or exempt from corporate income tax in the Netherlands; and

- holders of common shares who are individuals and for whom the common shares or any benefit derived from the common shares are a remuneration or deemed to be a remuneration for (employment) activities performed by such holders or certain individuals related to such holders (as defined in the Dutch Income Tax Act 2001).

Dividend Withholding Tax

Dividends distributed by us generally are subject to Dutch dividend withholding tax at a rate of 15%. Generally, we are responsible for the withholding of such dividend withholding tax at source; the Dutch dividend withholding tax is for the account of the holder of our common shares.

However, as long as we continue to have our place of effective management solely in Germany, and not in the Netherlands, under the double tax treaty between Germany and the Netherlands, we will be considered to be exclusively tax resident in Germany and we will not be required to withhold Dutch dividend withholding tax. This exemption from withholding does not apply to dividends distributed by us to a holder who is resident or deemed to be resident in the Netherlands for Dutch income tax purposes or to holders of common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder, in which case the following paragraph applies. See also "Risk factors — 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."

Dividends distributed by us to individuals and corporate legal entities who are resident or deemed to be resident in the Netherlands for Dutch income tax purposes ("Dutch Resident Individuals" and "Dutch Resident Entities," as the case may be) or to holders of common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder are subject to Dutch dividend withholding tax at a rate of 15%.

The expression "dividends distributed" includes, among other things:

- distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital not recognized for Dutch dividend withholding tax purposes;
- liquidation proceeds, proceeds of redemption of common shares, or proceeds of the repurchase of common shares by us or one of our subsidiaries or other affiliated entities to the extent such proceeds exceed the average paid-in capital of those common shares as recognized for purposes of Dutch dividend withholding tax;
- an amount equal to the par value of common shares issued or an increase of the par value of common shares, to the extent that it does not appear that a related contribution, recognized for purposes of Dutch dividend withholding tax, has been made or will be made; and
- partial repayment of the paid-in capital, recognized for purposes of Dutch dividend withholding tax, if and to the extent that we have net profits (*zuivere winst*), unless (i) the general meeting has resolved in advance to make such repayment and (ii) the par value of the common shares concerned has been reduced by an equal amount by way of an amendment of our articles of association.

Dutch Resident Individuals and Dutch Resident Entities generally are entitled to an exemption or a credit for any Dutch dividend withholding tax against their income tax or corporate income tax liability and to a refund of any residual Dutch dividend withholding tax. The same generally applies to holders of common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder.

Dividend stripping

Pursuant to legislation to counteract "dividend stripping," a reduction, exemption, credit or refund of Dutch dividend withholding tax is denied if the recipient of the dividend is not the beneficial owner (*uiteindelijk gerechtigde*) of the dividend.

The Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting 1965*) provides for a non-exhaustive negative description of a beneficial owner. According to this act, a holder of common shares will not be considered the beneficial owner of the dividends if as a consequence of a combination of transactions:

- a person other than the holder of common shares wholly or partly, directly or indirectly, benefits from the dividends;
- whereby this other person retains or acquires, directly or indirectly, an interest similar to that in our common shares on which the dividends were paid; and
- that other person is entitled to a credit, reduction or refund of Dutch dividend withholding tax that is less than that of the holder of common shares.

The Dutch State Secretary of Finance takes the position that the definition of beneficial owner introduced by this legislation will also be applied in the context of a double taxation convention.

Taxes on Income and Capital Gains

Dutch Resident Entities

Generally speaking, if the holder of common shares is a Dutch Resident Entity, any benefits derived or deemed to be derived from the common shares or any gain or loss realized on the disposal or deemed disposal of the common shares is subject to Dutch corporate income tax at a rate of 16.5% with respect to taxable profits up to €200,000 and 25% with respect to taxable profits in excess of that amount (rates and brackets for 2020).

Dutch Resident Individuals

If the holder of common shares is a Dutch Resident Individual, any benefits derived or deemed to be derived from the common shares or any gain or loss realized on the disposal or deemed disposal of the common shares is taxable at the progressive Dutch income tax rates (with a maximum of 49.50% in 2020), if:

(i) the common shares are attributable to an enterprise from which the holder of common shares derives a share of the profit, whether as an entrepreneur (*ondernemer*) or as a person who has a co-entitlement to the net worth (*medegerechtigd tot het vermogen*) of such enterprise without being a shareholder (as defined in the Dutch Income Tax Act 2001); or

(ii) the holder of common shares is considered to perform activities with respect to the common shares that go beyond ordinary asset management (*normaal, actief vermogensbeheer*) or derives benefits from the common shares that are taxable as benefits from other activities (*resultaat uit overige werkzaamheden*).

If the above-mentioned conditions (i) and (ii) do not apply to the individual holder of common shares, such holder will be taxed annually on a deemed return (with a maximum of 5.28% in 2020) on the individual's net investment assets (*rendementsgrondslag*) for the year, insofar the individual's net investment assets for the year exceed a statutory threshold (*heffingvrij vermogen*). The deemed return on the individual's net investment assets for the year is taxed at a flat rate of 30%. Actual income, gains or losses in respect of the common shares are as such not subject to Dutch income tax.

The net investment assets for the year are the fair market value of the investment assets less the allowable liabilities on January 1 of the relevant calendar year. The common shares are included as investment assets. For the net investment assets on January 1, 2020, the deemed return ranges from 1.7893% up to 5.28% (depending on the aggregate amount of the net investment assets of the individual on January 1, 2020). The deemed return will be adjusted annually on the basis of historic market yields.

Non-residents of the Netherlands

A holder of common shares that is neither a Dutch Resident Entity nor a Dutch Resident Individual will not be subject to Dutch taxes on income or capital gains in respect of any payment under the common shares or in respect of any gain or loss realized on the disposal or deemed disposal of the common shares, provided that:

(i) such holder does not have an interest in an enterprise or deemed enterprise (as defined in the Dutch Income Tax Act 2001 and the Dutch Corporate Income Tax Act 1969) which, in whole or in part, is either effectively managed in the Netherlands or carried on through a permanent establishment, a deemed permanent establishment or a permanent representative in the Netherlands and to which enterprise or part of an enterprise the common shares are attributable; and

(ii) in the event the holder is an individual, such holder does not carry out any activities in the Netherlands with respect to the common shares that go beyond ordinary asset management and does not derive benefits from the common shares that are taxable as benefits from other activities in the Netherlands.

Gift and Inheritance Taxes

Residents of the Netherlands

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of common shares by way of a gift by, or on the death of, a holder of such common shares who is resident or deemed resident of the Netherlands at the time of the gift or the holder's death.

Non-residents of the Netherlands

No gift or inheritance taxes will arise in the Netherlands with respect to a transfer of common shares by way of gift by, or on the death of, a holder of common shares who is neither resident nor deemed to be resident of the Netherlands, unless:

(i) in the case of a gift of common shares by an individual who at the date of the gift was neither resident nor deemed to be resident of the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident of the Netherlands; or

(ii) the transfer is otherwise construed as a gift or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident of the Netherlands.

For purposes of Dutch gift and inheritance taxes, among others, a person that holds the Dutch nationality will be deemed to be resident of the Netherlands if such person has been resident in the Netherlands at any time during the ten (10) years preceding the date of the gift or such person's death. Additionally, for purposes of Dutch gift tax, amongst others, a person not holding the Dutch nationality will be deemed to be resident of the Netherlands if such person has been resident in the Netherlands at any time during the twelve (12) months preceding the date of the gift. Applicable tax treaties may override deemed residency.

Value Added Tax (VAT)

No Dutch VAT will be payable by a holder of common shares in respect of any payment in consideration for the holding or disposal of the common shares.

Other Taxes and Duties

No Dutch registration tax, stamp duty or any other similar documentary tax or duty will be payable by a holder of common shares in respect of any payment in consideration for the holding or disposal of the common shares.

Material German Tax Considerations

The following section is the opinion of FALK GmbH & Co KG ("German Tax Counsel") of the material German tax considerations that become relevant when purchasing, holding or transferring the company's shares. The company expects and intends to have its sole place of management in Germany and, therefore, qualifies as a corporation subject to German unlimited income taxation; however, because a company's tax residency depends on future facts regarding the location in which the company is managed and controlled, German Tax Counsel cannot opine as to whether the company qualifies as a corporation

subject to German unlimited income taxation. This section does not set forth all German tax aspects that may be relevant for shareholders. The section is based on the German tax law applicable as of the date of this Prospectus. It should be noted that the law may change following the issuance of this Prospectus and that such changes may have retroactive effect.

The material German tax principles of purchasing, owning and transferring of shares are set forth in the following. This section does not purport to be a comprehensive or complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of shares and does not set forth all tax considerations that may be relevant to a particular person's decision to acquire common shares. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences set forth below. This section does not refer to any U.S. Foreign Account Tax Compliance Act aspects.

Shareholders are advised to consult their own tax advisers with regard to the application of German tax law to their particular situations, in particular with respect to the procedure to be complied with to obtain a relief of withholding tax on dividends and on capital gains (*Kapitalertragsteuer*) and with respect to the influence of double tax treaty provisions, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction. For German tax purposes, a shareholder may include an individual who or an entity that does not have the legal title to the shares, but to whom nevertheless the shares are attributed, based either on such individual or entity owning a beneficial interest in the shares or based on specific statutory provisions.

This section does not constitute a particular tax advice. Potential purchasers of the company's shares are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of shares in light of their particular circumstances.

Dividends Tax

Withholding Tax on Dividends

Dividends distributed from a company to its shareholders are subject to withholding tax, subject to certain exemptions (for example, repayments of capital from the tax equity account (*steuerliches Einlagekonto*)), as described in the following. The withholding tax rate is 25% plus 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon (in total 26.375%) of the gross dividend approved by the ordinary shareholders' meeting. Withholding tax is to be withheld and passed on for the account of the shareholders by a domestic branch of a domestic or foreign credit or financial services institution (*Kredit- und Finanzdienstleistungsinstitut*), by the domestic securities trading company (*inländisches Wertpapierhandelsunternehmen*) or a domestic securities trading bank (*inländische Wertpapierhandelsbank*) which keeps and administers the shares and disburses or credits the dividends or disburses the dividends to a foreign agent, or by the securities custodian bank (*Wertpapiersammelbank*) to which the shares were entrusted for collective custody if the dividends are distributed to a foreign agent by such securities custodian bank (which is referred to as the "Dividend Paying Agent"). In case the shares are not held in collective deposit with a Dividend Paying Agent, the company is responsible for withholding and remitting the tax to the competent tax office.

Such withholding tax is levied and withheld irrespective of whether and to what extent the dividend distribution is taxable at the level of the shareholder and whether the shareholder is a person residing in Germany or in a foreign country.

In the case of dividends distributed to a company within the meaning of Art. 2 of the amended EU Directive 2011/96/EU of the Council of November 30, 2011 (the "EU Parent Subsidiary Directive") domiciled in another Member State of the European Union, an exemption from withholding tax will begranted upon request if further prerequisites are satisfied (*Freistellung im Steuerabzugsverfahren*). This also applies to dividends distributed to a permanent establishment located in another Member State of the European Union of such a parent company or of a parent company tax resident in Germany if the participation in the company is effectively connected with this permanent establishment. The key prerequisite for the application of the EU Parent Subsidiary Directive is that the shareholder has held a direct participation in the share capital of the company of at least 10% for at least one year.

The withholding tax on distributions to other foreign resident shareholders is reduced in accordance with a double taxation treaty if Germany has concluded such double taxation treaty with the country of residence of the shareholder and if the shareholder does not hold his shares either as part of the assets of a permanent establishment or a fixed place of business in Germany or as business assets for which a permanent representative has been appointed in Germany. The reduction of the withholding tax is procedurally granted in such a manner that the difference between the total amount withheld, including the solidarity surcharge, and the tax liability determined on the basis of the tax rate set forth in the applicable double taxation treaty (15% unless further qualifications are met) is refunded by the German tax administration upon request (Federal Central Office for Taxes (*Bundeszentralamt für Steuern*), main office in Bonn-Beuel, An der Küppe 1, 53225 Bonn, Germany).

In the case of dividends received by corporations whose statutory seat and effective place of management are not located in Germany and who are therefore not tax resident in Germany, two-fifths of the withholding tax deducted and remitted are refunded without the need to fulfill all prerequisites required for such refund under the EU Parent Subsidiary Directive or under a double taxation treaty or if no double taxation treaty has been concluded between the state of residence of the shareholder.

In order to receive a refund pursuant to a double taxation treaty or the aforementioned option for foreign corporations, the shareholder has to submit a completed form for refund (available at the Federal Central Office for Taxes (http://www.bzst.de) as well as at the German embassies and consulates) together with a withholding tax certificate (*Kapitalertragsteuerbescheinigung*) issued by the institution that withheld the tax.

The exemption from withholding tax in accordance with the EU Parent Subsidiary Directive or a double tax treaty and the aforementioned options for a refund of the withholding tax (with or without protection under a double taxation treaty) depend on whether certain additional prerequisites (in particular so-called substance requirements) are fulfilled. The applicable withholding tax relief will only be granted if the preconditions of the German anti avoidance rules (so called Directive Override or Treaty Override), in particular Section 50d, paragraph 3, German Income Tax Act (*Einkommensteuergesetz*) are fulfilled.

The aforementioned reductions of (or exemptions from) withholding tax are further restricted if (i) the applicable double taxation treaty provides for a tax reduction resulting in an applicable tax rate of less than 15% and (ii) the shareholder is not a corporation that directly holds at least 10% in the equity capital of the company and is subject to tax on its income and profits in its state of residence without being exempt. In this case, the reduction of (or exemption from) withholding tax is subject to the following three cumulative prerequisites: (i) the shareholder must qualify as beneficial owner of the shares in the company for a minimum holding period of 45 consecutive days occurring within a period of 45 days prior and 45 days after the due date of the dividends, (ii) the shareholder has to bear at least 70% of the change in value risk related to the shares in the company during the minimum holding period without being directly or indirectly hedged and (iii) the shareholder must not be required to fully or largely compensate directly or indirectly the dividends to third parties. However, these further prerequisites do not apply if the shareholder has been the beneficial owner of the shares in the company for at least one uninterrupted year upon receipt of the dividends.

For individual or corporate shareholders tax resident outside Germany not holding the shares through a permanent establishment (*Betriebsstätte*) in Germany or as business assets (*Betriebsvermögen*) for which a permanent representative (*ständiger Vertreter*) has been appointed in Germany, the remaining and paid withholding tax (if any) is final (i.e., not refundable) and settles the shareholder's limited tax liability in Germany. For individual or corporate shareholders tax resident in Germany (that are, for example, shareholders whose residence, domicile, registered office or place of management is located in Germany) holding their shares as business assets, as well as for shareholders tax resident outside of Germany holding their shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany, the withholding tax withheld (including solidarity surcharge) can be credited against the shareholder's personal income tax or corporate income tax liability in Germany. Any withholding tax (including solidarity surcharge) in excess of such tax liability is refunded. For individual shareholders tax resident in Germany holding the company's shares as private assets, the withholding tax is a final tax (*Abgeltungsteuer*), subject to the exceptions described in the following section.

Pursuant to special rules on the restriction of withholding tax credit, the credit of withholding tax is subject to the following three cumulative prerequisites: (i) the shareholder must qualify as beneficial owner of the shares in the company for a minimum holding period of 45 consecutive days occurring within a period of 45 days prior and 45 days after the due date of the dividends, (ii) the shareholder has to bear at least 70% of the change in value risk related to the shares in the company during the minimum holding period without being directly or indirectly hedged and (iii) the shareholder must not be required to fully or largely compensate directly or indirectly the dividends to third parties. Absent the fulfillment of all of the three prerequisites, three-fifths of the withholding tax imposed on the dividends must not be credited against the shareholder's (corporate) income tax liability, but may, upon application, be deducted from the shareholder's tax base for the relevant assessment period. A shareholder that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit has to notify the competent local tax office accordingly and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit do not apply to a shareholder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the shares in the company for at least one uninterrupted year upon receipt of the dividends.

Taxation of dividend income of shareholders tax resident in Germany holding the company's shares as private assets

For individual shareholders (individuals) resident in Germany holding the company's shares as private assets, dividends are subject to a flat tax rate which is satisfied by the withholding tax actually withheld (*Abgeltungsteuer*). Accordingly, dividend income will be taxed at a flat tax rate of 25% plus 5.5% solidarity surcharge thereon (in total 26.375%) and church tax (*Kirchensteuer*) in case the shareholder is subject to church tax because of his individual circumstances. An automatic procedure for deduction of church tax by way of withholding will apply to shareholders being subject to church tax unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the German Federal Tax Office (details related to the computation of the concrete tax rate including church tax are to be discussed with the individual tax adviser of the relevant shareholder). Except for an annual lump sum savings allowance (*Sparer-Pauschbetrag*) of up to €801 (for individual filers) or up to €1,602 (for married couples and for partners in accordance with the registered partnership law (*Gesetz über die Eingetragene Lebenspartnerschaft*) filing jointly), private individual shareholders will not be entitled to deduct expenses incurred in connection with the capital investment from their dividend income.

The income tax owed for the dividend income is satisfied by the withholding tax withheld by the Dividend Paying Agent. However, if the flat tax results in a higher tax burden as opposed to the private shareholder's individual tax rate, the private shareholder can opt for taxation at his individual personal income tax rate. In that case, the final withholding tax will be credited against the income tax. However, pursuant to the German tax authorities and a court ruling, private shareholders are nevertheless not entitled to deduct expenses incurred in connection with the capital investment from their income. The option can be exercised only for all capital income from capital investments received in the relevant assessment period uniformly, and married couples as well as partners in accordance with the registered partnership law filing jointly may only jointly exercise the option.

Exceptions from the flat tax rate (satisfied by withholding at source) (*Abgeltungsteuer*) may apply — that is, only upon application — for shareholders who have a shareholding of at least 25% in a company and for shareholders who have a shareholding of at least 1% in the company and work for a company in a professional capacity. In such a case, the same rules apply as for sole proprietors holding the shares as business assets. See "— Taxation of dividend income of shareholders tax resident in Germany holding the company's shares as business assets — Sole proprietors."

Taxation of dividend income of shareholders tax resident in Germany holding the company's shares as business assets

If a shareholder holds the company's shares as business assets, the taxation of the dividend income depends on whether the respective shareholder is a corporation, a sole proprietor or a partnership.

Corporations

Dividend income of corporate shareholders is exempt from corporate income tax, provided that the incorporated entity holds a direct participation of at least 10% in the share capital of a company at the beginning of the calendar year in which the dividends are paid. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the purpose of this rule. Participations in the share capital of the company which a corporate shareholder holds through a partnership, including co-entrepreneurships (*Mitunternehmerschaften*), are attributable to such corporate shareholder only on a pro rata basis at the ratio of the interest share of the corporate shareholder in the assets of the relevant partnership. However, 5% of the tax exempt dividends are deemed to be non-deductible business expenses for tax purposes and therefore are subject to corporate income tax (plus solidarity surcharge) and trade tax, i.e., tax exemption of 95%. Business expenses incurred in connection with the dividends received are entirely tax-deductible.

For trade tax purposes the entire dividend income is subject to trade tax (i.e., the tax-exempt dividends must be added back when determining the trade taxable income), unless the corporation shareholder holds at least 15% of the company's registered share capital at the beginning of the relevant tax assessment period (*Erhebungszeitraum*). In case of an indirect participation via a partnership please refer to the section "Partnerships" below.

If the shareholding is below 10% in the share capital, dividends are taxable at the applicable corporate income tax rate of 15% plus 5.5% solidarity surcharge thereon and trade tax (the rate of which depends on the municipalities the corporate shareholder resides in).

Special regulations apply which abolish the 95% tax exemption if the company's shares are held as trading portfolio assets in the meaning of Section 340e of the German commercial code (*Handelsgesetzbuch*) by (i) a credit institution (*Kreditinstitut*), (ii) a financial service institution (*Finanzdienstleistungsinstitut*) or (iii) a financial enterprise within the meaning of the German Banking Act (*Kreditwesengesetz*), in case more than 50% of the shares of such financial enterprise are held directly or indirectly by a credit institution or a financial service institution, as well as by a life insurance company, a health insurance company or a pension fund in case the shares are attributable to the capital investments, resulting in fully taxable income.

Sole proprietors

For sole proprietors (individuals) resident in Germany holding shares as business assets dividends are subject to the partial income rule (*Teileinkünfteverfahren*). Accordingly, only (i) 60% of the dividend income will be taxed at his/her individual personal income tax rate plus 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the dividend income are deductible for tax purposes. In addition, the dividend income is entirely subject to trade tax if the shares are held as business assets of a permanent establishment in Germany within the meaning of the German Trade Tax Act (*Gewerbesteuergesetz*), unless the shareholder holds at least 15% of the company's registered share capital at the beginning of the relevant assessment period. The trade tax levied will be eligible for credit against the shareholder's personal income tax liability based on the applicable municipal trade tax rate and the individual tax situation of the shareholder.

Partnerships

In case shares are held by a partnership, the partnership itself is not subject to corporate income tax or personal income tax. In this regard, corporate income tax or personal income tax (and church tax, if applicable) as well as solidarity surcharge, are levied only at the level of the partner with respect to their relevant part of the profit and depending on their individual circumstances.

If the partner is a corporation, the dividend income will be subject to corporate income tax plus solidarity surcharge. See "— Corporations."

If the partner is a sole proprietor (individual), the dividend income will be subject to the partial income rule. See "— Sole Proprietors."

The dividend income is subject to trade tax at the level of the partnership (provided that the partnership is liable to trade tax), unless the partnership holds at least 15% of a company's registered share capital at the beginning of the relevant assessment period, in which case the dividend income is exempt from trade tax. There are no explicit statutory provisions concerning the taxation of dividends with regard to a corporate shareholder of the partnership. However, trade tax will be levied on 5% of the dividends to the extent they are attributable to the shares of such corporate partners to whom at least 10% of the shares of the company are attributable on a look-through basis, since such portion of the dividends will be deemed to be non-deductible business expenses.

If a partner is an individual, depending on the applicable municipal trade tax rate and the individual tax situation, the trade tax paid at the level of the partnership is partly or entirely be credited against the partner's personal income tax liability.

In case of a corporation being a partner, special regulations will apply with respect to trading portfolio assets of credit institutions, financial service institutions or financial enterprises within the meaning of the German Banking Act (*Kreditwesengesetz*) or life insurance companies, health insurance companies or pension funds. See "— Corporations."

Thus, the actual trade tax charge, if any, at the level of the partnership depends on the shareholding quota of the partnership and the nature of the partners (e.g., individual or corporation).

Taxation of dividend income of shareholders tax resident outside of Germany

For foreign individual or corporate shareholders tax resident outside of Germany not holding the shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany, the deducted withholding tax (possibly reduced by way of a tax relief under a double tax treaty or domestic tax law, such as in connection with the EU Parent Subsidiary Directive) is final (that is, not refundable) and settles the shareholder's limited tax liability in Germany, unless the shareholder is entitled to apply for a withholding tax refund or exemption.

In contrast, individual or corporate shareholders tax resident outside of Germany holding the company's shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany are subject to the same rules as applicable (and described above) to shareholders resident in Germany holding the shares as business assets. The withholding tax withheld (including solidarity surcharge) is credited against the shareholder's personal income tax or corporate income tax liability in Germany.

Taxation of Capital Gains

Withholding tax on capital gains

Capital gains realized on the disposal of shares are only subject to withholding tax if a German branch of a German or foreign credit or financial institution, a German securities trading company or a German securities trading bank stores or administrates or carries out the sale of the shares and pays or credits the capital gains. In those cases, the institution (and not the company) is required to deduct the withholding tax at the time of payment for the account of the shareholder and has to pay the withholding tax to the competent tax authority. In case the shares in CureVac N.V. are held (i) as business assets by a sole proprietor, a partnership or a corporation and such shares are attributable to a German business or (ii) in case of a corporation being subject to unlimited corporate income tax liability in Germany, the capital gains are not subject to withholding tax. In case of clause (i), the withholding tax exemption is subject to the condition that the paying agent has been notified by the beneficiary (*Gläubiger*) that the capital gains are exempt from withholding tax. The respective notification has to be filed by using the officially prescribed form.

Taxation of Capital Gains Realized by Shareholders Tax Resident in Germany Holding Shares as Private Assets

For individual shareholders (individuals) resident in Germany holding shares as private assets, capital gains realized on the disposal of shares are subject to final withholding tax. Accordingly, capital

gains will be taxed at a flat tax rate of 25% plus a 5.5% solidarity surcharge thereon (in total 26.375%) and church tax, in case the shareholder is subject to church tax because of his individual circumstances. An automatic procedure for deduction of church tax by way of withholding will apply to shareholders being subject to church tax unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the German Federal Tax Office (details related to the computation of the concrete tax rate including church tax are to be discussed with the individual tax adviser of the relevant shareholder). The taxable capital gain is calculated by deducting the acquisition costs of the shares and the expenses directly related to the disposal from the proceeds of the disposal. Apart from that, except for an annual lump sum savings allowance (*Sparer-Pauschbetrag*) of up to €801 (for individual filers) or up to €1,602 (for married couples and for partners in accordance with the registered partnership law (*Gesetz über die Eingetragene Lebenspartnerschaft*) filing jointly), private individual shareholders will not be entitled to deduct expenses incurred in connection with the capital investment from their capital gain.

In case the flat tax results in a higher tax burden as opposed to the private shareholder's individual tax rate, the private shareholder can opt for taxation at his or her individual personal income tax rate. In that case, the withholding tax (including solidarity surcharge) withheld will be credited against the income tax. However, pursuant to the German tax authorities the private shareholders are nevertheless not entitled to deduct expenses incurred in connection with the capital investment from their income. The option can be exercised only for all capital income from capital investments received in the relevant assessment period uniformly, and married couples as well as for partners in accordance with the registered partnership law filing jointly may only jointly exercise the option.

Capital losses arising from the sale of the shares can only be offset against other capital gains resulting from the disposition of the shares or shares in other stock corporations during the same calendar year. Offsetting of overall losses with other income (such as business or rental income) and other capital income is not possible. Such losses are to be carried forward and to be offset against positive capital gains deriving from the sale of shares in stock corporations in future years. In case of a derecognition or transfer of worthless shares (or other capital assets), the utilization of such loss is further restricted and can only be offset up to the amount of EUR 10,000 per calendar year.

The final withholding tax will not apply if the seller of the shares or, in the case of gratuitous transfer, its legal predecessor has held, directly or indirectly, at least 1% of the company's registered share capital at any time during the five years prior to the disposal. In that case capital gains are subject to the partial income rule. Accordingly, only (i) 60% of the capital gains will be taxed at his individual personal income tax rate plus a 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the capital gains are deductible for tax purposes. The withholding tax withheld (including solidarity surcharge) will be credited against the shareholder's personal income tax liability in Germany.

Taxation of capital gains realized by shareholders tax resident in Germany holding the company's shares as business assets

If a shareholder holds shares as business assets, the taxation of capital gains realized on the disposal of such shares depends on whether the respective shareholder is a corporation, a sole proprietor or a partnership:

Corporations

Capital gains realized on the disposal of shares by a corporate shareholder are generally exempt from corporate income tax and trade tax. However, 5% of the tax-exempt capital gains are deemed to be non-deductible business expenses for tax purposes and therefore are subject to corporate income tax (plus solidarity surcharge) and trade tax, i.e., tax exemption of 95%. Business expenses incurred in connection with the capital gains are entirely tax-deductible.

Capital losses incurred upon the disposal of shares or other impairments of the share value are not tax-deductible. A reduction of profit is also defined as any losses incurred in connection with a loan or security in the event the loan or the security is granted by a shareholder or by a related party thereto or by a third person with the right of recourse against the before-mentioned persons, and the shareholder holds directly or indirectly more than 25% of the company's registered share capital.

Special regulations apply if the shares are held as trading portfolio assets by a credit institution, a financial service institution or a financial enterprise within the meaning of the German Banking Act (*Kreditwesengesetz*) as well as by a life insurance company, a health insurance company or a pension fund. See "— Corporations."

Sole Proprietors

If the shares are held by a sole proprietor, capital gains realized on the disposal of the shares are subject to the partial income rule. Accordingly, only (i) 60% of the capital gains will be taxed at his/her individual personal income tax rate plus a 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the dividend income are deductible for tax purposes. In addition, 60% of the capital gains are subject to trade tax if the shares are held as business assets of a permanent establishment in Germany within the meaning of the German Trade Tax Act (*Gewerbesteuergesetz*). The trade tax levied, depending on the applicable municipal trade tax rate and the individual tax situation, is partly or entirely credited against the shareholder's personal income tax liability.

Partnerships

In case the shares are held by a partnership, the partnership itself is not subject to corporate income tax or personal income tax as well as a solidarity surcharge (and church tax) since partnerships qualify as transparent for German tax purposes. In this regard, corporate income tax or personal income tax as well as a solidarity surcharge (and church tax, if applicable), are levied only at the level of the partner with respect to their relevant part of the profit and depending on their individual circumstances.

If the partner is a corporation, the capital gains will be subject to corporate income tax plus a solidarity surcharge. See "— Corporations." Trade tax will be levied additionally at the level of the partner insofar as the relevant profit of the partnership is not subject to trade tax at the level of the partnership. However, with respect to both corporate income and trade tax, the 95% exemption rule as described above applies.

If the partner is a sole proprietor (individual), the capital gains are subject to the partial income rule. See "— Sole Proprietors."

In addition, if the partnership is liable to trade tax, 60% of the capital gains are subject to trade tax at the level of the partnership, to the extent the partners are individuals, and 5% of the capital gains are subject to trade tax, to the extent the partners are corporations. However, if a partner is an individual, depending on the applicable municipal trade tax rate and the individual tax situation, the trade tax paid at the level of the partnership is credited against the partner's personal income tax liability.

With regard to corporate partners, special regulations apply if they are held as trading portfolio assets by credit institutions, financial service institutions or financial enterprises within the meaning of the German Banking Act or life insurance companies, health insurance companies or pension funds, as described above.

Taxation of capital gains realized by shareholders tax resident outside of Germany

Capital gains realized on the disposal of the shares by a shareholder tax resident outside of Germany are subject to German taxation provided that (i) the company's shares are held as business assets of a permanent establishment or as business assets for which a permanent representative has been appointed in Germany, or (ii) the shareholder or, in case of a gratuitous transfer, its legal predecessor has held, directly or indirectly, at least 1% of the company's shares capital at any time during a five-year period prior to the disposal. In these cases, capital gains are generally subject to the same rules as described above for shareholders resident in Germany. However, in case the shares are not attributable to a German permanent establishment or permanent representative the 5% taxation (see "— Corporations — Taxation of capital gains realized by shareholders tax resident in Germany holding the company's shares as business assets") shall not apply and the capital gains are fully exempt from German tax.

However, except for the cases referred to in clause (i) above, some of the double tax treaties concluded with Germany provide for a full exemption from German taxation.

Inheritance and Gift Tax

The transfer of the company's shares to another person by way of succession or donation is subject to German inheritance and gift tax (*Erbschaft- und Schenkungsteuer*) if:

(i) the decedent, the donor, the heir, the donee or any other beneficiary has his/her/its residence, domicile, registered office or place of management in Germany at the time of the transfer, or is a German citizen who has not stayed abroad for more than five consecutive years without having a residence in Germany; or

(ii) (irrespective of the personal circumstances) the shares are held by the decedent or donor as business assets for which a permanent establishment in Germany is maintained or a permanent representative is appointed in Germany; or

(iii) (irrespective of the personal circumstances) at least 10% of the shares are held, directly or indirectly by, the decedent or person making the gift, himself or together with a related party in terms of Section 1 para. 2 Foreign Tax Act.

Special regulations apply to qualified German citizens who maintain neither a residence nor their domicile in Germany but in a low tax jurisdiction, and to former German citizens, also resulting in inheritance and gift tax. The few double tax treaties on inheritance and gift tax which Germany has entered into provide that German inheritance and gift tax is levied only in case of (i) and, with certain restrictions, in case of (ii).

Abolishment of Solidarity Surcharge

According to a bill enacted in December 2019, the solidarity surcharge will be partially abolished as of the assessment period 2021 for certain individuals. The solidarity surcharge shall, however, continue to apply for capital investment and, thus, on withholding taxes levied. In case the individual income tax burden for an individual shareholder is lower than 25%, the shareholder can apply for his/her capital investment income being assessed at his/her individual tariff-based income tax rate, in which case solidarity surcharge would be refunded.

Other Taxes

No German capital transfer tax (*Kapitalverkehrsteuer*), value-added tax (*Umsatzsteuer*), stamp duty (*Stempelgebühr*) or similar taxes are levied when acquiring, holding or transferring the company's shares. No value-added tax will be levied unless the shareholder validly opts for it. Net wealth tax (*Vermögensteuer*) is currently not levied in Germany.

On January 22, 2013, the Council of the European Union approved the resolution of the ministers of finance from 11 European Union member states (including Germany) to introduce a Financial Transaction Tax ("FTT") within the framework of enhanced cooperation. On February 14, 2013, the European Commission published a proposal for a Council Directive implementing enhanced cooperation in the area of financial transaction tax. The plan focuses on levying a tax of 0.1% (0.01% for derivatives) on the purchase and sale of financial instruments.

A joint statement issued by 10 of the 11 participating European Union member states in October 2016 reaffirmed the intention to introduce FTT. However, at the moment not many details are available. Recently, further discussions on an FTT on the basis of a draft provided by Germany were held. However, it is still unclear if and when the FFT will be implemented and what the exact scope will be. The FTT proposal remains subject to negotiation between the participating Member States and is subject to political discussion. It may, therefore, be altered prior to the implementation, the timing of which remains unclear. Additional European Union member states may decide to participate.

Prospective holders of the shares are advised to seek their own professional advice in relation to FTT.

Material U.S. Federal Income Tax Considerations to U.S. Holders

In the opinion of Davis Polk & Wardwell LLP, the following is a description of the material U.S. federal income tax consequences to the U.S. Holders, as defined below, of owning and disposing of our common shares. It does not describe all tax considerations that may be relevant to a particular person's decision to acquire common shares.

This discussion applies only to a U.S. Holder that holds common shares as capital assets for U.S. federal income tax purposes. In addition, it does not describe all of the U.S. federal income tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the Code known as the Medicare contribution tax and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or other integrated transaction or persons entering into a constructive sale with respect to the common shares;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities classified as partnerships for U.S. federal income tax purposes;
- tax-exempt entities, including an "individual retirement account" or "Roth IRA";
- persons that own or are deemed to own ten percent or more of our common shares (by vote or value); or
- persons holding common shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding common shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of the common shares.

This discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between the Federal Republic of Germany and the United States, or the Treaty, all as of the date hereof, any of which is subject to change or differing interpretations, possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our common shares, who is eligible for the benefits of the Treaty and who is:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust, the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of our common shares in their particular circumstances.

Taxation of Distributions

As discussed above under "Dividend Policy" we have never paid or declared any cash dividends on our common shares, and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. In the event that we do make distributions of cash or other property, subject to the passive foreign investment company rules described below, distributions paid on common shares, other than

certain pro rata distributions of common shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. For so long as our common shares are listed on the Nasdaq or another established securities market in the United States or we are eligible for benefits under the Treaty, dividends paid to certain non-corporate U.S. Holders may be eligible for taxation as "qualified dividend income" and therefore, subject to applicable limitations, taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holders. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. The amount of a dividend will include any amounts withheld by us in respect of German income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, German income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. German taxes withheld in excess of the rate applicable under the Treaty will not be eligible for credit against a U.S. Holder's federal income tax liability. The rules governing foreign tax credits are complex, and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any German income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or Other Disposition of Common Shares

Subject to the passive foreign investment company rules described below, gain or loss realized on the sale or other disposition of common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to various limitations. The Treaty generally exempts a U.S. Holder from German tax on capital gains realized on the sale or other disposition of common shares and, accordingly, no such tax will be creditable against the U.S. Holder's U.S. federal income tax liability.

Passive Foreign Investment Company Rules

Under 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 consist of assets that produce, or are held for the production of, "passive income." For purposes of the above calculations, we will be treated as if we hold our proportionate share of the assets of, and receive directly our proportionate share of the income of, any other corporation in which we directly or indirectly own at least 25%, by value, of the shares of such corporation. Passive income generally includes dividends, interest, rents, certain non-active 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 current taxable year. However, under the Proposed 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. Although no assurances may be given in this regard, we expect that we would be eligible in our 2020 taxable year to use the fair market value of our assets for purposes of the asset test, and U.S. investors are urged to consult their tax advisers whether they could apply the Proposed Regulations for purposes of the asset test. The remainder of this discussion assumes that U.S. Holders will choose to apply the Proposed Regulations in their entirety.

Based on the composition of our income and assets during 2019, we do not believe that we were a PFIC for our 2019 taxable year. However, PFIC status is a fact-intensive determination made on an annual basis after the end of each taxable year, and we have not yet determined our expected PFIC status for the current taxable year or any future taxable year. Whether we will be a PFIC in 2020 or any future year is uncertain because, among other things, (i) we currently own, and will own after the closing of this offering, 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 2020 or any future taxable year. If we are a PFIC for any year during which a U.S. Holder holds common shares, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds common shares, even if we ceased to meet the threshold requirements for PFIC status. In addition, the we may, directly or indirectly, have held or hold equity interests in other PFICs (collectively, "Lower-tier PFICs"). Under attribution rules, if the we are a PFIC, U.S. Holders will be deemed to own their proportionate shares of the stock of Lower-tier PFICs and will be subject to U.S. federal income tax according to the rules described in the following paragraphs on (i) certain distributions by a Lower-tier PFIC and (ii) a disposition of shares of a Lower-tier PFIC, in each case as if the U.S. Holder held such shares directly, even though holders have not received the proceeds of those distributions or dispositions directly. U.S. Holders should consult their tax advisors about the consequences to them of our investment in one or more Lower-tier PFICs.

If we were a PFIC for any taxable year during which a U.S. Holder held common shares (assuming such U.S. Holder has not made a timely mark-to-market election, as described below), gain recognized by a U.S. Holder on a sale or other disposition (including certain pledges) of the common shares would be allocated ratably over the U.S. Holder's holding period for the common shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the amount allocated to that taxable year. Further, to the extent that any distribution received by a U.S. Holder on its common shares exceeds 125% of the average of the annual distributions on the common shares received during the preceding three years or the U.S. Holder's holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain, described immediately above.

A U.S. Holder can avoid certain of the adverse rules described above by making a mark-to-market election with respect to its common shares, provided that the common shares are "marketable." Common shares will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable Treasury regulations. If a U.S. Holder makes the mark-to-market election, it generally will recognize as ordinary income any excess of the fair market value of the common shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the common shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in our common shares will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other

disposition of common shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). A mark-to-market election generally cannot be made for equity interests in any Lower-tier PFIC unless shares of such Lower-tier PFIC are themselves "marketable." As a result, if a U.S. Holder makes a mark-to-market election with respect to our common shares, the U.S. Holder would nevertheless be subject to the PFIC rules described above with respect to its indirect interest in any Lower-tier PFIC unless the U.S. Holder makes a QEF Election with respect to such Lower-tier PFIC, as discussed below.

In addition, in order to avoid the application of the foregoing rules, a U.S. Holder that owns stock in a PFIC for U.S. federal income tax purposes may make a QEF Election with respect to such PFIC if the PFIC provides the information necessary for such election to be made. If a U.S. Holder makes a QEF Election with respect to a PFIC, the United States person will be currently taxable on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC and will not be required to include such amounts in income when actually distributed by the PFIC. There is no assurance that we will provide information necessary for U.S. Holders to make QEF Elections. A QEF Election with respect to us will not apply to any Lower-tier PFIC. If we determine that any of our subsidiaries is a Lower-tier PFIC for any taxable year, there is no assurance that we will provide information necessary for U.S. Holders to make a QEF Election with respect to such Lower-tier PFIC.

In addition, if we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or for the prior taxable year, the preferential dividend rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If a U.S. Holder owns common shares during any year in which we are a PFIC, the U.S. Holder generally must file annual reports, containing such information as the U.S. Treasury may require on IRS Form 8621 (or any successor form) with respect to us, generally with the U.S. Holder's federal income tax return for that year.

U.S. Holders should consult their tax advisers concerning our potential PFIC status and the potential application of the PFIC rules.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

UNDERWRITING

BofA Securities, Inc., Jefferies LLC and Credit Suisse Securities (USA) LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of common shares set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
Jefferies LLC	
Credit Suisse Securities (USA) LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The expenses of the offering, not including the underwriting discount, are estimated at $ and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to $.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in

the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common shares or securities convertible into, exchangeable for, exercisable for, or repayable with common shares, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Jefferies LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common shares;
- sell any option or contract to purchase any common shares;
- purchase any option or contract to sell any common shares;
- grant any option, right or warrant for the sale of any common shares;
- lend or otherwise dispose of or transfer any common shares;
- request or demand that we file or make a confidential submission of a registration statement related to the common shares; or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common shares whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common shares and to securities convertible into or exchangeable or exercisable for or repayable with common shares. It also applies to common shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Nasdaq Global Market Listing

We expect the shares to be approved for listing on The Nasdaq Global Market, subject to notice of issuance, under the symbol "CVAC."

Before this offering, there has been no public market for our common shares. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters from bidding for and purchasing our common shares. However, the representatives may engage in transactions that stabilize the price of the common shares, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common shares in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common shares made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common shares or preventing or retarding a decline in the market price of our common shares. As a result, the price of our common shares may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common shares. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Stamp Taxes

If you purchase common shares offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the

accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no shares have been offered or will be offered to the public in that Relevant State in connection with this offering prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved by the competent authority in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

a. to any legal entity which is a qualified investor as defined in the Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters named above for any such offer; or

c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any representatives of the underwriters named above to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation. Neither we nor the representatives of the underwriters named above have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for us or the underwriters to publish a prospectus for such offer pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with our company and the representatives of the underwriters named above that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed to and with our company and the representatives of the underwriters named above that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of shares to the public other than their offer or resale in a Relevant State to qualified investors within the meaning of the Prospectus Regulation, in circumstances in which the prior consent of the representatives of the underwriters named above has been obtained to each such proposed offer or resale.

We, the representatives of the underwriters named above and our and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this selling restriction, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

References to the Prospectus Regulation include, in relation to the United Kingdom (and its constituent countries), the Prospectus Regulation as it forms part of the domestic law of the constituent countries of the United Kingdom by virtue of the European Union (Withdrawal) Act 2018.

This selling restriction is in addition to any other selling restrictions set out below.

Notice to Prospective Investors in the United Kingdom

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the "Financial Promotion Order"), (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth companies, unincorporated associations etc.") of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended ("FSMA")) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

This prospectus is not intended to constitute an offer or solicitation to purchase or invest in our Common Shares. The Common Shares may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act ("FinSA") and no application has or will be made to admit the Common Shares to trading on any trading venue (exchange or multilateral trading facility) in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the Common Shares constitutes a prospectus pursuant to the FinSA, and neither this prospectus nor any other offering or marketing material relating to the Common Shares may be publicly distributed or otherwise made publicly available in Switzerland.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an

exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

EXPENSES OF THE OFFERING

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

Expenses	Amount
U.S. Securities and Exchange Commission registration fee	$ *
Nasdaq listing fee	*
FINRA filing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
Total	*

* To be provided by amendment.

All amounts in the table are estimates except the U.S. Securities and Exchange Commission registration fee, the Nasdaq listing fee and the FINRA filing fee. We will pay all of the expenses of this offering.

LEGAL MATTERS

The validity of the common shares and certain other matters of Dutch law will be passed upon for us by NautaDutilh N.V. Certain matters of U.S. federal law will be passed upon for us by Davis Polk & Wardwell LLP. Certain matters will be passed upon for the underwriters by Latham & Watkins LLP, New York, New York, with respect to U.S. federal law, and De Brauw Blackstone Westbroek N.V., with respect to Dutch law.

EXPERTS

The consolidated financial statements of CureVac AG as of December 31, 2018 and 2019, and for each of the two years in the period ended December 31, 2019, appearing in this prospectus and registration statement, have been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The current address of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft is Arnulfstraße 59, 80636 Munich, Germany.

ENFORCEMENT OF JUDGMENTS

We are incorporated under the laws of the Netherlands, and our headquarters are located in Germany. Substantially all 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. Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities.

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 management board and supervisory board 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 management board and supervisory board and the experts named in this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the U.S. Securities and Exchange Commission a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. 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.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, managing directors, supervisory directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send the transfer agent a copy of all notices of shareholders' meetings and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

INDEX TO FINANCIAL STATEMENTS

Consolidated Financial Statements—CureVac AG

Report of Independent Registered Public Accounting Firm

To the Audit Committee of CureVac AG,

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of CureVac AG (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and other comprehensive income (loss), changes in shareholders' equity and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standard Board (IFRS).

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Dr. Elia Napolitano
Wirtschaftsprüfer
(German Public Auditor)

/s/ Steffen Maurer
Wirtschaftsprüfer
(German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company’s auditor since 2015.

Munich, Germany
April 29, 2020

CureVac AG

Consolidated Statements of Operations and Other Comprehensive Income (Loss)

(in thousands of EUR, except per share data)	Note	Years ended December 31, 2018	2019
Revenue	3.1	12,871	17,416
Cost of sales	3.2	(17,744)	(27,983)
Selling and distribution expenses	3.3	(1,085)	(1,755)
Research and development expenses	3.4	(41,722)	(43,242)
General and administrative expenses	3.5	(25,289)	(48,969)
Other operating income	3.6	808	5,587
Other operating expenses	3.7	(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)	14	(110)	252
Net loss for the year		**(71,241)**	**(99,873)**
Other comprehensive income			
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)		**(98.05)**	**(137.45)**

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

CureVac AG

Consolidated Statements of Financial Position

(in thousands of EUR)	Note	December 31, 2018	December 31, 2019
Assets			
Non-current assets			
Intangible assets	4	6,213	5,698
Property, plant and equipment	4	40,472	48,075
Other assets	4	5,771	6,061
Right-of-use assets	2	—	13,611
Deferred tax assets	14	133	—
Total non-current assets		**52,589**	**73,445**
Current assets			
Inventories	5	2,951	6,197
Trade receivables	3	5,476	15,690
Contract assets	3	1,382	1,463
Other financial assets	6	39,253	1,458
Prepaid expenses and other assets	7	2,628	1,683
Cash and cash equivalents		21,380	30,684
Total current assets		**73,070**	**57,175**
Total assets		**125,659**	**130,620**
Equity and liabilities			
Equity			
Issued capital		727	727
Capital reserve		447,440	472,396
Accumulated deficit		(416,074)	(515,947)
Other comprehensive income		(10)	22
Total equity	**8**	**32,083**	**(42,802)**
Non-current liabilities			
Convertible loans	12	—	65,018
Lease liabilities	2	—	12,126
Contract liabilities	3	64,583	66,040
Deferred tax liabilities	13	—	1,623
Other liabilities		863	529
Total non-current liabilities		**65,446**	**145,336**
Current liabilities			
Other financial liabilities		77	—
Lease liabilities	2	—	2,004
Trade and other payables	11	10,913	6,475
Other liabilities	12	11,146	12,015
Income Taxes payable	13	217	111
Contract liabilities	3	5,777	7,481
Total current liabilities		28,130	28,086
Total liabilities		**93,576**	**173,422**
Total equity and liabilities		**125,659**	**130,620**

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

CureVac AG

Consolidated Statements of Changes in Shareholders´ Equity

(in thousands of EUR)	Issued capital	Capital reserve	Accumulated deficit	Currency translation reserve	Total equity
Balance as of January 1, 2018	**727**	**447,438**	**(345,320)**	**(76)**	**102,768**
Effects from the first-time adoption of IFRS 9	—	—	(183)	—	(183)
Effects from the first-time adoption of IFRS 15	—	—	669	—	669
Adjusted balance as of January 1, 2018	**727**	**447,438**	**(344,834)**	**(76)**	**103,254**
Expenses from share-based payment plan	—	2	—	—	2
Net loss	—	—	(71,240)	—	(71,240)
Other comprehensive income (loss)	—	—	—	66	66
Total comprehensive income (loss)	—	2	(70,754)	66	(70,686)
Balance as of December 31, 2018	**727**	**447,440**	**(416,074)**	**(10)**	**32,083**
Equity component of convertible loans	—	7,604	—	—	7,604
Deferred taxes on convertible loans	—	(2,212)	—	—	(2,212)
Expenses from share-based payment plan	—	19,564	—	—	19,564
Net loss	—	—	(99,873)	—	(99,873)
Other comprehensive income (loss)	—	—	—	32	32
Total comprehensive income (loss)	—	24,956	(99,873)	32	(74,887)
Balance as of December 31, 2019	**727**	**472,396**	**(515,947)**	**22**	**(42,802)**

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

CureVac AG

Consolidated Statements of Cash Flows

(in thousands of EUR)	Years ended December 31, 2018	2019
Operating activities		
Loss before income tax	**(71,131)**	**(100,125)**
Adjustments to reconcile loss before tax to net cash flows		
Finance income	(1,968)	(833)
Finance expense	275	1,460
Depreciation and amortization	3,781	7,164
Loss on disposal of fixed assets	52	241
Share-based payment expense	(4,248)	19,564
Working capital changes		
Decrease / (increase) in trade receivables and contract assets	(5,595)	(10,117)
Decrease / (increase) in inventory	878	(3,246)
Decrease / (increase) in other assets	(6,106)	630
Receipts from grants from government agencies and similar bodies	214	9,304
(Decrease) / increase in trade and other payables and contract liabilities	9,402	(9,584)
(Decrease) / Increase in other current financial and other liabilities	336	(334)
Income taxes paid	(26)	(345)
Interest received	15	81
Interest paid	11	(824)
Net cash flow (used in) operating activities	**(74,110)**	**(86,963)**
Investing activities		
Purchase of property, plant and equipment	(9,406)	(11,172)
Purchase of intangible assets	(5,317)	(1,052)
Proceeds from asset-related grants	—	2,325
Proceeds from other financial assets	10,459	38,080
Net cash flow from (used in) investing activities	**(4,264)**	**28,181**
Financing activities		
Payments on lease obligation	(112)	(1,910)
Proceeds from the convertible loans	—	69,889
Net cash flow from (used in) financing activities	**(112)**	**67,979**
Net increase (decrease) in cash and cash equivalents	(78,486)	9,197
Effect of currency translation gains on cash and cash equivalents	213	107
Cash and cash equivalents, beginning of period	99,653	21,380
Cash and cash equivalents, end of period	**21,380**	**30,684**

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

CureVac AG

Notes to the Consolidated Financial Statements

1. Corporate Information

CureVac AG, ("CureVac" or "CV" or the "Company") is the parent company of CureVac Group ("Group"). The Company's registered headquarters is Friedrich-Miescher-Strasse 15, 72076 Tuebingen, Germany and the Company is registered in the commercial register (Handelsregister) at the local court (Amtsgericht) of Stuttgart, Germany under HRB 754041. CureVac is a leading global clinical-stage 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 Group was spun out of the University of Tuebingen (Germany) and is primarily funded by its major shareholder, the dievini Hopp BioTech holding GmbH & Co. KG (dievini), which is an investment company dedicated to the support of companies in health and life sciences.

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 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 Management Board for presentation to the Supervisory Board on April 29, 2020. 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 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.

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 generally concluded that it acts as a principal in sales transactions as it customarily 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 and (ii) research and development services. Such arrangements provide for various types of payments to the Group, including upfront fees, funding of research and development services, 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, 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.

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. 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 2019 and 2018, the Group only had the following financial assets to be measured at amortized cost and/or at fair value through profit or loss:

- 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 be 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 and Licenses	3 to 8 years

One intangible asset with a net carrying amount of EUR 3,108k and a remaining useful life of 7 years, relates to the rights to access a third-party's LNP formulation technology.

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:

Buildings:	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 to fiscal 2019. The residual values of the assets are generally considered to be zero.

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 2,188k borrowing costs during fiscal 2019 (2018: 0k). The capitalization rate used to determine the amount of the borrowing costs eligible for capitalization was during fiscal 2019 with a weighted-average of 9.13%.

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 fiscal 2019 and 2018.

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 income 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, which affects the Group's accounting policy for leases; refer to the section "Changes in accounting policies and disclosures — New and amended standards and interpretations" below for further information.

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.

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

Inventories are comprised of raw materials, work in progress and finished goods and are held for use in the fulfillment of collaboration agreements.

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.

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, members of management and other key employees were awarded rights in a virtual shares program. In 2019, rights were awarded in a new virtual shares program and other terms specific to certain individuals. 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 setting the awards in either cash or shares. It is the Group’s intention to settle in shares if such scenario materializes.

The Group considers an IPO scenario as more probable than other, cash-settled, scenarios and accounts for the virtual shares program as equity-settled.

The new awards granted in 2019 are also accounted for as equity-settled share-based payments on that basis and thus requires an estimation of the grant date fair value of the awards at the time when they were granted. Such estimates require significant judgment and, depending on when the awards are granted, are subject to change in line with the Group’s development but are also dependent on the likelihood of occurrence of the exit scenario underlying the valuation. For further details, refer to Note 9.

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 the end of the current fiscal year. 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.

Research and development costs and internally generated intangible assets

Research activities undertaken with the prospect of gaining new scientific or technical knowledge and understanding are expensed as incurred.

Development activities relate to the planning or designing of substantially improved products and processes. Development expenses are capitalized only if the cost involved can be measured reliably, the product or process under development is technically feasible, future economic benefits are probable and the Group has the intention and resources to complete development and use or sell it. Cost capitalized comprises costs of material and employee services as well as other directly attributable expenses.

Due to the regulatory environment and other types of uncertainty, management has determined that the criteria for capitalizing development costs to intangible assets, as set out in IAS 38, have not been met and therefore the Group has not capitalized any development costs in 2019 and 2018. See Note 3.4 for information relating to research and development expenses incurred in the reporting period.

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.

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 is measured using the market interest rate obtainable on similar debt instruments. The debt component is measured as liability at amortized cost until it is converted into equity or becomes due for repayment. The carrying amount of the debt component is based on an expected repayment in 2021, which is the earliest possible date at which repayment can be required by the lender, unless specified events occur.

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.

Based on these inputs, the carrying amount of the debt component was determined to be EUR 62,284k. The remainder of the proceeds is attributable to the below-market terms of the convertible loan. The amount is deemed to be a contribution by the related party and is recorded as such in equity (net of tax).

For further information on the convertible loan, see Note 12.

Changes in accounting policies and disclosures

New and amended standards and interpretations

IFRS 16 Leases

a) General

IFRS 16 supersedes IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model.

The Group adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of January 1, 2019. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application. The Group elected to use certain transition practical expedients, including applying the standard only to contracts that were previously identified as leases applying IAS 17 and IFRIC 4 at the date of initial application.

b) Nature of the effect of adoption of IFRS 16

The Group has lease contracts for the building, vehicles and equipment. Before the adoption of IFRS 16, the Group classified each of its leases (as lessee) at the inception date as either a finance lease or an operating lease. A lease was classified as a finance lease if it transferred substantially all of the risks and rewards incidental to ownership of the leased asset to the Group; otherwise it was classified as an operating lease. Finance leases were capitalized at the commencement of the lease at the inception date fair value of the leased property or, if lower, at the present value of the minimum lease payments. Lease payments were apportioned between interest (recognized as finance costs) and reduction of the lease liability. In an operating lease, the leased property was not capitalized and the lease payments were recognized as rent expense in the statement of operations on a straight-line basis over the lease term. Prepaid rent was recognized under “Non-current other assets.”

Leases previously classified as finance leases

The Group utilized the carrying amounts of recognized assets and liabilities at the date of initial application for leases previously classified as finance leases (i.e., the right-of-use assets and lease liabilities equal the lease assets and liabilities recognized under IAS 17). The requirements of IFRS 16 was applied to these leases from January 1, 2019.

Leases previously accounted for as operating leases

The Group recognized right-of-use assets and lease liabilities for those leases previously classified as operating leases, except for those exempted by the practical expedients listed below. The right-of-use

assets for all leases were recognized based on the amount equal to the lease liabilities. Lease liabilities were recognized based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application.

The Group also applied the available practical expedients wherein it:

- Relied on its assessment of whether leases are onerous immediately before the date of initial application
- Applied the short-term leases exemptions to leases with lease term that ends within 12 months at the date of initial application
- Excluded the initial direct costs from the measurement of the right-of-use asset at the date of initial application
- Used hindsight in determining the lease term where the contract contains options to extend or terminate the lease but did not use a single discount rate to a portfolio of leases with reasonably similar characteristics.

Based on the foregoing, as of January 1, 2019:

- Right-of-use assets of EUR 15,908k were recognized and presented separately in the statement of financial position. This includes the lease assets recognized previously under finance leases of EUR 69k that were reclassified from Property, plant and equipment and estimated costs to be incurred by the lessee for dismantling and removing the underlying asset.
- Additional lease liabilities of EUR 15,810k (included in “lease liabilities” from January 1, 2019; included in “finance lease liabilities” at December 31, 2018) were recognized.
- Prepaid rent recognized under “Non-current other assets” in the amount of EUR 4,333k was carried on forward in this line-item because the commencement date of the associated lease has not occurred as of January 1, 2019.
- Because there was no accrued rent related to previous operating leases at December 31, 2018 and Right-of-use asset equaled the additional lease liabilities and the provision for the restoration obligation, there was no deferred tax impact and no effect on accumulated deficit as of January 1, 2019.

The lease liabilities as at January 1, 2019 reconcile to the operating lease commitments as of December 31, 2018 as follows:

	EUR k
Existing commitments as at December 31, 2018	
Operating lease commitments	48,008
Minimum lease payments (notional amount) on finance lease liabilities	78
Relief option for short-term leases	(110)
Leases with commencement date after January 1, 2019 in the amounts included above as existing commitments as at December 31, 2018	(28,557)
Other	123
Gross lease liabilities as at January 1, 2019	**19,542**
Effect of discounting	(3,655)
Lease liabilities as at January 1, 2019	**15,887**
Present value of finance lease liabilities as at December 31, 2018	(77)
Lease liabilities upon initial application of IFRS 16 as at January 1, 2019	**15,810**

Weighted average incremental borrowing rate as at January 1, 2019 5.64%

The range of the incremental borrowing rate is between 2.32% and 7.90%.

c) Summary of new accounting policies

Set out below are the new accounting policies of the Group upon adoption of IFRS 16:

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.

Election (not) to separate 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.

d) Significant judgments

Determining the lease term of contracts with renewal options

The Group determines the lease term as the non-cancellable 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 (5 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 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 estimates (such as the subsidiary's stand-alone credit rating and discounts for collateral).

e) Amounts recognized in the statement of financial position and statement of operations and other comprehensive income (loss)

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
	EURk	EURk	EURk	EURk
As at January 1, 2019	15,536	132	239	15,907
Additions	82	59	13	154
Depreciation expense	(2,322)	(65)	(142)	(2,529)
Foreign currency translation	79	—	—	79
As at December 31, 2019	**13,375**	**126**	**110**	**13,611**

Below are the carrying amounts of lease liabilities and the movements during the period:

	EUR k
As at January 1, 2019	15,887
Additions	153
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

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	(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)**

The Group had total cash outflows for leases of EUR 3,073k in 2019.

The Group also had non-cash additions to right-of-use assets and lease liabilities of EUR 153k in 2019.

The non-cash additions to right-of-use assets and lease liabilities are the sum of the amounts disclosed above in the movements and the amounts resulting from the first-time adoption of IFRS 16 as at January 1, 2019 described above under b).

Leases not yet commenced to, which CureVac is committed at December 31, 2019, exist with fixed payment obligations for a lease of further two buildings in Tuebingen, Germany over a 15 year term in the gross amount of EUR 28,557k with a starting date of March 1, 2020 (and a respective earliest end date in 2035). In addition, optional lease payments for the renewal of this lease term for two 5 year extension options for the two buildings exist which could lead to further payments in a gross amount of EUR 21,653k (in addition to the EUR 12,548k) disclosed above under subsection d). Moreover, the Group is committed to further future cash outflows resulting from short-term leases in the amount of EUR 62k and leases of low-value assets in the amount of EUR 64k at December 31, 2019.

Other amendments of standards and/or new interpretations

The following several other amendments and interpretations apply for the first time in 2019:

- IFRIC Interpretation 23 Uncertainty over Income Tax Treatment
- Amendments to IFRS 9: Prepayment Features with Negative Compensation
- Amendments to IAS 19: Plan Amendment, Curtailment or Settlement
- Amendments to IAS 28: Long-term interests in associates and joint ventures
- Annual Improvements 2015-2017 Cycle
  - IFRS 3 Business Combinations
  - IFRS 11 Joint Arrangements
  - IAS 12 Income Taxes
  - IAS 23 Borrowing Costs

The standards did not have a material impact on the consolidated financial statements of the Group. 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 new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group’s financial statements and that might have an impact on the Group’s financial statements are disclosed below. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

- Amendments to IFRS 3: Definition of a Business
- Amendments to IAS 1 and IAS 8: Definition of Material
- Amendments to IAS 1: Presentation of Financial Statements: Classification of Liabilities as Current or Non-current
- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform
- Amendments to References to the Conceptual Framework in IFRS Standards

The amendments above are not expected to have a significant impact on the Group's consolidated financial statements.

3. Notes to the consolidated financial statements

3.1 Revenue from contract with customers

The Group recognized the following revenues in 2019 and 2018:

	December 31, 2018	December 31, 2019
	EUR k	EUR k
United States		
Eli Lilly and Company	8,927	14,319
Germany		
Boehringer Ingelheim	3,337	2,474
Others	5	104
Switzerland		
CRISPR	602	519
Total	**12,871**	**17,416**

Revenue recognized at a point-in-time	EUR292k	EUR3,021k
Revenue recognized over a period-of-time	EUR12,579k	EUR14,395k

Of these revenues, EUR 8,617k (2018: EUR 6,713k) was recognized from product sales as part of collaboration 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 received or receivable at December 31, 2019 (in thousands)	Upfront payments included in contract liabilities at December 31, 2019 (in thousands of Euro)	Revenue recognized from upfront payments (in thousands of Euro)	
			2018	2019
Eli Lilly and Company	USD 50,000 (EUR 42,200)	34,854	3,516	3,516
CRISPR	USD 3,000 (EUR 2,524)	1,859	310	310
Boehringer Ingelheim	EUR 30,000	15,870	2,035	1,951
Genmab	USD 10,000 (EUR 8,937)	8,937	—	—
Total		**61,520**	**5,861**	**5,777**

Contract balances:

	January 1, 2018	December 31, 2018	December 31, 2019
	EUR k	EUR k	EUR k
Trade receivables	463	5,476	15,690
Contract assets	—	1,382	1,463
Contract liabilities	69,220	70,360	73,521

Trade receivables are non-interest bearing and are generally settled within 30 to 45 days.

At December 31, 2019, the Group had four collaboration partners (2018: three) that owed 100% (2018: two) of all the receivables and contract assets outstanding. There were two collaboration partners (2018: two) with balances greater than 10% of the total amounts of receivable and contract assets. Under the terms of the licenses and collaboration agreement with Genmab, CureVac recognized a receivable of USD 10,000k (EUR 8,937k). To mitigate currency risk CureVac entered into a currency forward contract for the entire value of the receivable. The settlement date of the forward contract is February 7, 2020. CureVac did not apply hedge accounting for this derivative.

Contract liabilities include advances received from the Group's major license and collaboration agreements. The outstanding balances of these accounts increased in 2019 and 2018 due to upfront and milestone payments received or receivable of EUR 8,937k and EUR 7,000k, respectively, which were deferred and exceeded the revenues recognized from contract liabilities recorded under the collaboration agreements in each respective year.

Contract liabilities allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at year-end are as follows:

	Year ended	
	2018 EUR k	2019 EUR k
Within one year	5,777	7,481
More than one year	64,583	66,040
Total	**70,360**	**73,521**

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
	EUR k	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)**

3.3 Selling and distribution expenses

Selling and distribution expenses consist of the following:

	2018 EUR k	2019 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)**

Personnel expenses mainly include salary and salary-related expenses of EUR 520k (2018: 581k) and expenses from share-based payments of EUR 743k (2018: 0k). Refer to Note 9 for further information.

3.4 Research and development expenses

R&D expenses consists of the following:

	2018 EUR k	2019 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)**

Personnel expenses mainly include salary and salary-related expenses of EUR 14,127k (2018: 11,806k); additionally, in 2018, it includes a EUR 4,241k benefit recognized upon reversal of provisions due to expiration of certain virtual shares awarded under our Old VESOP (see Note 9).

Third-party services mainly relate to research services provided by third-party laboratories, clinical services and R&D consulting services.

3.5 General and administrative expenses

General and administrative expenses include the following:

	2018 EUR k	2019 EUR k
Personnel	(10,084)	(31,645)
Maintenance and lease costs	(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)**

Personnel expenses mainly include salary and salary-related expenses of EUR 13,083k (2018: 10,105k) and expenses from share-based payments of EUR 18,562k (2018: 0k). Other mainly consists of travel expenses of EUR 811k (2018: 853k) and office materials of EUR 1,647k (2018: 1,394k).

3.6 Other operating income

Other operating income relates to:

	2018 EUR k	2019 EUR k
Grants and other cost reimbursements from government agencies and similar bodies	808	5,385
Other	—	202
Total	**808**	**5,587**

In 2019 and 2018 income from grants with government agencies and similar bodies resulted from the following:

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.

During the year ended December 31, 2019, CureVac recognized the reimbursement of approved expenses of EUR 3,607k (2018: EUR 0k) as "other operating income" and EUR 2,325k (2018: EUR0k) were deducted from the carrying amount of qualifying assets recorded in property, plant and equipment.

As of December 31, 2019, EUR 2,886k in grant funds received have been deferred and are presented within other liabilities (as of December 31, 2018: EUR 0k).

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).

During the year ended December 31, 2019 CureVac recognized EUR 768k (2018: EUR 486k) from the amortization of the grants on a straight-line basis as other operating income.

As of December 31, 2019, EUR 1,262 in grant funds received have been deferred and presented within other liabilities (as of December 31, 2018: EUR 1,544k).

3.7 Other operating expenses

Other operating expenses relates to:

	2018 EUR k	2019 EUR k
Renumeration of supervisory board	(343)	(521)
Other	(320)	(30)
Total	**(663)**	**(552)**

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 year ended December 31, 2018 and 2019 were as follows:

Intangible assets

(in thousands of EUR)	Software and licenses	Advance payments	Total
Acquisition costs			
As of January 1, 2018	3,402	235	3,638
Additions	5,314	2	5,317
As of December 31, 2018	**8,717**	**238**	**8,954**
Cumulative amortization and impairment charges			
As of January 1, 2018	1,545	—	1,545
Amortization	1,197	—	1,197
As of December 31, 2018	**2,742**	**—**	**2,742**

(in thousands of EUR)	Software and licenses	Advance payments	Total
Acquisition costs			
As of January 1, 2019	8,717	238	8,954
Additions	738	44	782
Disposals	(6)	—	(6)
As of December 31, 2019	**9,449**	**282**	**9,731**
Cumulative amortization and impairment charges			
As of January 1, 2019	2,742	—	2,742
Amortization	1,295	—	1,295
Disposals	(4)	—	(4)
As of December 31, 2019	**4,033**	**—**	**4,033**
Carrying amount			
As of January 1, 2018	1,858	235	2,093
As of December 31, 2018	5,975	238	6,213
As of December 31, 2019	**5,416**	**282**	**5,698**

Property, plant and equipment

(in thousands of EUR)	Buildings	Technical equipment and machines	Other equipment, furniture and fixtures	Assets under construction	Total
Acquisition costs					
As of January 1, 2018	5,398	12,230	4,665	27,103	49,397
Additions	490	953	719	7,244	9,406
Disposals	—	(150)	(157)	—	(307)
Reclassifications	—	1,303	19	(1,323)	—
Currency translation	—	—	—	1	1
As of December 31, 2018	**5,888**	**14,336**	**5,247**	**33,025**	**58,497**
Cumulative depreciation and impairment charges					
As of January 1, 2018	1,337	4,610	2,654	7,120	15,721
Depreciation	371	1,299	890	—	2,559
Disposals	—	(99)	(157)	—	(255)
As of December 31, 2018	**1,708**	**5,810**	**3,387**	**7,120**	**18,025**

(in thousands of EUR)	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	58,497
Additions	854	2,152	712	7,435	11,152
Disposals	(65)	(319)	(248)	—	(632)
Reclassifications	167	883	187	(1,237)	—
Currency translation	—	—	3	4	6
As of December 31, 2019	**6,844**	**17,051**	**5,902**	**39,226**	**69,023**
Cumulative depreciation and impairment charges					
As of January 1, 2019	1,708	5,810	3,388	7,120	18,026
Depreciation	779	1,637	899	—	3,315
Disposals	(37)	(190)	(164)	—	(392)
Currency translation	—	—	1	—	1
As of December 31, 2019	**2,449**	**7,257**	**4,123**	**7,120**	**20,949**
Carrying amount					
As of January 1, 2018	4,061	7,621	2,011	19,982	33,675
As of December 31, 2018	4,181	8,526	1,860	25,904	40,472
As of December 31, 2019	**4,395**	**9,795**	**1,779**	**32,105**	**48,075**

4.2 Non-current other assets

Non-current other assets of EUR 6,061k (2018: EUR 5,771k) consist of costs to obtain a contract of EUR 966k (2018: EUR 749k), a security deposit for a building of EUR 390k (2018: EUR 390k) as well as a deposit payment for a lease of EUR 4,705k (2018: EUR 4,632k).

The amortization of capitalized costs to obtain a contract in 2019 was EUR 25k (2018: EUR 25k).

5. Inventories

Inventories include the following:

	2018 EUR k	2019 EUR k
Raw materials	2,742	6,177
Finished goods	—	14
Other	209	6
Total	**2,951**	**6,197**

Raw materials were written-down by EUR 4,136k (2018: EUR 375k) due to obsolescence and net selling prices being lower than carrying cost related to a specific collaboration arrangement.

6. Other financial assets

Other financial assets include the following:

	2018 EUR k	2019 EUR k
Short-term investments	39,024	430
Other	229	1,028
Total	**39,253**	**1,458**

7. Prepaid expenses and other current assets

Prepaid expenses and other current assets of EUR 1,683k (2018: 2,628k) mainly include prepayments for future service agreements and goods in the amount of EUR 1,150k (2018: EUR 421k) and outstanding VAT refund claims of EUR 533k (2018: EUR 1,761k). The net amount of VAT refund claims and VAT payables does not bear interest and is reported to the tax authorities on a monthly basis.

8. Equity

The issued capital consists of Series A, B and C shares which have a nominal value of EUR 1, full voting rights and are fully paid-in. The amount of Series A, B and C shares issued as of December 31, 2019 and 2018 and January 1, 2018 are as follows:

Series	Shares
A	23,400
B	688,692
C	14,500
Total	**726,592**

Series B and C shares include preference rights in the case of a defined exit event (e.g., trade sale or merger) of CureVac. The Series C shares also include a liquidation preference which grants the shareholders the right to adjust their shares by a factor of between 1 and 3 depending on the proceeds generated in such defined exit event. The Series C shares were issued for share-based compensation (see Note 9). In case of an initial public offering (IPO) of CureVac, the liquidation preferences of the Series B and C shares lapse. This liquidation preference is classified as an equity-settled share-based payment.

At the Annual General Meeting of June 17, 2019, it was decided that the number of (virtual) option rights to be issued as part of a new employee program (taking into account the scope of the existing employee participation program) will be set at 15% of the issued capital of CureVac AG.

The Series B shares held by the Bill and Melinda Gates Foundation (BMGF) include certain further rights under which CureVac would be obliged to buy back the shares at a specified minimum amount under defined circumstances if the buy-back is allowed according to German corporate law (Aktiengesetz). However, management has concluded the defined circumstances are all under the control of the Company.

Capital reserves

Capital reserves may only be released and distributed to shareholders to the extent that the additional paid-in capital as reported in the Group’s statutory financial statements prepared under German GAAP is available for release and exceeds the accumulated deficit, including current year losses, as reported in those statutory financial statements.

Recent financing rounds

The following financings were initiated by the end of fiscal 2019:

Pursuant to an Investment and Shareholders` Agreement (“ISA”), effective December 19, 2019, Genmab A/S, a Danish corporation, agreed to purchase 16,345 Series B shares in the Company in exchange for EUR 20,000k in cash.

As of December 31, 2019, CureVac 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.

Convertible loans

The total amount recognized in equity in fiscal 2019 has been EUR 7,604k. Directly attributable transaction costs from this transaction have been determined to be immaterial and therefore recognized as an expense in fiscal 2019. See Note 12 for further information.

9. Share-based payments

During the years ended December 31, 2019 and December 31, 2018, the Group had the following share-based arrangements.

9.1 Management share option plans

At January 1, 2018, a total of 8,932 share options granted to five members of (former) management were outstanding and exercisable. All these options grant the holder the right to acquire shares of CureVac at nominal value and are classified as equity-settled share-based payments. These management share options were granted and vested prior to January 1, 2013. 3,650 of these options expired on December 31, 2018 and the remaining 5,282 options will expire on December 31, 2021.

According to the shareholder`s agreement in place, sufficient authorized capital ("genehmigtes Kapital") to enable CureVac AG to fulfill the rights under these 5,282 remaining share options at December 31, 2019 was authorized at the Annual General Meeting in 2016 and can be utilized until July 25, 2021.

See the description of the accounting for the Series C shares under Note 8. Equity.

No expenses have been recognized during the years ended December 31, 2019 and December 31, 2018 under these programs.

9.2 Virtual shares program I

Description of the program

In addition to the management share option plans described above, since 2009, CureVac has operated a virtual shares program for selected key employees of the Group ("Old VESOP") originally up to 60,175 (2018: 60,175) Beteiligungspunkte (herein referenced as "virtual shares"). The main features of the Old VESOP were originally as follows:

- The beneficiaries do not hold direct interests in CureVac but receive virtual shares at no cost, the notional value of which is equal to EUR 1 per ordinary share.
- The virtual shares are earned on a monthly basis (graded vesting) over a period of one to five years.
- Virtual shares allocated and earned are settled by CureVac in cash if an exit event occurs (e.g. trade sale, merger). In the event of a change of the former CureVac GmbH to an AG, CureVac may convert those virtual shares to share options.
- If no exit event or no modification into share options occurs within the term of the virtual shares program all rights from the virtual shares program lapse / have lapsed (which, depending on the individual agreements, is / has been September 30, 2018, December 31, 2018, September 30, 2020 or December 31, 2020).
- Vested virtual shares of former employees are measured based on the relevant valuation of the Company at the time leaving the company.

In July 2016, the Company modified the Old VESOP adding an IPO as additional exit scenario. Under the terms of that scenario, participants would be able to exercise all or part of their (vested) virtual shares entitlement subject to further conditions such as the ability of the main shareholder to divest portions of its investment, minimum trading volumes or the ultimate marketing approval of relevant products. The Company may settle such entitlements in shares of the Company or in cash. As part of this modification the Company extended the term of the program until December 31, 2025 or by the end of 9 years after the day of the initial listing in the case of an IPO. Since then, the virtual shares program was accounted for as equity-settled.

However, according to the Investment and Shareholders` Agreement ("ISA") with an effective date as of December 19, 2019, in all defined exit events the economic burden of the Old VESOP shall be borne

exclusively by the existing shareholders before the financing round which took place in October 2015 and therefore this group of shareholders will settle the claims of the Old VESOP`s beneficiaries by transferring their shares to CureVac for nominal amount or by transferring cash, if CureVac has to settle or settles voluntarily in cash.

The development of the virtual shares in this program granted to management and key employees was as follows:

	2018	2019
Outstanding at the beginning of the period	59,908	49,899
Granted during the period	—	5,000
Expired during the period	(10,009)	—
Outstanding at the end of the period	49,899	54,899
Thereof vested (and expensed)	49,899	54,899

The 5,000 virtual shares awarded in April 2019 (2018: none) were to the management.

As of December 31, 2019, and 2018, none of the virtual shares of the Old VESOP are exercisable because an exit event or capital market transaction has not occurred.

(Expense) / benefit recognized in the statement of operations and other comprehensive income (loss)

The (expense) / benefit recognized for share-based payment plans during 2018 and 2019 is as follows:

	2018	2019
	EUR k	EUR k
Research and development expenses	4,229	—
General and administrative expenses	21	(6,074)
Total	**4,250**	**(6,074)**

Refer to Note 3 for further information regarding the benefit recognized in 2018.

Measurement of Fair Values

The grant date fair value of the 5,000 virtual shares granted on April 18, 2019 was derived from the estimated equity value of CureVac on that date because the beneficiary is entitled to shares of CureVac for nominal amount in the case of an IPO without taking into consideration the liquidation preferences of the Series B and C shares (as described in Note 8. Equity), which lead to a fair value of one virtual share of EUR 1,215 at that time.

The grant date fair value of the equity-settled virtual shares granted in prior years was estimated when the modification occurred in July 2016, based on the valuations underlying the financing round in 2016 as this was the best indicator of the grant date fair value 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.

Since all virtual shares have, in the case of an IPO, no exercise price, common inputs to option pricing models include expected volatility, risk-free interest rate, life of the virtual shares, dividends expected, and did not significantly affect the fair value of the virtual shares and the total share option expense in fiscal 2019 and 2018.

9.3 Virtual shares program II (new VESOP)

Description of the program

Effective November 25, 2019, the Group granted 5,600 share options to 11 key employees of CureVac Inc. under the New VESOP Program.

The main features of this program are as follows:

- Settlement conditions:
  - Options represent a cash-claim against CureVac if proceeds generated upon an exercise event exceed the exercise price
  - If CureVac's shares are publicly listed at the time of exercise, CureVac has the discretion to fulfill such cash-claim by delivering shares
- Exercise Price: USD 825.77 per share option
- Exercise Events include:
  - an Asset-, Share- or Merger-Deal,
  - an Equity Financing: if more than 50% of the investment is by parties other than the existing shareholders, or
- after IPO subject to lock up restrictions and applicable trading windows, the awards vest over a period of 4 years, which starts on date of awardee was hired by the Group, whereby:
  - 25% of the Options vest after the end of the 1st year after vesting start and
  - the remaining 75% shall vest monthly thereafter
- Term of the program: 10 years, which is also approximately the weighted-average remaining life of the option awards as of December 31, 2019

As CureVac considers an IPO-scenario most probable and has the discretion and the stated intent to settle in shares instead of cash, CureVac accounts for this program as equity-settled.

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. The inputs used in the measurement of the fair value at grant date were as follows:

Weighted average fair value	EUR505.48
Weighted average share price	EUR1,223.16
Exercise price (USD 825.77)	EUR750.99
Expected volatility (%)	50.0%
Expected life (years)	1.16
Risk-free interest rate (%)	1.77%

The awards' per share exercise price is the Euro translation of November 25, 2019, which was 0.90 USD / EUR. Expected volatility 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 life of the awards was based on the assumptions that the beneficiaries would exercise their fully vested award at the first time possible (taking into account lock-up and potential trading windows restrictions). The risk-free interest was derived from US-government bonds because the granted awards were only to US employees on US territories in an IPO-scenario for a Nasdaq listed company.

Reconciliation of outstanding awards

The number of awards in this program granted to key employees in 2019 were as follows:

Outstanding at the beginning of the period	—
Granted during the period	5,600
Outstanding at the end of the period	5,600
Thereof vested	1,318
Thereof expensed	2,137

As of December 31, 2019, none of the awards are exercisable because an exit event or capital market transaction has not occurred.

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, 2019 is shown in the following table:

	2019 EUR k
Research and development expenses	(258)
Selling and distribution expenses	(743)
General and administrative expenses	(79)
Total	**(1,080)**

9.4 Former Chief Executive Officer Grant

Description of the program

On October 14, 2019 CureVac, granted 29,053 options, which corresponded to 4 % of the outstanding share capital of the Company at that time, to Dan Menichella, the then Chief Executive Officer (CEO) of CureVac from June 20, 2018 to March 13, 2020.

The main features of this program are as follows:

- Settlement conditions:
    - Option represents a cash-claim against CureVac if the proceeds generated in an exercise event exceed the exercise price
    - If CureVac's shares are publicly listed at the exercise date, CureVac has the discretion to fulfill such cash-claim by delivering shares, subject to further details
- Exercise Price: USD 1,101.03 per share option
- Exercise Events: The options are exercisable at any time, if the Exercise Price is exceeded in case of:
    - a financing round at the level of the Company if and to the extent more than 50 % of the funds raised per any financing round (equity or non-equity) are contributed by parties other than the existing shareholders subject to further conditions, especially minimum amounts, or
    - a Change of Control of the Company, or
    - an IPO of the Company, or
    - no later than September 11, 2020, subject to further conditions,

  and

    - subject to applicable law and corporate governance rules after the respective vesting as described below and, in any case, not later than 10 years after the effective date, i.e. all options that are not exercised by June 20, 2028 expire without replacement and without compensation, which is also considered the remaining life of the options of 8.69 years as of December 31, 2019
- Vesting period of 4 years, whereby:
    - 25% of the Options vest one year following the original effective date, which is January 8, 2018 and

- the remainder shall vest on the last day of each successive month thereafter, provided that the beneficiary remains employed by the company on vesting
- Options, once vested, are non-forfeitable.
- Furthermore, subject to the approval of the supervisory board of the company, the awards will vest in full (accelerated vesting) in the case a change of control or if the beneficiary leads the company to an IPO or a merger into a company listed at an internationally recognized stock market
- Options not yet vested lapse if the service agreement is terminated by the beneficiary. However, unvested options vest immediately if the Company terminates the service agreement.

As CureVac considers an IPO-scenario most probable and has the discretion and the stated intent to settle in shares instead of cash, CureVac accounts for this program as equity-settled as of December 31, 2019. Refer to Note 20 regarding the vesting of this award subsequent to December 31, 2019.

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 October 14, 2019. The inputs used in the measurement of the fair value at grant date were as follows:

Weighted average fair value	EUR 514.93
Weighted average share price	EUR 1,223.16
Exercise price (USD 825.77)	EUR 998.38
Expected volatility (%)	50.0%
Expected life (years)	4.77
Risk-free interest rate(%)	1.71%

The options' per share exercise price is the Euro translation of October 14, 2019, which was 0.91 USD/EUR. Expected volatility 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 instalments 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 US-Government bonds because the options were granted only to a US beneficiary on US territories in an IPO-scenario for a Nasdaq listed company.

Reconciliation of outstanding options

The number of options in this program granted to the beneficiary in 2019 were as follows:

Outstanding at the beginning of the period	—
Granted during the period	29,053
Outstanding at the end of the period	29,053
Thereof vested	21,184
Thereof expensed	24,099

As of December 31, 2019, none of the options are exercisable because an exit event or capital market transaction has not occurred.

Expense recognized in the statement of operations and other comprehensive income (loss)

The expense recognized for services received during the years ended December 31, 2019 is shown in the following table:

	2019 EUR k
General and administrative expenses	(12,409)
Total	**(12,409)**

10. Trade and other payables

Trade payables and other payables are all due within one year and include the following:

	2018 EUR k	2019 EUR k
Trade payables	(9,029)	(5,331)
License fees payable	(501)	(537)
Miscellaneous liabilities	(1,383)	(607)
Total	**(10,913)**	**(6,475)**

There is no concentration of risk. Miscellaneous liabilities consist mainly of payroll-related and withholding taxes of EUR 104k (2018: EUR 893k) and of other payroll taxes and social liabilities of EUR 504k (2018: EUR 490k).

11. Other liabilities

Other current liabilities include the following:

	2018 EUR k	2019 EUR k
Accrued bonuses	1,903	2,477
Accrued vacation	682	780
Outstanding invoices	6,812	3,478
Professional fees	292	578
Grants from government agencies and similar bodies	1,186	4,148
Other	271	554
Total	**11,146**	**12,015**

In fiscal 2019 EUR 5,385k (2018: EUR 808k) of the grants from government agencies and similar bodies were recognized as other operating income.

12. Convertible loans

Dietmar Hopp (or the “Lender”), principal of dievini Hopp BioTech holding GmbH & Co. KG (dievini), the majority shareholder of the Group, granted on May 3, 2019 a loan (facility) fully convertible into equity of EUR 50,000k to CureVac (or the “Borrower”). Under the facility, CureVac had the right to use the loan in total or in tranches until March 1, 2020.

The loan was granted for an indefinite term and bears interest in the amount of 8.0% per annum. CureVac drew down the loan facility in tranches of

- EUR 20,000k at May 29, 2019
- EUR 20,000k at July 23, 2019 and

- EUR 10,000k at September 10, 2019

On October 24, 2019, the loan agreement was modified and fully replaced with a second loan agreement under which, in addition to the already disbursed amount of EUR 50,000k under the first loan, the lender granted the Borrower a second loan with a conversion option in a nominal amount of EUR 63,927k (equivalent to USD 70,000k calculated on the basis of the exchange rate applicable at the date of signing the modified agreement). Under the modified agreement, the interest on both loans is 8.0% per annum, is added to the amount of the loans and is due with the loans at maturity; compound interest is not due.

CureVac has the right to use this second loan in two tranches of EUR 20,000k and one final tranche of EUR 23,927k, if the Borrower's cash balance falls below EUR 15,000k, until December 31, 2021.

CureVac had drawn the first tranche of this second loan in the amount of USD 22,000k (EUR 19,888k) at December 19, 2019. As of December 31, 2019, the loans had accrued interest of EUR 1,960k.

According to the loan agreement in order to avoid the risk of indebtedness of the Borrower, the Lender subordinated its claim of repayment of the loans to all existing and future claims of the other creditors of the Borrower.

The potential effects the statement of operations resulting from foreign exchange fluctuations from the second loan are disclosed in the sensitivity analysis in the subsection "Foreign currency risk" in Note 15.

The effect on earnings per share in the case of a conversion of the loans is discussed at Note 14.

The loans can be terminated or converted into equity at any time in full or in part, however not before December 31, 2021 unless CureVac initiates or concludes a transaction amongst shareholders, issues further convertible loans or executes a cross-over financing round in direct or indirect preparation of an IPO.

13. Income tax

CureVac 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, tax profits in a given year can be offset against tax loss carryforwards up to an amount of EUR 1,000k. 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 EUR 1,000k are subject to taxation.

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 2019 and 2018, the Group recorded a consolidated income tax benefit and expense of EUR 252k and EUR -110k, respectively. The income tax benefit in fiscal 2019 results from income tax expenses from CureVac Inc. of EUR 203k (2018: EUR 243k) and deferred tax expenses on taxable temporary differences of EUR 656k (2018: EUR 472K), which were fully offset by deferred tax benefits of EUR 1,111k (2018: EUR 605K) recognized from net operating loss carryforwards. In fiscal 2019, the Group further recorded deferred tax liabilities of EUR 2,212k (2018: EUR 0) related to taxable temporary differences on the equity component of the convertible loans recognized in capital reserve. For outside basis differences of EUR 770k (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
	EUR k	EUR k
Loss before tax	(71,131)	(100,125)
Expected tax benefit (based on statutory tax rate of 29.13% in 2019 and 2018)	20,744	29,162
Adjustments in respect of current income tax of previous years	42	—
Effects from differences between Group and local tax rates	10	8
Effects resulting from non-recognition of tax loss carryforwards	(22,428)	(22,836)
Effects resulting from non-recognition of DTA/DTL	—	—
First-time-recognition of tax loss carryforwards	430	—
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)
− Other non-deductible expenses	(53)	(78)
Other effects	—	(114)
Effective tax benefit/ (expense)	(110)	252

The following unused tax losses had been carried forward as of the end of the reporting periods:

Tax loss carryforwards	2018	2019
	EUR k	EUR k
Unused tax losses for corporate income tax	330,753	407,434
Unused tax losses for trade tax	329,210	405,123

Deferred tax assets on tax loss carryforwards and deductible temporary differences in excess of 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. The accumulated unused tax losses relate entirely to Germany.

14. Earnings per share

Earnings per share is calculated pursuant to *IAS 33 Earnings per Share* by dividing the consolidated net loss in CureVac AG by the average weighted number of shares outstanding in the fiscal period.

There were no share issuances in fiscal 2018 and 2019 and, therefore, the weighted number of shares outstanding was 726,592 in both of these periods. This has led to basic loss per share of EUR 137.45 for fiscal 2019 and of EUR 98.05 for fiscal 2018.

The 5,282 share options granted to members of management described under Note 9 as well as the new issue of 16,345 shares in fiscal 2020 are potential ordinary shares for the purpose of calculating diluted earnings per share. 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 2019 and 2018, they are considered antidilutive. Therefore, the diluted earnings per share equals basic earnings per share in fiscal 2019 and 2018.

The same considerations should be taken into account for the potentially issuable 51,265 shares under the New VESOP described under Note 9. as well as the convertible loan granted in fiscal 2019 and described under Note 12.

15. Disclosure of financial instruments and risk management

Type 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). 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, 2019, the loss allowance for the "expected credit losses" totaled to EUR 76k (2018: EUR 447k), resulting in an effect recognized in profit and loss in the consolidated statement of operations and other comprehensive income in fiscal 2019 of EUR 371k (2018: EUR 264k).

Liquidity risk

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:

2019	less than 3 months EURk	3 to 12 months EURk	1 to 5 years EURk	> 5 years EURk	Total EURk
Convertible loans	—	—	(83,940)	—	(83,940)
Lease liabilities (Note 2)	(732)	(1,985)	(9,192)	(5,086)	(16,995)
Other liabilities	—	(12,015)	(362)	(167)	(12,544)
Trade and other payables	(5,938)	(537)	—	—	(6,475)
Total	**(6,670)**	**(14,537)**	**(93,494)**	**(5,253)**	**(119,954)**

2018	less than 3 months EURk	3 to 12 months EURk	1 to 5 years EURk	> 5 years EURk	Total EURk
Finance lease liabilities	(29)	(48)	—	—	(77)
Other liabilities	—	(11,146)	(688)	(175)	(12,009)
Trade and other payables	(10,378)	(535)	—	—	(10,913)
Total	**(10,407)**	**(11,729)**	**(688)**	**(175)**	**(22,999)**

Commitments according to IAS 17 as of December 31, 2018.

2018	less than 3 months EURk	3 to 12 months EURk	1 to 5 years EURk	> 5 years EURk	Total EURk
Operating lease commitments	—	(84)	(91)	—	(175)
Rental agreements	(683)	(2,576)	(21,160)	(23,589)	(48,008)
Total	**(683)**	**(2,660)**	**(21,251)**	**(23,589)**	**(48,183)**

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 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 2019 and 2018 is as follows:

	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
	84 EUR	92 CHF
	81 EUR	91 USD
Monetary assets in foreign currency	32,336 EUR	
Trade and other payables	505 EUR	567 USD
	219 EUR	186 GBP
	10 EUR	11 CHF
Monetary liabilities in foreign currency	734 EUR	

	2018 (in thousands)	
Cash and cash equivalents	16,941 EUR	19,398 USD
Trade and other receivables	2,059 EUR	3,374 USD
Monetary assets in foreign currency	19,000 EUR	22,772 USD
Trade and other payables	8,002 EUR	9,162 USD
	132 EUR	118 GBP
	46 EUR	51 CHF
Monetary liabilities in Foreign Currency	8,180 EUR	

As shown in the tables above, CureVac AG 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

2018 (1 EUR= 1.1450 USD) **2019** (1 EUR = 1.1234 USD)
EUR 10,544k from USD 13,090k **EUR 30,656k from USD 34,400k**

At December 31, 2019, 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 3,406k (2018: EUR 1,172k) lower and post-tax loss would have been EUR 2,414k (2018: EUR 831k). 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 2,787k (2018: EUR 959k) higher and post-tax loss would have been EUR 1,975k (2018: EUR 680k) 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, 2019.

CureVac did not have derivatives in fiscal 2018. Refer to Note 3 for discussion regarding a USD 10,000k forward contract in fiscal 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, 2019 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 307k (2018: EUR 218k) 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, 2019 and 2018 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, 2019 and December 31, 2018. Apart from this, liabilities from licenses agreements (i.e. acquired intangible assets) of EUR 848k (2018: EUR 850k), 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.

As of December 31, 2019, the amortized cost of the convertible loans approximate their fair value as the loans were agreed and drawn down on recently and there have been no significant changes in relevant interest rates since the agreement date. For further information regarding the convertible loan, see Note 13.

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 to rely almost exclusively on debt and equity funding by its shareholders until the Group can refinance itself in the future from marketable products as a result of successful development projects.

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. 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, 2019 and 2018.

16. Notes to the consolidated statements of cash flows

Changes in liabilities arising from financing activities

CureVac uses leases to acquire the right to use assets for a specified amount of time. Due to the first-time adoption of IFRS 16, lease liabilities at an amount of EUR 15,810k were recognized as of January 1, 2019. The liability arising from leases amounts to EUR 14,130k as of December 31, 2019.

in thousands of EUR	January 1, 2019	Cash flows	Reclassification	New leases	Accrued interest	Foreign Exchange Movements	December 31, 2019
Convertible loans	—	69,889	(7,604)	—	2,733	—	65,018
Lease liabilities	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. See Note 12.

in thousands of EUR	January 1, 2018	Changes from financing cash flows	December 31, 2018
Lease liabilities	188	(112)	77
Total liabilities from financing activities	**188**	**(112)**	**77**

17. Commitments and contingencies

In the course of its ordinary activities, no major claims have been made against the Company.

See Section “Changes in accounting policies and disclosures” for commitments and contingencies relating to IFRS 16 (Leases).

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 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.

The figures for fiscal 2018 were as follows:

Remuneration of key management in 2018	Management Board	Supervisory Board
	EUR k	EUR k
Short-term benefits	2,195	343
Total	**2,195**	**343**

19. Other related party disclosures

dievini Hopp BioTech holding GmbH & Co. KG

dievini Hopp BioTech holding GmbH & Co. KG (dievini) holds the majority 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. The Group incurred EUR 0k in fiscal 2019 and EUR 30k in July 2018 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 2019, consulting fees of 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 2019, advisory fees of EUR 240k (2018: 144k) were paid to Dr. Hoerr.

Dietmar Hopp

During 2019, Dietmar Hopp, principal of dievini Hopp BioTech holding GmbH & Co. KG (dievini), the majority shareholder of the Group, granted two convertible loans to the Group; see Note 12 Convertible loans for further information.

20. Subsequent events

In January 2020, CureVac AG and CEPI announced an additional 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 will build on the existing partnership between CureVac and CEPI to develop a rapid-response vaccine platform and includes additional initial funding of up to USD 8,300k by CEPI for accelerated vaccine development, manufacturing and clinical tests. For information relating to the existing collaboration with CEPI, see Note 3.

In March 2020, CureVac collected EUR 19,984k in funds due from Genmab in connection with issuance of Series B shares under the ISA and the related capital increase came into effect upon registration of the shares in the commercial register in February 2020.

On March 10, 2020, the service agreement with Dan Menichella (the then-CEO of the Group) was discontinued. As a result, at this date, 6,053 of unvested options awarded to him vested immediately.

The COVID-19 pandemic, which began in December 2019 in China and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The Company has taken a series of actions aimed at safeguarding the Company’s employees and business associates, including implementing a work-from-home policy for employees except for those related to our laboratory operations. The rapid development and fluidity of the situation presents uncertainty and risk with respect to the Company, its performance and its financial results.

Through and including , 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares

CureVac B.V.

Common Shares

PROSPECTUS

BofA Securities

Jefferies

Credit Suisse

, 2020

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 6. Indemnification of Directors and Officers

Under Dutch law, our managing directors and our supervisory directors may be held liable by the registrant for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to the registrant and third parties for infringement of our articles of association or certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities.

The liability of our managing directors and supervisory directors and other key employees will be covered by a directors' and officers' liability insurance policy. This policy will contain customary limitations and exclusions, such as willful misconduct or intentional recklessness (*opzet of bewuste roekeloosheid*).

Our current and former managing directors and supervisory directors (and such other current or former officer or employee as designated by the management board) have the benefit of the following indemnification provisions in our articles of association:

Indemnified persons shall be reimbursed for:

a. any financial losses or damages incurred by such indemnified person; and

b. any expense reasonably paid or incurred by such indemnified person in connection with any threatened, pending or completed suit, claim, action or legal proceedings of a civil, criminal, administrative or other nature, formal or informal, in which he becomes involved, in each case to the extent this relates to his current or former position with us and/or a group company and in each case to the extent permitted by applicable law.

No indemnification shall be given to an indemnified person:

a. if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions, which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);

b. to the extent that his financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);

c. in relation to proceedings brought by such indemnified person against us, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and us, which has been approved by the management board or pursuant to insurance taken out by us for the benefit of such indemnified person;

d. for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without the our prior consent.

Under our articles of association, our management board may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

Item 7. Recent Sales of Unregistered Securities

Set forth below are the sales of all securities sold by CureVac AG within the past three years (i.e., since January 1, 2017 up to the date of this registration statement) which were not registered under the Securities Act (and in each case not giving effect to the corporate reorganization):

As registered in the commercial register on December 27, 2017, CureVac AG issued 21,078 Series B shares. In addition to the nominal value of the shares (€21,078), the shareholders made cash contributions into the our capital reserves of €45,000,000.

As registered in the commercial register on February 18, 2020, CureVac AG issued 16,345 Series B shares. In addition to the nominal value of the shares (€16,345), the shareholders made cash contributions into our capital reserves of €20,000,000.

The issuances of restricted securities in the transactions described above were deemed to be exempt from registration under the Securities Act in reliance upon the Section 4(a)(2) of the Securities Act and/or Regulation S promulgated under the Securities Act.

Exhibits

(a) The following documents are filed as part of this registration statement:

1.1	Form of Underwriting Agreement.*
3.1	Form of Articles of Association of CureVac N.V. (translated into English), as they will be in effect immediately following the completion of the corporate reorganization.*
3.2	Form of internal rules of the management board of CureVac N.V., as they will be in effect immediately following the completion of the corporate reorganization.*
3.3	Form of internal rules of the supervisory board of CureVac N.V., as they will be in effect immediately following the completion of the corporate reorganization.*
3.4	Form of Share Issue Deed.*
5.1	Opinion of NautaDutilh N.V., Dutch counsel of CureVac, as to the validity of the common shares.*
8.1	Opinion of NautaDutilh N.V., Dutch counsel of CureVac, as to Dutch tax matters.*
8.2	Form of opinion of FALK GmbH & Co KG, as to German tax matters.*
8.3	Form of opinion of Davis Polk & Wardwell LLP, as to U.S. tax matters.*
10.1	Collaboration and License Agreement by and between CureVac AG and Genmab B.V., dated December 19, 2019.* †
10.2	Development and License Agreement by and between CureVac AG and CRISPR Therapeutics AG, dated November 9, 2017.* †
10.3	Exclusive Collaboration and License Agreement by and between CureVac GmbH and Boehringer Ingelheim International GmbH, dated August 21, 2014.* †
10.4	Global Access Commitments Agreement, by and between Bill & Melinda Gates Foundation and CureVac GmbH, dated February 13, 2015.* †
10.5	Framework Partnering Agreement between Coalition for Epidemic Preparedness Innovations and CureVac AG, dated February 15, 2019.* †
10.6	Development and Option Agreement, between CureVac AG and Acuitas Therapeutics Inc., dated April 29, 2016.* †
10.7	Development and Intellectual Property Agreement, between CureVac AG and Tesla Grohmann Automation GmbH, dated November 24, 2015.* †
10.8	Development and Option Agreement, between CureVac AG and Arcturus Therapeutics Inc., dated January 1, 2018.* †
14.1	Form of Code of Ethics of CureVac, as it will be in effect immediately following the completion of the corporate reorganization.*
21.1	List of subsidiaries.*
23.1	Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft.*
23.2	Consent of NautaDutilh N.V. (included in Exhibits 5.1 and 8.1).*
23.3	Consent of FALK GmbH & Co KG (included in Exhibit 8.2).*

23.4	Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.3).*
24.1	Powers of attorney (included on signature page to the registration statement). *

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* To be filed by amendment.

† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

(b) Financial Statement Schedules

None.

Item 9. Undertakings

The undersigned hereby undertakes:

(a) To provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of on , 2020.

CureVac B.V.

By: _____

Name: Ingmar Hoerr, PhD, MBA
Title: Chief Executive Officer

By: _____

Name: Pierre Kemula, B.Sc.
Title: Chief Financial Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints and and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the U.S. Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on , 2020 in the capacities indicated:

Name	Title
Ingmar Hoerr, PhD, MBA	Chief Executive Officer (principal executive officer)
Pierre Kemula, B.Sc.	Chief Financial Officer (principal financial officer and principal accounting officer)
Florian von der Mülbe, PhD, MBA	Managing Director
Franz-Werner Haas, LLD, LLM	Managing Director
Mariola Fotin-Mleczek, PhD	Managing Director
Baron Jean Stéphenne, MSc, MBA	Supervisory Director
Friedrich von Bohlen und Halbach, PhD	Supervisory Director
Ralf Clemens, MD, PhD	Supervisory Director
Mathias Hothum, PhD	Supervisory Director
Chris Tanner, PhD	Supervisory Director
Timothy M. Wright, MD, MD	Supervisory Director
Craig A. Tooman	Supervisory Director

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of CureVac B.V. has signed this registration statement on , 2020.

CureVac Inc.

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Name:
Title: