NOVAVAX INC
Form 10-K
March 18, 2019

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2018

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to .

Commission File No. 000-26770

NOVAVAX, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**20 Firstfield Road,**	**22-2816046**
(State of incorporation)	**Gaithersburg, Maryland 20878**	*(I.R.S. Employer Identification No.)*
	(Address of principal executive offices)	

Registrant's telephone number, including area code: (240) 268-2000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, Par Value $0.01 per share	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: Not Applicable

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large accelerated filer	¨	Accelerated filer x
Non-accelerated filer	¨	Smaller reporting company x
Emerging growth company ¨		

If an emerging growth company, indicate by check mark if the registrant had elected not to use the extended transition period for complying with any new or revised financial accounting standards provide pursuant to Section 13(a) of the Exchange Act. ¨

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (based on the last reported sale price of Registrants common stock on June 30, 2018 on the Nasdaq Global Select Market) was approximately $505,900,000.

As of March 12, 2019, there were 441,344,182 shares of the Registrant’s common stock outstanding.

Documents incorporated by reference: Portions of the Registrant’s Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2018 in connection with the Registrant’s 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent indicated herein.

NOVAVAX, INC.

TABLE OF CONTENTS

CERTAIN DEFINITIONS

All references in this Annual Report on Form 10-K to "Novavax," the "Company," "we," "us" and "our" refer to Novavax, Inc and its wholly-owned subsidiary, Novavax AB (unless the context otherwise indicates).

NOTE REGARDING TRADEMARKS

Novavax™, NanoFlu™, Matrix-M™, Matrix™, Prepare™, Resolve™, and ResVax™ are trademarks of Novavax. Any other trademarks referred to in this Annual Report on Form 10-K are the property of their owners. All rights reserved. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

FORWARD-LOOKING INFORMATION

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. Please also see the disclaimer under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

PART I

Item 1. BUSINESS

Overview

Novavax, Inc., together with our wholly-owned Swedish subsidiary, Novavax AB, is a late-stage biotechnology company focused on the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. Using innovative proprietary recombinant nanoparticle vaccine technology, we produce vaccine candidates to efficiently and effectively respond to both known and emerging disease threats.

We were incorporated in 1987 under the laws of the State of Delaware. Our principal executive offices are located at 20 Firstfield Road, Gaithersburg, Maryland, 20878, and our telephone number is (240) 268-2000. Our common stock is listed on the Nasdaq Global Select Market under the symbol "NVAX."

Our vaccine candidates, including our lead candidates, ResVax™ and NanoFlu™, are genetically engineered, three-dimensional nanostructures of recombinant proteins critical to disease pathogenesis and may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or traditional vaccines. Our product pipeline (see below) targets a variety of infectious diseases. We are also developing immune stimulating saponin-based adjuvants through our wholly owned Swedish subsidiary, Novavax AB. Our lead adjuvant, Matrix-M™, has been shown to enhance immune responses and was well-tolerated in multiple clinical trials.

Product Pipeline

Program	**Current Development Stage**
Respiratory Syncytial Virus ("RSV")	
·**ResVax* (Infants via Maternal Immunization)**	Phase 3
·**Older Adults**	Phase 2
·**Pediatrics**	Phase 1
Seasonal Influenza	
·**NanoFlu (Older Adults)**	Phase 2

Combination Seasonal Influenza/RSV	Preclinical

*Supported by a grant of up to $89.1 million from the Bill & Melinda Gates Foundation (“BMGF”)

A summary and status of these vaccine programs follows:

Respiratory Syncytial Virus (RSV)

Currently, there is no approved RSV vaccine available to combat the estimated 64 million RSV infections that occur globally each year. We have identified three susceptible target populations that we believe could benefit from the development of our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) in different formulations: (1) infants via maternal immunization, (2) older adults (60 years and older) and (3) children six months to five years old (“pediatrics”). With our current estimates of the annual global cost burden of RSV in excess of $88 billion, we believe our RSV F Vaccine represents a multi-billion dollar worldwide opportunity.

ResVax Program (Infants via Maternal Immunization)

ResVax, our adjuvanted RSV F Vaccine for infants via maternal immunization, is our lead vaccine program. RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide. In the U.S., RSV is the leading cause of hospitalization of infants and, globally, is second only to malaria as a cause of death in children under one year of age.

In February 2019, we announced top-line data from the Prepare trial, which we initiated in December 2015 to determine the efficacy of ResVax against medically significant RSV-positive lower respiratory tract infection ("LRTI") in infants through a minimum of the first 90 days of life and up through the first six months of life. While the Prepare trial did not meet its pre-specified primary efficacy endpoint, it did demonstrate efficacy against one of the secondary objectives (RSV LRTI hospitalizations), the first RSV vaccine to show efficacy in a Phase 3 clinical trial. In addition, in the Prepare trial, other pre-specified exploratory endpoints and post-hoc analyses highlight ResVax' potential to improve global health against RSV disease in this vulnerable population. Like previous clinical trials, ResVax showed a favorable safety and tolerability profile from the Prepare trial. With these results, we plan to meet with both the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") later in 2019, to discuss and assess opportunities for submitting a Biologics License Application ("BLA") with the FDA and/or a Marketing Authorization Application ("MAA") with the EMA, in 2020. We are also considering seeking licensure strategically in a number of geographic regions, other than the U.S. and Europe, where the Prepare results support such efforts. The development of ResVax and the conduct of the Prepare trial are supported by a grant of up to $89.1 million from BMGF for development activities, product licensing efforts and World Health Organization ("WHO") prequalification of ResVax.

RSV Older Adults Program

Older adults (60 years and older) are at increased risk for RSV disease due in part to immunosenescence, the age-related decline in the human immune system. RSV infection can also lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. In the U.S. alone, a reported RSV incidence rate of 5.5% in older adults would account for approximately 2.5 million infections per year. We estimate that approximately 900,000 medical interventions are caused by RSV disease in this U.S. population each year. In our 2017 Phase 2 clinical trial of our RSV F Vaccine in older adults, we assessed safety and immunogenicity of one and two dose regimens of our RSV F Vaccine, with and without aluminum phosphate or our proprietary Matrix-M adjuvant. Immunogenicity results indicate that both adjuvants increase the magnitude, duration and quality of the immune response versus the non-adjuvanted RSV F Vaccine. The 2016 Phase 3 clinical trial of our RSV F Vaccine failed to meet it pre-specified primary or secondary efficacy objectives and did not demonstrate vaccine efficacy. We are currently assessing the development opportunities for our RSV F Vaccine in older adults.

RSV Pediatrics Program

By the age of five, essentially all children will have been exposed to RSV and will likely develop natural immunity against the virus; however, children under five remain vulnerable to RSV disease, offering a strong rationale for a pediatric vaccine that could offer enhanced protection. In 2015, we announced positive results in our Phase 1 clinical trial evaluating the safety and immunogenicity of our RSV F Vaccine in healthy children between two and six years of age. To the extent we receive regulatory approval for ResVax, we expect to continue development of our RSV F Vaccine for pediatrics.

Seasonal Influenza

NanoFlu Program (Older Adults)

Influenza is a world-wide infectious disease with serious illness generally occurring in more susceptible populations such as pediatrics and older adults, but also occurring in the general population. According to influenza vaccines forecasts by Datamonitor in 2013, the market for seasonal influenza vaccines is expected to grow from approximately $3.2 billion in the 2015-16 flu season to approximately $5.3 billion in the 2021-22 flu season (in the countries comprising the top seven markets). The Center for Disease Control and Prevention estimates that each year since 2010, influenza in the U.S. has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations and between 12,000 and 56,000 deaths.

In January 2019, we announced positive top-line data from our Phase 2 clinical trial of NanoFlu in older adults. Top-line results showed that all formulations of NanoFlu were well-tolerated and elicited vigorous immune responses to all four strains included in the vaccine; importantly, use of our Matrix-M adjuvant resulted in significantly enhanced immune responses when compared to a non-adjuvanted formulation. NanoFlu also showed superior hemagglutination inhibition antibody responses against wild-type A(H3N2) viruses, including drifted strains, when compared to Fluzone High-Dose, the leading flu vaccine in older adults. During a pre-investigational new drug application meeting in 2018, the FDA indicated that an accelerated approval pathway for seasonal influenza vaccines could be available for NanoFlu. We plan to discuss the Phase 2 clinical trial data and the proposed Phase 3 study design, and reach agreement on the use of accelerated approval with the FDA during an End-of-Phase 2 meeting in the first half of 2019. We are currently planning a pivotal Phase 3 clinical trial of NanoFlu that could begin as early as the second half of 2019 in the United States.

Combination Seasonal Influenza/RSV F Vaccine

With the ongoing development of our NanoFlu and RSV F Vaccine, a strong rationale exists for developing a combination respiratory vaccine that is designed to protect susceptible populations against both diseases. Although testing is at an early stage, we believe that a combination vaccine against both influenza and RSV may be achievable.

Early-stage Vaccine Candidates

Because our nanoparticle technology targets antigens with conserved epitopes essential for viral function, our vaccine candidates have the potential to be applied broadly to a wide variety of human infectious diseases. Our nanoparticle vaccine technology has already demonstrated the ability to produce vaccine candidates against a wide variety of infectious diseases: in addition to our ResVax and NanoFlu vaccines, we have also developed nanoparticle vaccine candidates for clinic testing against ebola virus (positive Phase 1 clinical trial results) and MERS coronavirus (positive animal studies). While we have focused most of our corporate efforts towards our RSV and seasonal influenza vaccine candidates, we stand ready to continue work on emerging infectious disease vaccine candidates as circumstances warrant.

CPLB Joint Venture

CPL Biologicals Private Limited ("CPLB"), our joint venture between Novavax and Cadila Pharmaceuticals Limited ("Cadila"), is actively developing a number of vaccine candidates in India. In July 2018, we amended and restated our joint venture and license agreements with respect to CPLB to align them with our current and planned interactions with CPLB. CPLB continues to be owned 20% by Novavax and 80% by Cadila.

Vaccine Technology

Our recombinant protein nanoparticle vaccine technology is based on self-assembly of surface protein antigens from pathogenic organisms including viruses, bacteria or parasites. The conformations of these nanoparticles are similar but not identical to the natural structure of surface antigens of disease organisms, and lack the genetic material required for replication and therefore are not infectious. Potential immunological advantages of protein nanoparticles may be associated with the nanoparticle conformation and the presentation of key functional epitopes that are often immunologically hidden in the native pathogen. This leads to efficient recognition by the immune system's antigen presenting cells that trigger robust immune responses. Recognition of the nanoparticle vaccine's repeating protein

patterns by the antigen presenting cells' toll-like receptors to stimulate innate immunity and the high purity and lack of synthetic material adds to the potential safety of recombinant nanoparticle vaccines. Protein nanoparticle vaccine technology has expanded our early-stage vaccines in development to include both virus and non-virus disease targets. Our most advanced protein nanoparticle vaccine candidate is our RSV F Vaccine, which self-assembles from our highly purified F-protein antigen.

Matrix Adjuvants

Adjuvants are predominantly used to enable a vaccine to increase the amplitude of the immune response and qualitatively change it, broadening the immune systems attack against microorganisms and allow for effective immunization with much lower doses of antigen. Novavax AB has developed a number of adjuvant formulations, all based on our proprietary Matrix technology. These adjuvant formulations possess excellent immunostimulatory features with the ability to increase and prolong the protective benefits of vaccines.

While adjuvants based on novel, poorly characterized substances have been hampered by safety concerns and limited efficacy, Matrix adjuvants stimulate strong antibody and cell-mediated immune responses. Matrix adjuvants may allow for lower antigen doses, longer-duration immune responses and carry a lower risk for allergic reactions or other adverse events. Our Matrix technology typically induces strong cellular activation of both Th1 and Th2 types, thereby generating all classes and subclasses of antibodies, as well as potent cellular responses, including cytotoxic T lymphocytes. Our Matrix-M adjuvant provides a potent adjuvant effect that has been well-tolerated in clinical trials. We also believe that the strong immune response and opportunity to reduce the quantity of antigen dose can significantly reduce the production cost of our vaccines. This means that our Matrix-M adjuvant has the potential to be of significant value when there is inadequate vaccine manufacturing capacity during an emerging disease threat such as an influenza pandemic.

Competition in RSV and Influenza

The vaccine market is intensely competitive, characterized by rapid technological progress. Our technology is based upon utilizing the baculovirus expression system in insect cells to make recombinant vaccines. We believe this system offers many advantages when compared to other technologies and is uniquely well-suited for developing RSV and influenza vaccines, as well as vaccines against a number of other infectious diseases.

There is currently no approved RSV vaccine for sale in the world; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. These groups are developing products to prevent disease caused by RSV using a variety of technology platforms, including viral vectors, nucleic acid (RNA/DNA), live attenuated chimeric, antigens or monoclonal antibodies ("Mab"), and competitive recombinant technologies. Despite the recent announcement of results from the Prepare trial of ResVax, we continue to believe that our RSV F vaccine candidate, which is a recombinant prefusogenic F-protein nanoparticle, is likely to be more effective than other RSV vaccine candidates or other products in development by our competitors. We further believe that ResVax, our RSV vaccine program for infants via maternal immunization, is the only RSV vaccine to have ever demonstrated efficacy in a Phase 3 clinical trial. At this time, there are a number of companies and other organizations with vaccine candidates in Phase 1 and 2 trials, including Pfizer, GlaxoSmithKline, Sanofi, Bavarian Nordic, Janssen, Moderna, Ablynx, Immunovaccine, Intravaac, Vaxart and the NIAID. Presently, the two lead Mab programs seeking to develop product candidates to prevent RSV in young infants are being conducted by AstraZeneca PLC ("AstraZeneca"), and Merck. The AstraZeneca Mab, which is partnered with Sanofi Pasteur and Swedish Orphan Biovitrum AB, is completing Phase 2 trials for preterm infants and has recently obtained breakthrough designation from the FDA, while the Merck Mab is currently in Phase 1 trials in preterm and full-term infants.

There are a number of companies developing and selling vaccines for seasonal influenza employing both traditional (egg-based) and new vaccine technologies (cell-based). Many seasonal influenza vaccines are currently approved and marketed, and most of these are marketed by major pharmaceutical companies that have significantly greater financial and technical resources, experience and expertise. Competition in the sale of seasonal influenza vaccines is intense. Therefore, newly developed and approved products must be differentiated from existing vaccines in order to have commercial success. In order to show differentiation in the seasonal influenza market, a product may need to be more efficacious and/or be less expensive and quicker to manufacture. Many of our competitors are working on new products and new generations of current products, some by adding an adjuvant that is used to increase the immunogenicity of that product, each of which is intended to be more efficacious than currently marketed products. Despite the significant competition and advancing technologies, some of which are similar to our own, based on our recently completed Phase 2 trials results, we believe that NanoFlu, our nanoparticle seasonal influenza product could be as efficacious as, or more so than, current products or products being developed by our competitors. However, our seasonal influenza vaccine may not prove to be efficacious or our manufacturing system may not prove to be sufficiently effective and differentiated to ensure commercial success.

In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also may depend upon our ability to show differentiation with a product that is more efficacious and/or less expensive and quicker to manufacture. Other factors affecting our competitive position include our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the lengthy period between technological conception and commercial sale.

Patents and Proprietary Rights

We generally seek patent protection for our technology and product candidates in the U.S. and abroad. The patent position of biotechnology and pharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. Our success will depend, in part, on whether we can:

- obtain patents to protect our own technologies and product candidates;
- obtain licenses to use the technologies of third-parties, which may be protected by patents;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

Patent Rights; Licenses.

We have intellectual property (patents, licenses, know-how) related to our vaccines, manufacturing processes and other technologies. Currently, we have or have rights to over 350 U.S. patents and corresponding foreign patents and patent applications relating to vaccines and vaccine-related technologies.

Patents related to our VLP program include U.S. Patent No. 7,763,450, which covers, in part, the use of influenza gene sequences for high-yield production of consistent influenza VLP vaccines to protect against current and future seasonal and pandemic strains of influenza viruses. Corresponding European patent, European Patent No. 1644037 also covers this technology. U.S. Patent Nos. 8,080,255, 8,551,756, 8,506,967 and 8,592,197 are directed to methods of producing VLPs and inducing substantial immunity to an influenza virus infection by administering VLPs comprising HA and NA proteins, and our M1 protein derived from the avian influenza strain, A/Indonesia/5/05. Certain claims also encompass similar methods and compositions where the M1 protein is from a different strain of influenza virus than the influenza HA protein and the influenza NA protein. Related patent protection in Europe is provided by European Patent No. 2343084, which covers, in part, vaccine compositions containing VLPs that contain M1, HA, and NA proteins. Our VLP patent portfolio contains many other patents, including U.S. Patent Nos. 8,951,537, 8,992,939, 9,144,607, 9,050,290, 9,180,180, 9,381,239, 9,464,276, 9,474,799, and other patents in multiple ex-U.S. jurisdictions, and we continue to prosecute patents related to this program.

In addition to our VLP program, we have issued patents and pending applications directed to other programs, including our RSV and rabies programs. Issued patents directed to various aspects of the RSV program include U.S. Patent Nos. 8,715,692, 9,675,685, 9,731,000, 9,717,786, and 10,022,437. Additional patents in the family include EP237009 in Europe, as well as others throughout the world. Patents related to our rabies program include 9,724,405 and 10,086,065 in the U.S. and EP2635257 in Europe. Related patents have been issued in other world markets. In addition to our focus on vaccine programs, we also pursue patent protection for our Matrix Adjuvant program. Issued U.S. Patent Nos. 7,838,019, 9,205,147, 9,901,634 and 8,821,881 provide examples of patents related to our Matrix Adjuvant program.

We continue to prepare, file, and prosecute patent applications to provide broad and strong protection of our proprietary rights, including next generation applications focused on our RSV Program, our influenza nanoparticle program, and our adjuvant program.

The Federal Technology Transfer Act of 1986 and related statutory guidance encourages the dissemination of science and technology innovation. While our expired contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA") provided us with the right to retain ownership in our inventions that may have arisen during performance of that contract, with respect to certain other collaborative research efforts with the U.S. government, certain developments and results that may have commercial potential are to be freely published, not treated as confidential, and we may be required to negotiate a license to developments and results in order to commercialize products. There can be no assurance that we will be able to successfully obtain any such license at a reasonable cost, or that such development and results will not be made available to our competitors on an exclusive or non-exclusive basis.

Trade Secrets.

We also rely significantly on trade secret protection and confidentiality agreements to protect our interests. It is our policy to require employees, consultants, contractors, manufacturers, collaborators and other advisors to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with us. We also require confidentiality agreements from any entity that is to receive confidential information from us. With respect to employees, consultants and contractors, the agreements generally provide that all inventions made by the individual while rendering services to us shall be assigned to us as our property.

Government Regulations

The development, production and marketing of biological products, which include the vaccine candidates being developed by Novavax or our collaborators, are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. Although, we focus on the U.S. regulatory process and the standards imposed by the FDA, the International Conference on Harmonisation ("ICH") and other agencies because we believe meeting U.S. and ICH standards generally allows us to satisfy regulatory agencies in other countries where we intend to do business; however we are mindful that expectations in some venues, notably in the European Union, differ to some degree and we take proactive steps to address such differences by maintaining regular filings and correspondence and attending regular meetings with many other non-U.S. regulatory agencies. In the U.S., the development, manufacturing and marketing of human pharmaceuticals and vaccines are subject to extensive regulation under the Federal Food, Drug, and Cosmetic Act, and biological products are subject to regulation under provisions of that act and the Public Health Service Act. The FDA not only assesses the safety and efficacy of these products but it also regulates, among other things, the testing, manufacture, labeling, storage, record-keeping, advertising and promotion of such products. The process of obtaining FDA licensure for a new vaccine is costly and time-consuming.

Vaccine clinical development follows the same general regulatory pathway as drugs and other biologics. Before applying for FDA licensure to market any new vaccine candidate, we expect to first submit an investigational new drug application ("IND") that explains to the FDA, among other things, the results of preclinical toxicology testing conducted in laboratory animals, the method of manufacture, quality control tests for release, the stability of the investigational product and what we propose to do for human testing. At this stage, the FDA decides whether it is reasonably safe to move forward with testing the vaccine candidate in humans. We must then conduct Phase 1 clinical trials and larger-scale Phase 2 and 3 clinical trials that demonstrate the safety, immunogenicity and efficacy of our vaccine candidate to the satisfaction of the FDA. Once these trials are complete, a BLA can be submitted to the FDA requesting licensure of the vaccine for marketing based on the vaccine's safety and efficacy. Similar pathways exist in Europe and other geographies.

The FDA will only approve a BLA if the vaccine is demonstrated to be safe, pure, and potent. During the FDA's review of a BLA, the proposed manufacturing facility undergoes a pre-approval inspection during which the FDA examines in detail the production of the vaccine, the manufacturing facility and the quality documentation related to the vaccine. Vaccine licensure also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public. Until a vaccine is given to the general population, all potential adverse events cannot be anticipated. Thus, the FDA typically requires Phase 4 post-marketing clinical trials for vaccines after licensure to continue gathering safety, and sometimes effectiveness/efficacy data in the indicated and additional populations.

In order to ensure continuing safety, the FDA and most other non-U.S. based regulatory agencies continue to oversee the production of vaccines even after the vaccine and manufacturing processes are approved. For example, monitoring of the vaccine and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product. Manufacturers may also be required to submit the results of their own tests for potency, safety and purity for each vaccine lot, if requested by the relevant regulatory agency. They may also be required to submit samples of each vaccine lot to the agency for testing.

In addition to obtaining FDA licensure for each product, each domestic manufacturing establishment must be registered with the FDA, is subject to FDA inspection and must comply with current Good Manufacturing Practices ("GMP") regulations. To supply products for use either in the U.S. or outside the U.S., including clinical trials, U.S. and foreign manufacturing establishments, including third-party facilities, must comply with GMP regulations and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in their home country.

In 1992, the FDA instituted regulations that allow accelerated approval of certain products that treat serious or life-threatening illnesses and provide meaningful therapeutic benefit over existing treatments based on a surrogate endpoint, versus a clinical outcome, which can take many more years to demonstrate. Surrogate endpoints, generally a laboratory measurement or other physical sign shown to have some correlation with clinical benefit, can considerably shorten the development time leading up to FDA licensure. The FDA bases its decision on whether to accept a proposed surrogate endpoint on the scientific support for that endpoint. The company developing the product is required to conduct further studies to confirm the clinical benefit in Phase 4 confirmatory efficacy trials. We plan to seek accelerated approval for our seasonal influenza vaccine for older adults, but have not ruled out the potential use of traditional approval.

In addition to regulatory approvals that must be obtained in the U.S., an investigational product is also subject to regulatory approval in other countries in which it is intended to be marketed. No such product can be marketed in a country until the regulatory authorities of that country have approved an appropriate marketing application. FDA licensure does not guarantee approval by other regulatory authorities. In addition, in many countries, the government is involved in the pricing of the product. In such cases, the pricing review period often begins after market approval is granted.

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations, including national and local regulations that govern our facility in Sweden. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Act regulations.

In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers. Third-party payers include government authorities or programs, private health insurers (including managed care plans) and other organizations. These third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Third-party payers may also control access to, or manage utilization of, our products with various utilization management techniques.

Within the U.S., if we obtain appropriate approval in the future to market any of our product candidates, those products could potentially be covered by various government health benefit programs as well as purchased by government agencies. The participation in such programs or the sale of products to such agencies is subject to regulation. In exchange for coverage, we may be obligated to provide rebates or offer discounts under government health programs or to government and private purchasers.

The U.S. and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (“Healthcare Reform Act”) which includes changes to the coverage and reimbursement of drug products under

government health care programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act, and some modifications have been implemented. Recently, there has been considerable public and government scrutiny in the U.S. of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been several recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices or price increases. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Within the U.S., we may be subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws, for activities related to future sales of any of our product candidates that may in the future receive regulatory and marketing approval. Anti-kickback laws generally prohibit a pharmaceutical manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase, prescription or use of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such anti-kickback laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third party payers (including Medicare and Medicaid) that are false or fraudulent.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, any future activities (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) could be subject to challenge.

Manufacturing

Our primary manufacturing facility is located at our corporate headquarters at 20 Firstfield Road in Gaithersburg, Maryland. The facility has 53,000 square feet of combined GMP manufacturing, laboratory and office space. Our Rockville, Maryland facility houses our 10,000 square foot GMP pilot manufacturing facility that produces clinical trial material. Novavax AB, located in Uppsala, Sweden, produces our Matrix adjuvants in an approximately 24,000 square foot facility comprised of GMP manufacturing, laboratory and office space.

Sources of Supply

Most of the raw materials and other supplies required in our business are generally available from established vendors in quantities adequate to meet our needs. In some cases, we have only qualified one vendor for certain of our manufacturing components. Prior to the initiation of commercial production, we plan, where feasible, to qualify multiple vendors of critical raw materials. One key vendor is GE Healthcare Company ("GEHC"), which supplies disposable components, resins, media and buffers used in our manufacturing process. GEHC and other vendors that supply our key manufacturing materials have been or will be audited for compliance with GMP standards.

An important component of our Matrix adjuvant technology is extracted from a species of soap-bark tree (*Quillaja saponaria*) that grows mainly in Chile, and we have been able to acquire high-quality quillaja extract as needed from our current suppliers.

Business Development

We believe our proprietary vaccine technology affords us a range of traditional and non-traditional commercialization options. We strive to create sustainable value by working to obtain non-dilutive funding, similar to our agreement with

BMGF to fund our maternal RSV program, that would allow for:

- continued development of our vaccine candidates until such vaccines can be licensed;
- retained commercial rights in one or more major markets;
- product sales revenue; and/or
- commercialization through partners and other strategic relationships.

Employees

As of March 12, 2019, we have 379 full-time employees, of whom 66 hold M.D. or Ph.D. degrees and 117 of whom hold other advanced degrees. Of our total workforce, 329 are engaged primarily in research, development and manufacturing activities and 50 are engaged primarily in executive, business development, finance and accounting, legal and administrative functions. None of our U.S. employees are represented by labor unions or covered by collective bargaining agreements; 41 of our 42 Swedish employees are covered by typical collective bargaining agreements. We consider our relations with our employees to be good.

Availability of Information

Our website address is www.novavax.com. We make available, free of charge and through our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our other filings with the Securities and Exchange Commission ("SEC"), and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after filed with or furnished to the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

We use our website (www.novavax.com) as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures are included on our website (www.novavax.com) in the "Investors" or "News" sections. Accordingly, investors should monitor these portions of our website (www.novavax.com), in addition to following our press releases, SEC filings and public conference calls and webcasts.

Also available on our website is information relating to corporate governance at Novavax and our Board of Directors, including our Code of Business Conduct and Ethics. We intend to disclose on our website any future amendments to and waivers from this code that apply to our Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer and Controller, and persons performing similar functions, as promptly as practicable, as may be required under applicable SEC and Nasdaq rules.

We webcast our earnings calls and certain events we participate in or host with members of the investment community on the investor relations section of our website. Additionally, we provide notifications of news or announcements regarding press and earnings releases as part of the investor relations section of our website. The contents of our website are not part of this Annual Report on Form 10-K, or any other report we file with, or furnish to, the SEC.

Item 1A. RISK FACTORS

You should carefully consider the following risk factors in evaluating our business. A number of risk factors could cause our actual results to differ materially from those that are indicated by forward-looking statements. Some risks relate principally to our business and the industry in which we operate. Others relate principally to the securities market and ownership of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. You also should consider the other information included in this Annual Report on Form 10-K.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

We have a history of losses and our future profitability is uncertain.

Our expenses have exceeded our revenue since our formation in 1987, and our accumulated deficit at December 31, 2018 was $1.3 billion. Our revenue for the last three fiscal years was $34.3 million in 2018, $31.2 million in 2017, and $15.4 million in 2016. We may not be successful in entering into collaborations, strategic alliances and marketing, distribution or licensing arrangements with other companies or government agencies that result in significant revenue to offset our expenses. Our net losses for the last three fiscal years were $184.7 million in 2018, $183.8 million in 2017, and $280.0 million in 2016.

Our recent historical losses have resulted predominantly from research and development expenses for our vaccine candidates, manufacturing-related expenses, costs related to protection of our intellectual property and for other general operating expenses. Our expenses have exceeded our revenue since inception, and we believe our expenses will fluctuate over time, and may substantially increase some years, as a result of continuing research and development efforts to support our vaccine development efforts, and, if our product candidates are approved, future commercialization efforts. In 2016, for example, we experienced a significant increase in research and development expenses compared to prior years primarily due to additional RSV F Vaccine clinical trials in older adults and infants via maternal immunization, as well as higher employee-related costs to support development of our RSV F Vaccine and other potential vaccine candidates.

Although certain specified costs associated with the development of ResVax, our RSV vaccine program for infants via maternal immunization, may be reimbursed under our contract with BMGF, we expect to continue to incur significant operating expenses and anticipate significant losses over time as we seek to:

- conduct clinical trials for RSV F Vaccine and other potential vaccine candidates;
- conduct preclinical studies for other potential vaccine candidates;
- comply with the FDA's manufacturing facility and compliance requirements in anticipation of commercialization;
- invest in our manufacturing process for commercial-scale and cost-efficiency; and
- maintain, expand and protect our intellectual property portfolio.

As a result, we expect our cumulative operating losses to increase until such time, if ever, that product sales, licensing fees, royalties, milestones, contract research and other sources generate sufficient revenue to fund our operations. We may never achieve profitability and may not sustain profitability, if achieved.

We have limited financial resources and we may not be able to maintain our current level of operations or be able to fund the further development of our vaccine candidates.

We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in amounts sufficient to fully fund our operations for the foreseeable future, and we will therefore use our cash resources, and expect to require additional funds, to maintain our operations, continue our research and development programs, commence future preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our products. We anticipate seeking such additional funds through a combination of public or private equity or debt financings, as well as potential collaborations, strategic alliances and marketing, distribution or licensing arrangements and other sources. While we may continue to apply for contracts or grants from academic institutions, non-profit organizations and governmental entities, we may not be successful. Adequate additional funding may not be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our organization, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or vaccine candidates. If we raise additional funds through future offerings of shares of our common stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our common stock.

Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our vaccine candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. There is no certainty that the capital and credit markets will be available to raise additional capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our business plan as scheduled would be compromised. Moreover, we rely and intend to rely on third-parties, including clinical research organizations and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

The Grant Agreement with BMGF does not assure success of ResVax or that the vaccine candidate will be licensed by the FDA.

The grant agreement we entered into with BMGF in September 2015 (the "Grant Agreement") reimburses a portion of specified expenses associated with the development of ResVax, but we remain fully responsible for conducting these development activities. The Grant Agreement does not guarantee that any of these activities will be successful. Our inability to succeed with key clinical or development activities could jeopardize our ability to obtain FDA licensure to sell this vaccine.

Even with the Grant Agreement with BMGF, we may not be able to fully fund ResVax.

The Grant Agreement reimburses a portion of specified expenses associated with the development of ResVax, and additional activities likely will be needed and BMGF may not reimburse us for any portion of these activities.

Recently announced results from the Prepare trial, including that ResVax failed to meet the primary endpoint of the trial, will likely create challenges, some of which may be significant, around further development of that vaccine.

While the Prepare results indicate that ResVax showed efficacy in more serious manifestations of RSV disease, the trial failed to achieve its primary clinical endpoint. Not achieving the primary clinical endpoint has been viewed negatively by our investors, and may also be viewed negatively by potential collaborators and partners, and by regulatory agencies, which would make the ongoing development of ResVax, and any other RSV F Vaccine candidates, more challenging.

Collaborations and contracts of our wholly owned subsidiary Novavax AB, with regional partners, such as Cadila and BMGF, as well as with international providers, expose us to additional risks associated with doing business outside the U.S.

Swedish-based Novavax AB is a wholly owned subsidiary of Novavax, Inc. We also have formed a joint venture with Cadila in India, have established a clinical development agreement with BMGF and have entered into other agreements and arrangements with companies in other countries. We plan to continue to enter into collaborations or partnerships with companies, non-profit organizations and local governments in various parts of the world. Risks of conducting business outside the U.S. include negative consequences of:

- the costs associated with seeking to comply with multiple regulatory requirements that govern our ability to develop, manufacture and sell products in local markets;
- failure to comply with anti-bribery laws such as the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;
- existing, new or changes in interpretations of existing trade protections measures, including tariffs, embargoes and import and export licensing requirements;
- difficulties in and costs of staffing, managing and operating our international operations;
- changes in environmental, health and safety laws;
- fluctuations in foreign currency exchange rates;
- new, changes in or changes in interpretations of tax laws;
- political instability and actual or anticipated military or potential conflicts;
- economic instability, inflation, recession and interest rate fluctuations;
- minimal or diminished protection of intellectual property in many jurisdictions; and
- possible nationalization and expropriation.

These risks, individually or in the aggregate, could have a material adverse effect on our business, financial conditions, results of operations and cash flows.

Current or future regional relationships may hinder our ability to engage in larger transactions.

We have entered into regional collaborations to develop our vaccine candidates in certain parts of the world, and we may enter into additional regional collaborations. Our relationships with Cadila and BMGF are examples of these regional relationships. These relationships often involve the licensing of our technology to our partner or entering into a distribution agreement, frequently on an exclusive basis. Generally, exclusive agreements are restricted to certain territories. Because we have entered into exclusive license and distribution agreements, larger companies may not be interested, or able, to enter into collaborations with us on a worldwide-scale. Also, these regional relationships may make us an unattractive target for an acquisition.

We are a biotechnology company and face significant risk in developing, manufacturing and commercializing our products.

We focus our research and development activities on vaccines, an area in which we believe we have particular strengths and a technology that appears promising. The outcome of any research and development program is highly uncertain. Only a small fraction of biopharmaceutical development programs ultimately result in commercial products or even product candidates and a number of events could delay our development efforts and negatively impact our ability to obtain regulatory approval for, and to manufacture, market and sell, a vaccine. Vaccine candidates that initially appear promising often fail to yield successful products. In many cases, preclinical studies or clinical trials will show that a product candidate is not efficacious or that it raises safety concerns or has other side effects that outweigh its intended benefit. Success in preclinical or early clinical trials may not translate into success in large-scale clinical trials. Further, success in clinical trials often leads to increased investment, accelerating cumulative losses. Even if clinical trial results appear positive, regulatory approval may not be obtained if the FDA does not agree with our interpretation of the results, and we may face challenges when scaling-up the production process to commercial levels. Even after a product is approved and launched, general usage or post-marketing clinical trials may identify safety or other previously unknown problems with the product, which may result in regulatory approvals being suspended, limited to narrow indications or revoked, which may otherwise prevent successful commercialization. Intense competition in the vaccine industry could also limit the successful commercialization of any products for which we receive commercial approval.

Many of our competitors have significantly greater resources and experience, which may negatively impact our commercial opportunities and those of our current and future licensees.

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major pharmaceutical companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial and technical resources, experience and expertise in:

- research and development;
- preclinical testing;
- designing and implementing clinical trials;
- regulatory processes and approvals;
- production and manufacturing; and
- sales and marketing of approved products.

Principal competitive factors in our industry include:

- the quality and breadth of an organization's technology;
- management of the organization and the execution of the organization's strategy;
- the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees;
- an organization's intellectual property portfolio;
- the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development and commercialization activities.

Large and established companies, such as Merck & Co., Inc., GlaxoSmithKline plc, CSL Ltd, Sanofi Pasteur, SA, Pfizer Inc. and AstraZeneca, among others, compete in the vaccine market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products.

We are also aware that there are multiple companies with active RSV vaccine programs at various stages of development. Thus, while there is no RSV vaccine currently on the market, there is likely to be significant and consistent competition as these active programs mature. Different RSV vaccines may work better for different segments of the population, so it may be difficult for a single RSV vaccine manufacturer to provide vaccines that are marketable to multiple population segments. Geographic markets are also likely to vary significantly, which may make it difficult to market a single RSV vaccine worldwide. Even if a manufacturer brings an RSV vaccine to license, it is likely that competitors will continue to work on new products that could be more efficacious and/or less expensive. Our RSV vaccine candidate may not be as far along in development as other active RSV vaccine programs about which we are not aware, nor as efficacious as products under development by competing companies. Even if our RSV vaccine candidate receives regulatory approval, it may not achieve significant sales if other, more effective vaccines under development by our competitors are also approved.

Many seasonal influenza vaccines are currently approved and marketed. Competition in the sale of these seasonal influenza vaccines is intense. Therefore, newly developed and approved products must be differentiated from existing vaccines in order to have commercial success. In order to show differentiation in the seasonal influenza market, a product may need to be more efficacious, particularly in older adults, and/or be less expensive and quicker to manufacture. Many of our competitors are working on new products and new generations of current products, intended to be more efficacious than those currently marketed. Our nanoparticle seasonal influenza vaccine candidate may not prove to be more efficacious than current products or products under development by our competitors. Further, our manufacturing system may not provide enough savings of time or money to provide the required differentiation for commercial success.

Regardless of the disease, smaller or early-stage companies and research institutions also may prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. As these companies develop their technologies, they may develop proprietary positions, which may prevent or limit our product development and commercialization efforts. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and participant registration for clinical trials and in acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced.

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. We may not be successful in gaining significant market share for any vaccine. Our technologies and vaccines also may be rendered obsolete or non-competitive as a result of products introduced by our competitors to the marketplace more rapidly and at a lower cost.

If we are unable to attract or retain key management or other personnel, our business, operating results and financial condition could be materially adversely affected. These risks may be amplified by our recent announcement of the results of the Prepare trial of ResVax.

We depend on our senior executive officers, as well as key scientific and other personnel. The loss of these individuals could harm our business and significantly delay or prevent the achievement of research, development or business objectives. Turnover in key executive positions resulting in lack of management continuity and long-term history with our Company could result in operational and administrative inefficiencies and added costs.

We may not be able to attract qualified individuals for key positions on terms acceptable to us. Competition for qualified employees is intense among pharmaceutical and biotechnology companies, and the loss of qualified employees, or an inability to attract, retain and motivate additional highly skilled employees could hinder our ability to complete clinical trials successfully and develop marketable products. With our recent announcement of the results of our Prepare trial of ResVax, there is a concern that challenges associated with ResVax development may cause certain of our employees to look for job opportunities elsewhere.

We also rely from time to time on outside advisors who assist us in formulating our research and development and clinical strategy. We may not be able to attract and retain these individuals on acceptable terms, which could delay our development efforts.

We may have product liability exposure.

The administration of drugs or vaccines to humans, whether in clinical trials or after marketing approval, can result in product liability claims. We maintain product liability insurance coverage in the total amount of $20 million aggregate for all claims arising from the use of products in clinical trials prior to FDA approval. Coverage is relatively expensive, and the market pricing fluctuates significantly. Therefore, we may not be able to maintain insurance at a reasonable cost. We may not be able to maintain our existing insurance coverage or obtain coverage for the use of our other products in the future. This insurance coverage and our resources may not be sufficient to satisfy all liabilities that result from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace and would likely divert management's attention.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to participants or other claimants;
- loss of revenue; and
- inability to commercialize our vaccine candidates.

We may not be able to win government, academic institution or non-profit contracts or grants.

From time to time, we may apply for contracts or grants from government agencies, academic institutions, and non-profit organizations. Such contracts or grants can be highly attractive because they provide capital to fund the ongoing development of our technologies and vaccine candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for or to otherwise be eligible to receive certain contracts or grants that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded and the size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, we may not be a successful awardee. Therefore, we may not be able to win any contracts or grants in a timely manner, if at all.

Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders or require us to relinquish rights to our technologies or vaccine candidates.

If we are unable to partner with a third-party to advance the development of one or more of our vaccine candidates, we will need to raise money through additional debt or equity financings. To the extent that we raise additional capital by issuing equity securities, our stockholders will experience immediate dilution, which may be significant, especially when our stock price is at a lower level compared to market prices over recent years. There is also a risk that such equity issuances may cause an ownership change under the Internal Revenue Code of 1986, as amended, and similar state provisions, thus limiting our ability to use our net operating loss carryforwards and credits. To the extent that we raise additional capital through licensing arrangements or arrangements with collaborative partners, we may be required to relinquish, on terms that may not be favorable to us, rights to some of our technologies or vaccine candidates that we would otherwise seek to develop or commercialize ourselves. In addition, current economic conditions may also negatively affect the desire or ability of potential collaborators to enter into transactions with us. They may also have to delay or cancel research and development projects or reduce their overall budgets.

Our business may be adversely affected if we do not successfully execute our business development initiatives.

We anticipate growing through both internal development projects, as well as external opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. The availability of high quality opportunities is limited, and we may fail to identify candidates that we and our stockholders consider suitable or complete transactions on terms that prove advantageous. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. Even if we are able to successfully identify and complete acquisitions, like our business combination with Novavax AB, we may not be able to integrate the assets or take full advantage of the opportunities and, consequently, may not realize the benefits that we expect.

To effectively manage our current and future potential growth, we will need to continue to enhance our operational, financial and management processes and to effectively expand, train and manage our employee base. Supporting our growth initiatives will require significant expenditures and management resources, including investments in research and development, manufacturing and other areas of our business. If we do not successfully manage our growth and do not successfully execute our growth initiatives, then our business and financial results may be adversely impacted, and we may incur asset impairment or restructuring charges.

Litigation could have a material adverse impact on our results of operation and financial condition.

In addition to intellectual property litigation, from time to time, we may be subject to other litigation. Regardless of the merits of any claims that may be brought against us, litigation could result in a diversion of management's attention and resources and we may be required to incur significant expenses defending against these claims. If we are unable to prevail in litigation, we could incur substantial liabilities. Where we can make a reasonable estimate of the liability relating to pending litigation and determine that it is probable, we record a related liability. As additional information becomes available, we assess the potential liability and revise estimates as appropriate. However, because of uncertainties relating to litigation, the amount of our estimates could be wrong.

Given our current cash position, there is substantial doubt about our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued.

We adopted ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* in 2016, under which standard our management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that financial statements are

issued. During the year ended December 31, 2018, we have incurred a net loss of $184.7 million and had net cash flows used in operating activities of $184.8 million. At December 31, 2018, we had $103.9 million in cash and cash equivalents, marketable securities and restricted cash and had no committed source of additional funding from either debt or equity financings. Our management believes that, given the Company's current cash position, there is substantial doubt about our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued.

Our capital requirements and cash needs are significant and continuing. Over the next twelve months, we anticipate incurring additional net losses and negative cash flows from operating activities as we continue our product development activities, including our planned ResVax submission of a BLA with the FDA and/or a MAA with the EMA in 2020, and our planned Phase 3 clinical trial of NanoFlu following discussions with the FDA in the first half of 2019. Our ability to fund our operations is dependent upon management's plans, which include raising additional capital in the near term primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements and in the longer term, from revenue related to product sales, to the extent our product candidates receive marketing approval and can be commercialized. There can be no assurances that new financings or other transactions will be available to us on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances and marketing, distribution or licensing arrangements may require us to give up some or all of our rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If we are unable to obtain adequate capital resources to fund our operations, we may be required to delay, reduce the scope of or eliminate some or all of our operations, which may have a material adverse effect on our business, financial condition, results of operations and ability to operate as a going concern.

Security breaches and other disruptions could compromise our information and expose us to liability, and our failure to comply with data protection laws and regulations could lead to government enforcement actions, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and data about our clinical participants, suppliers and business partners and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by malicious third parties with a wide range of motives and expertise, including organized criminal groups, "hacktivists," patient groups, disgruntled current or former employees and others. Hacker attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached due to employee error or malfeasance. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Furthermore, if our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. Attacks could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, which could adversely affect our business. In addition, privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements, which can increase the costs incurred by us in complying with such laws. The European Union's General Data Protection Regulation ("GDPR"), which greatly increases the jurisdictional reach of European Union law and became effective in May 2018, adds a broad array of requirements for handling personal data including the public disclosure of significant data breaches, and imposes substantial penalties for non-compliance of up to the greater of €20 million or 4% of global annual revenue for the preceding financial year. Our efforts to comply with GDPR and other privacy and data protection laws may impose significant costs and challenges that are likely to increase over time, and we could incur substantial penalties or litigation related to violations of existing or future data privacy laws and regulations.

The comprehensive 2017 tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law legislation (the "Act") that significantly revised the Internal Revenue Code of 1986, as amended. The Act, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 percent (35%) to a flat rate of 21 percent (21%), limitation of the tax deduction for interest expense to 30 percent (30%) of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 percent (80%) of current-year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, modifying or repealing many business deductions and credits, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Act.

PRODUCT DEVELOPMENT RISKS

Because our vaccine product development efforts depend on new and rapidly evolving technologies, we cannot be certain that our efforts will be successful.

Our vaccine development efforts depend on new, rapidly evolving technologies and on the marketability and profitability of our products. Our development efforts and, if those are successful, commercialization of our vaccines could fail for a variety of reasons, and include the possibility that:

- our recombinant nanoparticle vaccine technologies, any or all of the products based on such technologies or our proprietary manufacturing process will be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances or commercial viability;
- we are unable to scale-up our manufacturing capabilities in a cost-effective manner;
- the products, if safe and effective, will be difficult to manufacture on a large-scale or uneconomical to market;

- our manufacturing facility will fail to continue to pass regulatory inspections;
- proprietary rights of third-parties will prevent us or our collaborators from exploiting technologies, and manufacturing or marketing products; and
- third-party competitors will gain greater market share due to superior products or marketing capabilities.

We have not completed the development of vaccine products and we may not succeed in obtaining the FDA licensure necessary to sell such vaccine products.

The development, manufacture and marketing of our pharmaceutical and biological products are subject to government regulation in the U.S. and other countries, including the European Medicines Agency and the Swedish Medical Products Agency with respect to our adjuvant product being developed in Sweden. In the U.S. and most foreign countries, we must complete rigorous preclinical testing and extensive clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. None of our vaccine candidates have yet gained regulatory approval in the U.S. or elsewhere. We also have vaccine candidates in clinical trials and preclinical laboratory or animal studies.

The steps generally required by the FDA before our proposed investigational products may be marketed in the U.S. include:

- performance of preclinical (animal and laboratory) tests;
- submissions to the FDA of an IND, which must become effective before clinical trials may commence;
- performance of adequate and well controlled clinical trials to establish the safety and efficacy of the investigational product in the intended target population;
- performance of a consistent and reproducible manufacturing process intended for commercial use, including appropriate manufacturing data and regulatory inspections;
- submission to the FDA of a BLA or a NDA; and
- FDA approval of the BLA or NDA before any commercial sale or shipment of the product.

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our vaccine candidates to the satisfaction of regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are out of our control. Safety concerns may emerge that could lengthen the ongoing clinical trials or require additional clinical trials to be conducted. Promising results in early clinical trials may not be replicated in subsequent clinical trials. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical trials. Moreover, if the FDA or a foreign regulatory body grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved products may not be approved, which could limit our revenue. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical

and clinical data are sufficient to support regulatory approval for our vaccine candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our vaccine candidates are not approved, our ability to generate revenue will be limited and our business will be adversely affected.

If we are unable to manufacture our vaccines in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for our vaccines, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our vaccine candidates require access to, or development of, facilities to manufacture our vaccine candidates at sufficient yields and at commercial-scale. We have limited experience manufacturing any of our vaccine candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

Manufacturing our vaccine candidates involves a complicated process with which we have limited experience. If we are unable to manufacture our vaccine candidates in clinical quantities or, when necessary, in commercial quantities and at sufficient yields, then we must rely on third-parties. Other third-party manufacturers must also receive FDA approval before they can produce clinical material or commercial products. Our vaccines may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third-parties give other products greater priority. We may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays.

Like influenza, a licensed RSV vaccine would likely be seasonal in nature. If a seasonal vaccine is not available early enough in the season, we would likely have difficulty selling that vaccine. For these reasons, any delay in the delivery of a seasonal vaccine could result in lower sales volumes, lower sale prices, or no sales. Strains of the seasonal influenza change annually, which means that inventory of seasonal vaccine cannot be sold during a subsequent influenza season. We believe that while RSV strains may also change annually, our RSV F Vaccine is directed at highly-conserved epitopes that are unlikely to change annually, although that has not yet been definitively demonstrated. Any delay in the manufacture of our vaccines could adversely affect our ability to sell the vaccines.

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

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

As a result, any delay or interruption could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We must identify vaccines for development with our technologies and establish successful third-party relationships.

The near and long-term viability of our vaccine candidates will depend in part on our ability to successfully establish new strategic collaborations with pharmaceutical and biotechnology companies, non-profit organizations and government agencies. Establishing strategic collaborations and obtaining government funding is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position or based on their internal pipeline; government agencies may reject contract or grant applications based on their assessment of public need, the public interest, our products' ability to address these areas, or other reasons beyond our expectations or control. If we fail to establish a sufficient number of collaborations or government relationships on acceptable terms, we may not be able to commercialize our vaccine candidates or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations or obtain government funding, these relationships may never result in the successful development or commercialization of any vaccine candidates for several reasons, including the fact that:

- we may not have the ability to control the activities of our partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development and commercialization of vaccine candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to our vaccine candidates or properly maintain or defend our intellectual property rights;

- any failure on the part of our partners to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our vaccine candidates and affect our ability to realize product revenue; and
- disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals and commercialization activities.

Our collaborators will be subject to the same regulatory approval of their manufacturing facility and process as us. Before we could begin commercial manufacturing of any of our vaccine candidates, we and our collaborators must pass a pre-approval inspection before FDA approval and comply with the FDA's GMP regulations. If our collaborators fail to comply with these requirements, our vaccine candidates would not be approved. If our collaborators fail to comply with these requirements after approval, we could be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products.

If we or our collaborators fail to maintain our existing agreements or in the event we fail to establish agreements as necessary, we could be required to undertake research, development, manufacturing and commercialization activities solely at our own expense. These activities would significantly increase our capital requirements and, given our lack of sales, marketing and distribution capabilities, significantly delay the commercialization of our vaccine candidates.

Because we depend on third-parties to conduct some of our laboratory testing, clinical trials, and manufacturing, we may encounter delays in or lose some control over our efforts to develop products.

We are dependent on third-party research organizations to conduct some of our laboratory testing, clinical trials and manufacturing activities. If we are unable to obtain any necessary services on acceptable terms, we may not complete our product development efforts in a timely manner. We may lose some control over these activities and become too dependent upon these parties. These third-parties may not complete testing or manufacturing activities on schedule, within budget, or when we request. We may not be able to secure and maintain suitable research organizations to conduct our laboratory testing, clinical trials and manufacturing activities. We have not manufactured any of our vaccine candidates at a commercial level and may need to identify additional third-party manufacturers to scale-up and manufacture our products.

We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the clinical trial participants are adequately protected. The FDA and foreign regulatory agencies also require us to comply with good manufacturing practices. Our reliance on third-parties does not relieve us of these responsibilities and requirements. These third-parties may not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines. In addition, these third-parties may need to be replaced or the quality or accuracy of the data they obtain

may be compromised or the product they manufacture may be contaminated due to the failure to adhere to our clinical and manufacturing protocols, regulatory requirements or for other reasons. In any such event, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval of, or commercially manufacture, our vaccine candidates.

Even if licensed to market, our vaccine products may not be initially or ever profitable.

Whether Novavax makes a profit from the sale of its vaccine products is dependent on a number of variables, including the costs we incur manufacturing, testing and releasing, packaging and shipping such vaccine product. The Grant Agreement with BMGF necessitates that we commit to a specific amount of sales in certain specified middle and lower income countries, which may impact our ability to make profits. In addition, we have not yet determined pricing for our vaccine products, which is a complicated undertaking that necessitates both regulatory agency and payer support. We cannot predict when, if at all, our approved vaccine products will be profitable to the Company.

Our collaborations may not be profitable.

We formed CPLB with Cadila in India, but we cannot predict when, if at all, this relationship will lead to additional approved products, sales, or otherwise provide revenue to the Company or become profitable.

We have limited marketing capabilities, and if we are unable to enter into collaborations with marketing partners or develop our own sales and marketing capability, we may not be successful in commercializing any approved products.

Although we have initiated preliminary activities in anticipation of commercialization of our vaccine candidates, we currently have no dedicated sales, marketing or distribution capabilities. As a result, we will depend on collaborations with third-parties that have established distribution systems and sales forces. To the extent that we enter into co-promotion or other licensing arrangements, our revenue will depend upon the efforts of third-parties, over which we may have little or no control. If we are unable to reach and maintain agreements with one or more pharmaceutical companies or collaborators, we may be required to market our products directly. Developing a marketing and sales force is expensive and time-consuming and could delay a product launch. We may not be able to attract and retain qualified sales personnel or otherwise develop this capability.

Our vaccine candidates may never achieve market acceptance even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the commercial sale of our vaccine candidates, the commercial success of these vaccine candidates will depend on, among other things, their acceptance by physicians, patients, third-party payers, such as health insurance companies and other members of the medical community, as a vaccine and cost-effective alternative to competing products. If our vaccine candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of adverse side effects;
- whether our vaccines are differentiated from other vaccines;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy;
- publicity concerning our products or competing products and treatments; and
- our ability to obtain sufficient third party insurance coverage or reimbursement.

Unlike RSV, where there is no current vaccine available, there are significant challenges to market seasonal influenza vaccines. For a seasonal vaccine to be accepted in the market, it must demonstrate differentiation from other seasonal vaccines that are currently approved and marketed. This can mean that the vaccine is more effective in certain populations, such as in older adults, or cheaper and quicker to produce. There are no assurances that our influenza vaccine can be differentiated from other influenza vaccines.

If our vaccine candidates do not become widely accepted by physicians, patients, third-party payers and other members of the medical community, our business, financial condition and results of operations could be materially and adversely affected.

We may not be able to secure sufficient supplies of a key component of our adjuvant technology.

Because an important component of our adjuvant technology is extracted from a species of soap-bark tree (*Quillaja saponaria*) grown in Chile, we need long term access to quillaja extract with a consistent and sufficiently high quality. We need a secure supply of raw material, as well as back-up suppliers, or our adjuvant products may be delayed.

If reforms in the health care industry make reimbursement for our potential products less likely, the market for our potential products will be reduced, and we could lose potential sources of revenue.

Our success may depend, in part, on the extent to which reimbursement for the costs of vaccines will be available from third-party payers, such as government health administration authorities, private health insurers (including managed care plans), and other organizations. Over the past decade, the cost of health care has risen significantly, and there have been numerous proposals by legislators, regulators and third-party health care payers to curb these costs. Some of these proposals have involved limitations on the amount of reimbursement for certain products. Similar federal or state health care legislation may be adopted in the future and any products that we or our collaborators seek to commercialize may not be considered cost-effective. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for realization of an appropriate return on our investment in product development. Moreover, the existence or threat of cost control measures could cause our corporate collaborators to be less willing or able to pursue research and development programs related to our vaccine candidates.

REGULATORY RISKS

We may fail to obtain regulatory approval for our products on a timely basis or comply with our continuing regulatory obligations after approval is obtained.

Delays in obtaining regulatory approval can be extremely costly in terms of lost sales opportunities, loss of any potential marketing advantage of being early to market and increased clinical trial costs. The speed with which we begin and complete our preclinical studies necessary to begin clinical trials, clinical trials and our applications for marketing approval will depend on several factors, including the following:

- our ability to manufacture or obtain sufficient quantities of materials for use in necessary preclinical studies and clinical trials;
- prior regulatory agency review and approval;
- approval of the protocol and the informed consent form by the review board of the institution conducting the clinical trial;
- the rate of participant enrollment and retention, which is a function of many factors, including the size of the participant population, the proximity of participants to clinical sites, the eligibility criteria for the clinical trial and the nature of the protocol;
- negative test results or side effects experienced by clinical trial participants;
- analysis of data obtained from preclinical and clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit or prevent further studies or regulatory approval;
- the availability of skilled and experienced staff to conduct and monitor clinical trials and to prepare the appropriate regulatory applications; and
- changes in the policies of regulatory authorities for drug or vaccine approval during the period of product development.

We have limited experience in conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory marketing approvals. We may not be permitted to continue or commence additional clinical trials. We also face the risk that the results of our clinical trials may be inconsistent with the results obtained in preclinical studies or clinical trials of similar products or that the results obtained in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the biotechnology and product development industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing.

Regulatory agencies may require us or our collaborators to delay, restrict or discontinue clinical trials on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. In addition, we or our collaborators may be unable to submit applications to regulatory agencies within the time frame we currently expect. Once submitted, applications must be approved by various regulatory agencies before we or our collaborators

can commercialize the product described in the application. All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated costs or delays in our clinical trials could delay our ability to generate revenue and harm our financial condition and results of operations.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We intend to have our vaccine candidates marketed outside the U.S. In furtherance of this objective, we have entered into relationships with Cadila in India. In order to market our products in the European Union, India, Asia and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by a regulatory agency, such as the FDA, does not ensure approval by any other regulatory agencies, for example in other foreign countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could harm our business.

Even if regulatory approval is received for our vaccine candidates, the later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions, including withdrawal of the product from the market.

Even if a product gains regulatory approval, such approval is likely to limit the indicated uses for which it may be marketed, and the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenue and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the vaccine itself, and only if the specific event occurs with some regularity over a period of time does the vaccine become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition.

Because we are subject to environmental, health and safety laws, we may be unable to conduct our business in the most advantageous manner.

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations.

Our facilities in Maryland are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, microorganisms and various hazardous compounds used in connection with our research and development activities. In the U.S., these laws include the

Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Similar national and local regulations govern our facility in Sweden. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state, and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, these hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use or the use by third-parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

Although we have general liability insurance, these policies contain exclusions from insurance against claims arising from pollution from chemicals or pollution from conditions arising from our operations. Our collaborators are working with these types of hazardous materials in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury we or our collaborators cause to persons or property by exposure to, or release of, any hazardous materials. However, we believe that we are currently in compliance with all material applicable environmental and occupational health and safety regulations.

Even if we successfully commercialize any of our vaccine candidates, either alone or in collaboration, we face uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could adversely affect any commercial success of our vaccine candidates.

Our ability to collect revenue from the commercial sale of our vaccines may depend on our ability, and that of any current or potential future collaboration partners or customers, to obtain adequate levels of approval, coverage and reimbursement for such products from third-party payers such as:

- government health administration authorities such as the Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention;
- private health insurers;
- managed care organizations;
- pharmacy benefit management companies; and
- other healthcare related organizations.

Third-party payers are increasingly challenging the prices charged for medical products and may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators; is not used in accordance with cost-effective treatment methods as determined by the third-party payer; or is experimental, unnecessary or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines. Some of these proposed and implemented reforms could result in reduced reimbursement rates for medical products, and while we have no current vaccines available for commercial sale, the impact of such reform could nevertheless adversely affect our business strategy, operations and financial results. For example, the Healthcare Reform Act contained several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid managed care organizations, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain healthcare providers. Additional provisions of the healthcare reform laws that may negatively affect our future revenue and

prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, as well as mandatory discounts on drugs (including vaccines) sold to certain Medicare Part D beneficiaries in the coverage gap (the so-called “donut hole”). Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. In addition, we face uncertainties because there are ongoing federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Healthcare Reform Act. For example, in 2017, the President announced that his administration will withhold the cost-sharing subsidies paid to health insurance exchange plans serving low-income enrollees. The Act was also enacted at the end of 2017 and includes provisions that will affect healthcare insurance coverage and payment, such as the elimination of the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). The Bipartisan Budget Act of 2018 contained various provisions that affect coverage and reimbursement of drugs, including an increase in the mandatory discounts on pharmaceuticals sold to certain Medicare Part D beneficiaries in the coverage gap starting in 2019. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

If our product candidates obtain marketing approval, we will be subject to additional healthcare laws and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Within the U.S., if we obtain approval for any of our product candidates and begin commercializing them, our operations may be directly, or indirectly through our customers, subject to additional healthcare regulation and enforcement by the federal and state governments. In addition to the laws mentioned above, the laws that may affect our ability to operate include:

- the Food, Drug and Cosmetic Act, which among other things, strictly regulates drug product marketing and promotion and prohibits manufacturers from marketing such products for off-label use;
- the federal anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce the referral for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law (also known as "open payments") which requires pharmaceutical and medical device manufacturers to report certain financial interactions to the federal government for re-disclosure to the public;
- the federal law known as HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state gift ban and transparency laws, many of which state laws differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts; and
- state laws restricting interactions with healthcare providers and other members of the healthcare community or requiring pharmaceutical manufacturers to implement certain compliance standards.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to, on a corporate or individual basis, penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and even imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results. In addition, the cost of implementing sufficient systems, controls, and processes to ensure compliance with all of the aforementioned laws could be significant.

INTELLECTUAL PROPERTY RISKS

Our success depends on our ability to maintain the proprietary nature of our technology.

Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third-parties or allowing third-parties to infringe our rights. We currently have or have rights to over 350 U.S. patents and corresponding foreign patents and patent applications covering our technologies. However, patent issues relating to pharmaceuticals and biologics involve complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the U.S. Patent and Trademark Office ("USPTO") or enforced by the federal courts. Therefore, we do not know whether our patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

There is a risk that third-parties may challenge our existing patents or claim that we are infringing their patents or proprietary rights. We could incur substantial costs in defending patent infringement suits or in filing suits against others to have their patents declared invalid or claim infringement. It is also possible that we may be required to obtain licenses from third-parties to avoid infringing third-party patents or other proprietary rights. We cannot be sure that such third-party licenses would be available to us on acceptable terms, if at all. If we are unable to obtain required third-party licenses, we may be delayed in or prohibited from developing, manufacturing or selling products requiring such licenses.

Although our patent filings include claims covering various features of our vaccine candidates, including composition, methods of manufacture and use, our patents do not provide us with complete protection against the development of competing products. Some of our know-how and technology is not patentable. To protect our proprietary rights in unpatentable intellectual property and trade secrets, we require employees, consultants, advisors and collaborators to enter into confidentiality agreements. These agreements may not provide meaningful protection for our trade secrets, know-how or other proprietary information.

Third parties may claim we infringe their intellectual property rights.

Our research, development and commercialization activities, including any vaccine candidates resulting from these activities, may infringe or be claimed to infringe patents owned by third-parties and to which we do not hold licenses or other rights. There may be rights we are not aware of, including applications that have been filed, but not published that, when issued, could be asserted against us. These third-parties could bring claims against us, and that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic drug candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third-party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries.

We may become involved in litigation to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time-consuming.

Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to counter infringement for unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at the risk of not issuing.

Even if we are successful, litigation may result in substantial costs and distraction to our management. Even with a broad portfolio, we may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required 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. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

The scope, validity, and ownership of our patent claims may be challenged in various venues and, if we do not prevail, our ability to exclude competitors may be harmed, potentially reducing our ability to succeed commercially.

We may be subject to a variety of challenges from third-parties that relate to the scope of the claims or to their validity. Such challenges can be mounted in post-grant review, ex parte re-examination, and inter partes review proceedings before the USPTO, or similar adversarial proceedings in other jurisdictions. If we are unsuccessful in any such challenge, the scope of our claims could be narrowed, and the patent or claims thereof could be invalidated. Any such outcome could impair our ability to exclude competitors from the market in those countries, potentially impacting our commercial success.

Our patents may be subject to various challenges related to ownership and inventorship, including interference or derivation proceedings. Third-parties may assert that they are inventors on our patents or that they are owners of the patents. While we perform inventorship analyses to insure that the correct inventors are listed on our patents, we cannot be certain that a court of competent jurisdiction would arrive at the same conclusions we do. If we are unsuccessful in defending against ownership or inventorship challenges, a court may require us to list additional inventors, may invalidate the patent, or may transfer ownership of the patent to a third-party. Any of these outcomes may harm our ability to exclude competitors and potentially impact our commercial success. Further, if ownership is transferred to a third-party we may be required to seek a license to those rights to preserve our exclusive ability to practice the invention. Such a license may not be available on commercially reasonable terms, or at all. If we are unable to obtain a license, we may be required to expend time, effort, and other resources to design around the patent. Any such license may be non-exclusive and if a competitor is able to obtain a license from the third-party, our ability to exclude that competitor from the market may be negatively impacted.

Even if we are ultimately successful, defending any such challenges may cause us to incur substantial expenses and may require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may need to license intellectual property from third-parties and, if our right to use the intellectual property we license is affected, our ability to develop and commercialize our vaccine candidates may be harmed.

We have in the past, and we expect in the future to license intellectual property from third-parties and that these licenses will be material to our business. We will not own the patents or patent applications that underlie these licenses, and we will not control the enforcement of the patents. We will rely upon our licensors to properly prosecute and file those patent applications and prevent infringement of those patents.

While many of the licenses under which we have rights provide us with rights in specified fields, the scope of our rights under these and other licenses may be subject to dispute by our licensors or third-parties. In addition, our rights to use these technologies and practice the inventions claimed in the licensed patents and patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. Any of our licenses may be terminated by the licensor if we are in breach of a term or condition of the license agreement, or in certain other circumstances.

Further, any disputes regarding obligations in licenses may require us to take expensive and time-consuming legal action to resolve, and, even if we are successful, may delay our ability to commercialize products and generate revenue. Further, if we are unable to resolve license issues that arise we may lose rights to practice intellectual property that is required to make, use, or sell products. Any such loss could compromise our development and commercialization efforts for current or future product candidates and/or may require additional effort and expense to design around.

Our vaccine candidates and potential vaccine candidates will require several components that may each be the subject of a license agreement. The cumulative license fees and royalties for these components may make the commercialization of these vaccine candidates uneconomical.

If patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize our discoveries.

Important legal issues remain to be resolved as to the extent and scope of available patent protection for biopharmaceutical products and processes in the U.S. and other important markets outside the U.S., such as Europe and Japan. In addition, foreign markets may not provide the same level of patent protection as provided under the U.S. patent system. Litigation or administrative proceedings may be necessary to determine the validity and scope of certain of our and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force us to do one or more of the following: cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; obtain a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; and redesign our products to avoid infringing the intellectual property rights of third-parties, which may be time-consuming or impossible to do. In addition, changes in, or different interpretations of, patent laws in the U.S. and other countries may result in patent laws that allow others to use our discoveries or develop and commercialize our products. We cannot provide assurance that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection.

If we do not obtain patent term extension and/or patent term adjustment in the United States under the Hatch-Waxman Act and similar extensions in foreign countries, our ability to exclude competitors may be harmed.

In the United States, the patent term is 20 years from the earliest U.S. non-provisional filing date. Extensions of patent term may be available under certain circumstances. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of one patent that covers a marketed product under the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Amendments") and similar legislation in the EU.

The Hatch-Waxman Amendments permit patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. We may not receive any extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail 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 the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner.

Patent term covering our products may also be extended for time spent during the prosecution of the patent application in the USPTO. This extension is referred to as Patent Term Adjustment ("PTA"). The laws and regulations governing how the USPTO calculates the PTA is subject to change and changes in the law can reduce or increase any such PTA.

Further, the PTA granted by the USPTO may be challenged by a third-party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, shortening the patent term, which may negatively impact our ability to exclude competitors.

Risks Related to OUR Convertible SENIOR Notes

Servicing our 3.75% convertible senior unsecured notes due 2023 (the "Notes") requires a significant amount of cash, and we may not have sufficient cash flow to pay our debt.

In 2016, we issued $325 million aggregate principal amount of Notes. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We do not expect our business to be able to generate cash flow from operations, in the foreseeable future, sufficient to service our debt and make necessary capital expenditures and may therefore be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness, which is non-callable and matures in 2023, will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, and limit our flexibility in planning for and reacting to changes in our business.

We may not have the ability to raise the funds necessary to repurchase the Notes as required upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes.

Holders of the Notes will have the right to require us to repurchase their Notes for cash upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, *plus* accrued and unpaid interest, if any. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change repurchase price in cash with respect to any Notes surrendered by holders for repurchase upon a fundamental change. In addition, restrictions in our then existing credit facilities or other indebtedness, if any, may not allow us to repurchase the Notes upon a fundamental change. Our failure to repurchase the Notes upon a fundamental change when required would result in an event of default with respect to the Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

Capped call transactions entered into in connection with our Notes may affect the value of our common stock.

In connection with our Notes, we entered into capped call transactions (the “capped call transactions”) with certain financial institutions. The capped call transactions are expected to generally reduce the potential dilution upon conversion of the Notes into shares of our common stock.

In connection with establishing their initial hedges of the capped call transactions, these financial institutions or their respective affiliates entered into various derivative transactions with respect to our common stock and/or to purchase our common stock. The financial institutions, or their respective affiliates, may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Notes, which could affect the value of our common stock.

RISKS RELATED TO OUR COMMON STOCK AND ORGANIZATIONAL STRUCTURE

Because our stock price has been and will likely continue to be highly volatile, the market price of our common stock may be lower or more volatile than expected.

Our stock price has been highly volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. From January 1, 2018 through December 31, 2018, the closing sale price of our common stock has been as low as $1.17 per share and as high as $2.48 per share. The market price of our common stock may be influenced by many factors, including:

- future announcements about us or our collaborators or competitors, including the results of testing, technological innovations or new commercial products;
- clinical trial results;
- depletion of our cash reserves;
- sale of equity securities or issuance of additional debt;
- announcement by us of significant strategic partnerships, collaborations, joint ventures, capital commitments or acquisitions;
- changes in government regulations;
- impact of competitor successes and in particular development success of vaccine candidates that compete with our own vaccine candidates;
- developments in our relationships with our collaboration partners;
- announcements relating to health care reform and reimbursement levels for new vaccines and other matters affecting our business and results, regardless of accuracy;
- sales of substantial amounts of our stock by existing stockholders (including stock by insiders or 5% stockholders);
- development, spread or new announcements related to pandemic diseases;
- litigation;
- public concern as to the safety of our products;

- significant set-backs or concerns with the industry or the market as a whole;
- regulatory inquiries, reviews and potential action, including from the FDA or the SEC;
- recommendations by securities analysts or changes in earnings estimates; and
- the other factors described in this Risk Factors section.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have particularly affected the market price for many of those companies. These fluctuations have often been unrelated to the operating performance of these companies. These broad market fluctuations may cause the market price of our common stock to be lower or more volatile than expected.

The Nasdaq Global Select Market has a listing requirement; if a participating company no longer meets such requirements and fails to correct the listing deficiency, its stock may be delisted.

The Nasdaq Global Select Market ("Nasdaq"), on which our common stock is listed and traded, has listing requirements that include a $1 minimum closing bid price requirement. If we fail to satisfy this or other listing requirements, Nasdaq may elect, subject to any potential cure periods, to initiate a process that may delist our common stock. Should such a delisting occur, it may adversely impact the liquidity and price of our common stock, impede our ability to raise capital and would constitute a fundamental change under our Notes.

Provisions of our Second Amended and Restated Certificate of Incorporation and Amended and Restated By-Laws and Delaware law could delay or prevent the acquisition of the Company, even if such acquisition would be beneficial to stockholders, and could impede changes in our Board.

Provisions in our organizational documents could hamper a third-party's attempt to acquire, or discourage a third-party from attempting to acquire control of, the Company. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Our organizational documents also could limit the price investors are willing to pay in the future for our securities and make it more difficult to change the composition of our Board in any one year. Certain provisions include the right of the existence of a staggered board with three classes of directors serving staggered three-year terms and advance notice requirements for stockholders to nominate directors and make proposals.

As a Delaware corporation, we are also afforded the protections of Section 203 of the Delaware General Corporation Law, which will prevent us from engaging in a business combination with a person who acquires at least 15% of our common stock for a period of three years from the date such person acquired such common stock, unless advance board or stockholder approval was obtained.

Any delay or prevention of a change of control transaction or changes in our Board or management could deter potential acquirers or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then current market price for their shares.

We have never paid dividends on our capital stock, and we do not anticipate paying any such dividends in the foreseeable future.

We have never paid cash dividends on our common stock. We currently anticipate that we will retain all of our earnings for use in the development of our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock would be the only source of gain for stockholders until dividends are paid, if at all.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease three facilities in Gaithersburg, Maryland and one in Rockville, Maryland. Novavax AB leases a facility in Uppsala, Sweden. A summary of our current facilities is set forth below. Although we believe that our facilities are suitable and adequate for our present needs, the Company’s management continues to review and assess real property requirements that may be necessary to address our current business plan.

Property Location	Approximate Square Footage	Brief Property Description
Rockville, MD	51,000	Vaccine research and development and manufacturing facility
20FF Gaithersburg, MD	53,000	Corporate headquarters, vaccine research and development and manufacturing facility
21FF Gaithersburg, MD	53,000	Research and development facility and offices
22FF Gaithersburg, MD	40,000	Executive, administrative, clinical and regulatory offices
Uppsala, Sweden	24,000	Adjuvant manufacturing and research and development facility and offices
Total square footage	221,000	

Item 3. LEGAL PROCEEDINGS

We currently have no material pending legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock trades on the Nasdaq Global Select Market under the symbol "NVAX." Our common stock was held by approximately 349 stockholders of record as of March 12, 2019, one of which is Cede & Co., a nominee for Depository Trust Company ("DTC"). All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder. We do not anticipate declaring or paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under our Equity Compensation Plans

Information regarding our equity compensation plans, including both stockholder approved plans and non-stockholder approved plans, is included in Item 12 of this Annual Report on Form 10-K.

Performance Graph

The graph below compares the cumulative total stockholders return on our common stock for the last five fiscal years with the cumulative total return on the Nasdaq Composite Index and the Russell 2000 Growth Biotechnology Index (which includes Novavax) over the same period, assuming the investment of $100 in our common stock, the Nasdaq Composite Index and the Russell 2000 Growth Biotechnology Index on December 31, 2013, and reinvestments of all dividends.

Value of $100 invested on December 31, 2013 in stock or index, including reinvestment of dividends, for fiscal years ended December 31:

	12/31/13	12/31/14	12/31/15	12/31/16	12/31/17	12/31/18
Novavax, Inc.	$100.00	$115.82	$163.87	$24.61	$24.22	$35.94
Nasdaq Composite Index	$100.00	$114.62	$122.81	$133.19	$172.11	$165.84
RUSSELL 2000 Growth Biotechnology Index	$100.00	$124.27	$138.15	$110.12	$176.01	$145.16

This graph is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Item 6. SELECTED FINANCIAL DATA

The following table sets forth selected financial data for each of the years in the five-year period ended December 31, 2018, which have been derived from our audited consolidated financial statements. The information below should be read in conjunction with our consolidated financial statements and notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report. These historical results are not necessarily indicative of results for future periods.

	Year Ended December 31,				
	2018(1)	2017(2)	2016(3)	2015(4)	2014(5)
	(in thousands, except per share amounts)				
Statements of Operations Data:					
Revenue	$34,288	$31,176	$15,353	$36,250	$30,659
Net loss	(184,748)	(183,769)	(279,966)	(156,937)	(82,947)
Basic and diluted net loss per share	(0.50)	(0.63)	(1.03)	(0.60)	(0.37)
Weighted average shares used in computing basic and diluted net loss per share	369,757	292,669	270,802	262,248	225,848

	As of December 31,				
	2018(1)	2017(2)	2016(3)	2015(4)	2014(5)
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents, marketable securities and restricted cash	$103,939	$186,427	$270,383	$268,062	$168,353
Total current assets	119,276	203,311	287,830	287,257	188,158
Working capital(6)	73,737	129,636	221,424	210,763	154,042
Total assets	207,978	302,493	394,301	386,038	276,002
Long-term debt, less current portion(7)	319,187	317,763	316,339	37	503
Accumulated deficit	(1,299,107)	(1,114,359)	(929,996)	(650,030)	(493,093)
Total stockholders' (deficit) equity	(167,935)	(101,732)	(5,546)	292,669	229,618

(1) In 2018, we had sales of 58,828,755 shares of common stock resulting in net proceeds of approximately $100 million.

(2) In 2017, we had sales of 50,889,910 shares of common stock resulting in net proceeds of approximately $63 million.

(3) In 2016, we issued $325 million aggregate principal amount of convertible senior unsecured notes resulting in net proceeds of approximately $315 million.

(4) In 2015, we had sales of 29,163,620 shares of common stock resulting in net proceeds of approximately $204 million.

(5)

In 2014, we had sales of 28,750,000 shares of common stock resulting in net proceeds of approximately $108 million.

(6) Working capital is computed as the excess of current assets over current liabilities.

(7) Includes non-current portion of capital leases.

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

Any statements in the discussion below and elsewhere in this Annual Report, about expectations, beliefs, plans, objectives, assumptions or future events or performance of Novavax, Inc. ("Novavax", and together with its wholly owned subsidiary Novavax AB, the "Company," "we" or "us") are not historical facts and are forward-looking statements. Such forward-looking statements include, without limitation, statements with respect to our capabilities, goals, expectations regarding future revenue and expense levels and capital raising activities, including possible proceeds from our December 2018 Sales Agreement (defined below); potential market sizes and demand for our product candidates; the efficacy, safety and intended utilization of our product candidates; the development of our clinical-stage product candidates and our recombinant vaccine and adjuvant technologies; the development of our preclinical product candidates; the conduct, timing and potential results from clinical trials and other preclinical studies; plans for and potential timing of regulatory filings; our expectation with respect to the anticipated commercialization of ResVax; the expected timing and content of regulatory actions; reimbursement by HHS BARDA; payments by BMGF; our available cash resources and the availability of financing generally; plans regarding partnering activities, business development initiatives and the adoption of stock incentive plans and amendments thereto and other matters referenced herein. You generally can identify these forward-looking statements by the use of words or phrases such as "believe," "may," "could," "will," "would," "possible," "can," "estimate," "continue," "consider," "anticipate," "intend," "seek," "plan," "project," "expect," "should," "would," or "assume" or the negative of these other comparable terminology, although not all forward-looking statements contain these words.

Forward-looking statements involved estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed or implied in the statements. Any or all of our forward-looking statements in this Annual Report may turn out to be inaccurate or materially different from actual results.

Because the risk factors discussed in this Annual Report, and other risk factors of which we are not aware, could cause actual results or outcomes to differ materially from those expressed or implied in any forward-looking statements made by or on behalf of us, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. We have included important factors in the cautionary statements included in this Annual Report, particularly those identified in Part I, Item 1A, "Risk Factors" of this Annual Report, which could cause actual results or events to differ materially from forward-looking statements. These and other risks may also be detailed and modified or updated in our reports and other documents filed with the SEC from time to time. You are encouraged to read these filings as they are made.

We cannot guarantee future results, events, level of activity, performance or achievement. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor 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.

Overview

We are a late-stage biotechnology company focused on the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. Our vaccine candidates, including our lead candidates, ResVax™ and NanoFlu™, are genetically engineered, three-dimensional nanostructures of recombinant proteins critical to disease pathogenesis and may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or traditional vaccines. Our product pipeline (see below) targets a variety of infectious diseases. We are also developing immune stimulating saponin-based adjuvants through our wholly owned Swedish subsidiary, Novavax AB. Our lead adjuvant, Matrix-M™, has been shown to enhance immune responses and was well-tolerated in multiple clinical trials.

Product Pipeline

Program	Current Development Stage
Respiratory Syncytial Virus ("RSV")	
·**ResVax* (Infants via Maternal Immunization)**	Phase 3
·**Older Adults**	Phase 2
·**Pediatrics**	Phase 1
Seasonal Influenza	
·**NanoFlu (Older Adults)**	Phase 2
Combination Seasonal Influenza/RSV	Preclinical

*Supported by a grant of up to $89.1 million from BMGF

A summary and status of these vaccine programs follows:

Respiratory Syncytial Virus (RSV)

Currently, there is no approved RSV vaccine available to combat the estimated 64 million RSV infections that occur globally each year. We have identified three susceptible target populations that we believe could benefit from the development of our RSV F Vaccine in different formulations: (1) infants via maternal immunization, (2) older adults (60 years and older) and (3) children six months to five years old ("pediatrics"). With our current estimates of the annual global cost burden of RSV in excess of $88 billion, we believe our RSV F Vaccine represents a multi-billion dollar worldwide opportunity.

ResVax Program (Infants via Maternal Immunization)

ResVax, our adjuvanted RSV F Vaccine for infants via maternal immunization, is our lead vaccine program. RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide. In the U.S., RSV is the leading cause of hospitalization of infants and, globally, is second only to malaria as a cause of death in children under one year of age.

In February 2019, we announced top-line data from the Prepare trial, which we initiated in December 2015 to determine the efficacy of ResVax against medically significant RSV-positive LRTI in infants through a minimum of the first 90 days of life and up through the first six months of life. While the Prepare trial did not meet its pre-specified primary efficacy endpoint, it did demonstrate efficacy against one of the secondary objectives (RSV LRTI hospitalizations), the first RSV vaccine to show efficacy in a Phase 3 clinical trial. In addition, in the Prepare trial, other pre-specified exploratory endpoints and post-hoc analyses highlight ResVax' potential to improve global health against RSV disease in this vulnerable population. Like previous clinical trials, ResVax showed a favorable safety and tolerability profile from the Prepare trial. With these results, we plan to meet with both the FDA and the EMA later in 2019, to discuss and assess opportunities for submitting a BLA with the FDA and/or a MAA with the EMA, in 2020. We are also considering seeking licensure strategically in a number of geographic regions, other than the U.S. and Europe, where the Prepare results support such efforts. The development of ResVax and the conduct of the Prepare trial are supported by a grant of up to $89.1 million from BMGF for development activities, product licensing efforts and WHO prequalification of ResVax.

RSV Older Adults Program

Older adults (60 years and older) are at increased risk for RSV disease due in part to immunosenescence, the age-related decline in the human immune system. RSV infection can also lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. In the U.S. alone, a reported RSV incidence rate of 5.5% in older adults would account for approximately 2.5 million infections per year. We estimate that approximately 900,000 medical interventions are caused by RSV disease in this U.S. population each year. In our 2017 Phase 2 clinical trial of our RSV F Vaccine in older adults, we assessed safety and immunogenicity of one and two dose regimens of our RSV F Vaccine, with and without aluminum phosphate or our proprietary Matrix-M adjuvant. Immunogenicity results indicate that both adjuvants increase the magnitude, duration and quality of the immune response versus the non-adjuvanted RSV F Vaccine. The 2016 Phase 3 clinical trial of our RSV F Vaccine failed to meet it pre-specified primary or secondary efficacy objectives and did not demonstrate vaccine efficacy. We are currently assessing the development opportunities for our RSV F Vaccine in older adults in the United States.

RSV Pediatrics Program

By the age of five, essentially all children will have been exposed to RSV and will likely develop natural immunity against the virus; however, children under five remain vulnerable to RSV disease, offering a strong rationale for a pediatric vaccine that could offer enhanced protection. In 2015, we announced positive results in our Phase 1 clinical trial evaluating the safety and immunogenicity of our RSV F Vaccine in healthy children between two and six years of age. To the extent we receive regulatory approval for ResVax, we expect to continue development of our RSV F Vaccine for pediatrics.

Seasonal Influenza

NanoFlu Program (Older Adults)

Influenza is a world-wide infectious disease with serious illness generally occurring in more susceptible populations such as pediatrics and older adults, but also occurring in the general population. According to influenza vaccines forecasts by Datamonitor in 2013, the market for seasonal influenza vaccines is expected to grow from approximately $3.2 billion in the 2015-16 flu season to approximately $5.3 billion in the 2021-22 flu season (in the countries comprising the top seven markets). The Center for Disease Control and Prevention estimates that each year since 2010, influenza in the U.S. has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations and between 12,000 and 56,000 deaths.

In January 2019, we announced positive top-line data from our Phase 2 clinical trial of NanoFlu in older adults. Top-line results showed that all formulations of NanoFlu were well-tolerated and elicited vigorous immune responses to all four strains included in the vaccine; importantly, use of our Matrix-M adjuvant resulted in significantly enhanced immune responses when compared to a non-adjuvanted formulation. NanoFlu also showed superior hemagglutination inhibition antibody responses against wild-type A(H3N2) viruses, including drifted strains, when compared to Fluzone High-Dose, the leading flu vaccine in older adults. During a pre-investigational new drug application meeting in 2018, the FDA indicated that an accelerated approval pathway for seasonal influenza vaccines could be available for NanoFlu. We plan to discuss the Phase 2 clinical trial data and the proposed Phase 3 study design, and reach agreement on the use of accelerated approval with the FDA during an End-of-Phase 2 meeting in the first half of 2019. We are currently planning a pivotal Phase 3 clinical trial of NanoFlu that could begin as early as the second half of 2019.

Combination Seasonal Influenza/RSV F Vaccine

With the ongoing development of our NanoFlu and RSV F Vaccine, a strong rationale exists for developing a combination respiratory vaccine that is designed to protect susceptible populations against both diseases. Although testing is at an early stage, we believe that a combination vaccine against both influenza and RSV may be achievable.

Early-stage Vaccine Candidates

Because our nanoparticle technology targets antigens with conserved epitopes essential for viral function, our vaccine candidates have the potential to be applied broadly to a wide variety of human infectious diseases. Our nanoparticle vaccine technology has already demonstrated the ability to produce vaccine candidates against a wide variety of infectious diseases: in addition to our ResVax and NanoFlu vaccines, we have also developed nanoparticle vaccine candidates for clinic testing against ebola virus (positive Phase 1 clinical trial results) and MERS coronavirus (positive animal studies). While we have focused most of our corporate efforts towards our RSV and seasonal influenza vaccine candidates, we stand ready to continue work on emerging infectious disease vaccine candidates as circumstances warrant.

CPLB Joint Venture

CPLB, our joint venture between Novavax and Cadila, is actively developing a number of vaccine candidates in India. In July 2018, we amended and restated our joint venture and license agreements with respect to CPLB to align them with our current and planned interactions with CPLB. CPLB continues to be owned 20% by Novavax and 80% by Cadila.

Sales of Common Stock

In April 2018, we completed a public offering of 34,848,507 shares of our common stock, including 4,545,457 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of $1.65 per share resulting in net proceeds of approximately $54 million.

In December 2017, we entered into an At Market Issuance Sales Agreement ("December 2017 Sales Agreement"), which allows us to issue and sell up to $75 million in gross proceeds of our common stock. During 2018, we sold 17.2 million shares of common stock under the December 2017 Sales Agreement resulting in $35.9 million in net proceeds. From January 1 through March 12, 2019, we sold 50.3 million shares of common stock under the December 2017 Sales Agreement resulting in $37.9 million in net proceeds. The December 2017 Sales Agreement was fully utilized at that time.

In December 2018, we entered into an At Market Issuance Sales Agreement ("December 2018 Sales Agreement"), which allows us to issue and sell up to $100 million in gross proceeds of our common stock. On March 12, 2019, we sold 5.5 million shares of common stock under the December 2018 Sales Agreement resulting in $2.9 million in net proceeds.

Critical Accounting Policies and Use of Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States.

The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities and equity and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. These estimates, particularly estimates relating to accounting for revenue, the valuation of our marketable securities, stock-based compensation, long-lived assets and goodwill have a material impact on our consolidated financial statements and are discussed in detail throughout our analysis of the results of operations discussed below.

We base our estimates on historical experience and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets, liabilities

and equity that are not readily apparent from other sources. Actual results and outcomes could differ from these estimates and assumptions.

Revenue

The new revenue standard, Accounting Standards Update 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("Topic 606"), became effective for us on January 1, 2018, and was adopted using the modified retrospective method. The adoption of the new revenue standard did not materially change our timing of revenue recognition as the majority of our revenue continues to be recognized under our Grant Agreement with BMGF (see discussion below). Since we did not identify any accounting changes that impacted our revenue recognition timing, no adjustment to accumulated deficit was required upon adoption.

Under the new revenue standard for arrangements that are determined within the scope of Topic 606, we recognize revenue following the five-step model: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine the performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We perform research and development under grant, license and clinical development agreements. Payments received in advance of work performed are recorded as deferred revenue.

Our current revenue primarily consists of revenue under our Grant Agreement with BMGF. We are reimbursed for certain costs that support development activities, including our global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and efforts to obtain WHO prequalification of ResVax. The Grant Agreement does not provide a direct economic benefit to BMGF. Rather, we entered into an agreement with BMGF to make a certain amount of ResVax available and accessible at affordable pricing to people in certain low and middle income countries. Based on these circumstances, we do not consider BMGF to be a customer and concluded the Grant Agreement is outside the scope of Topic 606. Payments received under the Grant Agreement are considered conditional contributions under the scope of ASC 958-605, *Not-for-Profit Entities – Revenue Recognition*, and are recorded as deferred revenue until the period in which such research and development activities are performed and revenue can be recognized.

We analyzed the Grant Agreement with BMGF to determine whether the payments received should be recorded as revenue or as a reduction to research and development expenses. In reaching the determination that such payments should be recorded as revenue, we considered a number of factors, including whether we are the principal under the arrangement, and whether the arrangement is significant to, and part of, our core operations. Further, we have consistently applied our policy of presenting such amounts as revenue.

Marketable Securities

Our marketable securities consist of debt securities, which include commercial paper, asset-backed securities and corporate notes, that are classified as available-for-sale securities and are carried at fair value. Unrealized gains and losses on these securities, if determined not to be “other-than-temporary,” are included in accumulated other comprehensive income (loss) in stockholders’ deficit. Investments are evaluated periodically to determine whether a decline in value is “other-than-temporary.” Management reviews criteria, such as the magnitude and duration of the decline, as well as the Company’s ability to hold the securities until market recovery, to predict whether the loss in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the security is reduced and the impairment is recorded in the statements of operations. For marketable securities carried at fair value, we disclose the level within the fair value hierarchy as prescribed by Accounting Standard Codification (“ASC”) Topic 820, *Fair Value Measurements and Disclosures*. We evaluate the types of securities in our investment portfolio to determine the proper classification in the fair value hierarchy based on trading activity and market inputs. We generally obtain information from an independent third-party to help us determine the fair value of securities in Level 2 of the fair value hierarchy. Investment income is recorded when earned and included in investment income.

Stock-Based Compensation

We account for our stock-based compensation under our equity compensation plans in accordance with ASC Topic 718, *Compensation – Stock Compensation*. This standard requires us to measure the cost of employee services received in exchange for equity awards based on the grant-date fair value of the award. Employee stock-based compensation is estimated at the date of grant based on the award's fair value using the Black-Scholes option-pricing model and is recognized as an expense on a straight-line basis over the requisite service period for those awards expected to vest. The Black-Scholes option-pricing model requires the use of certain assumptions, the most significant of which are our estimates of the expected volatility of the market price of our common stock and the expected term of the award. Our estimate of the expected volatility is based on historical volatility over the look-back period corresponding to the expected term. The expected term represents the period during which our stock-based awards are expected to be outstanding. We estimate this amount based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements and expectation of future employee behavior, including post-vesting exercise and forfeiture history. We review our valuation assumptions at each grant date and, as a result, our assumptions in future periods may change. Also, the accounting estimate of stock-based compensation expense is reasonably likely to change from period to period as further equity awards are made and adjusted for cancellations.

Impairments of Long-Lived Assets

We account for the impairment of long-lived assets (including finite-lived intangible assets) by performing an evaluation of the recoverability of the carrying value of long-lived asset (group) whenever events or changes in circumstances indicate that the carrying value of the asset (group) may not be recoverable. Examples of events or changes in circumstances that indicate that the recoverability of the carrying value of an asset (group) should be assessed include, but are not limited to, the following: a significant decrease in the market value of an asset, a significant change in the extent or manner in which an asset is used, a significant physical change in an asset, a significant adverse change in legal factors or in the business climate that could affect the value of an asset, an adverse action or assessment by a regulator, an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset, a current period operating or cash flow loss combined with a history of operating or cash flow losses and/or a projection or forecast that demonstrates continuing losses associated with an asset used for the purpose of producing revenue. We consider historical performance and anticipated future results in our evaluation of potential impairment. Accordingly, when indicators of impairment are present, we evaluate the carrying value of these assets (group) in relation to the operating performance of the business and future undiscounted cash flows expected to result from the use of these asset (groups). Impairment losses are recognized when the sum of expected future cash flows is less than the assets' (group's) carrying value.

Goodwill

Goodwill is subject to impairment tests annually or more frequently should indicators of impairment arise. The Company has determined since its only business is the development of recombinant vaccines that it operates as a single operating segment and has one reporting unit. The Company primarily utilizes the market approach and, if considered necessary, the income approach to determine if it has an impairment of its goodwill. The market approach is based on market value of invested capital. To ensure that the Company's capital stock is the appropriate measurement of fair value, the Company considers factors such as its trading volume, diversity of investors and analyst coverage. If considered necessary, the income approach is used as a confirming look to the market approach. Goodwill impairment may exist if the carrying value of the reporting unit exceeds its estimated fair value. If the carrying value of the reporting unit exceeds its fair value, step two of the impairment analysis is performed. In step two of the analysis, an impairment loss is recorded equal to the excess of the carrying value of the reporting unit's goodwill over its implied fair value, should such a circumstance arise.

At December 31, 2018 and 2017, the Company used the market approach to determine if the Company had an impairment of its goodwill. The fair value of the Company's single reporting unit was substantially higher than its carrying value, resulting in no impairment to goodwill at December 31, 2018 and 2017.

Recent Accounting Pronouncements

See “Note 3 Summary of Significant Accounting Policies” included in our Notes to Consolidated Financial Statements (under the caption “*Recent Accounting Pronouncements*”).

Results of Operations for Fiscal Years 2018, 2017 and 2016

The following is a discussion of the historical financial condition and results of operations of Novavax, including Novavax AB’s operations, and should be read in conjunction with the consolidated financial statements and notes thereto set forth in this Annual Report. Additional information concerning factors that could cause actual results to differ materially from those in our forward-looking statements is described under Part I, Item 1A, “Risk Factors” of this Annual Report.

Revenue:

	2018	**2017**	2016	**Change 2017 to 2018**	**Change 2016 to 2017**
Revenue (in thousands):					
Total revenue	$34,288	$31,176	$15,353	$ 3,112	$15,823

Revenue for 2018 was $34.3 million as compared to $31.2 million for 2017, an increase of $3.1 million, or 10%. Revenue for 2018 and 2017 was primarily comprised of services performed under the Grant Agreement and to a much lesser extent, revenue from Novavax AB. Revenue increased under the Grant Agreement by $1.0 million as a result of increased enrollment of participants in the Prepare trial, and by an additional $2.1 million as a result of increased Novavax AB activities.

Revenue for 2017 was $31.2 million as compared to $15.4 million for 2016, an increase of $15.8 million, or 103%. Revenue for 2017 and 2016 was primarily comprised of services performed under the Grant Agreement and to a much lesser extent, the HHS BARDA contract and revenue from Novavax AB. Revenue increased under the Grant Agreement in the amount of $18.8 million as a result of increased enrollment of participants in the Prepare trial, which was partially offset by $2.2 million in decreased revenue from services performed under the HHS BARDA contract, which expired in accordance with its terms in September 2016.

We expect revenue in 2019 under the Grant Agreement to be significantly lower than in 2018 as the Prepare trial is expected to conclude in 2019.

Expenses:

	2018	2017	2016	**Change 2017 to 2018**	**Change 2016 to 2017**
Expenses (in thousands):					
Research and development	$173,797	$168,435	$237,939	$ 5,362	$(69,504)
General and administrative	34,409	34,451	46,527	(42)	(12,076)
Total expenses	$208,206	$202,886	$284,466	$ 5,320	$(81,580)

Research and Development Expenses

Research and development expenses include salaries, stock-based compensation, laboratory supplies, consultants and subcontractors, including external contract research organizations, and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for our programs. In addition, indirect costs such as fringe benefits and overhead expenses related to research and development activities, are also included in research and development expenses. Research and development expenses increased to $173.8 million for 2018 from $168.4 million for 2017, an increase of $5.4 million, or 3%. The increase in research and development expenses was primarily due to increased development activities of ResVax and NanoFlu, partially offset by lower employee-related expenses associated with the Company's reduced bonus expense in 2018 and rent expense resulting from the 1201 Clopper Road lease termination in the first quarter of 2018. At December 31, 2018, we had 324 employees dedicated to our research and development programs versus 300 employees as of December 31, 2017. For 2019, we expect research and development expenses overall to decrease primarily due to the completion of activities related to the conclusion of the Prepare trial and partially offset by our planned Phase 3 clinical trial of NanoFlu following discussions with the FDA in the first half of 2019.

Research and development expenses decreased to $168.4 million for 2017 from $237.9 million for 2016, a decrease of $69.5 million, or 29%. The decrease in research and development expenses was primarily due to reduced development activities of our RSV F Vaccine for older adults and lower employee-related costs.

Expenses by Functional Area

We track our research and development expenses by the type of costs incurred in identifying, developing, manufacturing and testing vaccine candidates. We evaluate and prioritize our activities according to functional area and therefore believe that project-by-project information would not form a reasonable basis for disclosure to our investors. Historically, we did not account for internal research and development expenses by project, since our employees' work time is spread across multiple programs and our internal manufacturing clean-room facility produces multiple vaccine candidates.

The following summarizes our research and development expenses by functional area for the years ended December 31, 2018, 2017 and 2016 (in millions).

	2018	2017	2016
Manufacturing	$79.7	$81.6	$115.6
Vaccine Discovery	6.4	5.5	6.1
Clinical and Regulatory	87.7	81.3	116.2
Total research and development expenses	$173.8	$168.4	$237.9

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. As we obtain data from preclinical studies and clinical trials, we may elect to discontinue or delay clinical trials in order to focus our resources on more promising vaccine candidates. Completion of clinical trials may take several years or more, but the length of time can vary substantially depending upon the phase, size of clinical trial, primary and secondary endpoints and the intended use of the vaccine candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of participants who participate in the clinical trials;
- the number of sites included in the clinical trials;
- if clinical trial locations are domestic, international or both;
- the time to enroll participants;
- the duration of treatment and follow-up;
- the safety and efficacy profile of the vaccine candidate; and
- the cost and timing of, and the ability to secure, regulatory approvals.

As a result of these uncertainties, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when, and to what extent, we will generate future cash flows from our research projects.

General and Administrative Expenses

General and administrative expenses were flat at $34.4 million for 2018 versus $34.5 million for 2017. At December 31, 2018, we had 50 employees dedicated to general and administrative functions versus 48 employees as of December 31, 2017. For 2019, we expect general and administrative expenses to decrease due to reduced activities related to the development and potential commercialization of ResVax.

General and administrative expenses decreased to $34.5 million for 2017 from $46.5 million for 2016, a decrease of $12.1 million, or 26%. The decrease was primarily due to lower professional fees, including for pre-commercialization activities of our RSV F Vaccine in older adults, and lower employee-related costs, as compared to 2016.

Other Income (Expense):

	2018	2017	2016	**Change 2017 to 2018**	**Change 2016 to 2017**
Other Income (Expense) (in thousands):					
Investment income	$2,674	$1,946	$2,143	$ 728	$(197)
Interest expense	(13,612)	(14,072)	(12,965)	460	(1,107)
Other income (expense)	108	67	(31)	41	98
Total other income (expense), net	$(10,830)	$(12,059)	$(10,853)	$ 1,229	$(1,206)

We had total other expense, net of $10.8 million for 2018 compared to total other expense, net of $12.1 million for 2017, a decrease of $1.2 million. Our investment income increased in 2018 as compared to 2017 due to higher rates of return on our marketable securities.

We had total other expense, net of $12.1 million for 2017 compared to total other expense, net of $10.9 million for 2016, an increase of $1.2 million. Our interest expense increased due to the issuance of our Notes in the first quarter of 2016.

Net Loss:

	2018	2017	2016	**Change 2017 to 2018**	**Change 2016 to 2017**
Net Loss (in thousands, except per share information):					
Net loss	$(184,748)	$(183,769)	$(279,966)	$(979)	$96,197
Net loss per share	$(0.50)	$(0.63)	$(1.03)	$0.13	$0.40
Weighted average shares outstanding	369,757	292,669	270,802	77,088	21,867

Net loss for 2018 was $184.7 million, or $0.50 per share, as compared to $183.8 million, or $0.63 per share, for 2017, an increased net loss of $1.0 million.

Net loss for 2017 was $183.8 million, or $0.63 per share, as compared to $280.0 million, or $1.03 per share, for 2016, a decreased net loss of $96.2 million. The decreased net loss was primarily due to lower research and development spending, including decreased costs relating to the clinical trials and development activities of our RSV F Vaccine in older adults, and lower overall employee-related costs, as compared to 2016.

The increase in weighted average shares outstanding for 2018 and 2017 is primarily a result of sales of our common stock in 2018 and 2017.

Liquidity Matters and Capital Resources

Our future capital requirements depend on numerous factors including, but not limited to, the commitments and progress of our research and development programs, the progress of preclinical and clinical testing, the time and costs involved in obtaining regulatory approvals, the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights and manufacturing costs. We plan to continue to have multiple vaccines and product candidates in various stages of development, and we believe our operating expenses and capital requirements will fluctuate depending upon the timing of events, such as the scope, initiation, rate and progress of our preclinical studies and clinical trials and other research and development activities. We have primarily funded our operations with

proceeds from the sale of common stock in equity offerings, the issuance of convertible debt and revenue under our former contract with HHS BARDA and our current Grant Agreement with BMGF.

As of December 31, 2018, we had $103.9 million in cash and cash equivalents, marketable securities and restricted cash as compared to $186.4 million as of December 31, 2017. These amounts consisted of $70.2 million in cash and cash equivalents, $22.0 million in marketable securities and $11.8 million in restricted cash as of December 31, 2018 as compared to $106.3 million in cash and cash equivalents, $51.0 million in marketable securities and $29.1 million in restricted cash as of December 31, 2017.

The following table summarizes cash flows for 2018 and 2017:

	2018	2017	Change 2017 to 2018
Summary of Cash Flows (in thousands):			
Net cash (used in) provided by:			
Operating activities	$(184,825)	$(144,476)	$ (40,349)
Investing activities	28,596	35,968	(7,372)
Financing activities	102,805	64,540	38,265
Effect on exchange rate on cash, cash equivalents and restricted cash	(48)	142	(190)
Net decrease in cash, cash equivalents and restricted cash	(53,472)	(43,826)	(9,646)
Cash, cash equivalents and restricted cash at beginning of year	135,431	179,257	(43,826)
Cash, cash equivalents and restricted cash at end of year	$81,959	$135,431	$ (53,472)

Net cash used in operating activities increased to $184.8 million for 2018, as compared to $144.5 million for 2017. The increase in cash usage is primarily due to the receipt of a $15 million payment under the Grant Agreement with BMGF in 2018, as compared to receipt of a $25 million payment in 2017, increased research and development activities of ResVax and NanoFlu in 2018 and the timing of vendor payments. This increase also includes $11.3 million of one-time payments in 2018 that included our lease termination fee and a milestone payment to Wyeth Holdings LLC (formerly Wyeth Holdings Corporation), a subsidiary of Pfizer Inc. ("Wyeth"), along with the Company's annual bonus (partially offset by the Company's retention bonus paid in 2017). We adopted a new accounting standard in 2018 that requires restricted cash to be included in the beginning and ending cash balances on the statements of cash flows for all periods presented.

During 2018 and 2017, our investing activities consisted primarily of purchases and maturities of marketable securities and capital expenditures. Capital expenditures for 2018 and 2017 were $1.4 million and $4.2 million, respectively. The decrease in capital expenditures was primarily due to reduced capital requirements based on our current operating plans. In 2019, we expect our capital expenditures to decrease due to reduced activities related to the development and potential commercialization of ResVax.

Our financing activities consisted primarily of sales of our common stock, and to a much lesser extent, stock option exercises and purchases under our employee stock purchase plan. In 2018, we completed a public offering of 34,848,507 shares of our common stock, including 4,545,457 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of $1.65 per share resulting in net proceeds of approximately $54 million, and we received net proceeds of $46.2 million from selling shares of common stock through our At Market Issuance Sales Agreement entered into in January 2017 ("January 2017 Sales Agreement") and December 2017 Sales Agreement. From January 1 to March 12, 2019, the Company sold 50.3 million shares of common stock under the December 2017 Sales Agreement resulting in $37.9 million in net proceeds. On March 12, 2019, we sold 5.5 million shares of common stock under our December 2018 Sales Agreement resulting in $2.9 million in net proceeds. In 2017, we received net proceeds of $63.4 million from selling shares of common stock through our January 2017 Sales Agreement.

In May 2016, we entered into a lease for a facility located in Gaithersburg, Maryland and under the terms of the lease the landlord provided us with a tenant improvement allowance of up to $9.6 million, of which $1.2 million was funded through the termination of the lease. In January 2018, this lease was terminated and we paid a termination fee to the landlord of $5.3 million in the first quarter of 2018, which we believe was less than the potential total lease and operating expense cash obligations that could have been incurred over one year.

In July 2018, we terminated a 2007 agreement to license certain rights from Wyeth. The Wyeth license offered a non-exclusive, worldwide license to a family of patents and patent applications covering virus-like-particles ("VLP") technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. At present, we have no programs to which the Wyeth license applies, and CPLB's recombinant trivalent seasonal VLP influenza vaccine ("CadiFlu") is only licensed in India. In September 2015, due to CPLB's initiation of a Phase 3 clinical trial of

CadiFlu in 2014, we entered into an amendment to the Wyeth license that, among other things, increased the milestone payment ("Milestone") from $3 million to as much as $4 million if not paid before December 31, 2017. The Milestone of $4 million was paid in the first quarter of 2018. The Milestone was recorded as a research and development expense in 2014. Payments under the Wyeth license as of December 31, 2018 aggregated to $11.6 million.

Going Concern

The accompanying consolidated financial statements included in Item 15.(a)(1) have been prepared assuming that the Company will continue as a going concern within one year after the date that the financial statements are issued. During 2018, we incurred a net loss of $184.7 million and had net cash flows used in operating activities of $184.8 million. At December 31, 2018, we had $103.9 million in cash and cash equivalents, marketable securities and restricted cash and had no committed source of additional funding from either debt or equity financings. Management believes that given the Company's current cash position and forecasted negative cash flows from operating activities over the next twelve months as we continue our product development activities, including our planned ResVax submission of a BLA with the FDA and/or a MAA with the EMA in 2020, and our planned Phase 3 clinical trial of NanoFlu following discussions with the FDA in the first half of 2019, there is substantial doubt about our ability to continue as a going concern through one year from the date that these financial statements are issued, without obtaining additional financing or entering into another form of non-equity or debt arrangement.

Our ability to fund Company operations is dependent upon management's plans, which include raising additional capital in the near term primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements and in the longer term, from revenue related to product sales, to the extent our product candidates receive marketing approval and can be commercialized. New financings may not be available to us on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances and marketing, distribution or licensing arrangements may require us to give up some or all of our rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If we are unable to obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of or eliminate one or more of our research and development programs, and/or downsize our organization.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

Contractual Obligations:	Total	Less than One Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Operating leases	$29,597	$ 6,682	$10,722	$12,193	$ —
Convertible notes payable	325,000	—	—	325,000	—
Total contractual obligations	$354,597	$ 6,682	$10,722	$337,193	$ —

See Note 9 to the consolidated financial statements included in the Annual Report regarding our convertible notes payable, which will mature on February 1, 2023, and bear cash interest of 3.75%, payable February 1 and August 1 of each year.

Off-Balance Sheet Arrangements

We are not involved in any off-balance sheet agreements that have or are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income. As of December 31, 2018, we had cash and cash equivalents of $70.2 million, marketable securities of $22.0 million, all of which are short-term in nature, $11.8 million in restricted cash and working capital of $73.7 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of December 31, 2018, our investments were classified as available-for-sale. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our marketable securities when they mature and the proceeds are reinvested into new marketable securities and, therefore, could impact our cash flows and results of operations.

Interest and dividend income is recorded when earned and included in investment income. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in investment income. The specific identification method is used in computing realized gains and losses on the sale of our securities.

We are headquartered in the U.S. where we conduct the vast majority of our business activities. We have one foreign consolidated subsidiary, Novavax AB, which is located in Sweden. A 10% decline in the exchange rate between the U.S. dollar and Swedish Krona would result in a decline of stockholders’ deficit of approximately $2.7 million at December 31, 2018.

Our Notes have a fixed interest rate and we have no additional material debt. As such, we do not believe that we are exposed to any material interest rate risk as a result of our borrowing activities.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is set forth on pages F-1 to F-24.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures" (defined in SEC Rule 13a-15(e)) refers to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (the "Exchange Act") is recorded, processed, summarized and reported, within time periods specified in the rules and forms of the Securities and Exchange Commission. "Disclosure controls and procedures" include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

The Company's management, with the participation of the chief executive officer and the chief financial officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this Annual Report (the "Evaluation Date"). Based on that evaluation, the Company's chief executive officer and chief financial officer have concluded that, as of the Evaluation Date, such controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange

Act, as a process designed by, or under the supervision of, the Company's principal executive officer and principal financial officer and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States ("GAAP"). Such internal control includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of an unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, our management has determined that, as of December 31, 2018, our internal controls over financial reporting are effective based on those criteria.

Ernst & Young LLP has issued a report on our internal control over financial reporting. This report is included in the Reports of Independent Registered Public Accounting Firm in Item 15.(a)(1).

Changes in Internal Control over Financial Reporting

Our management, including our chief executive officer and chief financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2018, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2018 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from our definitive Proxy Statement for our 2019 Annual Meeting of Stockholders scheduled to be held in June 2019 (the “2019 Proxy Statement”). We expect to file the 2019 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2018.

Item 11. EXECUTIVE COMPENSATION

We incorporate herein by reference the information required by this item concerning executive compensation to be contained in the 2019 Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

We incorporate herein by reference the information required by this item concerning security ownership of certain beneficial owners and management and related stockholder matters to be contained in the 2019 Proxy Statement.

The following table provides our equity compensation plan information as of December 31, 2018. Under these plans, our common stock may be issued upon the exercise of stock options and purchases under our Employee Stock Purchase Plan ("ESPP"). See also the information regarding our stock options and ESPP in Note 11 to the consolidated financial statements included herewith.

Equity Compensation Plan Information

Plan Category	**Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights**	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))**
	(a)		**(c)**
Equity compensation plans approved by security holders(1)	59,509,610	$3.15	11,184,100
Equity compensation plans not approved by security holders	N/A	N/A	N/A

(1) Includes our 2015 Stock Incentive Plan, 2005 Stock Incentive Plan and ESPP.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

We incorporate herein by reference the information required by this item concerning certain related party transactions set forth in Note 15 to our consolidated financial statements included herewith. We incorporate herein by reference other information required by this item concerning certain other relationships and related transactions and director

independence to be contained in the 2019 Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

We incorporate herein by reference the information required by this item concerning principal accountant fees and services to be contained in the 2019 Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of the Annual Report:

(1) Index to Financial Statements

(2) Financial Statement Schedules

Financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

(3) Exhibits

Exhibits marked with a single asterisk (*) are filed herewith.

Exhibits marked with a double plus sign (††) refer to management contracts, compensatory plans or arrangements.

Confidential treatment has been granted for portions of exhibits marked with a double asterisk (**).

All other exhibits listed have previously been filed with the SEC and are incorporated herein by reference.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant dated June 18, 2015 (Incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
3.2	Amended and Restated By-Laws of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 12, 2013 (File No. 000-26770))
4.1	Specimen stock certificate for shares of common stock of the Registrant, par value $.01 per share (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 10, filed on September 14, 1995 (File No. 000-26770))
4.2	Indenture (including form of Notes) with respect to Novavax, Inc.'s 3.75% Convertible Senior Notes due 2023, dated as of January 29, 2016, between Novavax, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on January 29, 2016 (File No. 000-26770))
10.1††	Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 12, 2013 (File No. 000-26770))

10.2††	Amendment to Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Appendix 1 of the Registrant's Definitive Proxy Statement filed on April 30, 2014 in connection with the Annual Meeting held on June 12, 2014 (File No. 000-26770))
10.3††	Form of Non-Statutory Stock Option Award Agreement granted under the Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 27, 2015 (File No. 000-26770))
10.4††	Form of Incentive Stock Option Award Agreement granted under the Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 27, 2015 (File No. 000-26770))
10.5††	Amended and Restated 2013 Employee Stock Purchase Plan (Incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement filed on April 30, 2018 in connection with the Annual Meeting held on June 14, 2018 (File No. 000-26770))
10.6††	Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement filed on April 30, 2018 in connection with the Annual Meeting held on June 14, 2018 (File No. 000-26770))
10.7††	Form of Non-Statutory Stock Option Award Agreement granted under the Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
10.8††	Form of Incentive Stock Option Award Agreement granted under the Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
10.9††	Form of Incentive Stock Option Award Agreement granted under the Novavax, Inc. Amended and Restated 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on February 27, 2017 (File No. 000-26770))
10.10††	Form of Incentive Stock Option Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Performance- and Time-Based Vesting) (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on November 16, 2016 (File No. 000-26770))
10.11††	Form of Restricted Stock Award Agreement granted under the Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
10.12*††	Form of Restricted Stock Unit Agreement granted under the Novavax, Inc. Amended and Restated 2015 Stock Incentive Plan
10.13††	Form of Director Deferred Fee Agreement (Incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 29, 2016 (File No. 000-26770))

10.14††	Employment Agreement between Novavax, Inc. and Stanley C. Erck, dated as of June 22, 2011 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed on August 9, 2011 (File No. 000-26770))
10.15††	Employment Agreement between Novavax, Inc. and Gregory M. Glenn dated July 1, 2010 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 6, 2010 (File No. 000-26770))

10.16††	Employment Agreement between Novavax, Inc. and John A. Herrmann dated April 1, 2012 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016 (File No. 000-26770))
10.17††	Employment Agreement between Novavax, Inc. and John J. Trizzino dated March 3, 2014 (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016 (File No. 000-26770))
10.18††	Novavax, Inc. Amended and Restated Change in Control Severance Benefit Plan (Incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on February 27, 2017 (File No. 000-26770))
10.19††	Form of Indemnification Agreement entered into between the Registrant and its directors and officers (Incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 16, 2010 (File No. 000-26770))
10.20	Lease Agreement for space at 9920 Belward Campus Drive between GP Rock One, LLC and Novavax, Inc., dated as of May 7, 2007 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 11, 2008 (File No. 000-26770))
10.21	First Amendment to Lease Agreement for space at 9920 Belward Campus Drive between BMR-9920 Belward Campus Q, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated as of May 30, 2008 (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 11, 2008 (File No. 000-26770))
10.22	Second Amendment to Lease Agreement for space at 9920 Belward Campus Drive between BMR-9920 Belward Campus Q, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated as of June 26, 2008 (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 11, 2008 (File No. 000-26770))
10.23	Third Amendment to Lease Agreement for space at 9920 Belward Campus Drive between BMR-9920 Belward Campus Drive, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated February 29, 2016 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016 (File No. 000-26770))
10.24	Fourth Amendment to Lease Agreement for space at 9920 Belward Campus Drive between BMR-9920 Belward Campus Drive, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated March 31, 2017 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed on May 8, 2017 (File No. 000-26770))
10.25*	Fifth Amendment to Lease Agreement for space at 9920 Belward Campus Drive between ARE-MARYLAND NO. 46, LLC and Novavax, Inc., dated January 16, 2019
10.26	Lease Agreement for space at 20 Firstfield Road between ARE-20/22/1300 Firstfield Quince Orchard, LLC and Novavax, Inc., dated as of November 18, 2011 (Incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 14, 2012 (File No. 000-26770))

10.27	Lease Agreement for space at 22 Firstfield Road between ARE-20/22/1300 Firstfield Quince Orchard, LLC and Novavax, Inc., dated as of November 18, 2011 (Incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 14, 2012 (File No. 000-26770))

10.28	Deed of Lease for space at 21 Firstfield Road between Firstfield Holdco, LLC and Novavax, Inc., dated as of February 4, 2015 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 21, 2015 (File No. 000-26770))
10.29	First Amendment to Deed of Lease for space at 21 Firstfield Road between Firstfield Holdco, LLC and Novavax, Inc., dated as of August 17, 2015 (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on August 21, 2015 (File No. 000-26770))
10.30	Second Amendment to Deed of Lease for space at 21 Firstfield Road between BMR-Firstfield LLC (formerly Firstfield Holdco, LLC) and Novavax, Inc., dated as of March 31, 2017 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed on May 8, 2017 (File No. 000-26770))
10.31	Deed of Lease for space at 1201 Clopper Road between IP9 1201 Clopper Road, LLC and Novavax, Inc., dated May 3, 2016 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016 (File No. 000-26770))
10.32	First Amendment to Deed of Lease for space at 1201 Clopper Road between IP9 1201 Clopper Road, LLC and Novavax, Inc., dated August 23, 2017 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 7, 2017 (File No. 000-26770))
10.33**	Contract, effective as of February 24, 2011, between Novavax, Inc. and HHS/OS/ASPR/BARDA (Incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A for the quarter ended on March 31, 2011, filed on November 4, 2011 (File No. 000-26770))
10.34**	Contract Amendment/Modification No. 5 between Novavax, Inc. and HHS/OS/ASPR/BARDA, dated February 21, 2014 (Incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 12, 2014 (File No. 000-26770))
10.35**	Contract Amendment/Modification No. 6 between Novavax, Inc. and HHS/OS/ASPR/BARDA, dated September 22, 2014 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed on November 6, 2014 (File No. 000-26770))
10.36**	Contract Amendment/Modification No. 8 between Novavax, Inc. and HHS/OS/ASPR/BARDA, dated June 5, 2015 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015 (File No. 000-26770))
10.37**	Second Amended and Restated Joint Venture Agreement between Novavax Inc. and Cadila Pharmaceuticals Limited, dated as of July 17, 2018 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed on November 7, 2018 (File No. 000-26770))
10.38**	Second Amended and Restated Novavax Product License Agreement between Novavax, Inc. and CPL Biologicals Private Limited, dated as of July 17, 2018 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed on November 7,

	2018 (File No. 000-26770))
10.39**	Grant Agreement between Bill and Melinda Gates Foundation and Novavax, Inc., dated as of September 25, 2015 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 9, 2015 (File No. 000-26770))

10.40**	Global Access Commitments Agreement between Bill and Melinda Gates Foundation and Novavax, Inc., dated as of September 25, 2015 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 9, 2015 (File No. 000-26770))
10.41	Base Call Option Transaction Confirmation, dated as of January 25, 2016, between Novavax and JPMorgan Chase Bank, National Association, London Branch (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 29, 2016 (File No. 000-26770))
10.42	Base Call Option Transaction Confirmation, dated as of January 25, 2016, between Novavax and Morgan Stanley & Co. LLC (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on January 29, 2016 (File No. 000-26770))
10.43	Additional Base Call Option Transaction Confirmation, dated as of February 2, 2016, between Novavax and JPMorgan Chase Bank, National Association, London Branch (Incorporated by reference to Exhibit 10.51 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 29, 2016 (File No. 000-26770))
10.44	Additional Base Call Option Transaction Confirmation, dated as of February 2, 2016, between Novavax and Morgan Stanley & Co. LLC (Incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 29, 2016 (File No. 000-26770))
14	Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed on August 9, 2011 (File No. 000-26770))
21*	Subsidiaries of the Registrant
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of December 31, 2018 and 2017, (ii) the Consolidated Statements of Operations for the three years in the period ended December 31, 2018, (iii) the Consolidated Statements of Comprehensive Loss for the three years in the period ended December 31, 2018, (iv) the Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the three years in the period ended December 31, 2018, (v) the Consolidated Statements

of Cash Flows for the three years in the period ended December 31, 2018, and (vi) the Notes to Consolidated Financial Statements.

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NOVAVAX, INC.

By: /s/ Stanley C. Erck
President and Chief Executive Officer

Date: March 18, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Name	Title	Date
/s/ Stanley C. Erck Stanley C. Erck	President and Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2019
/s/ John J. Trizzino John J. Trizzino	Senior Vice President, Chief Business Officer, Chief Financial Officer and Treasurer (Principal Financial and Principal Accounting Officer)	March 18, 2019
/s/ James F. Young James F. Young	Chairman of the Board of Directors	March 18, 2019
/s/ Richard H. Douglas Richard H. Douglas	Director	March 18, 2019
/s/ Gary C. Evans Gary C. Evans	Director	March 18, 2019
/s/ Rachel K. King	Director	

Rachel K. King		March 18, 2019
/s/ Michael A. McManus Michael A. McManus	Director	March 18, 2019
/s/ Rajiv I. Modi Rajiv I. Modi	Director	March 18, 2019

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2018, 2017 and 2016

Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Novavax, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Novavax, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 18, 2019 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2014.

Baltimore, Maryland

March 18, 2019

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Novavax, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Novavax Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Novavax, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated March 18, 2019 expressed an unqualified opinion thereon that included an explanatory paragraph regarding the Company's ability to continue as a going concern.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying *Management's Report on Internal Control over Financial Reporting* included in Item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was

maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Baltimore, Maryland
March 18, 2019

NOVAVAX, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2018	2017
	(in thousands, except share and per share information)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,154	$ 106,307
Marketable securities	21,980	50,996
Restricted cash	10,847	28,234
Prepaid expenses and other current assets	16,295	17,774
Total current assets	119,276	203,311
Restricted cash	958	890
Property and equipment, net	28,426	35,987
Intangible assets, net	6,541	7,873
Goodwill	51,967	53,563
Other non-current assets	810	869
Total assets	$ 207,978	$ 302,493
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,301	$ 5,613
Accrued expenses	19,550	29,610
Accrued interest	5,078	5,078
Deferred revenue	10,010	25,625
Other current liabilities	1,600	7,749
Total current liabilities	45,539	73,675
Deferred revenue	2,500	2,500
Convertible notes payable	319,187	317,763
Other non-current liabilities	8,687	10,287
Total liabilities	375,913	404,225
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common stock, $0.01 par value, 600,000,000 shares authorized at December 31, 2018 and 2017; and 384,906,037 shares issued and 384,450,607 shares outstanding at December 31, 2018 and 323,684,820 shares issued and 323,229,390 shares	3,849	3,237

outstanding at December 31, 2017		
Additional paid-in capital	1,140,964	1,020,457
Accumulated deficit	(1,299,107)	(1,114,359)
Treasury stock, 455,430 shares, cost basis at both December 31, 2018 and 2017	(2,450)	(2,450)
Accumulated other comprehensive loss	(11,191)	(8,617)
Total stockholders' deficit	(167,935)	(101,732)
Total liabilities and stockholders' deficit	$ 207,978	$ 302,493

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

NOVAVAX, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2018	2017	2016
	(in thousands, except per share information)		
Revenue:			
Government contract	$ —	$ —	$ 2,184
Grant and other	34,288	31,176	13,169
Total revenue	34,288	31,176	15,353
Expenses:			
Research and development	173,797	168,435	237,939
General and administrative	34,409	34,451	46,527
Total expenses	208,206	202,886	284,466
Loss from operations	(173,918)	(171,710)	(269,113)
Other income (expense):			
Investment income	2,674	1,946	2,143
Interest expense	(13,612)	(14,072)	(12,965)
Other income (expense)	108	67	(31)
Net loss	$ (184,748)	$ (183,769)	$ (279,966)
Basic and diluted net loss per share	$ (0.50)	$ (0.63)	$ (1.03)
Basic and diluted weighted average number of common shares outstanding	369,757	292,669	270,802

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Net loss	$(184,748)	$(183,769)	$(279,966)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities available-for-sale	12	(50)	54
Foreign currency translation adjustment	(2,586)	3,247	(2,744)
Other comprehensive income (loss)	(2,574)	3,197	(2,690)

Comprehensive loss	$(187,322)	$(180,572)	$(282,656)

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

NOVAVAX, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
Year Ended December 31, 2018, 2017 and 2016

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income(Loss)	Total Stockholders' Equity (Deficit)
	(in thousands, except share information)						
Balance at December 31, 2015	270,426,662	$ 2,704	$ 951,569	$ (650,030)	$ (2,450)	$ (9,124)	$ 292,669
Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	19,160	—	—	—	19,160
Exercise of stock options/Purchases under ESPP	1,254,735	13	3,789	—	—	—	3,802
Restricted stock issued as compensation	20,000	—	—	—	—	—	—
Payment of capped call transactions and costs	—	—	(38,521)	—	—	—	(38,521)
Unrealized gain on marketable securities	—	—	—	—	—	54	54
Foreign currency translation adjustment	—	—	—	—	—	(2,744)	(2,744)
Net loss	—	—	—	(279,966)	—	—	(279,966)
Balance at December 31, 2016	271,701,397	2,717	935,997	(929,996)	(2,450)	(11,814)	(5,546)
Cumulative effect of adoption of ASU 2016-09	—	—	594	(594)	—	—	—
Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	19,809	—	—	—	19,809
Exercise of stock options/Purchases under ESPP	1,093,513	11	1,141	—	—	—	1,152
Issuance of common stock, net of issuance costs of $1,065	50,889,910	509	62,916	—	—	—	63,425
Unrealized loss on marketable securities	—	—	—	—	—	(50)	(50)

Foreign currency translation adjustment	—	—	—	—	—	3,247	3,247
Net loss	—	—	—	(183,769)	—	—	(183,769)
Balance at December 31, 2017	323,684,820	3,237	1,020,457	(1,114,359)	(2,450)	(8,617)	(101,732)
Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	18,314	—	—	—	18,314
Exercise of stock options/Purchases under ESPP	2,411,212	24	2,721	—	—	—	2,745
Restricted stock cancelled	(18,750)	—	—	—	—	—	—
Issuance of common stock, net of issuance costs of $4,265	58,828,755	588	99,472	—	—	—	100,060
Unrealized gain on marketable securities	—	—	—	—	—	12	12
Foreign currency translation adjustment	—	—	—	—	—	(2,586)	(2,586)
Net loss	—	—	—	(184,748)	—	—	(184,748)
Balance at December 31, 2018	384,906,037	$3,849	$1,140,964	$(1,299,107)	$(2,450)	$ (11,191)	$(167,935)

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

NOVAVAX, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Operating Activities:			
Net loss	$(184,748)	$(183,769)	$(279,966)
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	8,159	9,817	8,505
(Gain) Loss on disposal of property and equipment	(55)	269	374
Non-cash impact of lease termination	(4,381)		
Amortization of debt issuance costs	1,424	1,424	1,305
Lease incentives received		1,933	1,963
Non-cash stock-based compensation	18,314	19,809	19,160
Other	(2,396)	2,715	663
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	1,212	2,590	(1,119)
Accounts payable and accrued expenses	(6,744)	5,192	(4,808)
Deferred revenue	(15,610)	(4,456)	(6,057)
Other liabilities			1,212
Net cash used in operating activities	(184,825)	(144,476)	(258,768)
Investing Activities:			
Capital expenditures	(1,372)	(4,189)	(18,202)
Purchases of marketable securities	(120,150)	(218,045)	(356,556)
Proceeds from maturities of marketable securities	150,118	258,202	402,775
Net cash provided by investing activities	28,596	35,968	28,017
Financing Activities:			
Principal payments of capital leases		(37)	(71)
Principal payments of notes payable			(395)
Proceeds from issuance of convertible notes			325,000
Payments of costs related to issuance of convertible notes			(9,966)
Payments for capped call transactions and costs			(38,521)
Net proceeds from sales of common stock	100,060	63,425	
Proceeds from the exercise of stock options and employee stock purchases	2,745	1,152	3,802
Net cash provided by financing activities	102,805	64,540	279,849
Effect of exchange rate on cash, cash equivalents and restricted cash	(48)	142	(335)
Net (decrease) increase in cash, cash equivalents and restricted cash	(53,472)	(43,826)	48,763
Cash, cash equivalents and restricted cash at beginning of year	135,431	179,257	130,494
Cash, cash equivalents and restricted cash at end of year	$81,959	$135,431	$179,257

Supplemental disclosure of non-cash activities:			
Capital expenditures included in accounts payable and accrued expenses	$519	$15	$697
Supplemental disclosure of cash flow information:			
Cash interest payments	$12,188	$12,188	$6,189

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

NOVAVAX, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2018, 2017 and 2016

Note 1 – Organization

Novavax, Inc. ("Novavax," and together with its wholly owned subsidiary, Novavax AB, the "Company") is a late-stage biotechnology company focused on the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. The Company's vaccine candidates, including ResVax™ and NanoFlu™, are genetically engineered, three-dimensional nanostructures of recombinant proteins critical to disease pathogenesis and may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or traditional vaccines. The Company's product pipeline targets a variety of infectious diseases.

Note 2 – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern within one year after the date that the financial statements are issued. During 2018, the Company incurred a net loss of $184.7 million and had net cash flows used in operating activities of $184.8 million. At December 31, 2018, the Company had $103.9 million in cash and cash equivalents, marketable securities and restricted cash and had no committed source of additional funding from either debt or equity financings. Management believes that given the Company's current cash position and forecasted negative cash flows from operating activities over the next twelve months as it continues its product development activities, including its planned ResVax submission of a Biologics License Application ("BLA") with the U.S. Food and Drug Administration ("FDA") and/or a Marketing Authorization Application ("MAA") with the European Medicines Agency in 2020, and its planned Phase 3 clinical trial of NanoFlu following discussions with the FDA in the first half of 2019, there is substantial doubt about its ability to continue as a going concern through one year from the date that these financial statements are issued, without obtaining additional financing or entering into another form of non-equity or debt arrangement.

The Company's ability to fund its operations is dependent upon management's plans, which include raising additional capital in the near term primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements and in the longer term, from revenue related to product sales, to the extent its product candidates receive marketing approval and can be commercialized. New financings may not be available to the Company on commercially acceptable terms, or at all. Also, any collaborations, strategic alliances and marketing, distribution or licensing arrangements may require the Company to give up some or all of its

rights to a product or technology, which in some cases may be at less than the full potential value of such rights. If the Company is unable to obtain additional capital, the Company will assess its capital resources and may be required to delay, reduce the scope of or eliminate one or more of its research and development programs, and/or downsize its organization.

The consolidated financial statements do not include any adjustments that might be necessary if the Company is not able to continue as a going concern.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Novavax, Inc. and its wholly owned subsidiary, Novavax AB. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid investments with maturities of three months or less from the date of purchase. Cash and cash equivalents consist of the following at December 31 (in thousands):

	2018	2017
Cash	$6,750	$10,482
Money market funds	39,168	36,762
Asset-backed securities	15,000	16,007
Corporate debt securities	9,236	43,056
Cash and cash equivalents	$70,154	$106,307

Cash equivalents are recorded at cost, which approximate fair value due to their short-term nature.

Marketable Securities

Marketable securities consist of debt securities with maturities greater than three months from the date of purchase that include commercial paper, asset-backed securities and corporate notes. Classification of marketable securities between current and non-current is dependent upon the maturity date at the balance sheet date taking into consideration the Company's ability and intent to hold the investment to maturity.

Interest and dividend income is recorded when earned and included in investment income in the consolidated statements of operations. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in investment income in the consolidated statements of operations. The specific identification method is used in computing realized gains and losses on the sale of the Company's securities.

The Company classifies its marketable securities with readily determinable fair values as "available-for-sale." Investments in securities that are classified as available-for-sale are measured at fair market value in the consolidated balance sheets, and unrealized gains and losses on marketable securities are reported as a separate component of stockholders' deficit until realized. Marketable securities are evaluated periodically to determine whether a decline in value is "other-than-temporary." The term "other-than-temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for a near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria, such as the magnitude and duration of the decline, as well as the Company's ability to hold the

securities until market recovery, to predict whether the loss in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the security is reduced and the impairment is recorded as other income (expense) in the consolidated statements of operations.

Concentration of Credit Risk

Financial instruments, which possibly expose the Company to concentration of credit risk, consist primarily of cash and cash equivalents and marketable securities. The Company's investment policy limits investments to certain types of instruments, including asset-backed securities, high-grade corporate debt securities and money market funds, places restrictions on maturities and concentrations in certain industries and requires the Company to maintain a certain level of liquidity. At times, the Company maintains cash balances in financial institutions, which may exceed federally insured limits. The Company has not experienced any losses relating to such accounts and believes it is not exposed to a significant credit risk on its cash and cash equivalents.

Fair Value Measurements

The Company applies Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), for financial and non-financial assets and liabilities.

ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

Restricted Cash

The Company's current and non-current restricted cash includes payments received under the Grant Agreement (as defined in Note 7) with the Bill & Melinda Gates Foundation ("BMGF") under which the Company was awarded a grant of up to $89.1 million and cash collateral accounts under letters of credit that serve as security deposits for certain facility leases. The Company has and will utilize the Grant Agreement funds as it incurs expenses for services performed under the agreement. At December 31, 2018 and 2017, the restricted cash balances (both current and non-current) consist of payments received under the Grant Agreement of $10.8 million and $27.4 million, respectively, and security deposits of $1.0 million and $1.7 million, respectively.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the statement of cash flows at December 31 (in thousands):

	2018	2017
Cash and cash equivalents	$70,154	$106,307
Restricted cash current	10,847	28,234
Restricted cash non-current	958	890
Cash, cash equivalents and restricted cash	$81,959	$135,431

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the assets, generally three to seven years. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the estimated useful lives of the improvements or the remaining term of the lease. Repairs and maintenance costs are expensed as incurred.

Other Intangible Assets

The Company's intangible assets include proprietary adjuvant technology and collaboration agreements, which were measured at their estimated fair values as of their acquisition dates. Amortization expense for intangible assets is recorded on a straight-line basis over the expected useful lives of the assets, ranging from seven to 20 years.

Impairment of Long-Lived Assets

Long-lived assets, including property and equipment and other intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable based on the criteria for accounting for the impairment or disposal of long-lived assets under ASC Topic 360, *Property, Plant and Equipment.*

Goodwill

Goodwill is subject to impairment tests annually or more frequently should indicators of impairment arise. The Company has determined that, because its only business is the development of recombinant vaccines, it operates as a single operating segment and has one reporting unit. The Company utilizes primarily the market approach and, if considered necessary, the income approach to determine if it has an impairment of its goodwill. The market approach is based on market value of invested capital. To ensure that the Company's capital stock is the appropriate measurement of fair value, the Company considers factors such as its trading volume, diversity of investors and analyst coverage. If considered necessary, the income approach is used to corroborate the results of the market approach. Goodwill impairment may exist if the carrying value of the reporting unit exceeds its estimated fair value. If the carrying value of the reporting unit exceeds its fair value, step two of the impairment analysis is performed. In step two of the analysis, an impairment loss is recorded equal to the excess of the carrying value of the reporting unit's goodwill over its implied fair value, should such a circumstance arise.

At December 31, 2018 and 2017, the Company used the market approach to determine if the Company had an impairment of its goodwill. The fair value of the Company's single reporting unit was substantially higher than its carrying value, resulting in no impairment to goodwill at December 31, 2018 and 2017.

Equity Method Investment

The Company has an equity investment in CPL Biologicals Private Limited ("CPLB"). The Company accounts for this investment using the equity method (see Note 7). Under the equity method of accounting, investments are stated at initial cost and are adjusted for subsequent additional investments and the Company's proportionate share of earnings or losses and distributions up to the amount initially invested or advanced.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board ("FASB"), issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09" or "Topic 606"), and subsequently issued amendments to ASU 2014-09, to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The new revenue standard became effective for the Company on January 1, 2018, and was adopted using the modified retrospective method. The adoption of the new revenue standard as of January 1, 2018 did not materially change the Company's timing of revenue recognition as the majority of its revenue continues to be recognized under its Grant Agreement with BMGF (see discussion below). Since the Company did not identify any accounting changes that impact its revenue recognition timing, no adjustment to accumulated deficit was required upon adoption.

Under the new revenue standard for arrangements that are determined within the scope of Topic 606, the Company recognizes revenue following the five-step model: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines the performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company performs research and development under grant, license and clinical development agreements. Payments received in advance of work performed are recorded as deferred revenue.

The Company's current revenue primarily consists of revenue under its Grant Agreement with BMGF (see Note 7). The Company is reimbursed for certain costs that support development activities, including the Company's global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and efforts to obtain World

Health Organization (“WHO”) prequalification of its RSV F Vaccine for infants via maternal immunization (“ResVax™”). The Company’s Grant Agreement does not provide a direct economic benefit to BMGF. Rather, the Company entered into an agreement with BMGF to make a certain amount of ResVax available and accessible at affordable pricing to people in certain low and middle income countries. Based on these circumstances, the Company does not consider BMGF to be a customer and concluded the Grant Agreement is outside the scope of Topic 606. Payments received under the Grant Agreement are considered conditional contributions under the scope of ASC 958-605, *Not-for-Profit Entities – Revenue Recognition*, and are recorded as deferred revenue until the period in which such research and development activities are performed and revenue can be recognized.

The Company analyzed the Grant Agreement with BMGF to determine whether the payments received should be recorded as revenue or as a reduction to research and development expenses. In reaching the determination that such payments should be recorded as revenue, management considered a number of factors, including whether the Company is principal under the arrangement, and whether the arrangement is significant to, and part of, the Company’s core operations. Further, management has consistently applied its policy of presenting such amounts as revenue.

Stock-Based Compensation

The Company accounts for stock-based compensation related to grants of stock options, restricted stock awards and purchases under the Company's Employee Stock Purchase Plan, as amended and restated (the "ESPP") at fair value. The Company recognizes compensation expense related to such awards on a straight-line basis over the requisite service period (generally the vesting period) of the equity awards, which typically occurs ratably over periods ranging from six months to four years. Effective January 1, 2017, the Company accounts for forfeitures when they occur (see discussion below).

The expected term of stock options granted is based on the Company's historical option exercise experience and post-vesting forfeiture experience using the historical expected term from the vesting date, whereas the expected term for purchases under the ESPP is based on the purchase periods included in the offering. The expected volatility is determined using historical volatilities based on stock prices over a look-back period corresponding to the expected term. The risk-free interest rate is determined using the yield available for zero-coupon U.S. Government issues with a remaining term equal to the expected term. The Company has never paid a dividend, and as such, the dividend yield is zero, and the Company does not intend to pay dividends in the foreseeable future.

The Company adopted ASU 2016-09, *Compensation – Stock Compensation (Topic 718)* on the effective date, January 1, 2017, and, as part of the adoption, elected to account for forfeitures when they occur. The impact from adoption of the provisions related to forfeitures was reflected in the Company's consolidated financial statements on a modified retrospective basis, resulting in an adjustment to accumulated deficit of $0.6 million on January 1, 2017.

Restricted stock awards are recorded as compensation expense over the expected vesting period based on the fair value at the award date using the straight-line method of amortization.

See Note 11 for a further discussion on stock-based compensation.

Research and Development Expenses

Research and development expenses include salaries, stock-based compensation, laboratory supplies, consultants and subcontractors, including external contract research organizations ("CROs"), and other expenses associated with the Company's process development, manufacturing, clinical, regulatory and quality assurance activities for its programs. In addition, related indirect costs such as, fringe benefits and overhead expenses, are also included in research and

development expenses. Research and development activities are expensed as incurred.

Accrued Research and Development Expenses

The Company accrues research and development expenses, including clinical trial-related expenses, as the services are performed, which may include estimates of those expenses incurred, but not invoiced. The Company uses information provided by third-party service providers and CROs, invoices and internal estimates to determine the progress of work performed on the Company's behalf. Assumptions based on clinical trial protocols, contracts and participant enrollment data are also developed to determine and analyze these estimates and accruals.

Income Taxes

The Company accounts for income taxes in accordance with ASC Topic 740, *Income Taxes*. Under the liability method, deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in income in the period such changes are enacted. A valuation allowance is established when necessary to reduce net deferred tax assets to the amount expected to be realized.

Tax benefits associated with uncertain tax positions are recognized in the period in which one of the following conditions is satisfied: (1) the more likely than not recognition threshold is satisfied; (2) the position is ultimately settled through negotiation or litigation; or (3) the statute of limitations for the taxing authority to examine and challenge the position has expired. Tax benefits associated with an uncertain tax position are reversed in the period in which the more likely than not recognition threshold is no longer satisfied.

Interest and penalties related to income tax matters are recorded as income tax expense. At December 31, 2018 and 2017, the Company had no accruals for interest or penalties related to income tax matters.

Net Loss per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. At December 31, 2018, 2017 and 2016, the Company had outstanding stock options and unvested restricted stock awards totaling 59,509,610, 46,513,399 and 39,277,732 underlying shares of the Company's common stock, respectively. At December 31, 2018 and 2017, the Company's Notes (as defined in Note 9) would have been convertible into approximately 47,716,900 shares of the Company's common stock assuming a common stock price of $6.81 or higher. These and any shares due to the Company upon settlement of its capped call transactions are excluded from the computation, as their effect is antidilutive.

Foreign Currency

The accompanying consolidated financial statements are presented in U.S. dollars. The functional currency of Novavax AB, which is located in Sweden, is the local currency (Swedish Krona). The translation of assets and liabilities of Novavax AB to U.S. dollars is made at the exchange rate in effect at the consolidated balance sheet date, while equity accounts are translated at historical rates. The translation of the statement of operations data is made at the average exchange rate in effect for the period. The translation of operating cash flow data is made at the average exchange rate in effect for the period, and investing and financing cash flow data is translated at the exchange rate in effect at the date of the underlying transaction. Translation gains and losses are recognized as a component of accumulated other comprehensive loss in the accompanying consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive loss was $11.2 million and $8.6 million at December 31, 2018 and 2017, respectively.

Segment Information

The Company manages its business as one operating segment: the development of recombinant vaccines. The Company does not operate separate lines of business with respect to its vaccine candidates. Accordingly, the Company does not have separately reportable segments as defined by ASC Topic 280, *Segment Reporting*.

Recent Accounting Pronouncements

Recently Adopted

In May 2014, the FASB issued ASU 2014-09, which supersedes nearly all existing revenue recognition guidance under Topic 605, *Revenue Recognition*. The new standard requires a company to recognize revenue when it transfers goods and services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014-09 defines a five-step process that includes identifying the contract with the customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. The Company completed its assessment of the potential changes from adopting ASU 2014-09, primarily by reviewing its current revenue streams and deferred revenue balances. Based on the Company's assessment, there were no material changes to the timing of recognition of its revenue as the majority of its revenue continues to be recognized under the Grant Agreement with BMGF. The Company applied ASU 2014-09 on a modified retrospective basis as of January 1, 2018, having no impact to the Company's consolidated financial position or results of operations.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows – Restricted Cash* ("ASU 2016-18"), which requires that the change in total cash and cash equivalents at the beginning of period and end of period on the statement of cash flows include restricted cash and restricted cash equivalents. ASU 2016-18 also requires companies who report cash and cash equivalents and restricted cash separately on the balance sheet to reconcile those amounts to the statement of cash flows. The standard was adopted on its effective date of January 1, 2018, and was applied using a retrospective transition method to each period presented. Although the Company's restricted cash is now included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the consolidated statements of cash flows, the adoption did not have a material impact on the other aspects of the Company's consolidated statements of cash flows, or its consolidated financial statements as a whole, including related disclosures.

Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, subsequently amended in 2018 by ASU 2018-01, ASU 2018-10, ASU 2018-11 and ASU 2018-20 (collectively, "Topic 842"), that increases transparency and comparability among organizations by requiring the recognition of right-of-use assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company is substantially complete with its evaluation of the impact that the adoption of this standard will have on its consolidated financial statements, which included reviews of its facility and equipment operating leases and contracts that may contain a right-of-use asset or embedded leasing arrangement.

Topic 842 became effective on January 1, 2019. The Company will adopt the standard under the optional transition method, which will not require restatement of prior periods. The Company will elect the package of practical expedients permitted under the transition guidance, which allows the Company to carryforward its historical lease classification, its assessment on whether a contract is or contains a lease and its initial direct costs for any leases that exist prior to adoption of the standard. The Company will also elect to combine lease and non-lease components and to keep leases with an initial term of 12 months or less off its consolidated balance sheet and recognize the associated lease payments in its consolidated statements of operations on a straight-line basis over the lease term. The Company expects to record approximately $12 million as total right-of-use assets, net of the deferred rent liability, and $22 million in total lease liabilities on its consolidated balance sheet as of January 1, 2019. The Company does not expect the adoption to have a material impact on its consolidated statements of cash flows or results of operations.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other (Topic 350)* ("ASU 2017-04"), which will simplify the goodwill impairment calculation by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. The Company will continue to perform its quantitative goodwill impairment test by comparing the fair value of its reporting unit to its carrying amount, but if the Company is required to recognize a goodwill impairment charge, under the new standard, the amount of the charge will be calculated by subtracting the reporting unit's fair value from its carrying amount. Under the current standard, if

the Company is required to recognize a goodwill impairment charge, Step 2 requires it to calculate the implied value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination and the amount of the charge is calculated by subtracting the reporting unit's implied fair value of goodwill from the goodwill carrying amount. The standard will be effective January 1, 2020 for the Company, with early adoption permitted, and should be applied prospectively from the date of adoption. The Company is currently evaluating when it will adopt ASU 2017-04 and its expected impact to related disclosures, but the adoption will not have an impact on the historical consolidated financial statements.

Note 4 – Fair Value Measurements

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair Value at December 31, 2018			Fair Value at December 31, 2017		
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Assets						
Money market funds(1)	$39,168	$	$	$36,762	$	$
Asset-backed securities(2)		19,997			29,750	
Corporate debt securities(3)		26,219			80,309	
Total cash equivalents and marketable securities	$39,168	$46,216	$	$36,762	$110,059	$
Liabilities						
Convertible notes payable	$	$197,935	$	$	$152,396	$

(1) Classified as cash and cash equivalents as of December 31, 2018 and 2017, respectively (see Note 3).

(2) Includes $15,000 and $16,007 classified as cash and cash equivalents as of December 31, 2018 and 2017, respectively, on the consolidated balance sheets.

(3) Includes $9,236 and $43,056 classified as cash and cash equivalents as of December 31, 2018 and 2017, respectively, on the consolidated balance sheets.

Fixed-income investments categorized as Level 2 are valued at the custodian bank by a third-party pricing vendor's valuation models that use verifiable observable market data, e.g., interest rates and yield curves observable at commonly quoted intervals and credit spreads, bids provided by brokers or dealers or quoted prices of securities with similar characteristics. Pricing of the Company's Notes (as defined in Note 9) has been estimated using other observable inputs, including the price of the Company's common stock, implied volatility, interest rates and credit spreads among others. Over time, the Company expects a market for the Notes to develop when there is sufficient volume of trading. At that time, the Company intends to use trade data as the principal basis for measuring fair value.

During the years ended December 31, 2018 and 2017, the Company did not have any transfers between Levels.

The amount in the Company's consolidated balance sheets for accounts payable and accrued expenses approximates its fair value due to its short-term nature.

Note 5 – Marketable Securities

Marketable securities classified as available-for-sale as of December 31, 2018 and 2017 were comprised of (in thousands):

	December 31, 2018				December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	$4,999	$	$ (2)	$ 4,997	$13,748	$	$ (5)	$ 13,743
Corporate debt securities	16,986		(3)	16,983	37,265		(12)	37,253
Total	$21,985	$	$ (5)	$ 21,980	$51,013	$	$ (17)	$ 50,996

Marketable Securities – Unrealized Losses

The Company owned 7 available-for-sale securities as of December 31, 2018. Of these 7 securities, 7 had combined unrealized losses of less than $0.1 million as of December 31, 2018. The Company did not have any investments in a loss position for greater than 12 months as of December 31, 2018. The Company has evaluated its marketable securities and has determined that none of these investments had an other-than-temporary impairment, as it has no intent to sell securities with unrealized losses and it is not likely that the Company will be required to sell any securities with material unrealized losses, given the Company's current and anticipated financial position.

Note 6 – Goodwill and Other Intangible Assets

Goodwill

The changes in the carrying amounts of goodwill for the years ended December 31, 2018 and 2017 were as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Beginning balance	$53,563	$51,673
Currency translation adjustments	(1,596)	1,890
Ending balance	$51,967	$53,563

Identifiable Intangible Assets

Purchased intangible assets consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018			December 31, 2017		
	Gross Carrying Amount	**Accumulated Amortization**	**Intangible Assets, Net**	**Gross Carrying Amount**	**Accumulated Amortization**	**Intangible Assets, Net**
Finite-lived intangible assets:						
Proprietary adjuvant technology	$8,357	$ (2,263)	$ 6,094	$9,086	$ (2,006)	$ 7,080
Collaboration agreements	3,773	(3,326)	447	4,103	(3,310)	793
Total identifiable intangible assets	$12,130	$ (5,589)	$ 6,541	$13,189	$ (5,316)	$ 7,873

Amortization expense for the years ended December 2018, 2017 and 2016 was $0.7 million, $2.2 million and $0.8 million, respectively. Estimated amortization expense for existing intangible assets for each of the five succeeding years ending December 31, is as follows (in thousands):

Year	Amount
2019	$ 700
2020	583
2021	418
2022	418
2023	418

Note 7 – Grant, U.S. Government Contract and Joint Venture

Bill & Melinda Gates Foundation Grant Agreement

In support of the Company's development of ResVax, in September 2015, the Company entered into the grant agreement with BMGF (the "Grant Agreement"), under which it was awarded a grant totaling up to $89.1 million (the "Grant"). The Grant supports development activities, including the Company's global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and efforts to obtain WHO prequalification of ResVax. Unless terminated earlier by BMGF, the Grant Agreement will continue in effect until the end of 2021. The Company concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as a part of the Grant Agreement. Under the terms of the GACA, among other things, the Company agreed to make a certain amount of

ResVax available and accessible at affordable pricing to people in certain low and middle income countries. Unless terminated earlier by BMGF, the GACA will continue in effect until the latter of 15 years from its effective date, or 10 years after the first sale of a product under defined circumstances. The term of the GACA may be extended in certain circumstances, by a period of up to five additional years.

Payments received in advance that are related to future performance are deferred and recognized as revenue when the research and development activities are performed. Cash payments received under the Grant Agreement are restricted as to their use until expenditures contemplated in the Grant Agreement are incurred. In 2018, the Company recognized revenue from the Grant of $30.8 million, and has recognized approximately $73 million in revenue since the inception of the agreement. At December 31, 2018, the Company's current restricted cash and deferred revenue balances on the consolidated balance sheet represent its estimate of costs to be reimbursed and revenue to be recognized, respectively, in the next twelve months under the Grant Agreement.

HHS BARDA Contract for Recombinant Influenza Vaccines

The Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA") awarded the Company a contract in 2011, which funded the development of both the Company's quadrivalent seasonal and pandemic influenza virus-like particle ("VLP") vaccine candidates. The contract with HHS BARDA was a cost-plus-fixed-fee contract, which reimbursed the Company for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee. The HHS BARDA contract expired in accordance with its terms in September 2016. Billings under the contract were provisional billings, subject to adjustment upon audit by the government, and were based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. These indirect rates are subject to audit by HHS BARDA on an annual basis. An audit of indirect rates for fiscal years 2013 and 2014 was completed in the first quarter of 2017 and an audit of indirect rates for fiscal year 2015 has been initiated, but has not been completed as of the date of this filing. When the final determination of the reimbursable costs for such fiscal years has been made, and such amount is known and collection of the amount is reasonably assured, revenue and billings will be adjusted accordingly. The Company has recognized approximately $114 million in revenue under the HHS BARDA contract since the inception of the contract.

CPLB Joint Venture

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited ("Cadila"), CPLB, to develop and manufacture vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by the Company and 80% by Cadila. Because CPLB's activities and operations are controlled and funded by Cadila, the Company accounts for its investment using the equity method. Since the carrying value of the Company's initial investment was nominal, and the Company has provided no guarantee or commitment to provide future funding, the Company has not recorded losses related to this investment. In July 2018, the Company amended and restated its joint venture and license agreements with respect to CPLB to align them with its current and planned interactions with CPLB. CPLB continues to be owned 20% by the Company and 80% by Cadila.

Note 8 – Other Financial Information

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following at December 31 (in thousands):

	2018	2017
Laboratory supplies	$11,974	$13,085
Other prepaid expenses and other current assets	4,321	4,689
Prepaid expenses and other current assets	$16,295	$17,774

Property and Equipment, net

Property and equipment is comprised of the following at December 31 (in thousands):

	2018	2017
Machinery and equipment	$35,723	$35,409
Leasehold improvements	22,276	23,664
Computer hardware	4,763	5,091
Construction in progress	1,347	1,129
	64,109	65,293

Less accumulated depreciation	(35,683)	(29,306)
Property and equipment, net	$28,426	$35,987

Depreciation expense was approximately $7.4 million, $7.6 million and $7.7 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Accrued Expenses

Accrued expenses consist of the following at December 31 (in thousands):

	2018	2017
Employee benefits and compensation	$9,632	$11,186
Research and development accruals	8,476	17,542
Other accrued expenses	1,442	882
Accrued expenses	$19,550	$29,610

Note 9 – Long-Term Debt

Convertible Notes

In the first quarter of 2016, the Company issued $325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (the "Notes"). The Notes are senior unsecured debt obligations and were issued at par. The Notes were issued pursuant to an indenture dated January 29, 2016 (the "Indenture"), between the Company and the trustee. The Company received $315.0 million in net proceeds from the offering after deducting underwriting fees and offering expenses. The Notes bear cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year, beginning on August 1, 2016. The Notes are not redeemable prior to maturity and are convertible into shares of the Company's common stock. The Notes are initially convertible into approximately 47,716,900 shares of the Company's common stock based on the initial conversion rate of 146.8213 shares of the Company's common stock per $1,000 principal amount of the Notes. This represents an initial conversion price of approximately $6.81 per share of the Company's common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of the Company's common stock of $5.56 per share on January 25, 2016. In addition, the holders of the Notes may require the Company to repurchase the Notes at par value plus accrued and unpaid interest following the occurrence of a Fundamental Change (as described in the Indenture). If a holder of the Notes converts upon a Make-Whole Adjustment Event (as described in the Indenture), they may be eligible to receive a make-whole premium through an increase to the conversion rate up to a maximum of 179.8561 shares per $1,000 principal amount of Notes (subject to other adjustments as described in the Indenture).

The Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and ASC 815-40, *Contracts in Entity's Own Equity* ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or nonbifurcation, if embedded) the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. Based upon the Company's analysis, it was determined the Notes do contain embedded features indexed to its own stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the convertible debt were recorded as a liability on the consolidated balance sheets.

In connection with the issuance of the Notes, the Company also paid $38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the "capped call transactions"). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. The cap price of the capped call transactions will initially be $9.73 per share, which

represented a premium of approximately 75% based on the last reported sale price of the Company's common stock of $5.56 per share on January 25, 2016, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price. The Company evaluated the capped call transactions under ASC 815-10, *Derivatives and Hedging – Overall* and determined that it should be accounted for as a separate transaction and that the capped call transactions will be classified as an equity instrument.

The Company incurred approximately $10.0 million of debt issuance costs during the first quarter of 2016 relating to the issuance of the Notes, which were recorded as a reduction to the Notes on the consolidated balance sheet. The $10.0 million of debt issuance costs is being amortized and recognized as additional interest expense over the seven-year contractual term of the Notes on a straight-line basis, which approximates the effective interest rate method. The Company also incurred $0.9 million of expenses related to the capped call transactions, which were recorded as a reduction to additional paid-in-capital.

Total convertible notes payable consisted of the following at (in thousands):

	December 31, 2018	December 31, 2017
Principal amount of Notes	$ 325,000	$ 325,000
Unamortized debt issuance costs	(5,813)	(7,237)
Total convertible notes payable	$ 319,187	$ 317,763

Interest expense incurred in connection with the Notes consisted of the following for the years ended December 31 (in thousands):

	2018	2017	2016
Coupon interest at 3.75%	$12,188	$12,188	$11,240
Amortization of debt issuance costs	1,424	1,424	1,305
Total interest expense on Notes	$13,612	$13,612	$12,545

Note 10 – Stockholders' Equity

In December 2018, the Company entered into an At Market Sales Agreement ("December 2018 Sales Agreement"), which allows it to issue and sell up to $100 million in gross proceeds of its common stock. On March 12, 2019, the Company sold 5.5 million shares of common stock under the December 2018 Sales Agreement resulting in $2.9 million in net proceeds, leaving $97.1 million remaining.

In April 2018, the Company completed a public offering of 34,848,507 shares of its common stock, including 4,545,457 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of $1.65 per share resulting in net proceeds, net of offering costs of $3.6 million, of approximately $54 million.

In December 2017, the Company entered into an At Market Issuance Sales Agreement ("December 2017 Sales Agreement"), which allows it to issue and sell up to $75 million in gross proceeds of its common stock. During 2018, the Company sold 17.2 million shares of common stock under the December 2017 Sales Agreement resulting in $35.9 million in net proceeds at a weighted average sales price of $2.11 per share. From January 1 through March 12, 2019, the Company sold 50.3 million shares of common stock under the December 2017 Sales Agreement resulting in $37.9 million in net proceeds. The December 2017 Sales Agreement was fully utilized at that time.

In January 2017, the Company entered into an At Market Issuance Sales Agreement ("January 2017 Sales Agreement"), which allowed it to issue and sell up to $75 million in gross proceeds of its common stock. During 2017, the Company sold 50.9 million shares of common stock under the January 2017 Sales Agreement resulting in $63.4 million in net proceeds at a weighted average sales price of $1.27 per share. In January 2018, the Company sold 6.8 million shares of common stock resulting in $10.3 million in net proceeds at a weighted average sales price of $1.54 per share. The January 2017 Sales Agreement was fully utilized at that time.

During the first quarter of 2016, in connection with the Company's issuance of the Notes, the Company also entered into privately negotiated capped call transactions as discussed in Note 9. The cost of the capped call transactions and associated expenses totaling $38.5 million were recorded as a reduction to additional paid-in-capital.

Note 11 – Stock-Based Compensation

Stock Options

The 2015 Stock Incentive Plan, as amended ("2015 Plan"), was approved at the Company's annual meeting of stockholders in June 2015. Under the 2015 Plan, equity awards may be granted to officers, directors, employees and consultants of and advisors to the Company and any present or future subsidiary.

The 2015 Plan authorizes the issuance of up to 56,000,000 shares of the Company's common stock under equity awards granted under the plan, including an increase of 20,000,000 shares approved at the Company's 2018 annual meeting of stockholders. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 4, 2025.

The Amended and Restated 2005 Stock Incentive Plan ("2005 Plan") expired in February 2015 and no new awards may be made under such plan, although awards will continue to be outstanding in accordance with their terms.

The 2015 Plan permits and the 2005 Plan permitted the grant of stock options (including incentive stock options), restricted stock, stock appreciation rights and restricted stock units. In addition, under the 2015 Plan, unrestricted stock, stock units and performance awards may be granted. Stock options and stock appreciation rights generally have a maximum term of 10 years and may be or were granted with an exercise price that is no less than 100% of the fair market value of the Company's common stock at the time of grant. Grants of stock options are generally subject to vesting over periods ranging from one to four years.

Stock Options Awards

The following is a summary of option activity under the 2015 Plan and the 2005 Plan for the year ended December 31, 2018:

	2015 Plan		2005 Plan	
	Stock Options	**Weighted-Average Exercise Price**	**Stock Options**	**Weighted-Average Exercise Price**
Outstanding at January 1, 2018	33,675,720	$ 3.61	12,818,929	$ 3.26
Granted	16,613,409	$ 2.24	—	$ —
Exercised	(252,728)	$ 1.35	(563,125)	$ 1.73
Canceled	(2,180,163)	$ 4.18	(602,432)	$ 4.15
Outstanding at December 31, 2018	47,856,238	$ 3.12	11,653,372	$ 3.29
Shares exercisable at December 31, 2018	15,815,855	$ 4.65	11,653,372	$ 3.29
Shares available for grant at December 31, 2018	7,821,034			

The fair value of stock options granted under the 2015 Plan was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2018	2017	2016
Weighted average fair value of options granted	$1.74	$1.06	$1.88
Risk-free interest rate	2.26%-3.10%	1.61%-2.34%	0.97%-1.78%
Dividend yield	0%	0%	0%
Volatility	93.31%-115.61%	88.91%-114.10%	57.86%-108.88%
Expected term (in years)	4.07-7.50	4.14-7.46	4.22-7.28
Expected forfeiture rate(1)	N/A	N/A	0%-16.33%

(1) See Note 3 regarding the Company’s adoption of ASU 2016-09 in 2017.

The Company used the Monte Carlo simulation model to determine the fair value of its 1.7 million stock options containing a market condition that were granted in 2016 (the “Performance Options”). The fair value of the Performance Options was estimated with the following assumptions: 99.11% volatility, a 1.74% risk-free interest rate, 5.62% forfeiture rate and 0% dividend yield, which resulted in fair values of $0.74 to $0.92 per share, and expected terms of 1.35 years to 3.50 years.

The total aggregate intrinsic value and weighted-average remaining contractual term of stock options outstanding under the 2015 Plan and 2005 Plan as of December 31, 2018 was $10.2 million and 7.5 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable under the 2015 Plan and 2005 Plan as of December 31, 2018 was $4.3 million and 5.7 years, respectively. The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2018. This amount is subject to change based on changes to the closing price of the Company's common stock. The aggregate intrinsic value of options exercised and vesting of restricted stock awards for 2018, 2017 and 2016 was $0.4 million, $0.1 million and $2.4 million, respectively.

Employee Stock Purchase Plan

The ESPP was approved at the Company annual meeting of stockholders in June 2013. The ESPP currently authorizes an aggregate of 7,600,000 shares of the Company's common stock to be purchased, and the aggregate amount of shares will continue to increase 5% on each anniversary of its adoption up to a maximum of 8,000,000 shares. The number of authorized shares and the maximum number of shares both include an increase of 4,000,000 shares approved at the Company's 2018 annual meeting of stockholders. The ESPP allows employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15% of their compensation, at 85% of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period (or, if later, the date during the option period when the employee was first eligible to participate). At December 31, 2018, there were 3,363,066 shares available for issuance under the ESPP.

The ESPP is considered compensatory for financial reporting purposes. As such, the fair value of ESPP shares was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2018	2017	2016
Range of Black-Scholes fair values of ESPP shares granted	$0.36-$3.53	$0.45-$5.47	$1.86-$4.76
Risk-free interest rate	0.66%-2.24%	0.45%-1.13%	0.22%-0.61%
Dividend yield	0%	0%	0%
Volatility	52.19%-203.83%	45.98%-267.85%	43.03%-86.75%
Expected term (in years)	0.5-2.0	0.5-2.0	0.5-2.0
Expected forfeiture rate(1)	N/A	N/A	5%

(1) See Note 3 regarding the Company's adoption of ASU 2016-09 in 2017.

Restricted Stock Awards

The following is a summary of restricted stock awards activity for the year ended December 31, 2018:

	Number of Shares	**Per Share Weighted-Average Grant-Date Fair Value**
Outstanding and Unvested at January 1, 2018	18,750	$ 4.99
Restricted stock granted		$
Restricted stock vested		$
Restricted stock forfeited	(18,750)	$ 4.99
Outstanding and Unvested at December 31, 2018		$

The Company recorded stock-based compensation expense for awards issued under the above mentioned plans in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Research and development	$10,575	$11,750	$11,168
General and administrative	7,739	8,059	7,992

Total stock-based compensation expense	$18,314	$19,809	$19,160

As of December 31, 2018, there was approximately $45 million of total unrecognized compensation expense related to unvested stock options and the ESPP. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.6 years, and will be allocated between research and development and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

Note 12 – Employee Benefits

The Company maintains a defined contribution 401(k) retirement plan, pursuant to which employees may elect to contribute up to 100% of their compensation on a tax deferred basis up to the maximum amount permitted by the Internal Revenue Code of 1986, as amended.

The Company matches 100% of the first 3% of the participants' deferral, and 50% on the next 2% of the participants' deferral, up to a potential 4% Company match. The Company's matching contributions to the 401(k) plan vest immediately. Under its 401(k) plan, the Company has recorded expense of $1.2 million, $1.5 million and $1.5 million in 2018, 2017 and 2016, respectively.

The Company's foreign subsidiary has a pension plan under local tax and labor laws and is obligated to make contributions to this plan. Contributions and other expenses related to this plan were $0.8 million in 2018 and $0.5 million in 2017 and 2016.

Note 13 – Income Taxes

The Company's loss from operations before income tax expense by jurisdiction for the years ended December 31 are as follows (in thousands):

	2018	2017	2016
Domestic	$(176,290)	$(173,749)	$(273,134)
Foreign	(8,458)	(10,020)	(6,832)
Total net loss	$(184,748)	$(183,769)	$(279,966)

As a result of current and historical losses, there is no income tax provision for the years ended December 31, 2018, 2017 and 2016.

Deferred tax assets (liabilities) consist of the following at December 31 (in thousands):

	2018	2017
Deferred tax assets:		
Federal and State net operating loss carryforward	$270,177	$240,550
Foreign net operating loss carryforward	12,321	11,577
Research tax credits	33,633	27,571
Non-cash stock-based compensation	10,888	8,048
Original discount interest	5,687	7,167
Other	7,987	9,116
Total deferred tax assets	340,693	304,029
Valuation allowance	(337,515)	(299,862)
Net deferred tax assets	$3,178	$4,167
Deferred tax liabilities:		
Intangibles	(1,492)	(1,789)
Other	(1,686)	(2,378)
Total deferred tax liabilities	(3,178)	(4,167)

Net deferred tax assets	$—	$—

The valuation allowance increased by $37.7 million for the year ended December 31, 2018 due to increases in deferred tax assets. The valuation allowance decreased $54.7 million during the year ended December 31, 2017 primarily due to the impact of the enactment of the Tax Cuts and Jobs Act of 2017 (the “Act”) and was partially offset by the generation of net operating losses in 2017.

At December 31, 2017, the Company had provided provisional accounting for the tax effects of enactment of the Act. The Company re-measured certain of its U.S. deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future. As a result, the Company’s U.S. deferred tax balances at December 31, 2017 were revalued at the newly enacted tax rate of 21%, decreasing the net deferred tax asset (before valuation allowance) by approximately $132 million, offset by a decrease in the valuation allowance by the same amount. The Company completed its analysis of the Act in 2018, which resulted in no adjustment to income tax expenses on the Company’s consolidated statements of operations.

The differences between the U.S. federal statutory tax rate and the Company’s effective tax rate are as follows:

	2018	2017	2016
Statutory federal tax rate	(21)%	(34)%	(34)%
State income taxes, net of federal benefit	(3)%	(3)%	(3)%
Research and development and other tax credits	(3)%	(2)%	(2)%
Other	1 %	(1)%	2 %
Change in tax rate	5 %	70 %	0 %
Change in valuation allowance	21 %	(30)%	37 %
Income tax provision	0 %	0 %	0 %

The change in the tax rate in 2018 is primarily related to changes in applicable state apportionment factors; whereas the change in the tax rate in 2017 resulted from the Act as discussed above.

Realization of net deferred tax assets is dependent on the Company's ability to generate future taxable income, which is uncertain. Accordingly, a full valuation allowance was recorded against these assets as of December 31, 2018 and 2017 as management believes it is more likely than not that the assets will not be realizable.

As of December 31, 2018, the Company had net operating losses and research tax credits available as follows (in thousands):

	Amount
Federal and State net operating losses expiring through the year 2037	$969,452
Federal and State net operating losses (no expiration)	164,443
Foreign net operating losses (no expiration)	56,003
Research tax credits expiring through the year 2038	33,539

Utilization of the net operating loss carryforwards and credits may be subject to an annual limitation due to prior ownership change of the Company. The Company does not expect such limitation, if any, to impact the use of the net operating losses and business tax credits.

At December 31, 2018 and 2017, the Company did not have any unrecognized tax benefits. To the extent unrecognized tax benefits are ultimately recognized, it would affect the annual effective income tax rate unless otherwise offset by a corresponding change in the valuation allowance. The Company does not expect that the amounts of unrecognized tax benefits will change significantly within the next twelve months.

The Company files income tax returns in the U.S. federal jurisdiction and in various states, as well as in Sweden. The Company had U.S. tax net operating losses and credit carryforwards that are subject to examination from 1999 through 2018. The statute extends for a number of years beyond the year in which the losses were generated for tax purposes. Since a portion of these carryforwards may be utilized in the future, many of these attribute carryforwards remain subject to examination. The returns in Sweden are subject to examination from 2013 through 2018.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2018 and 2017, the Company had no accruals for interest or penalties related to income tax matters.

Note 14 – Commitments and Contingencies

Operating Leases

The Company conducts its operations from leased facilities. The operating leases for these facilities have terms expiring through 2026, unless earlier terminated by the Company in 2023. The leases contain provisions for future rent increases. Also, the leases obligate the Company to pay building operating costs. The Company has recorded a deferred rent liability to account for the funding under improvement allowances and to record rent expense on a straight-line basis for these operating leases.

Future minimum rental commitments under non-cancelable leases as of December 31, 2018 are as follows (in thousands):

Year	Operating Leases
2019	$ 6,682
2020	5,372
2021	5,350
2022	6,910
2023	5,283
Total minimum lease payments	$ 29,597

Total facility rent expense was approximately $5.0 million, $8.4 million and $7.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

In January 2018, the Company's 1201 Clopper Road lease was terminated, and the Company paid a termination fee to the landlord of $5.3 million, which the Company believes was less than the potential total lease and operating expense cash obligations that could have been incurred over one year. The Company recorded total expense, which includes the termination fee and write-down of the related leasehold improvements, and is partially offset by deferred rent expense previously recorded, of $0.9 million in the first quarter of 2018 in connection with the termination of the 1201 Clopper Road lease.

Contingencies

In July 2018, the Company terminated a 2007 agreement to license certain rights from Wyeth Holdings LLC (formerly Wyeth Holdings Corporation), a subsidiary of Pfizer Inc. ("Wyeth"). The Wyeth license offered a non-exclusive, worldwide license to a family of patents and patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. At present, the Company has no programs to which the Wyeth license applies, and CPLB's recombinant trivalent seasonal VLP influenza vaccine ("CadiFlu") is only licensed in India. In September 2015, due to CPLB's initiation of a Phase 3 clinical trial of CadiFlu in 2014, the Company entered into an amendment to the Wyeth license that, among other things, increased the milestone payment ("Milestone") from $3 million to as much as $4 million if not paid before December 31, 2017. The Milestone of $4 million was paid in the first quarter of 2018. The Milestone was recorded as a research and development expense in 2014. Payments under the Wyeth license as of December 31, 2018 aggregated to $11.6 million.

Note 15 – Related Party Transaction

In July 2017, the Company entered into a consulting agreement with Dr. Sarah Frech, the spouse of Mr. Stanley C. Erck, the Company's President and Chief Executive Officer. Dr. Frech is a seasoned biotechnology executive with significant experience managing multiple clinical programs. Under the agreement, Dr. Frech provides clinical development and operations services related to the Company's Phase 3 clinical trial of ResVax and other professional services. The agreement has been extended to terminate in July 2019. In 2018 and 2017, the Company incurred $0.3 million and $0.2 million, respectively, in consulting expenses under the agreement. The amount due and unpaid for services performed under the agreement at December 31, 2018 and 2017 was less than $0.1 million.

Note 16 – Quarterly Financial Information (Unaudited)

The Company's unaudited quarterly information for the years ended December 31, 2018 and 2017 is as follows:

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
2018:				
Revenue	$9,653	$10,773	$ 7,735	$ 6,127
Net loss	$(46,352)	$(44,492)	$ (44,570)	$ (49,334)
Net loss per share	$(0.14)	$(0.12)	$ (0.12)	$ (0.13)

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
2017:				
Revenue	$5,680	$6,732	$ 8,352	$ 10,412
Net loss	$(43,854)	$(44,465)	$ (44,607)	$ (50,843)
Net loss per share	$(0.16)	$(0.16)	$ (0.15)	$ (0.16)

The net loss per share was calculated for each three-month period on a stand-alone basis. As a result, the sum of the net loss per share for the four quarters may not equal the net loss per share for the respective twelve-month period.