

NOVAVAX INC  
Form 10-K  
March 12, 2014

**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, 2013**

**OR**

o **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. 0-26770**

**NOVAVAX, INC.**

(Exact name of Registrant as specified in its charter)

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Delaware

20 Firstfield Road  
Garthersburg, Maryland 20878

22-2816046

(State of incorporation)

(Address of principal executive offices) (I.R.S. Employer Identification No.)

**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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  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.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

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 Registrant's common stock on June 30, 2013 on the NASDAQ Global Select Market) was \$246,500,000.

As of March 6, 2014, there were 209,056,800 shares of the Registrant's common stock outstanding.

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Portions of the Registrant's Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2013 in connection with the Registrant's 2014 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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When used in this Annual Report on Form 10-K, except where the context otherwise requires, the terms we, us, our, Novavax and the Company refer to Novavax, Inc.

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## PART I

Item 1.

BUSINESS

*This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act that involve risks and uncertainties. In some cases, forward-looking statements are identified by words such as believe, anticipate, intend, plan, will, may and similar expressions. You should not place reliance on these forward-looking statements, which speak only as of the date of this report. All of these forward-looking statements are based on information available to us at this time, and we assume no obligation to update any of these statements. Actual results could differ from those projected in these forward-looking statements as a result of many factors, including those identified in the section titled Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere. We urge you to review and consider the various disclosures made by us in this report, and those detailed from time to time in our filings with the Securities and Exchange Commission (SEC), that attempt to advise you of the risks and factors that may affect our future results.*

### Program Overview

Novavax, Inc. ( Novavax, the Company, we or us ) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Our vaccine technology platform is based on proprietary recombinant nanoparticle vaccine technology that includes both virus-like particles (VLPs) and protein nanoparticle vaccine candidates. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important proteins. Our vaccine product pipeline targets a variety of infectious diseases with candidates currently in clinical development for respiratory syncytial virus (RSV), seasonal influenza, and pandemic influenza. Further, CPL Biologics Private Limited (CPLB), our joint venture company in India, is actively developing a number of vaccine candidates that were genetically engineered by Novavax. These include its seasonal and pandemic influenza vaccine candidates that have completed Phase 1/2 clinical trials in India in 2012, and its rabies vaccine that began a Phase 1/2 clinical trial in India in early 2014.

#### Respiratory Syncytial Virus (RSV)

RSV is a widespread disease that causes infections of the lower respiratory tract. While RSV affects persons of all ages, it acutely impacts infants, young children, the elderly, and others with compromised immune systems. A current study indicated that RSV is responsible for over 30 million new acute lower respiratory infection episodes and between 150,000 and 200,000 deaths in children under five years old.<sup>1</sup> In the U.S., nearly all children become infected with RSV before they are two years old; it has been associated with 20% of hospitalizations and 15% of office visits for acute respiratory infection in young children.<sup>2</sup> The World Health Organization (WHO) estimates that the global disease burden for RSV is 64 million cases. Because there is no approved prophylactic vaccine, the unmet need of an RSV vaccine has the potential to protect millions of patients from this far-reaching disease.

We are developing a vaccine candidate to prevent RSV and are looking at three susceptible target populations: infants (receiving protection through antibodies transferred from their mothers who would be immunized during the last trimester of pregnancy), the elderly and young children.

#### **RSV Maternal Immunization Program**

In April 2013, we announced top-line data from a Phase 2 dose-ranging clinical trial in women of childbearing age that were similar to, or exceeded, immune responses seen in our first Phase 1 clinical trial. This randomized, blinded,

placebo-controlled Phase 2 clinical trial evaluated the safety and immunogenicity of two dose levels of our RSV vaccine candidate, with and without an aluminum phosphate adjuvant, in 330 women of childbearing age. We further reported that the vaccine candidate was well-tolerated, the two-dose alum-adjuvanted groups showed a 13- to 16-fold rise in anti-F IgG antibodies to the F protein compared to a six- to ten-fold rise in the non-alum groups, and palivizumab-like antibody titers rose eight-fold to nine-fold with four-fold rises in 92% of subjects in the two-dose alum-adjuvanted groups.

<sup>1</sup> Nair, H., *et al.*, (2010) *Lancet*. 375:1545-1555.

<sup>2</sup> Hall, CB, *et al.*, (2009) *N Engl J Med*. 360(6):588-98.

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In October 2013, we initiated and completed enrollment in a Phase 2 dose-confirmation clinical trial in 720 women of childbearing age. The top-line data from this trial, expected in the second quarter of 2014, will supplement the data from our other clinical trials, and is expected to support the advancement of our maternal immunization program in pregnant women; we plan to initiate a Phase 2 clinical trial of our RSV vaccine candidate in pregnant women in the fourth quarter of 2014.

In conjunction with our development of an RSV maternal vaccine, in July 2012 we entered into a clinical development agreement with PATH Vaccine Solutions (PATH) to develop our RSV vaccine candidate in low-resource countries.

We refer to this as our RSV Collaboration Program. We were awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support our Phase 2 dose-ranging clinical trial in women of childbearing age described above. In October 2013, the funding under this agreement was increased by \$0.4 million to support reproductive toxicology studies, which are necessary before we conduct clinical trials in pregnant women. In December 2013, we entered into an amendment with PATH providing an additional \$3.5 million in funding to support the Phase 2 dose-confirmation clinical trial in 720 women of childbearing age described above. We retain global rights to commercialize the product and will support PATH in its goal to make an RSV maternal vaccine product affordable and available in low-resource countries. To the extent PATH elects to continue to fund 50% of our external clinical development costs for the RSV Collaboration Program, but we do not continue development, we would then grant PATH a fully-paid license to our RSV vaccine technology for use in pregnant women in such low-resource countries.

### **RSV Elderly Program**

In July 2013, we announced top-line data from the Phase 1 clinical trial in the elderly that was initiated in October 2012. This clinical trial was a randomized, blinded, placebo-controlled Phase 1 clinical trial that evaluated the safety and immunogenicity in 220 enrolled elderly adults, 60 years of age and older, who received a single intramuscular injection of our RSV vaccine candidate (with and without alum) or placebo plus a single dose of licensed influenza vaccine or placebo at days 0 and 28. The top-line data further corroborated our previous clinical experiences with our RSV vaccine candidate: we reported that the vaccine candidate was well-tolerated, that the higher dose groups had better overall immune responses than the lower dose groups and that essentially undetectable Day 0 levels of antibodies that compete with palivizumab increased to between 80% and 97% of active vaccine recipients by Day 28. Our expected path forward in the elderly would include a dose-confirmation clinical trial in late 2014 or early 2015.

### **RSV Pediatric Program**

While the burden of RSV disease falls heavily on newborn infants, RSV is also a prevalent and currently unaddressed problem in pediatric patients. This third market segment for our RSV vaccine candidate remains an important opportunity. We expect to initiate clinical trials in pediatric subjects as step-downs from our past clinical trials in healthy adults. We also expect that our clinical experience in pregnant women will be equally important to understanding a vaccine for this patient population. Our pre-clinical development efforts support such a clinical development plan that is expected to be launched in late 2014.

### **Influenza**

We have significant experience developing recombinant VLP influenza vaccine candidates, including:

nine clinical trials for our seasonal and pandemic influenza vaccine candidates;



administering our seasonal and pandemic influenza VLPs (multiple distinct strains, including both influenza A and B and strains of avian and swine origin, alone or with saponin-based adjuvants) to more than 5,000 subjects demonstrating vaccine tolerability and immunogenicity;  
more than sixty (60) distinct batches of VLP vaccine produced under current good manufacturing practices (cGMP);  
and

capacity to produce vaccine in 1,000 liter single-use bioprocessors.

We believe our influenza VLP vaccines have potential immunological advantages over currently available products because our influenza VLPs contain three of the major virus proteins that are important for fighting

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influenza: hemagglutinin (HA) and neuraminidase (NA), both of which stimulate the body to produce antibodies that neutralize the influenza virus and/or prevent its spread through the cells in the respiratory tract, and matrix 1 (M1), which may stimulate cytotoxic T lymphocytes to kill cells that are already infected. Our VLPs are not made from live viruses and have no functional genetic material in their inner core, which render them incapable of replicating and causing disease.

Novavax insect cell culture based platform production technology, combined with single-use bioprocessing technology employed strategically throughout the manufacturing process, is a key strength. This distinctive combination of technology has advantages over traditional vaccine production methods that use chicken eggs or mammalian cells, including: (1) smaller facility footprint to achieve comparable yields to traditional egg-based or mammalian cell-based systems, (2) faster facility commissioning, (3) significantly lower capital expenditures on facility infrastructure, (4) competitive cost of goods and (5) the potential for advance seed production, which could provide a shorter lead time to produce commercial quantities of vaccine than egg-based technology in the face of strain changes.

### **Seasonal Influenza Program**

Developing and commercializing a Novavax seasonal influenza vaccine remains an important strategic goal and viable opportunity for us. The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (CDC) recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with these universal recommendations, attention from the 2009 influenza H1N1 pandemic, along with reports of cases of avian-based influenza strains, has increased public health awareness of the importance of seasonal influenza vaccination, the market for which is expected to continue to grow worldwide in both developed and developing global markets.

There are currently four quadrivalent (four influenza strains: two influenza A strains and two influenza B strains) influenza vaccines licensed in the U.S., but in the coming years, additional quadrivalent seasonal influenza vaccines are expected to be produced and licensed within and outside of the U.S., as opposed to trivalent (three influenza strains: two influenza A strains and one influenza B strain) influenza vaccines. With two distinct lineages of influenza B viruses circulating, governmental health authorities have advocated for the addition of a second influenza B strain to provide additional protection. Current estimates for seasonal influenza vaccines growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from the current market of approximately \$3.2 billion (2012/13 season) to \$5.3 billion by the 2021/2022 season.<sup>3</sup> Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of vaccines can be quickly and cost-effectively manufactured without the use of either the live influenza virus or eggs.

Top-line data from our most recent Phase 2 clinical trial for our quadrivalent influenza vaccine candidate were announced in July 2012. In that clinical trial, our quadrivalent VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, and was also well-tolerated, as evidenced by the absence of any observed vaccine-related serious adverse events (SAEs) and an acceptable reactogenicity profile. Our vaccine candidate met the FDA accelerated approval seroprotection rates criterion for all four viral strains. The potential to fulfill the seroconversion rates criterion was demonstrated for three of the four viral strains. The fourth strain, B/Brisbane/60/08, despite fulfilling the seroprotection criterion, failed to demonstrate a satisfactory seroconversion rate. Following our last Phase 2 clinical trial, we have focused our seasonal influenza vaccine candidate activities on a manufacturing process that ensures consistent and enhanced immune responses in all strains. We completed these activities in September 2013 and have begun manufacturing A and B strain influenza VLPs for the next Phase 2 clinical trial with our quadrivalent vaccine candidate, which we expect to initiate in the fourth quarter

## **Pandemic Influenza Program**

An influenza pandemic refers to a situation where there is a significant and geographically widespread disease outbreak in humans across multiple age groups, typically resulting from an influenza virus for which the majority of the population has little or no immunity. Pandemic influenza strains are a major concern to world health groups because such diseases can quickly and easily spread worldwide and can cause serious

<sup>3</sup> Influenza Vaccines Forecasts. Datamonitor (2013)

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illness or death before vaccines are available to limit the spread of the disease. There have been notorious examples of pandemic influenza crises. In 2009, the World Health Organization (WHO) declared a pandemic of the H1N1 strain of influenza. In the aftermath of the 2009 H1N1 influenza pandemic, recognition of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 pandemic led to the production of approximately 126 million doses of monovalent (single strain) vaccine. Public health awareness and government preparedness for the next potential influenza pandemic are driving development of vaccines that can be manufactured quickly against a potentially threatening influenza strain. Until the spring of 2013, industry and health experts focused attention on developing a monovalent H5N1 influenza vaccine as a potential key defense against a future pandemic threat; however, a rising number of reported cases in China of an avian influenza strain of A(H7N9) has shifted attention to the potential development of an H7N9 influenza vaccine.

In October 2012, under our collaboration with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA), we reported positive results from two Phase 1 clinical trials of our pandemic (H5N1) vaccine candidate in combination with two different adjuvants, both of which are designed to improve the immunogenicity of vaccines at lower doses and thus provide antigen dose-sparing. The top-line data demonstrated safety and immunogenicity of varying dose-levels of the vaccine, with and without adjuvant, and further demonstrated statistically significant robust adjuvant effects on immune response.

In April 2013, we initiated manufacturing of a new monovalent influenza vaccine candidate against the prototype A(H7N9) strain. This strain was first recognized by Chinese health authorities as a potential pandemic influenza threat in late March 2013. In a three month period, we developed a recombinant baculovirus expressing the published A(H7N9) viral HA and NA gene sequences, developed and purified a VLP vaccine antigen, conducted multiple animal studies and initiated a Phase 1 clinical trial in Australia independent of our HHS BARDA contract. In November 2013, we announced the publication of the clinical results from the Phase 1 clinical trial in *The New England Journal of Medicine*. The publication highlighted the fact that 81% of subjects treated with 5ug of adjuvanted vaccine dose achieved protective HAI levels, and 97% of subjects showed an anti-neuraminidase antibody response. We achieved protective levels from vaccinations within 116 days of the announcement of the H7N9 outbreak from the industry's first clinical trial of a vaccine against an A(H7N9) influenza strain.

In February 2014, we modified our contract with HHS BARDA to focus our development of a monovalent pandemic influenza vaccine against the A(H7N9) strain with a Phase 1/2 clinical trial with our H7N9 candidate and our Matrix-M™ adjuvant, which began in the first quarter of 2014 and for which, top-line data is scheduled to be released in the second half of 2014; however, HHS BARDA has also indicated that our H5N1 vaccine program remains a viable development opportunity under our contract.

## **Potential Accelerated Approval Pathway for Influenza**

In the past, we have referenced attainment of accelerated approval immunogenicity endpoints for seroprotection and seroconversion as a potential pathway for licensure of our influenza vaccines. The criteria for granting such accelerated approval of a Biologics License Application (BLA, the biologic equivalent to a New Drug Application or NDA) for new seasonal and pandemic influenza vaccines was published by the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA). Under FDA guidance, developers that can demonstrate results that meet or exceed certain specified immunogenicity endpoint criteria in their clinical trials may, at the FDA's discretion, be granted a license to market a product prior to submission of traditional clinical endpoint efficacy trial data. It should be noted that FDA licensure based on accelerated approval nevertheless requires sponsors to conduct a post-licensure efficacy study to demonstrate the clinical benefit of the vaccine, which would thereby support

traditional approval of the vaccine. Because it is not possible to conduct a clinical endpoint efficacy study for a pandemic vaccine in advance of a declared pandemic, FDA's pandemic guidance allows for submission of seasonal influenza clinical efficacy data for the purpose of confirming clinical benefit of a pandemic vaccine manufactured by the same process. Thus, the demonstration of efficacy with a seasonal vaccine provides a key link between the

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seasonal and pandemic programs. Accelerated approval further necessitates a shortage of influenza vaccine relative to the total population recommended to receive such vaccine, a situation that persists with seasonal influenza vaccines.

Although we have not ruled out this accelerated approval approach, particularly for our pandemic program or certain subject populations within the seasonal influenza program, we do not expect to pursue accelerated approval of our quadrivalent seasonal influenza vaccine, largely because of the uncertainty as to whether the accelerated approval pathway will be available to us at the time of our BLA submissions and the unknown ability of current and new influenza strains to meet such accelerated approval criteria. We are planning, therefore, to pursue traditional licensure of our quadrivalent seasonal influenza vaccine by conducting a clinical endpoint efficacy study for the purpose of submitting the data within the original BLA. These efficacy data will also support the requirement for clinical efficacy data for our pandemic vaccine program. We plan to discuss with the FDA our licensure pathways (both the traditional pathway for seasonal and possible accelerated pathways for pandemic and certain subject populations within the seasonal program) during future formal meetings. The likely impact of such an efficacy trial would be an additional year or more before the FDA grants licensure to our seasonal influenza vaccine.

### **HHS BARDA Contract for Recombinant Influenza Vaccines**

HHS BARDA awarded us a contract in February 2011, which funds the development of both our seasonal and pandemic influenza vaccine candidates. Our contract with HHS BARDA is a cost-plus-fixed-fee contract, which reimburses us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic influenza vaccines. During 2013, we recognized revenue of approximately \$17.4 million and have recognized approximately \$52 million in revenue since the inception of the contract. The contract, valued at \$97 million for the first three-year base-period, was extended in February 2014 by approximately seven months to September 2014; this extension is intended to allow us to continue to access the remainder of the base-period funding. In addition, the contract provides \$79 million for an HHS BARDA optional two-year period.

Although HHS BARDA originally directed us to develop our monovalent pandemic influenza vaccine against the A(H5N1) strain, after achieving positive results with our H7N9 vaccine candidate last year, HHS BARDA has directed us to develop our monovalent pandemic influenza vaccine against the A(H7N9) strain. Nevertheless, our H5N1 vaccine program remains a viable development opportunity under the contract.

### **Combination Respiratory Vaccine (Influenza and RSV)**

Given the ongoing development of our seasonal influenza vaccine candidate and our RSV vaccine candidate, we see an important opportunity to develop a combination respiratory vaccine. This opportunity presents itself most evidently in the elderly population, although we have not ruled out developing a combination respiratory vaccine for younger persons, including children. Early pre-clinical development efforts have given us confidence that such a combination vaccine is viable and, in animal models, provides acceptable immunogenicity. We intend to explore this development opportunity by conducting a Phase 1 clinical trial in such a combination vaccine in late 2014 or early 2015.

### **Rabies**

Rabies is a disease that causes acute encephalitis, or swelling of the brain, in warm-blooded animals, including humans. The disease can be transmitted from one species of animal to another, such as from dogs to humans, most commonly by a bite from an infected animal. For humans, rabies left untreated is almost invariably fatal. In Asia and Africa, estimates show a combined 55,000 annual human deaths from endemic canine rabies, with annual treatment

costs approaching \$600 million, although human deaths from rabies may be underreported in a number of countries, particularly in the youngest age groups. In India alone, 20,000 deaths are estimated to occur annually. Internal market data of vaccine manufacturers suggest that at the global level, greater than 15 million people receive rabies prophylaxis annually, the majority of whom live in China and India. It is estimated that in the absence of post-exposure prophylaxis, about 327,000 persons would die from rabies in Asia and Africa each year. Marketed rabies vaccine is mostly used for post-exposure prophylaxis that requires generally between four and five administrations of vaccine. Pre-exposure prophylaxis

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is recommended for anyone who will be at increased risk to the rabies virus, including travelers with extensive outdoor exposure in rural high-risk areas.<sup>4</sup>

CPLB is developing a rabies G protein vaccine candidate that we genetically engineered and has initiated a Phase 1/2 clinical trial in India in January 2014. Our common objective with CPLB is to develop a recombinant vaccine that can be administered both as a pre-exposure prophylaxis for residents of certain higher-risk geographies, as well as travelers to such locations, and also has potential to provide post-exposure prophylaxis with fewer doses. Pre-clinical results have demonstrated that this vaccine candidate has the potential to evoke antibody responses which are active in the neutralization of the rabies virus and could prevent the virus from entering the central nervous system, thus preventing death. The CPLB candidate protects mice from rabies in an assay known as the NIH potency test, which is used as one predictor of the clinical effect of rabies vaccines.

### **Discovery Programs**

Our vaccine platform technology provides an efficient system to rapidly develop antigens to selected targets, refine manufacturing processes and optimize development across multiple vaccine candidates. In addition to our RSV, seasonal influenza, pandemic influenza and rabies vaccine candidates, we currently have a number of undisclosed discovery programs, some of which are being tested in pre-clinical models. In addition, we pay close attention to global reports of emerging diseases for which there do not appear to be immediate cures and where a vaccine protocol could offer potential protection. In addition to our response to the A(H7N9) influenza strain (see discussion above), we have been monitoring reports concerning the Middle East Respiratory Syndrome Coronavirus (MERS), a novel coronavirus first identified in September 2012 by an Egyptian virologist. Beginning in 2013, MERS became an emerging threat, with more than 50 confirmed cases of infection and 30 deaths. The MERS virus is a part of the coronavirus family that includes the severe acute respiratory syndrome coronavirus (SARS). Because of the public health priority given to MERS, within weeks of getting the virus sequence, we successfully produced a vaccine candidate designed to provide protection against MERS. This vaccine candidate, which was made using our recombinant nanoparticle vaccine technology, is based on the major surface spike protein, which we had earlier identified as the antigen of choice in our work with a SARS vaccine candidate. Although the development of this vaccine candidate currently remains a pre-clinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities.

## **Vaccine Platform Technologies**

We believe that our platform technology offers time-saving advantages both in terms of production time against traditional egg-base vaccine manufacturing, and in terms of establishing a vaccine production facility (either as a new green-field project or through a retrofit of an existing facility). Currently approved influenza vaccines are typically produced by growing virus in chicken eggs, from which the virus is extracted and further processed. This 50-year-old egg-based production method requires four to six months of lead time for production of a new strain of virus and significant investment in fixed production facilities. Moreover, there can be additional delays because manufacturers must modify the selected influenza virus strain in order for it to be produced efficiently in the egg. The vaccine shortage during the 2004 influenza season (caused in part by a contamination issue at a facility in the United Kingdom) highlighted the limitations of current production methods and the need for increased vaccine manufacturing capacity. It also heightened concerns regarding manufacturers capacity to respond to a pandemic, when the number of vaccine doses required will be higher than the number required for seasonal influenza vaccines and manufacturing lead times will be even shorter. This concern was borne out again in the 2009 H1N1 influenza pandemic as, despite an intensive effort to develop a pandemic vaccine, the 2009 H1N1 vaccine arrived too late to have a significant effect on the dynamics of the fall disease wave.<sup>5</sup> Compared with traditional vaccine production, we believe our processes allow



for faster production of vaccine. Because our process uses genetic information and not the virus itself, we can quickly construct clones of the virus as soon as the genetic information is available. This factor alone can shorten the time for creating new vaccine by several weeks compared to traditional egg-based manufacturing.

<sup>4</sup> Yousaf, *et al.* Virology Journal (2012) 9:50

<sup>5</sup> BARDA Strategic Plan 2011 – 2016 (2010)

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Importantly, we also believe that a manufacturing facility that produces our vaccines can be implemented and validated in significantly less time than traditional cell-based vaccine manufacturing facilities and without the costly containment features associated with handling live viruses. We produce our vaccine candidates using a baculovirus expression system in insect cells with lower-cost equipment that can be readily deployed both nationally and internationally. By not requiring significant production batch sizes, production capacity can be employed quickly. We estimate the time to qualify a facility that utilizes our processes can be six to nine months faster than a fixed-pipe bioreactor facility used in cell-based manufacturing.

### Virus-Like Particles

Our VLP vaccine technology platform is based on self-assembling protein structures that visually resemble viruses. However, these are non-infectious particles that, for many viral diseases, have been shown in animal studies and clinical trials to make effective vaccines. VLPs closely mimic natural virus particles with repeating protein structures that can elicit broad and strong antibody and cellular immune responses, but lack the genetic material required for replication. VLP technology is a proven technology that is employed in currently marketed products such as Merck's Gardasil®. Our proprietary VLPs are more advanced than earlier approaches and they include multiple proteins and lipids and can be tailored to induce robust and broad immune responses similar to natural infections. Our advanced VLP technology has the potential to develop vaccines for a wide range of human infectious diseases where there are significant unmet medical needs, some of which have not been addressed by other technologies. We have used formal criteria based upon medical need, technical feasibility and commercial value to select vaccine candidates for development.

We believe that our influenza vaccines are designed to address many of the significant unmet needs related to seasonal and pandemic influenza. There are several points of differentiation of our influenza vaccines when compared to traditional egg-based, or new mammalian-based approaches that form the basis to address unmet medical needs and capitalize on commercial opportunities. Our influenza VLPs contain components that provide a broad and robust immune response. Specifically, the VLPs contain the viral components HA, NA and M1. Traditional egg-based vaccines contain meaningful levels of HA, but not of NA or M1. The HA sequence in our VLPs is the same as in the wild-type virus and could prove to be more effective/immunogenic than influenza vaccines produced using egg or mammalian cell-lines, which alter HA. In addition, the NA and M1 in our VLPs may play a role in reducing the severity of the disease by inducing antibody responses and cell mediated immunity. NA and M1 are both highly conserved, and immunity to these viral components may help provide additional protection throughout an entire influenza season, even as strains mutate. Data from our seasonal influenza Phase 2a clinical trial in healthy adults showed that 50 to 73% of the volunteers immunized with our VLP vaccine had a four-fold increase in the antibody that blocks NA activity. Finally, because of the VLP structure and components, they may have greater immunogenicity in two vulnerable populations – the pediatric and elderly.

### Protein Nanoparticle Vaccines

Our protein nanoparticle vaccine technology is also based on self-assembling protein structures, which differ from traditional VLPs in that these particles do not generally occur in nature and can be made from proteins from any pathogenic organism including viruses, bacteria, parasites or even cancer cells. Protein nanoparticles closely resemble the natural structure of surface antigens of disease organisms, but lack the genetic material required for replication and therefore are not infectious. An advantage of this technology is that the formation of nanoparticles is done *in vitro* thereby making it possible to assemble nanoparticles from one or more highly purified proteins. This results in high purity vaccines with certain manufacturing advantages over more traditional products. Potential immunological advantages of protein nanoparticle vaccines are presentation of epitopes (antibody binding sites) in a more native configuration for improved efficacy, efficient recognition by the immune system's antigen presenting cells (APCs) and

triggering robust immune responses. Recognition of the nanoparticle vaccine's repeating protein patterns by the APCs 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 fusion (F) protein vaccine candidate, which is manufactured from highly purified F protein.

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## **Matrix Adjuvant Technology**

During 2013, we acquired Isconova AB (now Novavax AB), a company located in Uppsala, Sweden that produces proprietary saponin-based adjuvants. Adjuvants are mostly used as an additional component in various vaccines in order to enable the vaccine to induce a strong immune response for protection against virus and bacterial infections. 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 improve, *i.e.* increase and prolong, the effects of vaccines. Our research and development over the years have resulted in a range of high-quality products on the international veterinary vaccine market, and more recently, into the human vaccine market.

The goals of our adjuvant technology are strong antibody and cell-mediated immune responses induced by low antigen doses, long-duration immune responses, with low risk for allergic reactions or other adverse events. We believe these qualities give our Matrix adjuvants a number of important advantages over many other types of adjuvants, where novel, less well-characterized substances are often hampered by safety concerns or limited efficacy. Our new-generation 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 immense value when there is inadequate vaccine manufacturing capacity during an emerging threat such as an influenza pandemic.

## **Competition in RSV and Influenza Vaccines**

The biopharmaceutical industry and the vaccine market are intensely competitive and are characterized by rapid technological progress. Our technology is based upon utilizing the baculovirus expression system in insect cells to make VLPs and protein nanoparticle vaccines. We believe this system offers many advantages when compared to other technologies and is uniquely suited for developing an RSV vaccine, seasonal and pandemic influenza vaccines, as well as 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. In addition, many other companies are developing products to prevent disease caused by RSV using a variety of technology platforms, including various viral vector technologies and competitive VLP technologies. Although early in clinical development, we believe that our RSV vaccine candidate, utilizing recombinant F-protein antigens, could be more effective than RSV vaccine candidates in development by our competitors; however, such efficaciousness cannot be guaranteed. Although we are not aware of all our competitors' efforts, we believe that MedImmune LLC, a subsidiary of AstraZeneca PLC, may have the most advanced RSV vaccine program after Novavax, as it has reported testing in Phase 1 and Phase 1/2 clinical trials, in an intranasal, recombinant, live attenuated, RSV vaccine for the prevention of lower respiratory tract disease caused by RSV, as well as a combination intranasal vaccine for the prevention of several infant respiratory illnesses, including RSV. Additional entities have also entered into early clinical trials including GlaxoSmithKline and the National Institute of Allergy and Infectious Diseases, an institute under the U.S. National Institute of Health.

Unlike the low level of competition in the development of an RSV vaccine, there are a number of companies developing and selling vaccines for seasonal and pandemic influenza employing historic vaccine technology, as well as new technologies. The table below provides a list of major vaccine competitors and corresponding licensed influenza vaccine technologies.

Company	Competing Technology Description
Sanofi Pasteur, SA	Inactivated sub-unit (egg-based)
MedImmune, LLC (a subsidiary of AstraZeneca PLC)	Nasal, live attenuated (egg-based)
GlaxoSmithKline plc	Inactivated split-vaccine (egg-based)
Novartis, Inc.	Inactivated sub-unit (cell and egg-based)
Merck & Co., Inc.	Inactivated sub-unit (egg-based)
Protein Sciences Corporation	Recombinant HA trivalent (insect cell-based)

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There are many seasonal influenza vaccines 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 than we have. 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 should 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. Another differentiating factor is recombinant manufacturing, which we believe can be quicker and less-expensive than traditional egg-based manufacturing. In January 2013, the FDA approved the first recombinant seasonal influenza vaccine called Flublok manufactured by Protein Sciences Corporation.

Despite the significant competition and advancing technologies, some of which are similar to our own, we believe that our seasonal influenza product will be as efficacious as, or more so than, current products or products being developed by our competitors, and that our manufacturing system provides savings in both time and money; however, there can be no guarantee that our seasonal influenza vaccine will prove to be efficacious or that our manufacturing system will 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 depends upon our ability to show differentiation with a product that is more efficacious, particularly in the relevant target populations and/or be less expensive and quicker to manufacture. It also depends upon 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 often substantial 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 biopharmaceutical 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 process and other technologies. Currently, we have or have rights to over 100 U.S. patents and corresponding foreign patents and patent applications relating to vaccines and biologics. Our core vaccine-related intellectual property extends beyond the year 2025.

In July 2007, we entered into a non-exclusive license agreement with Wyeth Holdings Corporation, a subsidiary of Pfizer Inc. (Wyeth), to obtain rights 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.

In July 2010, U.S. Patent No. 7,763,450 for Functional Influenza Virus-Like Particles was issued by the U.S. Patent & Trademark Office. The patent 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. In December 2011, European Patent No. 1644037 was issued by the European Patent Office covering this technology.

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In December 2011, U.S. Patent No. 8,080,255 for Functional Influenza Virus-Like Particles was issued by the U.S. Patent & Trademark Office. The patent covers, in part, methods of inducing substantial immunity to an influenza virus infection in a human and administering to the human a VLP comprising M1, HA and NA proteins. The M1 protein is derived from a particular avian influenza strain, A/Indonesia/5/05.

In April 2013, European Patent No. 2343084 for Functional Influenza Virus-Like Particles was issued by the European Patent Office. The patent covers, in part, vaccine compositions containing VLPs that contain M1, HA, and NA proteins. The VLPs are self-assembled from host cells.

In August 2013, U.S Patent No. 8,506,967 for Functional Influenza Virus-Like Particles was issued by the U.S. Patent & Trademark Office. The patent covers, in part, methods of inducing substantial immunity to an influenza virus infection in a human and administering to the human a VLP comprising M1, HA and NA proteins. The M1 protein is from an avian influenza M1 protein from a different strain of influenza virus than the influenza HA protein and the influenza NA protein.

In October 2013, U.S Patent No. 8,551,756 for Avian influenza chimeric VLPs was issued by the U.S. Patent & Trademark Office. The patent covers, in part, methods of increasing the efficiency of VLP production using M1 proteins derived from strain A/Indonesia/5/05.

In November 2013, U.S Patent No. 8,592,197 for Functional Influenza Virus-Like Particles was issued by the U.S. Patent & Trademark Office. The patent covers, in part, influenza VLP vaccines containing M1, HA, and NA proteins where the M1 protein is from a different stain than the HA and NA proteins.

The Federal Technology Transfer Act of 1986 and related statutory guidance encourages the dissemination of science and technology innovation. While our recent contract with HHS BARDA provides us with the right to retain ownership in our inventions that may arise 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.* To a more limited extent, we rely 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 included 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. As a U.S. based company, we focus on the U.S. regulatory process and the standards imposed by the FDA and other agencies because we believe, for the most part, meeting U.S. standards will allow us to meet other international standards and satisfy regulatory agencies in other countries where we intend to do business. 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 approval 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 approval to market any new vaccine candidate, we must first submit an investigational new drug application (IND) that explains to the FDA, among other things, the results of pre-clinical testing conducted in laboratory animals, the method of manufacture, quality control tests for

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release 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 in humans. We must then conduct Phase 1 clinical trials and larger-scale Phase 2 and 3 clinical trials that demonstrate the safety and efficacy of our vaccine candidate to the satisfaction of the FDA.

Once these trials are complete, a BLA can be filed with the FDA requesting approval of the vaccine for marketing based on the vaccine's effectiveness and safety.

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 as it is in progress. Vaccine approval 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, many vaccines are required by the FDA to undergo Phase 4 confirmatory clinical trials after the BLA has been approved and the vaccine is on the market.

The FDA continues to oversee the production of vaccines after the vaccine and the manufacturing processes are approved, in order to ensure continuing safety. For example, monitoring of the vaccine and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds an approved BLA for the product. Manufacturers may also be required to submit to the FDA the results of their own tests for potency, safety and purity for each vaccine lot, if requested by the FDA. They may also be required to submit samples of each vaccine lot to the FDA for testing.

In addition to obtaining FDA approval for each product, each domestic manufacturing establishment must be registered with the FDA, is subject to FDA inspection and must comply with cGMP 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 cGMP regulations and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in their home country.

The development process for a biological product, such as a vaccine, typically takes a long period of time to complete. Pre-clinical studies may take several years to complete and there is no guarantee that the FDA will permit an IND to become effective and allow the product to advance to clinical testing. Clinical trials may take several years to complete. After the completion of the required phases of clinical trials, if the data indicate that the vaccine is safe and effective, a BLA is filed with the FDA to approve the marketing and commercial shipment of the vaccine. This process takes substantial time and effort and the FDA may not accept the BLA for filing. Even if filed and accepted, the FDA might not grant approval. FDA approval of a BLA may take up to two years and may take longer if substantial questions about the filing arise. The FDA may require post-marketing testing and surveillance to monitor the safety of the applicable products.

As discussed in the section entitled "Potential Accelerated Approval Pathway for Influenza" on page 4, we do not expect to pursue accelerated approval of our quadrivalent seasonal influenza vaccine, largely because of the uncertainty as to whether the accelerated approval pathway will be available to us at the time of our BLA submissions and the unknown ability of current and new influenza strains to meet such accelerated approval criteria. We nevertheless expect that our pandemic influenza vaccine may qualify for accelerated approval using surrogate endpoints described in published FDA guidance documents. We would thus expect to perform Phase 4 confirmatory clinical trials that will demonstrate the clinical benefit of our pandemic influenza vaccine candidate after the BLA is approved. However, there can be no guarantee that the FDA will grant accelerated approval of our pandemic influenza vaccine candidate.

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 approval does not assure 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. These and other laws govern our use, handling and

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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.

There have been a number of federal and state legislative changes made over the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system of the U.S. It is uncertain how such legislative changes will be adopted or what actions federal, state or private payers for medical goods and services may take in response to such legislation. We cannot predict the effect such healthcare changes will have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

## **Manufacturing**

In November 2011, we announced that we had entered into a long-term lease arrangement to occupy 74,000 square feet of manufacturing, laboratory and office space in two facilities in Gaithersburg, Maryland. During 2013, the main facility, located at 20 Firstfield Road in Gaithersburg, Maryland, became the primary late-stage clinical and commercial-scale manufacturing facility for production of our vaccines, following modifications that were completed in late 2012 and qualified in 2013. Our corporate offices were officially relocated to the same facility at 20 Firstfield Road.

Our Rockville, Maryland facility houses our 10,000 square foot cGMP pilot facility that produces clinical trial material.

In 2013, we acquired Isonova AB, now renamed Novavax AB, the producer of our Matrix adjuvants. Located in Uppsala, Sweden, Novavax AB has an approximately 15,400 square foot facility comprised of GMP manufacturing, laboratory and administrative space.

## **Sources of Supply**

Most of the raw materials and other supplies required in our business are generally available from various suppliers in quantities adequate to meet our needs. In some cases, we have only qualified one supplier for certain of our manufacturing components. Where feasible, we plan to seek qualification of multiple suppliers for all critical supplies before the time we would put any of our vaccine candidates into commercial production. Two of our major suppliers are GE Healthcare Company (GEHC), which supplies disposable components used in our manufacturing process, and Xcellerex, Inc., which was acquired by GEHC in 2012, and which supplies our single-use bioreactor production system and related supplies. The vendors that supply our key manufacturing materials are or will be audited for compliance with cGMP standards based on a schedule of when such materials would be needed during our own cGMP bioprocessing efforts.

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 while we have been able to acquire quillaja extract as needed from our current suppliers, we remain focused on establishing appropriate back-up supply arrangements for high-quality quillaja extract.

## **Business Development**

We believe our proprietary vaccine technology affords us a range of traditional and non-traditional commercialization options that are broader than those of existing vaccine companies. We strive to create sustainable value by working to obtain non-dilutive funding, similar to our agreements with HHS BARDA or PATH, to fund future trials for our RSV, seasonal influenza and pandemic influenza vaccine candidates, to continue development of our vaccine candidates until such vaccines can be licensed on a regional basis, to retain commercial rights in major markets and generate product sales revenue and, in certain markets, to commercialize our products through partners and other strategic relationships.

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In addition to our aforementioned contract with HHS BARDA, some examples of our strategic relationships are the joint venture we established with Cadila Pharmaceuticals, Ltd. (Cadila), our licensing agreement with LG Life Sciences, Ltd. (LGLS) and, most recently, our clinical development collaboration with PATH.

CPLB is owned 20% by us and 80% by Cadila. It was established in March 2009 to develop and manufacture certain vaccine candidates, biogeneric products and diagnostic products for the territory of India. CPLB operates a state-of-the-art manufacturing facility for the production of influenza vaccine and other vaccine candidates. CPLB is actively developing a number of vaccine candidates that were genetically engineered by Novavax. CPLB's seasonal and pandemic influenza vaccine candidates began Phase 1/2 clinical trials in 2012. Also in 2012, CPLB formed a new collaboration to develop a novel malaria vaccine in India with the International Centre for Genetic Engineering and Biotechnology. CPLB's rabies vaccine candidate began Phase 1/2 clinical trials in India in early 2014.

In February 2011, we entered into a license agreement with LGLS that allows LGLS to use our technology to develop and commercially sell our influenza vaccines in South Korea and certain other emerging-market countries. LGLS received an exclusive license to our influenza VLP technology in South Korea and a non-exclusive license in the other specified countries. At its own cost, LGLS is responsible for funding both its clinical development of the influenza VLP vaccines and a manufacturing facility to produce such vaccine in South Korea. We received an upfront payment and may receive reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments in the high single digits from LGLS's future commercial sales of influenza VLP vaccines.

In July 2012, we entered into a clinical development agreement with PATH to develop our vaccine candidate to protect against RSV through maternal immunization in low-resource countries (the RSV Collaboration Program). We were awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support our Phase 2 dose-ranging clinical trial in women of childbearing age as described above. In October 2013, the funding under this agreement was increased by \$0.4 million to support our reproductive toxicology studies, which are necessary before we conduct clinical trials in pregnant women. In December 2013, we entered into an amendment with PATH providing an additional \$3.5 million in funding to support the Phase 2 dose-confirmation clinical trial in 720 women of childbearing age. We retain global rights to commercialize the product and have made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH has continued to fund 50% of our external clinical development costs for the RSV Collaboration Program, but we do not continue development, we would then grant PATH a fully-paid license to our RSV vaccine technology for use in pregnant women in such low-resource countries.

## **Employees**

As of March 6, 2014, we had 213 full-time employees, of whom 44 hold M.D. or Ph.D. degrees and 52 of whom hold other advanced degrees. Of our total workforce, 175 are engaged primarily in research, development and manufacturing activities and 38 are engaged primarily in executive, business development, finance and accounting, legal and administrative functions. None of our U.S. based employees are represented by a labor union or covered by a collective bargaining agreement, while the majority of our employees located in our facility in Uppsala, Sweden are covered by industry-typical collective bargaining agreements, and in both cases we consider our employee relations to be good.

## **Executive Officers**

Our executive officers hold office until the first meeting of the Board of Directors (the Board) following the Annual Meeting of Stockholders and until their successors are duly chosen and qualified, or until they resign or are removed from office in accordance with our By-laws.

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The following table provides certain information with respect to our executive officers.

Name	Age	Principal Occupation and Other Business Experience During the Past Five Years
Stanley C. Erck	65	<b>President and Chief Executive Officer and Director</b> of Novavax since April 2011, formerly Executive Chairman since February 2010, and a Director since June 2009. From 2000 to 2008, Mr. Erck served as President and Chief Executive Officer of Iomai Corporation, a developer of vaccines and immune system therapies, which was acquired in 2008 by Intercell AG. He also previously held leadership positions at Procept, a publicly traded immunology company, Integrated Genetics, now part of Sanofi, and Baxter International. Mr. Erck also serves on the Board of Directors of BioCryst Pharmaceuticals, MaxCyte, Inc. and MdBio Foundation.
Barclay A. Phillips	51	<b>Senior Vice President, Chief Financial Officer and Treasurer</b> of Novavax since June 2013. Prior to joining the Company, Mr. Phillips served as Senior Vice President and Chief Financial Officer of Micromet, Inc., which was acquired by Amgen in 2012. Previously, he was Managing Director of Vector Fund Management and a Biotechnology Analyst and Director of Venture Investments at Invesco Funds Group, Inc.
Gregory Glenn, M.D.	60	<b>Senior Vice President, Research and Development</b> of Novavax since January 2011. Senior Vice President and Chief Scientific Officer from July 2010 to January 2011. Prior to joining the Company, Dr. Glenn was the Chief Scientific Officer and founder of Iomai Corporation, which was acquired in 2008 by Intercell AG, an associate in international health at Johns Hopkins University's School of Public Health and a clinical and basic research scientist at Walter Reed Army Institute of Research.
Timothy J. Hahn, Ph.D.	50	<b>Senior Vice President, Manufacturing and Process Development</b> of Novavax since June 2011. Prior to joining the Company, Dr. Hahn was Vice President of Antibody Manufacturing and later Vice President of Vaccine Manufacturing at MedImmune, LLC, with responsibilities for both U.S. and non-U.S. manufacturing sites. Dr. Hahn spent more than 15 years in vaccine manufacturing with Merck & Co.
Russell P. Wilson	54	<b>Senior Vice President, Business Development</b> of Novavax since November 2011. Mr. Wilson was most recently the Chief Financial Officer at Supernus Pharmaceuticals beginning in 2009. He was previously Senior Vice President, Chief Financial Officer and General Counsel of Iomai Corporation, which was acquired in 2008 by Intercell AG. He was the Acting General Counsel of North American Vaccine, Inc. until its acquisition by Baxter International in 2000.

## Availability of Information

Novavax was incorporated in 1987 under the laws of the State of Delaware. Our principal executive offices are located at 20 Firstfield Road, Gaithersburg, Maryland, 20878. Our telephone number is (240) 268-2000 and our website address is *novavax.com*. The contents of our website are not part of this Annual Report on Form 10-K.



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 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.

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Item 1A.

RISK FACTORS

You should carefully consider the following risk factors in evaluating our business. There are a number of risk factors that could cause our actual results to differ materially from those that are indicated by forward-looking statements.

Some of the risks described 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 facing us. Additional risks and uncertainties that we are unaware of, 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 should also consider the other information included in this Annual Report on Form 10-K.

## **RISKS RELATED TO OUR BUSINESS**

*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, 2013 was \$410.1 million. Our revenue for the last three fiscal years was \$20.9 million in 2013, \$22.1 million in 2012, and \$14.7 million in 2011. Prior to 2011, we recorded limited revenue from research contracts, licenses and agreements to provide vaccine candidates, services and technologies. We cannot be certain that we will be successful in entering into strategic alliances or collaborative arrangements with other companies and government agencies that will result in significant revenue to offset our expenses. Our net losses for the last three fiscal years were \$52.0 million in 2013, \$28.5 million in 2012, and \$19.4 million in 2011.

Our recent historical losses have predominantly resulted 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. We believe our expenses will continue to increase, as a result of higher research and development efforts to support the development of our vaccine candidates.

Although certain specified costs associated with the development of our influenza vaccines may be reimbursed under the contract with HHS BARDA, and to a more limited extent, certain outside costs associated with the development of our RSV maternal vaccine may be reimbursed under our contract with PATH, nevertheless we expect to continue to incur significant operating expenses and anticipate that our losses will increase in the foreseeable future as we seek to:

- conduct clinical trials for RSV and an RSV-influenza combination vaccine candidate;
- conduct pre-clinical studies for other early-stage vaccine candidates;
- comply with the FDA's manufacturing facility requirements;

invest in our manufacturing process for commercial-scale and cost-efficiency (not including technology transfer to our new manufacturing facility in Gaithersburg, Maryland that may be partially reimbursed by HHS BARDA); 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 cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

*We have limited financial resources and we are not certain that we will 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 an amount 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 pre-clinical studies and clinical trials, seek

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regulatory approvals and manufacture and market our products. We will seek such additional funds through public or private equity or debt financings, collaborative licensing and development arrangements, non-dilutive government contracts and grants and other sources. While we continue to apply for contracts or grants from academic institutions, non-profits and governmental entities, there are no assurances that we would be successful. We cannot be certain that adequate additional funding will 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 general and administrative infrastructure, 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.

***Capital and credit market conditions may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.***

Access to capital markets is critical to our ability to operate. Traditionally, biopharmaceutical 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, our inability to access the capital markets on favorable terms due to our low stock price, could affect our ability to execute our business plan as scheduled. Moreover, we rely and intend to rely on third-parties, including our clinical research organizations and certain other important vendors and consultants. As a result of the global economic situation, there may be 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.

***Even with the HHS BARDA contract award, we may not be able to fully fund our influenza programs.***

The HHS BARDA contract is a cost-plus-fixed-fee contract that only reimburses certain specified activities that have been previously authorized by HHS BARDA. There is no guarantee that additional activities will not be needed and, if so, that HHS BARDA will reimburse us for these activities. Additionally, we have limited experience meeting the significant requirements of a federal government contractor, which includes having appropriate accounting, project tracking and earned-value management systems implemented and operational, and our existing operations may not meet these requirements in a timely way or at all. Performance under the HHS BARDA contract requires that we comply with appropriate regulations and operational mandates, with which we have minimal operational experience.

Our ability to be regularly and fully reimbursed for our activities will depend on our ability to comply and demonstrate compliance with such requirements.

***The HHS BARDA contract award does not guarantee that we will be successful in future clinical trials, that the vaccine candidates will be licensed by the FDA, or that the contract award will continue to be available throughout the contract period.***

The HHS BARDA contract provides a cost-plus-fixed-fee reimbursement opportunity for certain specified clinical and development activities, but we remain fully responsible for conducting these activities. The award of the HHS BARDA contract does not guarantee that any of these activities will be successful. Our inability to be successful with certain key clinical or development activities could jeopardize our ability to get FDA licensure to sell our vaccines.

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***HHS BARDA could decide to potentially delay certain of our activities, and we may elect to move forward with certain activities at our own risk and without HHS BARDA reimbursement.***

Under the HHS BARDA contract, HHS BARDA regularly reviews our development efforts and clinical activities. Under certain circumstances, HHS BARDA may advise us to delay certain activities and invest additional time and resources before proceeding. If we follow such HHS BARDA advice, overall program delays and costs associated with additional resources for which we had not planned may result. Also, the costs associated with following such advice may or may not be reimbursed by HHS BARDA under our contract. Finally, we may decide not to follow the advice provided by HHS BARDA and instead pursue activities that we believe are in the best interest of the program and of the Company, even if HHS BARDA would not reimburse us under our contract.

***We may not meet the milestones of our contract with HHS BARDA during the contract period and HHS BARDA may elect not to extend the contract period for us to meet these milestones.***

The HHS BARDA contract anticipates that we file Biologics License Applications (BLA, the biologic equivalent to a New Drug Application or NDA) for licensure of both a seasonal influenza vaccine and a pandemic influenza vaccine; however, the recently-modified contract is for a base-period of three years and seven months plus an option-period of two additional years, and there is no guarantee that we will successfully complete all of the tasks required to file these BLAs during the anticipated contract period. For example, while we have made significant progress during the last year in addressing our goal of consistent and enhanced immune responses in all strains of our influenza vaccine candidates, there is no guarantee that we will ever be successful in having all the strains meet the immunogenicity criteria for accelerated approval by the FDA. The inability to meet such goals could cause delays in our influenza vaccine candidate programs.

***HHS BARDA may decide not to extend our contract beyond the recently extended base-period for a two-year option period.***

The HHS BARDA contract anticipates a three-year base-period, which has recently been extended by an additional seven months, followed by an optional two-year period. Depending on how we perform during the base-period, HHS BARDA will decide whether or not to extend the contract to include the option period. Although we believe that, based on our progress to date and the activities that we have planned in the future, HHS BARDA will want to extend the contract, there can be no guarantee that HHS BARDA will decide to extend our contract to an option period.

***HHS BARDA directed activities under the contract may require us to change our plans such that other activities anticipated under the contract may not occur during the contract period, which may necessitate that we fund such activities ourselves or not conduct them at all.***

HHS BARDA has directed us to focus on developing our pandemic influenza vaccine against the A(H7N9) strain; while we expect to be able to initiate a Phase 2 clinical trial for our pandemic (H7N9) influenza vaccine candidate, certain work that had been conducted on our pandemic (H5N1) influenza vaccine candidate may need to be duplicated or re-conducted on our pandemic (H7N9) influenza vaccine candidate. To the extent that such work is reimbursed by HHS BARDA under our contract, such funds may not be available for other development activities that we had anticipated would be performed under the contract. In such cases, we will need to decide whether to conduct the activities at our own expense or to determine that such activities are unnecessary.

***Our expectation that our pandemic influenza vaccine candidate will be granted accelerated approval by the FDA is not guaranteed and if we don't get accelerated approval, development of this vaccine will take longer and cost significantly more prior to BLA approval.***

As is the case with seasonal influenza, FDA has articulated the immunogenicity criteria for accelerated approval of vaccines that address potential pandemic influenza strains. Because a controlled efficacy clinical trial of a pandemic vaccine candidate is not logistically or ethically possible, accelerated approval will require evidence that a seasonal vaccine made by the same manufacturing process as the pandemic vaccine is efficacious. There is no guarantee the FDA will grant accelerated approval of our pandemic vaccine before we provide seasonal influenza efficacy data. If our seasonal influenza vaccine does not get accelerated approval

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from the FDA, it is likely that we will need to conduct larger and more expensive efficacy clinical trials and that licensure of our seasonal vaccine will be materially delayed for a year or more, assuming such licensure occurs at all, which may, in turn, delay the FDA approval of our pandemic vaccine.

***Because of changes to the influenza vaccine industry and regulatory environment, accelerated approval by the FDA of our seasonal influenza vaccine candidate may not be available in which case development of this vaccine will take longer and cost significantly more prior to BLA approval.***

While FDA regulations allow for the accelerated approval of a seasonal influenza vaccine based on surrogate endpoint criteria for products that treat serious diseases and fill an unmet medical need, which can allow developers to obtain licensure well ahead of the timeline for demonstrating clinical results in a traditional efficacy trial, the seasonal influenza vaccine industry has made significant steps to provide sufficient supply to the recommended population in the U.S. Thus, the FDA may no longer view the development of our seasonal influenza vaccine as meeting an unmet medical need. If our seasonal influenza vaccine does not receive accelerated approval from the FDA, we will need to conduct larger and more expensive efficacy clinical trials and that licensure of our seasonal vaccine will be materially delayed for a year or more, assuming such licensure occurs at all.

***Our recent acquisition of Novavax AB, collaborations with regional partners, such as Cadila, LGLS, and PATH, as well as contracts with international providers, expose us to additional risks associated with doing business outside the U.S., and any adverse event could have a material negative impact on our operations.***

We acquired Swedish-based Novavax AB on July 31, 2013. We have also formed a joint venture with Cadila in India, entered into a license agreement with LGLS in South Korea, a clinical development agreement with PATH 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 other parts of the world. Risks of conducting business outside the U.S. include:

multiple regulatory requirements could affect our ability to develop, manufacture and sell products in such local markets;  
compliance with anti-bribery laws such as the United States Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;  
trade protections measures and import and export licensing requirements;  
different labor regulations;  
changes in environmental, health and safety laws;  
exchange rates;  
potentially negative consequences from changes in or 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 some countries; 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, LGLS, and PATH are examples of these regional relationships. These relationships are likely to involve the licensing of our technology to our partner or



entering into a distribution agreement, frequently on an exclusive basis.

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Generally, these 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 biopharmaceutical 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 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, pre-clinical 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 pre-clinical or early clinical trials may not translate into success in large-scale clinical trials. Further, success in clinical trials will likely lead to increased investment, accelerating cumulative losses to bring such products to market. 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 our products.

***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;  
pre-clinical 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;

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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, Novartis, Inc., Sanofi Pasteur, SA, Pfizer Inc. and MedImmune, LLC (a subsidiary of AstraZeneca PLC), 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.

There are many seasonal influenza vaccines 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 must 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, each of which is intended to be more efficacious than products currently being marketed. Our 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.

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 a vaccine that is marketable to multiple segments of the population. 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, nor as efficacious as products under development by competing companies.

Smaller or early-stage companies and research institutions may also 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 subject 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. There is no assurance that we will 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, we may experience delays in product development.*

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. We have had several turnover situations in key executive positions and the lack of management continuity and resulting lack of long-term history with our Company along with the

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learning curve that executives experience when they join our management team could result in operational and administrative inefficiencies and added costs. If we were to experience additional turnover at the executive level, these risks would be exacerbated.

We may not be able to attract qualified individuals for other key management or other personnel 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 required for the expansion of our activities, could hinder our ability to complete clinical trials successfully and develop marketable products.

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 have a material adverse effect on our business, financial condition and results of operations.

***We may have product liability exposure.***

The administration of drugs or vaccines to humans, whether in clinical trials or after marketing clearances are obtained, 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 can significantly fluctuate. Therefore, we may not be able to maintain insurance at a reasonable cost. There can be no assurance that we will 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 resulting 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 subjects 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 academic institutions, government agencies and non-profit entities. 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, there is no guarantee that we will be a successful awardee. Therefore, we may not be able to win any contracts or grants in a timely manner, if at all.



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***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. 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.

## **RISKS RELATED TO OUR ACQUISITION OF NOVAVAX AB**

***We may not be able to successfully integrate our business with the business of Novavax AB.***

The acquisition of Novavax AB involves the integration of two companies based in different countries that had been operating independently. This integration will be a complex, costly and time-consuming process. We may encounter difficulties in integrating our operations, technology and personnel with those of Novavax AB and this may continue for some time. Our management has limited experience integrating operations as substantial and geographically diverse as those of Novavax AB. We may not successfully integrate our operations and Novavax AB's operations in a timely manner, or at all. The failure to successfully integrate the businesses' operations could adversely affect our business, financial condition and results of operations. The anticipated benefits relate to utilizing Novavax AB's proprietary adjuvants, including Matrix-M, with one or more of Novavax' product candidates and retaining the full economics and developmental control of these adjuvanted vaccines, as well as other opportunities resulting from Novavax' and Novavax AB's complementary product candidates, industry specialties and technology platforms.

However, these anticipated benefits are based on projections and assumptions, not actual experience, and assume a successful integration.



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***As a result of the combination with Novavax AB, we may face risks upon entering into certain specific areas of vaccine development for which we have limited or no experience.***

Novavax AB develops adjuvants in veterinary vaccines. The development and improvement of vaccines for the global veterinary market is an area of vaccine development for which we have limited or no experience. Although comprising a small part of our business, this lack of experience may have a negative impact to operations.

***Novavax AB adjuvants, including Matrix-M, may prove to have limited or no benefit to our vaccine development programs.***

We cannot guarantee that Matrix-M, or any other of Novavax AB's saponin-based adjuvants, will offer immunogenic benefits to any of our vaccine programs until such adjuvants are tested in clinical trials.

***We may not be able to achieve the anticipated strategic benefits of our recent combination with Novavax AB.***

We are not able to guarantee that anticipated strategic benefits from the completed acquisition of Novavax AB, including cost savings from operational activities, will be realized within the time periods contemplated or that they will be realized at all. We are not able to guarantee that the combination of Novavax and Novavax AB will result in the realization of the full benefits.

***Adjuvants, including saponin-based adjuvants such as Matrix-M, are likely to face increased regulatory scrutiny and may prove to be unpopular with vaccine-using consumers and advocacy groups.***

Regulatory agencies, including the FDA, have been cautious in approving adjuvants for use in commercial vaccines. Recent reports on adjuvants that contain squalene, a commercially extracted adjuvant derived from shark liver oil, as an active ingredient, and links to neurological disorders like narcolepsy may cause regulatory agencies to increase their scrutiny of all adjuvants, whether they contain squalene or not. Although none of the adjuvants made by Novavax AB contain squalene, the impact of such regulatory scrutiny may be detrimental to vaccine products containing non-squalene adjuvants. In addition, adjuvant usage has been unpopular with a small group of vaccine advocacy and consumer groups who oppose the addition of further active ingredients in vaccines; their opposition may gain support and have a detrimental impact on commercialization efforts and opportunities.

***As a result of the acquisition of Novavax AB, we will have revenue and expenses outside of the U.S., so we will be subject to fluctuations in foreign currency rates, and if our management is unable to manage our exposure to foreign currencies successfully, our operating results will suffer.***

With the acquisition of Novavax AB, we will be exposed to risks associated with the translation of Novavax AB's Swedish Krona (SEK)-denominated financial results and balance sheet into U.S. dollars. Our reporting currency will remain as the U.S. dollar. Any inability to successfully manage fluctuations in foreign currency rates could have a material adverse effect on our results of operations and, as a result, on the market price of our common stock.

***The uncertainties associated with our combination with Novavax AB may cause key personnel to leave.***

Our employees, including the employees of Novavax AB, may perceive uncertainty about their future role with the combined business until strategies with regard to the combined business are fully executed. Any uncertainty may affect either our ability to retain key management, sales, marketing, technical and financial personnel. Novavax AB's technology is based, in part, on trade secret and know-how, so if we are not able to retain key technical employees, we might have difficulties in continuing to develop and maintain Novavax AB's proprietary adjuvants, which may impede

the achievement of our objectives with this acquisition.

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## 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 approval 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 pre-clinical 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 pre-clinical laboratory or animal studies.

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

- performance of pre-clinical (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



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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 pre-clinical 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 vaccines 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.

Influenza vaccines are seasonal in nature. If a vaccine is not available early enough in the influenza season, we would likely have difficulty selling the vaccine. Further, pandemic outbreaks present only short-term opportunities for us.

There is no way to predict when there will be a pandemic outbreak, the strain of the influenza or how long the pandemic will last. For these reasons, any delay in the delivery of an influenza vaccine could result in lower sales volumes, lower sale prices, or no sales. Because the strain of the seasonal influenza changes annually, inventory of seasonal vaccine cannot be sold during a subsequent influenza season. Any delay in the manufacture of our influenza 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 product 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.

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***Expanded capacity in our new manufacturing facility, if required, may not be fully available during 2014, which may impede or delay our ability to manufacture one or more vaccine candidates for subsequent clinical trials.***

Although our new manufacturing facility in Gaithersburg, Maryland, designed to manufacture later stage vaccine candidates, has completed refurbishment and is currently qualified, the new facility may require new equipment in order to expand its manufacturing capacity. There are risks associated with expanding the capacity of such a facility that include but are not limited to contractor issues and delays, licensing and permitting delays or rejections, limitations and delays on the installation of new or custom-ordered equipment, issues associated with validating such equipment, and processes or other aspects of insuring cGMP manufacturing. There are many aspects of the project that rely on third party contractors and subcontractors, and we and they encounter delays.

***We expect to continue to use all of our Rockville manufacturing facility; however, if we choose not to do so, we may not be able to defray the lease payments and operating expenses of that facility.***

With our new late-stage and commercial launch manufacturing facility in Gaithersburg, Maryland, we have the opportunity to continue to fully utilize our facility in Rockville, Maryland to develop early-stage clinical material and perform other pilot manufacturing activities. Although we expect to utilize the entire Rockville facility, depending on our needs, we may decide to sublease a portion or all of the Rockville facility prior to the end of our lease on January 31, 2017. The expenses of leasing two manufacturing facilities are significant, however, if we decide to sublease a portion or all of the Rockville facility, such a sublease may prove difficult to obtain and even if we are able to do so, the sublease payments may not cover our lease payments and operating expenses for the space that we would sublet.

***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 partner 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

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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 Novavax. 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 cGMP. 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 would 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 pre-clinical 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.

***Our collaborations may not be profitable.***

We entered a co-marketing agreement with GEHC in December 2007 for a pandemic influenza vaccine solution for select international countries, and our collaboration continues to incorporate GEHC's bioprocessing/manufacturing solutions and design expertise with our VLP manufacturing platform.

We have formed CPLB with Cadila in India and, in connection with it, entered into a master services agreement pursuant to which we may request certain services from Cadila in the areas of biologics research, pre-clinical



development, clinical development, process development, manufacturing scale-up and general manufacturing related services in India. We and Cadila amended the master services agreement first in July 2011, and subsequently in March 2013 and March 2014, in each case to extend the term by one year for which services can be provided by Cadila under this agreement. Under the revised terms, if, by March 2015, the amount of services provided by Cadila under the master services agreement is less than \$7.5 million, we

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will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. We and Cadila also agreed to an amendment that allows CPLB, as of the beginning of 2013, to provide services on behalf of Cadila. Through December 31, 2013, we have purchased \$3.0 million in services from Cadila pursuant to this agreement, including amounts in which CPLB provided the services on behalf of Cadila.

We have entered into a license agreement with LGLS that allows them to use our manufacturing and production technology to develop and sell our influenza vaccines. We have also entered into a clinical development agreement with PATH related to our RSV vaccine for maternal immunization in low-resource countries. To the extent PATH continues to fund 50% of the Company's external clinical development costs, but the Company does not continue development, the Company would grant PATH a fully-paid license to its RSV vaccine technology for use in pregnant women in such low-resource countries at terms that may not be favorable to the Company.

We cannot predict when, if at all, these relationships will lead to 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.***

We currently have no 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 cannot be certain that we will 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 based on immunogenicity;
- 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.

In particular, there are significant challenges to market acceptance for seasonal influenza vaccines. For our seasonal vaccine to be accepted in the market, we 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 vaccine will be more efficacious than

other vaccines.

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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 would 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 recently-acquired 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 the introduction of 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, managed care programs 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, losing any potential marketing advantage of being early to market and increased clinical trial costs. The speed with which we begin and complete our pre-clinical 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 pre-clinical 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 subject or patient enrollment and retention, which is a function of many factors, including the size of the subject or patient population, the proximity of subjects and patients 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 pre-clinical 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 pre-clinical studies and clinical trials necessary to obtain regulatory marketing approvals. We may not be permitted to continue or commence

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additional clinical trials. We also face the risk that the results of our clinical trials may be inconsistent with the results obtained in pre-clinical 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 biopharmaceutical 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 subjects or patients 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, LGLS in South Korea and PATH. 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.

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***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 and in Sweden 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. 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 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 coverage and reimbursement for such products from third-party payers such as:

government health administration authorities;  
private health insurers;  
health maintenance 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 health maintenance organizations that control or significantly



influence purchases 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

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could nevertheless adversely affect our business strategy, operations and financial results. In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010 (PPACA). As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. The long-term ramifications of PPACA remain unclear and many details regarding implementation of PPACA are yet to be determined, however the cost-containment measures that healthcare providers are instituting and the results of healthcare reforms may negatively impact the commercial prospects of one or more of our vaccine candidates currently in development.

## **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 100 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 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.

*If we infringe or are alleged to infringe the intellectual property rights of third-parties, it will adversely affect our business, financial condition and results of operations.*

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

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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. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U.S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology.

***We may become involved in lawsuits 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.

Interference proceedings brought by the U.S. Patent and Trademark Office, or similar proceedings in foreign jurisdictions, may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. 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.

***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 expect that we will need to license intellectual property from third-parties in the future 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.

Our license agreement with Wyeth, which gives us rights to a family of patents and patent applications that are expected to expire in early 2022, covering VLP technology for use in human vaccines in certain fields of use, is non-exclusive. These applications are very significant to our business. If each milestone is achieved for any particular vaccine candidate, we would likely be obligated to pay an aggregate of \$14 million to Wyeth for each vaccine

candidate developed and commercialized under the agreement. Achievement of each milestone is subject to many risks, including those described in these Risk Factors. Annual license fees under the Wyeth agreement aggregate to \$0.2 million per year.

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

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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.

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. 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.

## **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 biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. From January 1, 2013 through December 31, 2013, the closing sale price of our common stock has been as low as \$1.75 per share and as high as \$5.16 per share. The market price of our common stock may be influenced by many factors, including:

future announcements about our Company 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;  
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 influenza;

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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; and  
the other factors described in this Risk Factors section.

The stock market has experienced extreme price and volume fluctuations that have particularly affected the market price for many emerging and biopharmaceutical 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.

***Provisions of our Certificate of Incorporation and 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.***

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.

The Company also is 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.



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## Item 2.

## PROPERTIES

We lease two facilities in Gaithersburg, Maryland and one in Rockville, Maryland. In conjunction with our acquisition of Isconova AB in 2013, we acquired a facility lease in Uppsala, Sweden. We continue to lease space at our former corporate headquarters in Malvern, Pennsylvania, all of which is currently subleased. A summary of our current facilities is set forth below.

Property Location	Approximate Square Footage	
Rockville, MD	51,200	Vaccine research and development and manufacturing facility
20FF Gaithersburg, MD	53,000	Corporate headquarters, vaccine research and development and manufacturing facility
22FF Gaithersburg, MD	21,000	Administrative, clinical and regulatory offices
Uppsala, Sweden	15,400	Adjuvant manufacturing facility and research and development and administrative offices
Malvern, PA	32,900	Former corporate headquarters and research and development
Total square footage	173,500	
Malvern, PA sublease	(32,900 )	
Net square footage	140,600	

## Item 3.

## LEGAL PROCEEDINGS

We currently have no material legal proceedings underway.

## Item 4.

## MINE SAFETY DISCLOSURES

Not applicable.

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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. The following table sets forth the range of high and low closing sale prices for our common stock as reported on The NASDAQ Global Select Market for each quarter in the two most recent years:

Quarter Ended	High	Low
December 31, 2013	\$ 5.16	\$ 2.76
September 30, 2013	\$ 3.38	\$ 2.11
June 30, 2013	\$ 2.69	\$ 1.79
March 31, 2013	\$ 2.28	\$ 1.75
December 31, 2012	\$ 2.39	\$ 1.57
September 30, 2012	\$ 2.23	\$ 1.71
June 30, 2012	\$ 1.56	\$ 1.16
March 31, 2012	\$ 1.52	\$ 1.23

On March 6, 2014, the last sale price reported on The NASDAQ Global Select Market for our common stock was \$6.05. Our common stock was held by approximately 452 stockholders of record as of March 6, 2014, one of which is Cede & Co., a nominee for Depository Trust Company (or 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 have not paid any cash dividends on our common stock since our inception. 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 (Annual Report).

TABLE OF CONTENTS**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, 2008, and reinvestments of all dividends.

Value of \$100 invested on December 31, 2008 in stock or index, including reinvestment of dividends, for fiscal years ended December 31:

	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12	12/31/13
Novavax, Inc.	\$100.00	\$140.74	\$128.57	\$66.67	\$100.00	\$270.90
NASDAQ Composite Index	\$100.00	\$144.88	\$170.58	\$171.30	\$199.99	\$283.39
RUSSELL 2000 Growth Biotechnology Index	\$100.00	\$131.12	\$146.22	\$141.62	\$162.66	\$254.04

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 Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

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The following table sets forth selected financial data for each of the years in the five-year period ended December 31, 2013, which has been derived from our audited financial statements. The information below should be read in conjunction with our 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 that may be expected for future periods.

	For The Years Ended December 31,				
	2013	2012	2011	2010	2009
	(in thousands, except per share amounts)				
<b>Statements of Operations Data:</b>					
Revenue	\$20,915	\$22,076	\$14,688	\$343	\$325
Net loss	(51,983 )	(28,507 )	(19,364 )	(35,708 )	(40,346)
Basic and diluted net loss per share	(0.31 )	(0.22 )	(0.17 )	(0.34 )	(0.47 )
Weighted average shares used in computing basic and diluted net loss per share	169,658	131,726	113,610	104,768	85,555
	As of December 31,				
	2013	2012	2011	2010	2009
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and investments <sup>(1)</sup>	\$133,068	\$50,344	\$18,309	\$31,676	\$42,950
Total current assets	145,001	50,408	26,109	33,337	44,503
Working capital <sup>(2)</sup>	126,067	38,733	18,530	23,071	36,476
Total assets <sup>(3)</sup>	235,937	102,345	66,576	74,844	85,605
Long-term debt, less current portion	1,199	990	300	320	406
Accumulated deficit	(410,146)	(358,163)	(329,656)	(310,292)	(274,584)
Total stockholders' equity <sup>(3)</sup>	203,234	80,240	53,849	59,050	69,952

(1) Includes non-current investments of \$6,233 at December 31, 2012.

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

At December 31, 2013, total assets and total stockholders' equity include approximately \$45 million and \$42 (3) million, respectively, relating to the acquisition of Isconova AB (see Note 4 to the consolidated financial statements included herewith).

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

Any statements in the discussion below and elsewhere in this report, about the expectations, beliefs, plans, objectives, assumptions or future events or performance of Novavax, Inc. (Novavax, and together with its 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 regarding our expectations regarding future revenue and expense levels, 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 future development of our product candidates by us, the conduct, timing and results of future clinical trials, plans regarding regulatory filings, our available cash resources and the availability of financing generally, our plans regarding partnering activities and business development initiatives, and other factors referenced herein. You can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, possible, can, estimate, consider, anticipate, intend, seek, plan, project, expect, should, would, or assume or the negative or other comparable terminology, although not all forward-looking statements contain these words.

Any or all of our forward-looking statements in the Annual Report may turn out to be inaccurate or materially different than actual results. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation, the progress, timing or success of our clinical trials; difficulties or delays in development, testing, GMP manufacturing and scale-up, obtaining regulatory approval for producing and marketing our product candidates; regulatory developments in the United States or in foreign countries; the risks associated with our reliance on collaborations for the development and commercialization of our product candidates; unexpected adverse side effects or inadequate efficacy of our product candidates that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; our ability to attract and retain key scientific, management or operational personnel; the size and growth potential of the markets for our product candidates and our ability to serve those markets; the scope and validity of patent protection for our product candidates; competition from other pharmaceutical or biotechnology companies; our ability to establish and maintain strategic collaborations or to otherwise obtain additional financing to support our operations on commercially reasonable terms; successful administration of our business and financial reporting capabilities; and other risks detailed in this report, including those identified in Part I, Item 1A, Risk Factors of this Annual Report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this Annual Report may not occur as we contemplate, and actual results could differ materially from those anticipated or implied by the forward-looking statements and we therefore caution readers not to place undue reliance on such forward-looking statements contained in this Annual Report.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

**Overview**

Novavax, Inc. (Novavax, and together with its subsidiary, Novavax AB, the Company, we or us) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant protein nanoparticle vaccines and adjuvants. Our vaccine technology platform is based on proprietary recombinant nanoparticle vaccine technology that includes virus-like particles ( VLPs ) vaccines and protein nanoparticle vaccines. These vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate

immunologically important proteins. Our vaccine product pipeline targets a variety of infectious diseases with candidates currently in clinical development for seasonal influenza, pandemic influenza and respiratory syncytial virus ( RSV ). We operate in one business segment: developing recombinant vaccines. Therefore, our results of operations are discussed on a consolidated basis.

Through our Swedish subsidiary, Novavax AB (formerly Isconova AB), we are also developing proprietary technology for the production of immune stimulating saponin-based adjuvants, which we expect to

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utilize in conjunction with our pandemic influenza vaccine candidates and potentially with other vaccine candidates that may benefit from such an adjuvant. The Matrix™ technology utilizes selected quillaja fractions, which form separate matrix structures, to develop modern, multi-purpose immune-modulating adjuvant products for a broad range of potential vaccine applications. We acquired the Matrix technology through our acquisition of Isconova AB in the third quarter of 2013 because we believe this saponin-based adjuvant technology is a powerful complement to our recombinant vaccine programs. Our lead adjuvant for human applications, Matrix-M™, is in clinical trials with our partner Genocea Biosciences, and we plan to initiate a clinical trial using Matrix-M in combination with our H7N9 vaccine candidate in the first half of 2014. This trial will be conducted under our contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA).

In 2009, we formed a joint venture with Cadila Pharmaceuticals Limited ( Cadila ) named CPL Biologicals Private Limited ( CPLB ) to develop and manufacture vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by us and 80% by Cadila. CPLB operates a state-of-the-art manufacturing facility for the production of influenza vaccines and other vaccine candidates and is actively developing a number of vaccine candidates that were genetically engineered by us.

## Clinical Product Pipeline

A current summary of our significant research and development programs and status of related products in development follows:

Program	Development Phase	Collaborator
Respiratory Syncytial Virus (RSV)		
Maternal Immunization	Phase 2	PATH
Elderly	Phase 1	
Pediatric	Pre-clinical	
Influenza		
Seasonal Quadrivalent	Phase 2	HHS BARDA/LGLS
Pandemic (H5N1)	Phase 1/2	HHS BARDA/LGLS
Pandemic (H7N9)	Phase 1	HHS BARDA/LGLS
Combination (Influenza/RSV)	Pre-clinical	
CPLB Programs (India)		
Seasonal Trivalent Influenza	Phase 1/2	
Pandemic (H1N1) Influenza	Phase 1/2	
Rabies	Phase 1/2	

### Respiratory Syncytial Virus (RSV)

RSV is a widespread disease that causes infections of the lower respiratory tract. While RSV affects persons of all ages, it acutely impacts infants, the elderly, young children and others with compromised immune systems. Current estimates indicate that RSV is responsible for over 30 million new acute lower respiratory infection episodes and between 150,000 and 200,000 deaths in children under five years old.<sup>7</sup> In the U.S., nearly all children become infected with RSV before they are two years old; it has been associated with 20% of hospitalizations and 15% of office visits for acute respiratory infection in young children.<sup>8</sup> The

Although we initiated development of our pandemic influenza vaccine program under our contract with HHS BARDA against the A(H5N1) strain, because of concern over the potential mutation and spread of the A(H7N9) influenza strain in China, we independently initiated a second pandemic vaccine program in the first half of 2013 against A(H7N9). In February 2014, we amended our contract with HHS BARDA to re-focus our development of a pandemic influenza vaccine against the A(H7N9) strain with a Phase 1/2 clinical trial with our H7N9 candidate and Matrix-M™ adjuvant, which began in the first quarter of 2014; however, HHS BARDA has also indicated that the H5N1 vaccine program remains a viable potential development opportunity under the contract.

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Nair, H., *et al.*, (2010) *Lancet*. 375:1545-1555

8

Hall, CB, *et al.*, (2009) *N Engl J Med*. 360(6):588-98.



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World Health Organization (WHO) estimates that the global disease burden for RSV is 64 million cases. Because there is no approved prophylactic vaccine, the unmet medical need of an RSV vaccine has the potential to protect millions of patients from this far-reaching disease.

We are developing a vaccine candidate to prevent RSV disease, and are looking at three susceptible target populations: infants who may receive protection through antibodies transferred from their mothers who would be immunized during the last trimester of pregnancy, the elderly and young children.

### **Maternal Immunization Development Program    Clinical Experience**

In April 2013, we announced top-line data from a Phase 2 dose-ranging clinical trial in women of childbearing age that were similar to, or exceeded, immune responses seen in our first Phase 1 clinical trial. This randomized, blinded, placebo-controlled Phase 2 clinical trial evaluated the safety and immunogenicity of two dose levels of our RSV vaccine candidate, with and without an aluminum phosphate adjuvant, in 330 women of childbearing age. We further reported that the vaccine candidate was well-tolerated, the two-dose alum-adjuvanted groups showed a 13 to 16-fold rise in anti-F IgG antibodies to the F protein compared to a six to ten-fold rise in the non-alum groups, and Palivizumab-like antibody titers rose eight to nine-fold with four-fold rises in 92% of subjects in the two-dose alum-adjuvanted groups.

In October 2013, we initiated and completed enrollment in a Phase 2 dose-confirmation clinical trial in 720 women of childbearing age. The data from this trial, expected in the second quarter of 2014, will supplement the data from our other clinical trials, and is expected to support the advancement of our maternal immunization program in pregnant women; we plan to initiate a Phase 2 clinical trial of our RSV vaccine candidate in pregnant women in the fourth quarter of 2014.

### **Elderly Development Program    Clinical Experience**

In July 2013, we announced top-line data from the Phase 1 clinical trial in the elderly that was initiated in October 2012. This clinical trial was a randomized, blinded, placebo-controlled Phase 1 clinical trial that evaluated the safety and immunogenicity in 220 enrolled elderly adults, 60 years of age and older, who received a single intramuscular injection of our RSV vaccine candidate (with and without alum) or placebo plus a single dose of licensed influenza vaccine or placebo at days 0 and 28. The top-line data further corroborated our previous clinical experiences with our RSV vaccine candidate: we reported that the vaccine candidate was well-tolerated, that the higher dose groups had better overall immune responses than the lower dose groups and that essentially undetectable Day 0 levels of antibodies that compete with palivizumab increased to between 80% and 97% of active vaccine recipients by Day 28. Our expected path forward in the elderly would include a dose-confirmation clinical trial in late 2014 or early 2015.

### **Pediatric Development Program    Pre-clinical Experience**

While the burden of RSV disease falls heavily on newborn infants, RSV is also a prevalent and currently unaddressed problem in pediatric patients. This third market segment for our RSV vaccine candidate remains an important opportunity. We expect to initiate clinical trials in pediatric subjects as step-downs from our past clinical trials in healthy adults. We also expect that our clinical experience in pregnant women will be equally important to understanding a vaccine for this patient population. Our preclinical development efforts support such a clinical development plan that is expected to be launched in late 2014.

## **PATH Vaccine Solutions (PATH) Clinical Development Agreement**

In July 2012, we entered into a clinical development agreement with PATH to develop our vaccine candidate to protect against RSV through maternal immunization in low-resource countries (RSV Collaboration Program). We were awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support our Phase 2 dose-ranging clinical trial in women of childbearing age as described above. The funding under the agreement was increased by \$0.4 million to support our reproductive toxicology studies, which are necessary before we conduct clinical trials in pregnant women. In December 2013, we entered into an amendment with PATH providing an additional \$3.5 million in funding to support the Phase 2 dose-confirmation clinical trial in 720 women of childbearing age as described above. We retain global rights to commercialize the product and will support PATH in its goal to make an RSV maternal vaccine product affordable and available in low-resource countries.

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To the extent PATH elects to continue to fund 50% of our external clinical development costs for the RSV Collaboration Program, but we do not continue development, we would then grant PATH a fully-paid license to our RSV vaccine technology for use in pregnant women in such low-resource countries.

# Influenza

## Seasonal Influenza Vaccine

Developing and commercializing a Novavax seasonal influenza vaccine remains an important strategic goal and viable opportunity for us. The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (CDC) recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with these universal recommendations, attention from the 2009 influenza H1N1 pandemic, along with reports of other cases of avian-based influenza strains, has increased public health awareness of the importance of seasonal influenza vaccination, the market for which is expected to continue to grow worldwide in both developed and developing global markets.

There are currently four quadrivalent influenza vaccines licensed in the U.S., but in the coming years, additional seasonal influenza vaccines are expected to be produced and licensed within and outside of the U.S. in a quadrivalent formulation (four influenza strains: two influenza A strains and two influenza B strains), as opposed to trivalent formulations (three influenza strains: two influenza A strains and one influenza B strain). With two distinct lineages of influenza B viruses circulating, governmental health authorities have advocated for the addition of a second influenza B strain to provide additional protection. Current estimates for seasonal influenza vaccines growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from the current market of approximately \$3.2 billion (2012/13 season) to \$5.3 billion by the 2021/2022 season.<sup>9</sup> Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of vaccines can be quickly and cost-effectively manufactured without the use of either the live influenza virus or eggs.

Top-line data from our most recent Phase 2 clinical trial for our quadrivalent influenza vaccine candidate were announced in July 2012. In that clinical trial, our quadrivalent VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, and was also well-tolerated, as evidenced by the absence of any observed vaccine-related serious adverse events (SAEs) and an acceptable reactogenicity profile. Our vaccine candidate met the FDA accelerated approval seroprotection rates criterion for all four viral strains. The potential to fulfill the seroconversion rates criterion was demonstrated for three of the four viral strains. The fourth strain, B/Brisbane/60/08, despite fulfilling the seroprotection criterion, failed to demonstrate a satisfactory seroconversion rate. Following our last Phase 2 clinical trial, we focused our seasonal influenza vaccine candidate activities on locking the manufacturing process that will ensure consistent and enhanced immune responses in all strains. We completed these activities in September 2013. We have begun manufacturing A and B strain influenza VLPs for the next Phase 2 clinical trial with our quadrivalent vaccine candidate, which we expect to initiate in the fourth quarter of 2014.

## Pandemic Influenza Vaccine

In the aftermath of the 2009 H1N1 influenza pandemic, recognition of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 pandemic led to the production of approximately 126 million doses of monovalent (single strain) vaccine. Public health awareness and government preparedness for the next potential influenza

pandemic are driving development of vaccines that can be manufactured quickly against a potentially threatening influenza strain. Until the spring of 2013, industry and health experts focused attention on developing a monovalent H5N1 influenza vaccine as a potential key defense against a future pandemic threat; however, recent attention from a significant number of reported cases in China of an avian-based influenza strain of H7N9 has shifted to the potential development of an H7N9 influenza vaccine.

In October 2012, under our collaboration with HHS BARDA, we reported positive results from two Phase 1 clinical trials of our pandemic (H5N1) vaccine candidate in combination with two different adjuvants,

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both of which are designed to improve the immunogenicity of vaccines at lower doses and thus provide antigen dose-sparing. The top-line data demonstrated safety and immunogenicity of varying dose-levels of the vaccine, with and without adjuvant, and further demonstrated statistically significant robust adjuvant effects on immune response.

In April 2013, we initiated manufacturing of a new monovalent influenza vaccine candidate against prototype A(H7N9). This strain was first recognized by Chinese health authorities as a potential pandemic influenza threat in late March 2013. In a three month period, we developed a recombinant baculovirus expressing the published A(H7N9) viral HA and NA gene sequences, developed and purified a VLP vaccine antigen, conducted multiple animal studies and initiated a Phase 1 clinical trial in Australia independent of our HHS BARDA contract. In November 2013, we announced the publication of the clinical results from the Phase 1 clinical trial in *The New England Journal of Medicine*. The publication highlighted the fact that 81% of subjects treated with 5ug of adjuvanted vaccine dose achieved protective HAI levels, and 97% of subjects showed an anti-neuraminidase antibody response. We achieved protective levels from vaccinations within 116 days of the announcement of the H7N9 outbreak from the industry's first clinical trial of a vaccine against an A(H7N9) influenza strain.

In February 2014, we modified our contract with HHS BARDA to focus our development of a monovalent pandemic influenza vaccine against the A(H7N9) strain with a Phase 1/2 clinical trial with our H7N9 candidate and Matrix-M adjuvant, which began in the first quarter of 2014 and for which top-line data is scheduled to be released in the second half of 2014; however, HHS BARDA has also indicated that our H5N1 vaccine program remains a viable development opportunity under our contract.

## **Potential Accelerated Approval Pathway for Influenza**

In the past, we have referenced attainment of accelerated approval immunogenicity endpoints for seroprotection and seroconversion as a potential pathway for licensure of our influenza vaccines. The criteria for granting such accelerated approval of a Biologics License Application (BLA, the biologic equivalent to a New Drug Application or NDA) for new seasonal and pandemic influenza vaccines was published by the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA). Under FDA guidance, developers that can demonstrate results that meet or exceed certain specified immunogenicity endpoint criteria in their clinical trials may, at the FDA's discretion, be granted a license to market a product prior to submission of traditional clinical endpoint efficacy trial data. It should be noted that FDA licensure based on accelerated approval nevertheless requires sponsors to conduct a post-licensure efficacy study to demonstrate the clinical benefit of the vaccine, which would thereby support traditional approval of the vaccine. Because it is not possible to conduct a clinical endpoint efficacy study for a pandemic vaccine in advance of a declared pandemic, FDA's pandemic guidance allows for submission of seasonal influenza clinical efficacy data for the purpose of confirming clinical benefit of a pandemic vaccine manufactured by the same process. Thus, the demonstration of efficacy with a seasonal vaccine provides a key link between the seasonal and pandemic programs. Accelerated approval further necessitates a shortage of influenza vaccine relative to the total population recommended to receive such vaccine, a situation that persists with seasonal influenza vaccines.

Although we have not ruled out this accelerated approval approach, particularly for our pandemic program or certain subject populations within the seasonal influenza program, we do not expect to pursue accelerated approval of our quadrivalent seasonal influenza vaccine, largely because of the uncertainty as to whether the accelerated approval pathway will be available to us at the time of our BLA submissions and the unknown ability of current and new influenza strains to meet such accelerated approval criteria. We are planning, therefore, to pursue traditional licensure of our quadrivalent seasonal influenza vaccine by conducting a clinical endpoint efficacy study for the purpose of submitting the data within the original BLA. These efficacy data will also support the requirement for clinical efficacy data for our pandemic vaccine program. We plan to discuss with the FDA our licensure pathways (both the traditional

pathway for seasonal and possible accelerated pathways for pandemic and certain subject populations within the seasonal program) during future formal meetings. The likely impact of such an efficacy trial would be an additional year or more before the FDA grants licensure to our seasonal influenza vaccine.

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## **HHS BARDA Contract for Recombinant Influenza Vaccines**

HHS BARDA awarded us a contract in February 2011, which funds the development of both our seasonal and pandemic influenza vaccine candidates. The contract, valued at \$97 million for the first three-year base-period, was extended in February 2014 by seven months to September 2014; this extension is intended to allow us to continue to access the remainder of the base-period funding. In addition, the contract provides \$79 million for an HHS BARDA optional two-year period. Our contract with HHS BARDA is a cost-plus-fixed-fee contract in which they reimburse us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic influenza vaccines. HHS BARDA originally directed us to develop our monovalent pandemic influenza vaccine against the A(H5N1) strain. With the recent amendment, we are developing our monovalent pandemic influenza vaccine against the A(H7N9) strain; nevertheless, our H5N1 vaccine program remains a viable development opportunity under the contract. We recognized revenue of approximately \$17.4 million during 2013, and have recognized approximately \$52 million in revenue since the inception of the contract. Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, we decided to conduct a Phase 2 clinical trial of our quadrivalent seasonal influenza vaccine candidate (the 205 Trial) under our existing U.S. investigational new drug application (IND) for our trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for our quadrivalent vaccine candidate (Quadrivalent IND). Based on our discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by us after we submit the clinical trial data in a future Quadrivalent IND. The submission of the Quadrivalent IND is expected shortly before we initiate the next Phase 2 dose-confirmatory clinical trial, which is currently expected in the fourth quarter of 2014. The outside clinical trial costs of the 205 Trial conducted in 2012 total \$2.9 million. These costs have been recorded as an expense and are included in cost of government contracts revenue.

## **LG Life Sciences, Ltd. (LGLS) License Agreement**

In February 2011, we entered into a license agreement with LGLS that allows LGLS to use our technology to develop and commercially sell our influenza vaccines in South Korea and certain other emerging-market countries. LGLS received an exclusive license to our influenza VLP technology in South Korea and a non-exclusive license in the other specified countries. At its own cost, LGLS is responsible for funding both its clinical development of the influenza VLP vaccines and a manufacturing facility to produce such vaccines in South Korea. We received an upfront payment and may receive reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments in the high single digits from LGLS's future commercial sales of influenza VLP vaccines.

## **Combination Respiratory (Influenza and RSV)**

Given the ongoing development of our seasonal influenza vaccine candidate and our RSV vaccine candidate, we see an important opportunity to develop a combination respiratory vaccine. This opportunity presents itself most evidently in the elderly population, although we have not ruled out developing a combination respiratory vaccine for younger persons, including children. Early pre-clinical development efforts have given us confidence that such a combination vaccine is viable and in animal models, provides acceptable immunogenicity. We intend to explore this development opportunity by conducting a Phase 1 clinical trial in such a combination vaccine in late 2014 or early 2015.

## **CPLB Programs (India)**

### **Influenza**

CPLB initiated Phase 1/2 clinical trials on its seasonal trivalent VLP vaccine candidate and pandemic H5N1 influenza vaccine candidate in 2012. The results of these trials showed safety and immunogenicity data similar to our experiences, particularly when taking into account differences between the Indian subjects baseline titers and the baseline titers of the subjects in our trials. In August 2013, CPLB submitted a Phase 3 clinical trial application to the office of the drug controller general of India (DCGI) and in October 2013, initiated the manufacture of Phase 3 material in anticipation of starting this trial in 2014.



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### **Rabies**

CPLB is developing a rabies G protein vaccine candidate that we genetically engineered and has initiated a Phase 1/2 clinical trial in India in January 2014. Our common objective with CPLB is to develop a recombinant vaccine that can be administered both as a pre-exposure prophylaxis for residents of certain higher-risk geographies, as well as travelers to such locations, and also has potential to provide post-exposure prophylaxis with fewer doses. Pre-clinical results have demonstrated that this vaccine candidate has the potential to evoke antibody responses that are active in the neutralization of the rabies virus and could prevent the virus from entering the central nervous system, thus preventing death. The CPLB candidate protects mice from rabies in an assay known as the NIH potency test, which is used as one predictor of the clinical effect of rabies vaccines.

### **Discovery Programs**

Our vaccine platform technology provides an efficient system to rapidly develop antigens to selected targets, refine manufacturing processes and optimize development across multiple vaccine candidates. In addition we pay close attention to global reports of emerging diseases for which there do not appear to be immediate cures and where a vaccine protocol could offer potential protection. In addition to our response to the A(H7N9) influenza strain (see discussion above), we have been monitoring reports concerning the Middle East Respiratory Syndrome Coronavirus (MERS), a novel coronavirus first identified in September 2012 by an Egyptian virologist. MERS has become an emerging threat in 2013, with more than 50 confirmed cases of infection and 30 deaths. The MERS virus is a part of the coronavirus family that includes the severe acute respiratory syndrome coronavirus (SARS). Because of the public health priority given to MERS, within weeks of getting the virus sequence, we successfully produced a vaccine candidate designed to provide protection against MERS. This vaccine candidate, which was made using our recombinant nanoparticle vaccine technology, is based on the major surface spike protein, which we had earlier identified as the antigen of choice in our work with a SARS vaccine candidate. Although the development of this vaccine candidate currently remains a pre-clinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities.

### **Sales of Common Stock**

In October 2012, we entered into an At Market Issuance Sales Agreement (2012 Sales Agreement), under which our Board of Directors (the Board) approved the sale of up to an aggregate of \$50 million in gross proceeds of our common stock. The shares of common stock are being offered pursuant to a shelf registration statement filed with the SEC in March 2013, which replaced the previous shelf registration statement filed in 2010. The Board's standing Finance Committee (the Committee) assists with its responsibilities to monitor, provide advice to our senior management and approve all capital raising activities. The Committee has been authorized by the Board, absent any action by the Board to the contrary, to take any additional actions necessary to carry out the Board's authorization of the issuance and sale of the common stock sold pursuant to the 2012 Sales Agreement. In doing so, the Committee is authorized to set the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. During 2013, we sold 12.6 million shares at sales prices ranging from \$2.06 to \$3.38 per share, resulting in approximately \$34.0 million in net proceeds. As of December 31, 2013, we have approximately \$15.0 million available under the 2012 Sales Agreement. The most recent sales to occur under the 2012 Sales Agreement were on September 10, 2013.

In September 2013, we completed a public offering of 31,846,950 shares of our common stock, including 4,153,950 shares of common stock that were issued upon the exercise in full of the over-allotment granted to the underwriters, at

a price of \$3.14 per share resulting in net proceeds of approximately \$95 million.

## **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 accounting principles generally accepted 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

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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 investments, stock-based compensation, long-lived assets, goodwill and estimated recovery of our net deferred tax assets 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**

We perform research and development for U.S. Government agencies and other collaborators under cost reimbursable and fixed price contracts, including license and clinical development agreements. We recognize revenue under research contracts when a contract has been executed, the contract price is fixed and determinable, delivery of services or products has occurred and collection of the contract price is reasonably assured. Payments received in advance of work performed are recorded as deferred revenue and losses on contracts, if any, are recognized in the period in which they become known.

Under cost reimbursable contracts, we are reimbursed and recognize revenue as allowable costs are incurred plus a portion of the fixed-fee earned. We consider fixed-fees under cost reimbursable contracts to be earned in proportion to the allowable costs incurred in performance of the work as compared to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed. Under our HHS BARDA contract, certain activities must be pre-approved by HHS BARDA in order for their costs to be deemed allowable direct costs. Direct costs incurred under cost reimbursable contracts are recorded as cost of government contracts revenue. Our government contracts, including the HHS BARDA contract, provide the U.S. government (or agency) the ability to terminate the contract for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work. We believe that if the government were to terminate one of its contracts for convenience, including the HHS BARDA contract, the costs incurred through the effective date of such termination and any settlement costs resulting from such termination would be allowable costs. Payments to us under cost reimbursable contracts with agencies of the U.S. Government, including the contract with HHS BARDA, are provisional payments subject to adjustment upon annual audit by the government. An audit by the U.S government of fiscal years 2011 and 2012 has been completed as of the date of this filing. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly.

Our collaborative research and development agreements may include an upfront payment, payments for research and development services, milestone payments and royalties. Agreements with multiple deliverables are evaluated to determine if the deliverables can be divided into more than one unit of accounting. A deliverable can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. Deliverables that cannot be divided into separate units are combined and treated as one unit of accounting. Consideration received is allocated among the separate units of accounting based on the relative selling price method. Deliverables under these arrangements typically include rights to intellectual property, research and development

services and involvement by the parties in steering committees. Historically, deliverables under our collaborative research and development agreements have been deemed to have no stand-alone value and as a result have been treated as a single unit of accounting. In addition, we analyze our contracts and collaborative agreements to determine whether the payments received should be recorded as revenue or as a reduction to research and development expenses.

In reaching this determination, management considers 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

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operations. Historically, payments received under its contracts and collaborative agreements have been recognized as revenue since we act as a principal in the arrangement and the activities are core to our operations.

When the performance under a fixed price contract can be reasonably estimated, revenue for fixed price contracts is recognized under the proportional performance method and earned in proportion to the contract costs incurred in performance of the work as compared to total estimated contract costs. Costs incurred under fixed price contracts represent a reasonable measurement of proportional performance of the work. Direct costs incurred under collaborative research and development agreements are recorded as research and development expenses. If the performance under a fixed price contract cannot be reasonably estimated, we recognize the revenue on a straight-line basis over the contract term.

Revenue associated with upfront payments under arrangements is recognized over the contract term or when all obligations associated with the upfront payment have been satisfied.

Revenue from the achievement of research and development milestones, if deemed substantive, is recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, we would recognize such milestone as revenue upon its achievement on a straight-line basis over the remaining expected term of the research and development period. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable; (2) there is substantive uncertainty of achievement of the milestone at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone and such achievement relates to past performance; and (4) the amount of the milestone appears reasonable in relation to the effort expended and all of the deliverables and payment terms in the arrangement.

## **Investments**

Our investments are classified as available-for-sale securities and are carried at fair value. Unrealized gains and losses on these securities, if determined to be other-than-temporary, are included in accumulated other comprehensive income (loss) in stockholders' equity. 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 investments carried at fair value, we disclose the level within the fair value hierarchy as prescribed by Accounting Standard Codification (ASC) 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 interest income.

## **Stock-Based Compensation**

We account for our stock-based compensation under our equity compensation plans in accordance with ASC 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.

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## **Impairments of Long-Lived Assets**

We account for the impairment of long-lived assets by performing a periodic evaluation of the recoverability of the carrying value of long-lived assets and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Examples of events or changes in circumstances that indicate that the recoverability of the carrying value of an asset 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 in relation to the operating performance of the business and future undiscounted cash flows expected to result from the use of these assets. Impairment losses are recognized when the sum of expected future cash flows is less than the assets' carrying value.

## **Goodwill and Intangible Assets**

Goodwill and finite-lived intangible assets were generated from two business acquisitions. Our goodwill is not amortized, but is subject to impairment tests annually, or more frequently should indicators of impairment arise. Because the Company's only business is the development of recombinant vaccines, the Company operates as a single operating segment and reporting unit. We utilize the market approach and, if considered necessary, the income approach to determine if we have an impairment of our goodwill. The market approach serves as the primary approach and is based on market value of invested capital. To ensure that our capital stock is the appropriate measurement of fair value, we have considered factors such as our trading volume, diversity of investors and analyst coverage. The concluded fair value of our reporting unit significantly exceeded the carrying value at December 31, 2013 and 2012. The income approach is used as a confirming look to the market approach. Goodwill impairment is deemed to exist if the carrying value of a reporting unit exceeds its estimated fair value, which we test annually at December 31.

The fair value of our acquired finite-lived intangible assets, proprietary technology and agreements, were determined based on estimates of expected future net cash flows. The present value of future net cash flows was then determined utilizing an estimate of the appropriate discount rate, which is consistent with the uncertainties of the cash flows utilized. The fair value measurements are based on significant unobservable inputs that were developed by us using publicly available information, market participant assumptions, cost and development assumptions, expected synergies and other cost savings that a market participant would be expected to realize as a result of the combination and certain other high-level assumptions. The proprietary technology is amortized over its estimated remaining useful life based on our expected future net cash flows. The agreements are amortized over the estimated periods of expected future net cash flows. We believe the fair values assigned to these finite-lived intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition date. Impairment losses are measured and recognized to the extent the carrying value of such intangible assets exceeds their fair values.

Given the current economic conditions and the uncertainties regarding their impact on us, there can be no assurance that the estimates and assumptions made for purposes of our goodwill and intangible assets impairment testing will prove to be accurate predictions of the future, or that any change in the assumptions or the current economic conditions will not trigger more frequently than on an annual basis. If our assumptions are not achieved or economic conditions deteriorate further, we may be required to record goodwill and/or intangible asset impairment charges in

future periods.

## **Income Taxes**

We recognize deferred tax assets and liabilities for expected future tax consequences of temporary differences between the carrying amounts and tax basis of assets and liabilities. Income tax receivables and liabilities, and deferred tax assets and liabilities, are recognized based on the amounts that more likely than not would be sustained upon ultimate settlement with taxing authorities.

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Developing our provision for income taxes and analyzing our tax position requires significant judgment and knowledge of federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and any valuation allowances that may be required for deferred tax assets.

We assess the likelihood of realizing our deferred tax assets to determine whether an income tax valuation allowance is required. Based on such evidence that can be objectively verified, we determine whether it is more likely than not that all or a portion of the deferred tax assets will be realized. The main factors that we consider include: cumulative losses in recent years; income/losses expected in future years; the applicable statute of limitations; and potential limitations on available net operating loss and tax credit carryforwards.

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.

A valuation allowance is established when necessary to reduce net deferred tax assets to the amount expected to be realized. We concluded that the realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, our net deferred tax assets have been fully offset by a valuation allowance.

## **Recent Accounting Guidance Not Yet Adopted**

We have considered the applicability and impact of all Financial Accounting Standards Board's Accounting Standards Updates (ASUs). Recently issued ASUs were evaluated and determined to be not applicable in this Annual Report.

**Results of Operations for Fiscal Years 2013, 2012 and 2011** (amounts in tables are presented in thousands, except per share information)

The following is a discussion of the historical financial condition and results of operations of Novavax, Inc., which includes Novavax AB's operations since the acquisition date of July 31, 2013, 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:**

	2013	2012	2011	Change 2012 to 2013	Change 2011 to 2012
Revenue:					
Total revenue	\$ 20,915	\$ 22,076	\$ 14,688	\$ (1,161 )	\$ 7,388

Revenue for 2013 was \$20.9 million as compared to \$22.1 million for 2012, a decrease of \$1.2 million, or 5%.

Revenue for 2013 and 2012 is primarily comprised of services performed under the HHS BARDA contract and, to a much lesser extent, the PATH clinical development agreement and in 2013, revenue of \$0.7 million from recently acquired Novavax AB. The decrease in revenue is primarily due to the higher level of activity in 2012 associated with

our influenza clinical trials under the HHS BARDA contract as compared to 2013 when no similar clinical trials were initiated. In connection with the recent amendment of the HHS BARDA contract, we recorded revenue of \$2.7 million in the fourth quarter of 2013 relating to manufacturing and other activities that support the Phase 1/2 clinical trial of our H7N9 candidate and Matrix-M adjuvant, which began in the first quarter of 2014.

Revenue for 2012 was \$22.1 million as compared to \$14.7 million for 2011, an increase of \$7.4 million, or 50%. Revenue for 2012 and 2011 is primarily comprised of services performed under the HHS BARDA contract and, to a much lesser extent in 2012, the PATH clinical development agreement. The increase in revenue is primarily due to the pandemic (H5N1) influenza clinical trials and product development activities that occurred during 2012 under the HHS BARDA contract (see below regarding the 205 Trial).

Revenue for 2012 was negatively impacted by the Company's election to conduct the 205 Trial without immediate HHS BARDA reimbursement of its outside clinical trial cost of \$2.9 million (see discussion of the

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HHS BARDA Contract for Recombinant Influenza Vaccines in Management's Discussion and Analysis of Financial Condition and Results of Operations Overview beginning on page 45). For 2014, we expect a significant increase in revenue associated with our increased clinical trial and product development activities under the HHS BARDA contract to support the initiation of later-stage clinical trials of our seasonal influenza and pandemic (H7N9) influenza vaccine candidates.

**Costs and Expenses:**

	2013	2012	2011	Change 2012 to 2013	Change 2011 to 2012
Costs and Expenses:					
Cost of government contracts revenue	\$ 8,222	\$ 14,692	\$ 7,003	\$(6,470 )	\$ 7,689
Research and development	50,308	26,907	18,364	23,401	8,543
General and administrative	&nbs				