

NOVAVAX INC  
Form 10-K  
February 29, 2016

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
X 1934**

**For the fiscal year ended December 31, 2015**

**OR**

**..TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
OF 1934**

**For the transition period from    to    .**

**Commission File No. 0-26770**

**NOVAVAX, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**                                 **20 Firstfield Road,**                                 **22-2816046**  
**Gaithersburg, Maryland 20878**  
*(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:**

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
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   
(Do not check if a smaller reporting company) 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

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The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (based on the last reported sale price of Registrants common stock on June 30, 2015 on the NASDAQ Global Select Market) was approximately \$2,949,700,000.

As of February 24, 2016, there were 270,305,396 shares of the Registrant's common stock outstanding.

Documents incorporated by reference: Portions of the Registrant's Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2015 in connection with the Registrant's 2015 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent indicated herein.

NOVAVAX, INC.

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## **CERTAIN DEFINITIONS**

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

## **NOTE REGARDING TRADEMARKS**

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

## **FORWARD-LOOKING INFORMATION**

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. In some cases, forward-looking statements are identified by words such as “believe,” “anticipate,” “intend,” “plan,” “will,” “may,” “expect” and similar expressions. All forward-looking statements are based on information available to us at this time and speak only as of the date of this Annual Report on Form 10-K. We assume no obligation to update any of these statements. Actual results could differ materially from those projected in these forward-looking statements as a result of many factors, including those identified in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”. 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 other filings with the Securities and Exchange Commission (“SEC”), that identify risks and factors that may affect our future results. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

## **PART I**

### **Item 1. BUSINESS**

#### **Recent Events**

In February 2016, Novavax completed the issuance of \$325 million of 3.75% Convertible Senior Notes due in 2023, resulting in net proceeds of approximately \$315 million, after deducting initial purchasers' discounts and commissions, and approximately \$314 million after deducting offering expenses. We used approximately \$38 million of the net proceeds to pay the costs of a capped call transaction, which will function to reduce dilution from issuance of additional shares upon conversion of the notes between the note conversion price of \$6.81 and the cap price of \$9.73 per share. The resulting final net proceeds to the company were approximately \$276 million.

Our cash, cash equivalents and marketable securities on December 31, 2015 of approximately \$231 million, as adjusted to give effect to the final net proceeds of the Convertible Senior Note offering of approximately \$276 million, before giving effect to the anticipated use of the final net proceeds, would result in an as adjusted cash, cash equivalents and marketable securities balance of approximately \$507 million.

#### **Overview**

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

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

Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate recombinant proteins critical to disease pathogenesis. Our product pipeline targets a variety of infectious diseases with vaccine candidates currently in clinical development for respiratory syncytial virus ("RSV"), seasonal influenza, pandemic

influenza, and Ebola virus (“EBOV”). We have additional preclinical stage programs for a variety of infectious diseases.

We are also developing proprietary technology for the production of immune stimulating saponin-based adjuvants, through Novavax AB. Our lead adjuvant, Matrix-M™, has been successfully tested in a Phase 1/2 clinical trial for our pandemic influenza H7N9 vaccine candidate and in a Phase 1 clinical trial for our EBOV vaccine candidate. Genocea Biosciences, Inc. has licensed rights to our Matrix technology and is now conducting Phase 2 clinical trials with its herpes simplex 2 vaccine candidate using Matrix-M.

### **Clinical Product Pipeline**

Our clinical product pipeline includes vaccine candidates engineered to elicit differentiated immune responses with potential to provide increased protection. Our nanoparticle technology platform targets antigens with conserved epitopes essential for viral function. Unlike traditional vaccines that ‘mimic’ viruses and elicit the naturally occurring immune responses to them, our nanoparticles are engineered to elicit differentiated immune responses, which may be more efficacious than naturally-occurring immunity. We believe our vaccine technology can be applied broadly to a wide variety of human infectious diseases.



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

<b>Program</b>	<b>Development Stage</b>	<b>Funding Collaborator</b>
<b>Respiratory Syncytial Virus (RSV)</b>		
· <b>Older Adults</b>	Phase 3	
· <b>Infants via Maternal Immunization</b>	Phase 3	BMGF*
· <b>Pediatric</b>	Phase 1	
<b>Influenza</b>		
· <b>Seasonal Quadrivalent</b>	Phase 2	HHS BARDA
· <b>Pandemic H7N9</b>	Phase 2	HHS BARDA
<b>Combination (Influenza/RSV)</b>	Preclinical	
<b>Ebola Virus (EBOV)</b>	Phase 1	

\*As detailed herein, our funding and development arrangement with PATH expired in April 2015; we entered into a grant agreement with the Bill and Melinda Gates Foundation (BMGF) in September 2015.

### **Respiratory Syncytial Virus (RSV)**

We are developing our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) for three susceptible target populations: older adults (60 years of age and older), infants via maternal immunization and children six months to five years of age (“pediatrics”). We estimate RSV F Vaccine peak revenue potential of six to eight billion dollars worldwide. Currently, there is no approved RSV vaccine available.

Repeat infections and lifelong susceptibility to RSV are common; we estimate the current global cost burden of RSV in excess of \$88 billion. Despite decades of effort to develop an RSV vaccine, there are currently no licensed vaccines. Although the monoclonal antibody palivizumab (Synagis®) is effective in pre-term infants, it is not indicated for use in other populations. Novavax made a breakthrough in developing a vaccine that targets the fusion protein, or F-protein, of the RSV virus. The F-protein contains a highly conserved amino acid sequence called antigenic site II, which we believe is an ideal vaccine target. Palivizumab, which also targets antigenic site II, has demonstrated protection in five randomized clinical trials. We genetically engineered a novel F-protein antigen and enhanced its immunogenicity by exposing antigenic site II. Novavax’ RSV F Vaccine assembles into a recombinant protein nanoparticle optimized for F-protein antigen presentation. The RSV F Vaccine elicits palivizumab-competing antibodies at levels that we expect to confer protection. The Novavax RSV F Vaccine is the first RSV vaccine to

demonstrate efficacy in a clinical trial, and Novavax is positioned to bring the first RSV vaccine to market to combat the 64 million RSV infections that occur each year.<sup>1,2</sup>

### ***RSV Older Adults Program***

#### *Burden of Disease*

Adults 60 years of age and older are at increased risk for RSV disease due to age related declines in their immune systems. In this population, RSV is an important respiratory virus, distinct from influenza viruses, that is responsible for serious lower respiratory tract disease and may lead to hospitalization or even death. Additionally, RSV infection can lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. RSV infection occurs as a recurrent and predictable annual epidemic throughout the world. In the U.S. alone, the incidence rate is 2.5 million infections per year, and RSV is increasingly recognized as a significant cause of morbidity and mortality in the population of 64 million older adults.<sup>3,4</sup> Based on our analysis of published literature applied to 2014 population estimates in the U.S., the disease causes 207,000 hospitalizations and 16,000 deaths among adults older than 65. Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease across all populations in the U.S.

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

<sup>2</sup>WHO Acute Respiratory Infections September 2009 Update:  
[http://apps.who.int/vaccine\\_research/diseases/ari/en/index2.html](http://apps.who.int/vaccine_research/diseases/ari/en/index2.html)

<sup>3</sup>Falsey, A.R. *et al.* (2005) *NEJM*. 352:1749–59 extrapolated to 2015 census population

<sup>4</sup>Falsey, A.R. *et al.* (1995) *JID*.172 :389-94

### *Clinical Trial Update*

In August 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 1,600 older adults. The clinical trial was designed to prospectively examine the incidence of all symptomatic respiratory illnesses associated with RSV infection, in community-living older adults who were treated with placebo. The trial also evaluated safety and immunogenicity of our RSV F Vaccine compared to placebo. Finally, the trial estimated the efficacy of our RSV F Vaccine in reducing the incidence of respiratory illness due to RSV. The trial was the first to demonstrate efficacy of an active RSV immunization in any clinical trial population. In the per protocol population, the clinical trial showed statistically significant vaccine efficacy in prevention of all symptomatic RSV disease (41%) and, in an *ad hoc* analysis, showed a decrease in RSV disease with symptoms of lower respiratory tract infection (45%) in older adults. The clinical trial established an attack rate for symptomatic RSV disease of 4.9% in older adults, 95% of which included lower respiratory tract symptoms. Efficacy against more severe RSV illness, defined by the presence of multiple lower respiratory tract symptoms associated with difficulty breathing, was 64% in *ad hoc* analyses.

We initiated a pivotal Phase 3 clinical trial, known as Resolve™, of our RSV F Vaccine in older adults in November 2015, and in December 2015 we completed enrollment of 11,850 older adult subjects at 60 sites in the U.S. The primary objective of the clinical trial is the prevention of moderate-severe RSV-associated lower respiratory tract disease, as defined by the presence of multiple lower respiratory tract symptoms. We expect to provide top-line data from this clinical trial in the third quarter of 2016.

In October 2015, we completed enrollment of 1,330 older adults in our Phase 2 rollover clinical trial of our RSV F Vaccine in the older adults who had participated in the recently concluded prior Phase 2 clinical trial. This trial is designed to evaluate safety and immunogenicity in response to immunization with the RSV F Vaccine during a second RSV season, and we expect to provide top-line data from this trial in the second half of 2016.

### ***RSV Infants via Maternal Immunization Program***

#### *Burden of Disease*

RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide.<sup>5</sup> In the U.S., RSV is the leading cause of hospitalization of infants, and globally, is second only to malaria as a cause of death in children under one year of age.<sup>6,7</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.<sup>8,9</sup>

*Clinical Trial Update*

In September 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 50 healthy pregnant women and their infants. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine in pregnant women in their third trimester, and assessed the transplacental transfer of maternal antibodies induced by the vaccine. The trial also examined the impact of maternal immunization on infant safety during the first year of life and RSV-specific antibody levels through the infants' first six months of life. Immunized women demonstrated a geometric mean 14-fold rise in anti-F IgG, 29-fold rise in palivizumab-competing antibodies and a 2.7 and 2.1-fold rise in microneutralization titers against RSV/A and RSV/B respectively. In contrast, women who received placebo demonstrated no significant change in antibody levels. The infants' antibody levels at delivery averaged 90-100% of the mothers' levels, indicating efficient transplacental transfer of antibodies from mother to infant. The estimated half-lives of infant PCA, anti-F IgG, RSV/A and RSV/B microneutralizing antibodies, based on data through day 60, were 41, 30, 36 and 34 days, respectively.

<sup>5</sup>Nair, H., *et al.*, (2010) *Lancet*. 375:1545 - 1555

<sup>6</sup>Hall, C.B. *et al.* (2013) *Pediatrics*; 132(2):E341-348

<sup>7</sup>Oxford Vaccine Group: <http://www.ovg.ox.ac.uk/rsv>

<sup>8</sup>Glezen, W.P. *et al.* (1986) *Am J Dis Child*; 140:543-546

<sup>9</sup>Glenn, G.M. *et al.* (2016) *JID*; 213(3):411-12

We announced the initiation of a global pivotal Phase 3 clinical trial, known as Prepare™, of the RSV F Vaccine in 5,000 to 8,255 healthy pregnant women in December 2015. The primary objective of the Prepare trial is to determine the efficacy of maternal immunization with the RSV F Vaccine against symptomatic RSV lower respiratory tract infection with hypoxemia in infants through the first 90 days of life. This Phase 3 trial utilizes a group sequential design and is expected to take between two and four years to complete. This trial is supported by a grant (the “Grant”) of up to \$89.1 million from the Bill & Melinda Gates Foundation (“BMGF”). The Grant will support development activities, product licensing efforts and WHO prequalification of our RSV F Vaccine. We concurrently entered into a Global Access Commitments Agreement (“GACA”) with BMGF as a part of the grant agreement (the “Grant Agreement”). Under the terms of the GACA, we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

In November 2014, the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (“FDA”) granted Fast Track designation to our RSV F Vaccine for protection of infants via maternal immunization. Fast Track designation is intended for products that treat serious or life-threatening diseases or conditions, and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is designed to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

### ***RSV Pediatric Program***

#### *Burden of Disease*

There are currently approximately 18 million children in the U.S. between six months and five years of age.<sup>10</sup> Based on our analysis of published literature applied to 2014 population estimates, we estimate nearly 9.8 million RSV infections annually. In the U.S., RSV is responsible for approximately 57,000 hospitalizations of children under five years of age annually, the vast majority of which occur in infants less than one year old, and especially those under six months of age.<sup>11,12,13,14,15</sup>

#### *Clinical Trial Update*

In September 2015, we announced positive top-line data from a Phase 1 clinical trial of our RSV F Vaccine in healthy children between two and six years of age. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine, with one or two doses, with or without aluminum phosphate adjuvant. Trial enrollment was concluded with a smaller than planned cohort so that dosing could be completed ahead of the 2014-15 RSV season. The vaccine was well-tolerated and serum samples collected from a subset of 18 immunized children in the per-protocol population

demonstrated that the RSV F Vaccine was highly immunogenic at all formulations and regimens. There were greater than 10-fold increases in both anti-F IgG and PCA antibody titers in the adjuvanted group and greater than 6-fold increases in anti-F IgG and PCA antibody titers in the unadjuvanted group. We are assessing the data from this clinical trial and evaluating the next steps in the development of our RSV F Vaccine for pediatrics.

## Influenza

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. Serious illness occurs not only in susceptible populations such as pediatrics and older adults, but also in the general population when unique strains of influenza arise, for which most humans have not developed protective antibodies. We are developing vaccine candidates for both seasonal and pandemic influenza. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from approximately \$3.2 billion in the 2012/13 season to \$5.3 billion by the 2021/2022 season.<sup>16</sup>

<sup>10</sup>U.S. Census. [www.census.gov/population/international/data/idb/informationGateway.php](http://www.census.gov/population/international/data/idb/informationGateway.php)

<sup>11</sup>Stockman, L.J. *et al.* (2012) *Pediatr Infect Dis J.* 31:5-9

<sup>12</sup>CDC update May 5, 2015. <http://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>13</sup>Boyce, T.G. *et al.* (2000) *J Pediatr.* 137:865-870

<sup>14</sup>Hall, C.B. *et al.* (2009) *NEJM.* 360(6):588-98

<sup>15</sup>Hall, C.B. *et al.* (2013) *Pediatrics.* 132(2):E341-8

<sup>16</sup>Influenza Vaccines Forecasts. *Datamonitor* (2013)

Traditional vaccine manufacturing methods utilize live influenza virus to infect eggs in order to produce trivalent seasonal influenza vaccine candidates. Our recombinant nanoparticle technology does not utilize either a live influenza virus or eggs, but rather a recombinant baculovirus and insect cells which allows for the product to be potentially rapidly manufactured and quickly adapted to changing influenza strains. We are developing a quadrivalent seasonal influenza vaccine candidate, which we expect to elicit broader protection from circulating influenza strains; we are also exploring the development of novel influenza nanoparticle vaccine candidates. There are currently four quadrivalent seasonal influenza vaccines licensed in the U.S., although additional quadrivalent seasonal influenza vaccines are expected to be licensed over the next several years.

### *Quadrivalent Seasonal Influenza Vaccine*

#### *Burden of Disease*

The Advisory Committee for Immunization Practices of the CDC recommends that all persons aged six months and older be vaccinated annually against seasonal influenza. Influenza is a major burden on public health worldwide; an estimated one million deaths each year are attributed to influenza.<sup>17</sup> It is further estimated that, each year, influenza attacks 5%-10% of adults and 20%-30% of children, causing significant levels of illness, hospitalization and death.<sup>18</sup> Recombinant seasonal influenza vaccines, like the candidate we are developing, have important advantages: once licensed for commercial sale, large quantities of vaccines can be potentially manufactured quickly and in a cost-effective manner, without the use of either the live influenza virus or eggs.

#### *Clinical Trial Update*

In July 2015, we reported positive data from our Phase 2 clinical trial of our quadrivalent seasonal influenza virus-like particle (“VLP”) vaccine candidate in 400 healthy adults that we initiated in November 2014. These data show that our quadrivalent seasonal influenza VLP vaccine candidate is well-tolerated, and can induce influenza antibody responses that met the immunogenicity targets. These results demonstrate the potential for our seasonal quadrivalent influenza VLP vaccine candidate to meet the FDA criteria for accelerated approval.

We were awarded a contract by the U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”) in 2011 to fund the development of both our quadrivalent seasonal influenza and pandemic influenza vaccine candidates. This is a cost-plus-fixed-fee contract, which reimburses us for allowable direct contract costs incurred, allowable indirect costs, plus a fixed-fee, earned in the ongoing clinical development and product scale-up of our vaccine candidates. We announced that HHS BARDA had exercised and initiated a two-year option to our contract in September 2014. The option not only extended the contract until

September 2016, but also added scope to support our development activities leading up to planned Phase 3 clinical studies and \$70 million of funding on top of the remainder of the \$97 million base period funding. In June 2015, the contract was amended to increase the funding by \$7.7 million to allow for the recovery of additional costs under the contract relating to the settlement of indirect rates for fiscal years 2011 and 2012. This additional amount was received and recorded as revenue in the second quarter of 2015. During 2015, we recognized revenue of \$33.3 million and have recognized approximately \$112 million in revenue since the inception of the contract. In recent meetings with HHS BARDA, we have been discussing the next steps in both our seasonal influenza VLP vaccine program and our pandemic influenza VLP vaccine program, as well as some of the delays associated with our development of both vaccine candidates. We expect to continue discussions with HHS BARDA during 2016 and to present plans for continued clinical and product development, although there can be no guarantee that the HHS BARDA contract will not be terminated early or will be extended beyond September 2016.

<sup>17</sup>Resolution of the World Health Assembly. (2003) WHA56.19

<sup>18</sup>WHO position paper (2012) Weekly Epidemiol Record;87(47):461–76



## ***Pandemic H7N9 Influenza Vaccine***

### *Burden of Disease*

Prevention 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 influenza 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. Industry and health experts have focused attention on developing a monovalent influenza vaccine against either the H5N1 strain or the H7N9 strain as potential key defenses against future pandemic disease threats.

### *Clinical Trial Update*

We have developed and delivered compelling safety and immunogenicity data on two pandemic vaccine candidates, H5N1 and H7N9. In September 2014, we announced positive results from a Phase 1/2 clinical trial of our pandemic H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M in 610 healthy adults. The Phase 1/2 clinical trial was designed as a dose-ranging, randomized, observer-blinded, placebo-controlled clinical trial, to determine the contribution of Matrix-M to potential antigen dose sparing regimens. Our H7N9 influenza vaccine candidate, with and without Matrix-M, was highly immunogenic and well tolerated. Matrix-M adjuvanted formulations demonstrated immunogenicity and dose-sparing benefits relative to unadjuvanted antigen. Hemagglutination-inhibiting antibody titers were comparable to those reported in prior studies and the vaccine elicited significant anti-neuraminidase antibodies. In October 2014, the FDA granted Fast Track designation to our pandemic H7N9 influenza vaccine candidate with Matrix-M.

Our pandemic influenza vaccine program is supported by our HHS BARDA contract. Like our seasonal influenza vaccine program, we expect to continue discussions with HHS BARDA during 2016 and to present plans for continued clinical and product development of our pandemic influenza vaccine candidate, although there can be no guarantee that the HHS BARDA contract will not be terminated early or will be extended beyond September 2016.

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

Given the ongoing development of our seasonal influenza vaccine candidate and our RSV F Vaccine, we see an important opportunity to develop a combination respiratory vaccine candidate. Early preclinical development efforts have given us confidence that such a combination vaccine is viable, and in animal models, provides acceptable immunogenicity. We expect to initiate a Phase 1 clinical trial of a combination respiratory vaccine in the first half of 2017.

### **Ebola Virus (EBOV)**

EBOV, formerly known as Ebola hemorrhagic fever, is a severe, often fatal illness in humans. Multiple strains of EBOV have been identified, the most recent of which, the Makona EBOV strain, is associated with a case fatality rate of between 50% and 90%.<sup>19</sup> There are currently no licensed treatments proven to neutralize the virus, but a range of blood, immunological and drug therapies are under development. It should be noted, however, that recent vaccine approaches target either a previous strain of the virus or were initially developed to be delivered by genetic vectors. In contrast, our EBOV glycoprotein vaccine candidate (“Ebola GP Vaccine”) was developed using the Makona EBOV strain.

In July 2015, we announced data from our Phase 1 clinical trial of our Ebola GP Vaccine in ascending doses, with and without our Matrix-M adjuvant, in 230 healthy adults. Participants received either one or two intramuscular injections ranging from 6.5µg to 50µg of antigen, with or without adjuvant, or placebo. Immunogenicity was assessed at multiple time points, including days 28 and 35. These Phase 1 data demonstrated that our Ebola GP Vaccine is highly immunogenic, well-tolerated and, in conjunction with our proprietary Matrix-M adjuvant, resulted in significant antigen dose-sparing. Although the adjuvanted Ebola GP Vaccine was highly immunogenic at all dose levels, the adjuvanted two-dose regimens induced Ebola anti-GP antibody geometric mean responses between 45,000 and 70,000 ELISA units, representing a 500 to 750-fold rise over baseline at day 35. In 2015, we also announced successful data from two separate non-human primate challenge studies of our Ebola GP Vaccine in which, in both cases, the challenge was lethal for the control animal, whereas 100% of the immunized animals were protected.

<sup>19</sup>WHO. <http://www.who.int/mediacentre/factsheets/fs103/en/>

## **CPLB Programs (India)**

Our joint venture with Cadila Pharmaceuticals Limited (“Cadila”), CPL Biologics Private Limited (“CPLB”), is actively developing and manufacturing vaccine candidates in India that were genetically engineered by Novavax. CPLB is owned 20% by us and 80% by Cadila.

### *Seasonal Influenza*

CPLB received marketing authorization, the Indian equivalent of approval of a Biologics License Application (“BLA”), for its recombinant trivalent seasonal VLP influenza vaccine in 2015. Because the market for seasonal influenza vaccines in India is limited and highly competitive, CPLB is currently evaluating its marketing strategy for this vaccine.

### *Rabies*

CPLB successfully completed Stage II of its 2-stage Phase 1/2 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered. The objective was to select a dose and regimen for a recombinant vaccine that can be administered both as a pre-exposure prophylaxis for residents of certain higher-risk geographies and travelers to such locations, and as a post-exposure prophylaxis using fewer doses than the current standard of care. In October 2014, CPLB presented clinical results from Stage I of the Phase 1/2 clinical trial, demonstrating that vaccine recipients, at various doses levels and schedules, showed seroprotective antibody levels at day 14 that were sustained through day 180. The vaccine candidate, which was found to be well-tolerated, also induced seroprotective levels with two-dose and three-dose regimens. CPLB has received permission to conduct a Phase 3 clinical trial and is considering the optimal schedule for its conduct.

## **Discovery Programs**

Our vaccine platform technology provides an efficient system that has the potential to rapidly develop antigens to selected targets, refine manufacturing processes and optimize development across multiple vaccine candidates. In conjunction with global health authorities and government agencies, we believe we can address emerging disease threats with pandemic potential. In addition to our response to the H7N9 influenza strain, we have developed a vaccine candidate to Middle East respiratory syndrome (“MERS”), caused by a novel coronavirus first identified in 2012. MERS emerged as a disease threat in 2013, and is currently being monitored by global health agencies, with the

WHO reporting significant confirmed cases of infection and deaths. The MERS virus is a part of the coronavirus family that includes the severe acute respiratory syndrome coronavirus (“SARS”). Within weeks of obtaining the sequence of the circulating MERS strain, we successfully produced a vaccine candidate designed to provide protection. This vaccine candidate is based on the major surface spike protein, which we had previously identified as the antigen of choice in our work with a SARS vaccine candidate. In 2014, in collaboration with the University of Maryland, School of Medicine, we published results that showed our investigational vaccine candidates against both MERS and SARS blocked infection in laboratory studies. Although the development of a MERS vaccine candidate currently remains a preclinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities.

### **Vaccine Platform Technology**

Our recombinant protein nanoparticle vaccine technology is based on self-assembly of surface protein antigens from pathogenic organisms including viruses, bacteria or parasites. The conformations of these nanoparticles are similar but not identical to the natural structure of surface antigens of disease organisms, and lack the genetic material required for replication and therefore are not infectious. One advantage of this technology is that the assembly of nanoparticles is done *in vitro* during the purification of these proteins. Potential immunological advantages of protein nanoparticles may be associated with the nanoparticle conformation and the presentation of key functional epitopes that are often immunologically hidden in the native pathogen. This leads to efficient recognition by the immune system’s antigen presenting cells (“APCs”) that trigger 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 F Vaccine, which self-assembles from our highly purified F-protein antigen.

## **Matrix Adjuvants**

Adjuvants are predominantly used to enable a vaccine to induce a strong immune response including a greater production of antibodies and longer lasting protection against viral and bacterial infections. Adjuvants may increase the amplitude of the immune response and qualitatively change it, broaden its specificity to provide protection against related microorganisms and allow for effective immunization with much lower doses of antigen. Novavax AB has developed a number of adjuvant formulations, all based on our proprietary Matrix™ technology. These adjuvant formulations possess excellent immunostimulatory features with the ability to increase and prolong the protective benefits of vaccines.

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

## **Competition in RSV, Influenza, EBOV and Other Vaccines**

The vaccine market is intensely competitive, characterized by rapid technological progress. Our technology is based upon utilizing the baculovirus expression system in insect cells to make recombinant vaccines. We believe this system offers many advantages when compared to other technologies and is uniquely well-suited for developing an RSV vaccine, seasonal and pandemic influenza vaccines, as well as vaccines against 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 recombinant technologies. We believe that our RSV vaccine candidate, utilizing a recombinant F-protein antigen, is 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 second most advanced RSV vaccine program after Novavax, as it has reported testing in Phase 1 and Phase 1/2 clinical trials of 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 Institutes of Health (“NIAID”).

Unlike the comparatively low number of competitors developing RSV vaccines, there are a number of companies developing and selling vaccines for seasonal and pandemic influenza employing both historic and new vaccine technologies. 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. Competition in the sale of these seasonal influenza vaccines is intense. Therefore, newly developed and approved products must be differentiated from existing vaccines in order to have commercial success. In order to show differentiation in the seasonal influenza market, a product may need to be more efficacious 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. 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.

Vaccine candidates against Ebola virus have been in development for more than a decade; however, with the recent epidemic in West Africa, focus on viable vaccine candidates has intensified. In addition to the Phase 1 clinical trial that we initiated in February 2015, WHO reports two other vaccine candidates that are currently being tested in humans: one by GlaxoSmithKline in collaboration with NIAID, and the other by a collaboration of NewLink Genetics, Merck Vaccines USA and the Public Health Agency of Canada. While these other vaccine candidates offer promise, we believe there are accompanying challenges, including: high-dose level requirements; utilization of glycoprotein from older strains that have a significant number of amino acid changes when compared to the 2014 Makona strain; difficult storage requirements at temperatures below  $-60^{\circ}\text{C}$ ; and challenges associated with immunity to the viral vectors which could limit their multi-dose vaccine potential. In contrast, we have developed a Phase 1 vaccine candidate that has performed well with low doses utilizing our Matrix-M adjuvant, was derived from the 2014 Makona strain, appears to be stable at  $2-8^{\circ}\text{C}$  and appears to provide enhanced immunogenicity as a multi-dose vaccine.

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

## **Patents and Proprietary Rights**

We generally seek patent protection for our technology and product candidates in the U.S. and abroad. The patent position of 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 processes and other technologies. Currently, we have or have rights to over 200 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.

Since 2007, we have maintained a non-exclusive license arrangement with Wyeth Holdings LLC (formerly Wyeth Holdings Corporation), a subsidiary of Pfizer Inc. (“Wyeth”), 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.

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 Virus-Like Particles 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.

In April 2014, U.S. Patent No. 8,697,088 for Novel VLPs Derived From Cells That do not Express a Viral Matrix or Core Protein was issued by the U.S. Patent & Trademark Office. The patent covers, in part, methods of making influenza VLP that contain HA and NA proteins but lack any viral matrix or core protein.

In May 2014, U.S. Patent No. 8,715,692 for Modified RSV F Proteins and Methods of Their Use was issued by the U.S. Patent & Trademark Office. The patent covers, in part, RSV F vaccines.

Between February 2015 and December 31, 2015, U.S. Patent Nos. 8,951,537, 8,992,939, 9,144,607, 9,050,290, and 9,180,180 were issued by the U.S. Patent & Trademark Office. These patents all relate to aspects of our influenza VLP program. In addition, 9,205,147, directed to our Matrix Adjuvant program, issued in January 2015.

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.***

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

## Government Regulations

The development, production and marketing of biological products, which 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, International Conference on Harmonisation (“ICH”) and other agencies because we believe, for the most part, meeting U.S. and ICH standards will allow us to satisfy regulatory agencies in other countries where we intend to do business. We are aware that expectations in some venues, notably in the European Union, differ to some degree and we are taking proactive steps to address such differences. In the U.S., the development, manufacturing and marketing of human pharmaceuticals and vaccines are subject to extensive regulation under the Federal Food, Drug, and Cosmetic Act, and biological products are subject to regulation under provisions of that Act and the Public Health Service Act. The FDA not only assesses the safety and efficacy of these products but it also regulates, among other things, the testing, manufacture, labeling, storage, record-keeping, advertising and promotion of such products. The process of obtaining FDA licensure for a new vaccine is costly and time-consuming.

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

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

In order to ensure continuing safety, the FDA continues to oversee the production of vaccines even after the vaccine and manufacturing processes are approved. For example, monitoring of the vaccine and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product. Manufacturers may also be required to submit 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 licensure 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 GMP regulations and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in their home country.

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

In addition to regulatory approvals that must be obtained in the U.S., an investigational product is also subject to regulatory approval in other countries in which it is intended to be marketed. No such product can be marketed in a country until the regulatory authorities of that country have approved an appropriate marketing application. FDA licensure does not 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, including national and local regulations that govern our facility in Sweden. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Act regulations.

There have been numerous federal and state legislative changes made over the last few years regarding the pricing of pharmaceutical and biological products, the exertion of 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**

Our primary manufacturing facility is located at our corporate headquarters at 20 Firstfield Road in Gaithersburg, Maryland. The facility has 53,000 square feet of combined GMP manufacturing, laboratory and office space. Our Rockville, Maryland facility houses our 10,000 square foot GMP pilot manufacturing facility that produces early-stage clinical trial material. Novavax AB, located in Uppsala, Sweden, produces our Matrix adjuvants in an approximately 16,000 square foot facility comprised of GMP manufacturing, laboratory and office space.

## **Sources of Supply**

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

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

## **Business Development**

We believe our proprietary vaccine technology affords us a range of traditional and non-traditional commercialization options 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 and BMGF, to fund future trials in our seasonal and pandemic influenza programs and our RSV program, to continue development of our vaccine candidates until such vaccines can be licensed, to retain commercial rights in one or more major markets and generate product sales revenue and, in certain markets, to commercialize our products through partners and other strategic relationships.

In addition to our aforementioned contracts with HHS BARDA and BMGF, another example of our strategic relationships is our joint venture we established with Cadila. CPLB is owned 20% by us and 80% by Cadila. It was established in 2009 to develop and manufacture certain vaccine candidates, biogeneric products and diagnostic products for the territory of India. CPLB operates a manufacturing facility in India for the production of vaccines and is actively developing a number of vaccine candidates that were genetically engineered by us.

## **Employees**

As of February 24, 2016, we have 443 full-time employees, of whom 95 hold M.D. or Ph.D. degrees and 109 of whom hold other advanced degrees. Of our total workforce, 390 are engaged primarily in research, development and manufacturing activities and 53 are engaged primarily in executive, business development, finance and accounting, legal and administrative functions. None of our U.S. employees are represented by labor unions or covered by collective bargaining agreements; 32 of our 33 Swedish employees are covered by typical collective bargaining agreements. We consider our relations with our employees to be good.

## **Availability of Information**

Our website address is [www.novavax.com](http://www.novavax.com). We make available, free of charge and through our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our other filings with the SEC, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after filed with or furnished to the SEC. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov).

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

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

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



## Item 1A. RISK FACTORS

You should carefully consider the following risk factors in evaluating our business. 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 AND INDUSTRY

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

Our expenses have exceeded our revenue since our formation in 1987, and our accumulated deficit at December 31, 2015 was \$650 million. Our revenue for the last three fiscal years was \$36.3 million in 2015, \$30.7 million in 2014 and \$20.9 million in 2013. 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 \$156.9 million in 2015, \$82.9 million in 2014 and \$52.0 million in 2013.

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 and 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. For example, we have experienced a significant increase in research and development expenses in the fourth quarter of 2015 over prior years primarily due to additional RSV F Vaccine clinical trials in the primary indications of older adult immunization and infants via maternal immunization, as well as higher employee-related costs to support product development of our RSV F Vaccine and other potential vaccine candidates.

Although certain specified costs associated with the development of our influenza vaccines may be reimbursed under our contract with HHS BARDA, and to a more limited extent, certain specified costs associated with the development of our RSV maternal vaccine may be reimbursed under our contract with BMGF, 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 RSV-influenza combination respiratory vaccine candidates;
- conduct preclinical studies for other vaccine candidates;
- comply with the FDA's manufacturing facility and compliance requirements in anticipation of commercialization;
- invest in our manufacturing process for commercial-scale and cost-efficiency; and
- maintain, expand and protect our intellectual property portfolio.

As a result, we expect our cumulative operating losses to increase until such time, if ever, that product sales, licensing fees, royalties, milestones, contract research and other sources generate sufficient revenue to fund our operations. We 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 preclinical studies and clinical trials, seek 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.

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

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, 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, if we are unable to access the capital markets on favorable terms, this 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 Grant Agreement with BMGF, we may not be able to fully fund our RSV F Vaccine for infants via maternal immunization.***

The Grant Agreement reimburses a portion of specified expenses associated with the development of our RSV F Vaccine for infants via maternal immunization and there is no guarantee that additional activities will not be needed and, if so, that BMGF will partially reimburse us for these activities.

***The Grant Agreement with BMGF does not guarantee that we will be successful in future clinical trials associated with our RSV F Vaccine for infants via maternal immunization or that the vaccine candidate will be licensed by the FDA.***

The Grant Agreement reimburses a portion of specified expenses associated with the development of our RSV F Vaccine for infants via maternal immunization, but we remain fully responsible for conducting these development activities. The Grant Agreement does not guarantee that any of these activities will be successful. Our inability to be successful with certain key clinical or development activities could jeopardize our ability to obtain FDA licensure to sell this vaccine.

***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. Performance under the HHS BARDA contract requires that we comply with appropriate regulations and operational mandates, which require us to engage internal and external expertise for compliance. 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.***

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 approved 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 obtain FDA licensure to sell our vaccines.

***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.

***HHS BARDA may decide not to extend our contract beyond the exercised option period or may decide to terminate our contract.***

The HHS BARDA contract was extended by an additional two years through the option period for a total performance period of approximately five and a half years. Depending on how we perform during the option period, HHS BARDA may decide whether or not to extend the contract to include additional periods of time to complete the contract deliverables or may decide to terminate the contract. For example, the HHS BARDA contract anticipates that we file BLAs for licensure of both our seasonal influenza vaccine and our pandemic influenza vaccine; however, there is no guarantee that we will successfully complete all of the tasks required to file BLAs during this period. There can be no guarantee that the HHS BARDA contract will not be terminated early or will be extended beyond September 2016.

***Because of changes to the influenza vaccine industry and regulatory environment, we do not expect to seek accelerated approval by the FDA of our seasonal influenza vaccine candidate.***

FDA regulations allow for the accelerated approval of a seasonal influenza vaccine based on a surrogate endpoint (i.e., HAI data) when there is a shortage of vaccine because influenza is a serious and sometimes, life-threatening disease. This may allow developers to obtain licensure well ahead of the timeline for demonstrating clinical efficacy, which is necessary for traditional approval. However, the seasonal influenza vaccine industry has made significant steps to provide sufficient supply to the recommended population in the U.S., and thus, we no longer expect to seek accelerated approval from the FDA for our seasonal influenza vaccine. Because we do not expect such approval, it is likely that we would 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.

***Our wholly-owned subsidiary Novavax AB, collaborations with regional partners, such as Cadila and BMGF, 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.***

Swedish-based Novavax AB is a wholly-owned subsidiary of Novavax, Inc. We have also formed a joint venture with Cadila in India, a clinical development agreement with BMGF and have entered into other agreements and arrangements with companies in other countries. We plan to continue to enter into collaborations or partnerships with companies, non-profit organizations and local governments in 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;
- difficulties in and costs of staffing, managing and operating our international operations;
- changes in environmental, health and safety laws;
- fluctuations in foreign currency exchange rates;
- 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; and
- possible nationalization and expropriation.

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

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

We have entered into regional collaborations to develop our vaccine candidates in certain parts of the world, and we may enter into additional regional collaborations. Our relationships with Cadila and BMGF are examples of these regional relationships. These relationships are likely to involve the licensing of our technology to our partner or entering into a distribution agreement, frequently on an exclusive basis. 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, preclinical studies or clinical trials will show that a product candidate is not efficacious or that it raises safety concerns or has other side effects that outweigh its intended benefit. Success in preclinical or early clinical trials may not translate into success in large-scale clinical trials.

Further, success in clinical trials 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;
- preclinical testing;
- designing and implementing clinical trials;
- regulatory processes and approvals;
- production and manufacturing; and
- sales and marketing of approved products.

Principal competitive factors in our industry include:

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

Large and established companies, such as Merck & Co., Inc., GlaxoSmithKline plc, CSL Ltd, Sanofi Pasteur, SA, Pfizer Inc. and 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 may need to be more efficacious, particularly in older adults, and/or be less expensive and quicker to manufacture. Many of our competitors are working on new products and new generations of current products, 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 vaccines that are marketable to multiple population segments. Geographic markets are also likely to vary significantly, which may

make it difficult to market a single RSV vaccine worldwide. Even if a manufacturer brings an RSV vaccine to license, it is likely that competitors will continue to work on new products that could be more efficacious and/or less expensive. Our RSV vaccine candidate may not be as far along in development as other active RSV vaccine programs about which we are not aware, nor as efficacious as products under development by competing companies.

We believe that there are at least two EBOV vaccine candidates that are currently being tested in late stage clinical trials: one by GlaxoSmithKline in collaboration with the United States National Institute of Allergy and Infectious Diseases, and the other by a collaboration of NewLink Genetics, Merck Vaccines USA and the Public Health Agency of Canada. Additional vaccine candidates are also being tested, although in earlier stage clinical trials. Vaccine candidates against EBOV have been in development for more than a decade by large pharmaceutical companies, smaller biotech companies, government agencies and academic labs worldwide, and with the high visibility of the recent West Africa epidemic, continued development activities are likely to continue and potentially increase.

Regardless of the disease, 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, our business, operating results and financial condition could be materially adversely affected.***

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 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 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 could 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 government agencies, academic institutions, 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.

***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.

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

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

*Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.*

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and data about our clinical subjects, suppliers, and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by malicious third parties with a wide range of motives and expertise, including organized criminal groups, “hactivists,” patient groups, disgruntled current or former employees, and others. Hacker attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached due to employee error or malfeasance. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Furthermore, if our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. Attacks could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, which could adversely affect our business.

## **PRODUCT DEVELOPMENT RISKS**

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

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

- our recombinant nanoparticle vaccine technologies, any or all of the products based on such technologies or our proprietary manufacturing process will be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances or commercial viability;
- we are unable to scale-up our manufacturing capabilities in a cost-effective manner;
- the products, if safe and effective, will be difficult to manufacture on a large-scale or uneconomical to market;
- our manufacturing facility will fail to continue to pass regulatory inspections;
- proprietary rights of third-parties will prevent us or our collaborators from exploiting technologies, and manufacturing or marketing products; and
- third-party competitors will gain greater market share due to superior products or marketing capabilities.

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

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



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

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

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

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

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

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

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.

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

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

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

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

such partners may not devote sufficient resources to our vaccine candidates or properly maintain or defend our intellectual property rights; any failure on the part of our partners to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our vaccine candidates and affect our ability to realize product revenue; and disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals and commercialization activities.

Our collaborators will be subject to the same regulatory approval of their manufacturing facility and process as 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 GMP regulations. If our collaborators fail to comply with these requirements, our vaccine candidates would not be approved. If our collaborators fail to comply with these requirements after approval, we could be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products.

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

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

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

We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the clinical trial participants are adequately protected. The FDA and foreign regulatory agencies also require us to comply with good manufacturing practices. Our reliance on third-parties does not relieve us of these responsibilities and requirements. These third-parties may not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines. In addition, these third-parties may need to be replaced or the quality or accuracy of the data they obtain may be compromised or the product they manufacture may be contaminated due to the failure to adhere to our clinical and manufacturing protocols, regulatory requirements or for other reasons. In any such event, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval of, or commercially manufacture, our vaccine candidates.

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

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

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

We formed CPLB with Cadila in India 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, preclinical development, clinical development, process development, manufacturing scale-up and general manufacturing related services in India. We cannot predict when, if at all, this relationship 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.***

Although we have initiated preliminary activities in anticipation of commercialization of our vaccine candidates, we currently have no dedicated sales, marketing or distribution capabilities. As a result, we will depend on collaborations with third-parties that have established distribution systems and sales forces. To the extent that we enter into co-promotion or other licensing arrangements, our revenue will depend upon the efforts of third-parties, over which we may have little or no control. If we are unable to reach and maintain agreements with one or more pharmaceutical companies or collaborators, we may be required to market our products directly. Developing a marketing and sales force is expensive and time-consuming and could delay a product launch. We 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.

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

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

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

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

Our success may depend, in part, on the extent to which reimbursement for the costs of vaccines will be available from third-party payers, such as government health administration authorities, private health insurers, 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, loss of any potential marketing advantage of being early to market and increased clinical trial costs. The speed with which we begin and complete our preclinical studies necessary to begin clinical trials, clinical trials and our applications for marketing approval will depend on several factors, including the following:



- our ability to manufacture or obtain sufficient quantities of materials for use in necessary preclinical studies and clinical trials;
- prior regulatory agency review and approval;
- approval of the protocol and the informed consent form by the review board of the institution conducting the clinical trial;
- the rate of 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 preclinical and clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit or prevent further studies or regulatory approval;
- the availability of skilled and experienced staff to conduct and monitor clinical trials and to prepare the appropriate regulatory applications; and
- changes in the policies of regulatory authorities for drug or vaccine approval during the period of product development.

We have limited experience in conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory marketing approvals. We may not be permitted to continue or commence additional clinical trials. We also face the risk that the results of our clinical trials may be inconsistent with the results obtained in preclinical studies or clinical trials of similar products or that the results obtained in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the 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. In order to market our products in the European Union, India, Asia and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing and data

review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by a regulatory agency, such as the FDA, does not ensure approval by any other regulatory agencies, for example in other foreign countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could harm our business.

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

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

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

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

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

Our facilities in Maryland are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, microorganisms and various hazardous compounds used in connection with our research and development activities. In the U.S., these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Similar national and local regulations govern our facility in Sweden. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state, and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, these hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use or the use by third-parties of these

materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

Although we have general liability insurance, these policies contain exclusions from insurance against claims arising from pollution from chemicals or pollution from conditions arising from our operations. Our collaborators are working with these types of hazardous materials in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury we or our collaborators cause to persons or property by exposure to, or release of, any hazardous materials. However, we believe that we are currently in compliance with all 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 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 (the "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 200 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.

***Third parties may claim we infringe their intellectual property rights.***

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. 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 litigation to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time-consuming.***

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

Interference proceedings brought by the U.S. Patent and Trademark Office 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 \$15 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 \$0.3 million per year. In September 2015, the Company entered into an amendment to the license agreement with Wyeth. Among other things, the amendment restructured the \$3 million milestone payment owed as a result of CPLB's initiation of a Phase 3 clinical trial for its recombinant trivalent seasonal VLP influenza vaccine candidate in 2014. Under the amendment, the milestone payment, which may increase slightly over time, shall be due in connection with the initiation of a Phase 3 clinical trial for the initial seasonal influenza VLP vaccine candidate being developed outside India, but in any case no later than December 31, 2017.

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

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

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

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

technology we hold will afford us significant commercial protection.

### **Risks Related to OUR Convertible SENIOR Notes**

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

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

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

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

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

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

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

## **RISKS RELATED TO OUR COMMON STOCK AND ORGANIZATIONAL STRUCTURE**

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

Our stock price has been highly volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. From January 1, 2015 through December 31, 2015, the closing sale price of our common stock has been as low as \$5.74 per share and as high as \$14.14 per share. The market price of our common stock may be influenced by many factors, including:

future announcements about us or our collaborators or competitors, including the results of testing, technological innovations or new commercial products;

clinical trial results;

depletion of our cash reserves;

sale of equity securities or issuance of additional debt;

announcement by us of significant strategic partnerships, collaborations, joint ventures, capital commitments or acquisitions;

changes in government regulations;

impact of competitor successes and in particular development success of vaccine candidates that compete with our own vaccine candidates;

developments in our relationships with our collaboration partners;

announcements relating to health care reform and reimbursement levels for new vaccines and other matters affecting our business and results, regardless of accuracy;

- sales of substantial amounts of our stock by existing stockholders (including stock by insiders or 5% stockholders);
- development, spread or new announcements related to pandemic influenza;
- litigation;
- public concern as to the safety of our products;
- significant set-backs or concerns with the industry or the market as a whole;
- regulatory inquiries, reviews and potential action, including from the FDA or the SEC;
- recommendations by securities analysts or changes in earnings estimates; and
- the other factors described in this Risk Factors section.

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

***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.***

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

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

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

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

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

#### **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **Item 2. PROPERTIES**

We lease three facilities in Gaithersburg, Maryland and one in Rockville, Maryland. In conjunction with our acquisition of Novavax AB in 2013, we acquired a facility lease in Uppsala, Sweden. A summary of our current facilities is set forth below. Although we believe that our facilities are suitable and adequate for our present needs, the Company's management continues to review and assess real property expansion opportunities that may be necessary to address our expectations for future growth.

<b>Property Location</b>	<b>Approximate Square Footage</b>	<b>Brief Property Description</b>
Rockville, MD	51,000	Vaccine research and development and manufacturing facility
20FF Gaithersburg, MD	53,000	Corporate headquarters, vaccine research and development and manufacturing facility
21FF Gaithersburg, MD	40,000	Research and development laboratory facility and offices
22FF Gaithersburg, MD	40,000	Executive, administrative, clinical and regulatory offices
Uppsala, Sweden	16,000	Adjuvant manufacturing facility and research and development and administrative offices
Total square footage	200,000	

**Item 3. LEGAL PROCEEDINGS**

We currently have no material pending legal proceedings.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

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

Our common stock trades on The NASDAQ Global Select Market under the symbol "NVAX." 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, 2015	\$8.77	\$6.59
September 30, 2015	\$14.14	\$6.41
June 30, 2015	\$11.19	\$7.66
March 31, 2015	\$9.71	\$5.74
December 31, 2014	\$5.98	\$4.05
September 30, 2014	\$5.01	\$4.08
June 30, 2014	\$5.13	\$3.69
March 31, 2014	\$6.65	\$4.13

On February 24, 2016, the last sale price reported on The NASDAQ Global Select Market for our common stock was \$4.79. Our common stock was held by approximately 391 stockholders of record as of February 24, 2016, 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.

**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, 2010, and reinvestments of all dividends.

Value of \$100 invested on December 31, 2010 in stock or index, including reinvestment of dividends, for fiscal years ended December 31:

	12/31/10	12/31/11	12/31/12	12/31/13	12/31/14	12/31/15
Novavax, Inc.	\$100.00	\$51.85	\$77.78	\$210.70	\$244.03	\$345.27
NASDAQ Composite Index	\$100.00	\$100.53	\$116.92	\$166.19	\$188.78	\$199.95
RUSSELL 2000 Growth Biotechnology Index	\$100.00	\$96.86	\$111.24	\$173.74	\$215.91	\$240.03

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.

**Item 6. SELECTED FINANCIAL DATA**

The following table sets forth selected financial data for each of the years in the five-year period ended December 31, 2015, 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,				
	2015(1)	2014(2)	2013(3)	2012	2011
	(in thousands, except per share amounts)				
Statements of Operations Data:					
Revenue	\$36,250	\$30,659	\$20,915	\$22,076	\$14,688
Net loss	(156,937)	(82,947)	(51,983)	(28,507)	(19,364)
Basic and diluted net loss per share	(0.60)	(0.37)	(0.31)	(0.22)	(0.17)
Weighted average shares used in computing basic and diluted net loss per share	262,248	225,848	169,658	131,726	113,610

	As of December 31,				
	2015(1)	2014(2)	2013(3)	2012	2011
	(in thousands)				
Balance Sheet Data:					
Cash and marketable securities(4)	\$230,656	\$168,056	\$133,068	\$50,344	\$18,309
Total current assets	287,257	188,158	145,001	50,408	26,109
Working capital(5)	210,763	154,042	126,879	38,733	18,530
Total assets	386,038	276,002	235,125	102,345	66,576
Long-term debt, less current portion(6)	37	503	1,199	990	300
Accumulated deficit	(650,030)	(493,093)	(410,146)	(358,163)	(329,656)
Total stockholders’ equity	292,669	229,618	203,234	80,240	53,849

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

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

(3) In 2013, we completed the acquisition of Novavax AB (see Note 4 to consolidated financial statements in Item 8) and had sales of 44,452,343 shares of common stock resulting in net proceeds of approximately \$129 million.

(4) Includes non-current marketable securities of \$6,233 at December 31, 2012.

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

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

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

Any statements in the discussion below and elsewhere in this Annual Report, about expectations, beliefs, plans, objectives, assumptions or future events or performance of Novavax, Inc. (“Novavax”, and together with its wholly owned subsidiary Novavax AB, the “Company,” “we” or “us”) are not historical facts and are forward-looking statements. Such forward-looking statements include, without limitation, statements with respect to our capabilities, goals, expectations regarding future revenue and expense levels; potential market sizes and demand for our product candidates; the efficacy, safety and intended utilization of our product candidates; the development of our clinical-stage product candidates and our recombinant vaccine and adjuvant technologies; the development of our preclinical product candidates; the conduct, timing and potential results from clinical trials and other preclinical studies; plans for and potential timing of regulatory filings; the expected timing and content of regulatory actions; reimbursement by the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”); payments under our license with Wyeth Holdings LLC (formerly known as Wyeth Holdings Corporation), a subsidiary of Pfizer Inc. (“Wyeth”); payments by the Bill & Melinda Gates Foundation (“BMGF”); our available cash resources and the availability of financing generally, plans regarding partnering activities, business development initiatives and the adoption of stock incentive plans, and other factors referenced herein. You generally can identify these forward-looking statements by the use of words or phrases such as “believe,” “may,” “could,” “will,” “would,” “possible,” “can,” “estimate,” “continue,” “ongoing,” “consider,” “anticipate,” “intend,” “seek,” “plan,” “project,” “would,” or “assume” or the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

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

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

## Recent Events

In February 2016, Novavax completed the issuance of \$325 million of 3.75% Convertible Senior Notes due in 2023, resulting in net proceeds of approximately \$315 million, after deducting initial purchasers' discounts and commissions, and approximately \$314 million after deducting offering expenses. We used approximately \$38 million of the net proceeds to pay the costs of a capped call transaction, which will function to reduce dilution from issuance of additional shares upon conversion of the notes between the note conversion price of \$6.81 and the cap price of \$9.73 per share. The resulting final net proceeds to the company were approximately \$276 million.

Our cash, cash equivalents and marketable securities on December 31, 2015 of approximately \$231 million, as adjusted to give effect to the final net proceeds of the Convertible Senior Note offering of approximately \$276 million, before giving effect to the anticipated use of the final net proceeds, would result in an as adjusted cash, cash equivalents and marketable securities balance of approximately \$507 million.

## Overview

We are a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine platform technology, we produce vaccine candidates to efficiently and effectively respond to both known and emerging disease threats. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate recombinant proteins critical to disease pathogenesis. Our product pipeline targets a variety of infectious diseases with vaccine candidates currently in clinical development for respiratory syncytial virus (“RSV”), seasonal influenza, pandemic influenza and Ebola virus (“EBOV”). We have additional preclinical stage programs for a variety of infectious diseases.

We are also developing proprietary technology for the production of immune stimulating saponin-based adjuvants through our wholly owned Swedish subsidiary, Novavax AB. Our lead adjuvant, Matrix-M™, has been successfully tested in a Phase 1/2 clinical trial for our pandemic H7N9 influenza virus-like particle vaccine candidate, and in a Phase 1 clinical trial for our EBOV vaccine candidate. Genocea Biosciences, Inc. (“Genocea”) has licensed rights to our Matrix technology and is now conducting Phase 2 clinical trials with its herpes simplex 2 vaccine candidate using Matrix-M.

## Clinical Product Pipeline

Our clinical product pipeline includes vaccine candidates engineered to elicit differentiated immune responses with potential to provide increased protection. Our nanoparticle technology platform targets antigens with conserved epitopes essential for viral function. Unlike traditional vaccines that ‘mimic’ viruses and elicit naturally occurring immune responses to them, our nanoparticles are engineered to elicit differentiated immune responses, which may be more efficacious than naturally-occurring immunity. Our vaccine technology has the potential to be applied broadly to a wide variety of human infectious diseases.

A current summary of our significant research and development programs, along with the programs of our joint venture, CPLB, and status of the related products in development follows:

Program	Development Stage	Funding	Collaborator
<b>Respiratory Syncytial Virus (RSV)</b>			
· Older Adults	Phase 3		
· Infants via Maternal Immunization	Phase 3	BMGF*	

<b>Pediatrics</b>	Phase 1	
<b>Influenza</b>		
·Seasonal Quadrivalent	Phase 2	HHS BARDA
·Pandemic H7N9	Phase 2	HHS BARDA
<b>Combination (Influenza/RSV)</b>	Preclinical	
<b>Ebola Virus (EBOV)</b>	Phase 1	

\*As detailed herein, our funding and development arrangement with PATH expired in April 2015; we entered into a grant agreement with BMGF in September 2015.

### **Respiratory Syncytial Virus (RSV)**

We are developing our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) for three susceptible target populations: older adults (60 years of age and older), infants via maternal immunization and children six months to five years of age (“pediatrics”). We estimate RSV F Vaccine peak revenue potential of six to eight billion dollars worldwide. Currently there is no approved RSV Vaccine available.



Repeat infection and lifelong susceptibility to RSV are common and we currently estimate the global cost burden of RSV in excess of \$88 billion. Despite decades of effort to develop an RSV vaccine, there are currently no licensed vaccines. Although the monoclonal antibody palivizumab (Synagis®) is effective in pre-term infants, it is not indicated for use in other populations. Novavax made a breakthrough in developing a vaccine that targets the fusion protein, or F-protein, of the virus. The F-protein has a highly conserved amino acid sequence called antigenic site II, which we believe is an ideal vaccine target. Palivizumab, which also targets antigenic site II, has demonstrated protection in five randomized clinical trials. We genetically engineered a novel F-protein antigen and enhanced its immunogenicity by exposing antigenic site II. Novavax' RSV F Vaccine assembles into a recombinant protein nanoparticle optimized for F-protein antigen presentation. The RSV F Vaccine elicits palivizumab-competing antibodies at levels that we expect to confer protection. The Novavax RSV F Vaccine is the first RSV vaccine to demonstrate efficacy in a clinical trial and Novavax is positioned to bring the first RSV vaccine to market to combat the 64 million RSV infections that occur globally each year.<sup>20,21</sup>

### ***RSV Older Adults Program***

#### *Burden of Disease*

Adults 60 years of age and older are at increased risk for RSV disease due to age related declines in their immune systems. In this population, RSV is an important respiratory virus, distinct from influenza viruses, that is responsible for serious lower respiratory tract disease and may lead to hospitalization or even death. Additionally, RSV infection can lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. RSV infection occurs as a recurrent and predictable annual epidemic throughout the world. In the U.S., the incidence rate is 2.5 million infections per year, and RSV is increasingly recognized as a significant cause of morbidity and mortality in the population of 64 million older adults.<sup>22,23</sup> Based on our analysis of published literature applied to 2014 population estimates, the disease causes 207,000 hospitalizations and 16,000 deaths among adults older than 65. Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease across all populations.

#### *Clinical Trial Update*

In August 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 1,600 older adults. The clinical trial was designed to prospectively examine the incidence of all symptomatic respiratory illnesses associated with RSV infection, in community-living older adults who were treated with placebo. The trial also evaluated safety and immunogenicity of our RSV F Vaccine compared to placebo. Finally, the trial estimated the efficacy of our RSV F Vaccine in reducing the incidence of respiratory illness due to RSV. The trial was the first to demonstrate efficacy of an active RSV immunization in any clinical trial population. In the per protocol population, the clinical trial showed statistically significant vaccine efficacy in prevention of all symptomatic RSV disease (41%)

and, in an *ad hoc* analysis, showed a decrease in RSV disease with any symptoms of lower respiratory tract infection (45%) in older adults. The clinical trial established an attack rate for symptomatic RSV disease of 4.9% in older adults, 95% of which included lower respiratory track symptoms. Efficacy against more severe RSV illness, defined by the presence of multiple lower respiratory tract symptoms or signs associated with difficulty breathing, was 64% in *ad hoc* analyses.

We initiated a pivotal Phase 3 clinical trial, known as Resolve™, of our RSV F Vaccine in older adults in November 2015, and in December 2015, we completed enrollment of 11,850 older adult subjects at 60 sites in the U.S. The primary objective of the clinical trial is the prevention of moderate-severe RSV-associated lower respiratory tract disease, as defined by the presence of multiple lower respiratory tract symptoms. We expect to provide top-line data from this clinical trial in the third quarter of 2016.

In October 2015, we completed enrollment of 1,330 older adults in our Phase 2 rollover clinical trial of our RSV F Vaccine in the older adults who had participated in the recently concluded prior Phase 2 clinical trial. This trial is designed to evaluate safety and immunogenicity in response to immunization with the RSV F Vaccine during a second RSV season. We expect to provide top-line data from this trial in the second half of 2016.

<sup>20</sup> Nair, H., et al., (2010) *Lancet*. 375:1545 - 1555

<sup>21</sup> WHO Acute Respiratory Infections September 2009 Update:  
[http://apps.who.int/vaccine\\_research/diseases/ari/en/index2.html](http://apps.who.int/vaccine_research/diseases/ari/en/index2.html)

<sup>22</sup> Falsey, A.R. *et al.* (2005) *NEJM*. 352:1749–59 extrapolated to 2015 census population

<sup>23</sup> Falsey, A.R. *et al.* (1995) *JID*.172:389-94

## *RSV Infants via Maternal Immunization Program*

### *Burden of Disease*

RSV is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide.<sup>24</sup> In the U.S., RSV is the leading cause of hospitalization of infants, and globally, is second only to malaria as a cause of death in children under one year of age.<sup>25,26</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.<sup>27,28</sup>

### *Clinical Trial Update*

In September 2015, we announced positive top-line data from a Phase 2 clinical trial of our RSV F Vaccine in 50 healthy pregnant women and their infants. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine in pregnant women in their third trimester, and assessed the transplacental transfer of maternal antibodies induced by the vaccine. The trial also examined the impact of maternal immunization on infant safety during the first year of life and RSV-specific antibody levels through the infants' first six months of life. Immunized women demonstrated a geometric mean 14-fold rise in anti-F IgG, 29-fold rise in palivizumab-competing antibodies and a 2.7 and 2.1-fold rise in microneutralization titers against RSV/A and RSV/B, respectively. In contrast, women who received placebo demonstrated no significant change in antibody levels. The infants' antibody levels at delivery averaged 90-100% of the mothers' levels, indicating efficient transplacental transfer of antibodies from mother to infant. The estimated half-lives of infant PCA, anti-F IgG, RSV/A and RSV/B microneutralizing antibodies, based on data through day 60, were 41, 30, 36 and 34 days, respectively.

We announced the initiation of a global pivotal Phase 3 clinical trial, known as Prepare™, of the RSV F Vaccine in 5,000 to 8,255 healthy pregnant women in December 2015. The primary objective of the Prepare trial is to determine the efficacy of maternal immunization with the RSV F Vaccine against symptomatic RSV lower respiratory tract infection with hypoxemia in infants through the first 90 days of life. This Phase 3 trial utilizes a group sequential design and is expected to take between two and four years to complete. This trial is supported by a grant (the "Grant") of up to \$89.1 million from the Bill & Melinda Gates Foundation. The Grant will support development activities, product licensing efforts and WHO prequalification of our RSV F Vaccine. We concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as a part of the grant agreement (the "Grant Agreement"). Under the terms of the GACA, we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

In November 2014, the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (“FDA”) granted Fast Track designation to our RSV F Vaccine for protection of infants via maternal immunization. Fast Track designation is intended for products that treat serious or life-threatening diseases or conditions, and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is designed to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

### ***RSV Pediatrics Program***

#### *Burden of Disease*

There are currently approximately 18 million children in the U.S. between six months and five years of age.<sup>29</sup> In the U.S., RSV is responsible for approximately 57,000 hospitalizations of children under five years of age annually, the vast majority of which occur in infants less than one year old, and especially those under six months of age.  
30,31,32,33,34

<sup>24</sup> Nair, H., et al., (2010) *Lancet*. 375:1545 - 1555

<sup>25</sup> Hall, C.B. *et al.* (2013) *Pediatrics*; 132(2):E341-348

<sup>26</sup> Oxford Vaccine Group: <http://www.ovg.ox.ac.uk/rsv>

<sup>27</sup> Glezen, W.P. *et al.* (1986) *Am J Dis Child*; 140:543-546

<sup>28</sup> Glenn, G.M. *et al.* (2016) *JID*; 213(3):411-12

<sup>29</sup> U.S. Census. [www.census.gov/population/international/data/idb/informationGateway.php](http://www.census.gov/population/international/data/idb/informationGateway.php)

<sup>30</sup> Stockman, L.J. et al (2012) *Pediatr Infect Dis J*. 31: 5-9

<sup>31</sup> CDC update May 5, 2015. <http://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>32</sup> Boyce, T.G. et al (2000) *Pediatrics*; 137: 865-870

<sup>33</sup> Hall, C.B. et al (2009) *NEJM*; 360(6): 588-98

<sup>34</sup> Hall, C.B. et al (2013) *Pediatrics*; 132(2): E341-8

### *Clinical Trial Update*

In September 2015, we announced positive top-line data from a Phase 1 clinical trial of our RSV F Vaccine in healthy children between two and six years of age. This clinical trial evaluated the safety and immunogenicity of our RSV F Vaccine, with one or two doses, with or without aluminum phosphate adjuvant. Trial enrollment was concluded with a smaller than planned cohort so that dosing could be completed ahead of the 2014-15 RSV season. The vaccine was well-tolerated and serum samples collected from a subset of 18 immunized children in the per-protocol population, demonstrated that the RSV F Vaccine was highly immunogenic at all formulations and regimens. There were greater than 10-fold increases in both anti-F IgG and PCA antibody titers in the adjuvanted group and greater than 6-fold increases in anti-F IgG and PCA antibody titers in the unadjuvanted group. We are assessing the data from this clinical trial and evaluating the next steps in the development of our RSV F Vaccine for pediatrics.

### **Influenza**

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. Serious illness occurs not only in susceptible populations such as pediatrics and older adults, but also in the general population because of unique strains of influenza for which most humans have not developed protective antibodies. We are developing vaccine candidates for both seasonal and pandemic influenza. Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show a potential increase from approximately \$3.2 billion in the 2012/13 season to \$5.3 billion by the 2021/2022 season.<sup>35</sup>

Traditional vaccine manufacturing methods utilize live influenza virus to infect eggs in order to produce trivalent seasonal influenza vaccine candidates. Our egg-free recombinant nanoparticle technology does not utilize either a live influenza virus or eggs, but rather a recombinant baculovirus and insect cells, which allows for the product to potentially be rapidly manufactured and quickly adapted to changing influenza strains. Further, we are developing a quadrivalent seasonal vaccine candidate, which we expect to elicit broader protection from circulating influenza strains. We are also exploring the development of novel influenza nanoparticle vaccine candidates. There are currently four quadrivalent seasonal influenza vaccines licensed in the U.S., although additional quadrivalent seasonal influenza vaccines are expected to be licensed over the next several years.

### ***Quadrivalent Seasonal Influenza Vaccine***

#### *Burden of Disease*

The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (“CDC”) recommends that all persons aged six months and older be vaccinated annually against seasonal influenza. Influenza is a major burden on public health worldwide: an estimated one million deaths each year are attributed to influenza.<sup>36</sup> It is further estimated that, each year, influenza attacks between 5% and 10% of adults and 20% to 30% of children, causing significant levels of illness, hospitalization and death.<sup>37</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 potentially be manufactured quickly and in a cost-effective manner, without the use of either the live influenza virus or eggs.

#### *Clinical Trial Update*

In July 2015, we reported positive data from our Phase 2 clinical trial of our quadrivalent seasonal influenza virus-like-particle (“VLP”) vaccine candidate in 400 healthy adults that we initiated in November 2014. These data show that our quadrivalent seasonal influenza VLP vaccine candidate is well-tolerated, and can induce influenza antibody responses that met the immunogenicity targets. These results demonstrate the potential for our quadrivalent seasonal influenza VLP vaccine candidate to meet the FDA criteria for accelerated approval.

<sup>35</sup> Influenza Vaccines Forecasts. Datamonitor (2013)

<sup>36</sup> Resolution of the World Health Assembly. (2003) WHA56.19. 28

<sup>37</sup> WHO position paper (2012) Weekly Epidemiol Record;87(47):461–76

We were awarded a contract by HHS BARDA in 2011 to fund the development of both our quadrivalent seasonal influenza and pandemic influenza VLP vaccine candidates. This 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 vaccine candidates. We announced that HHS BARDA had exercised and initiated a two-year option to our contract in September 2014, which not only extended the expected term of the contract until September 2016, but also added scope to support our development activities leading up to planned Phase 3 clinical trials and \$70 million of funding on top of the remainder of the \$97 million base period funding. In June 2015, the contract was amended to increase the funding by \$7.7 million to allow for the recovery of additional costs under the contract relating to the settlement of indirect rates for fiscal years 2011 and 2012. This additional amount was received and recorded as revenue in the second quarter of 2015. During 2015, we recognized revenue of \$33.3 million and have recognized approximately \$112 million in revenue since the inception of the contract. In recent meetings with HHS BARDA, we have been discussing the next steps in both our seasonal influenza VLP vaccine program and our pandemic influenza VLP vaccine program, as well as some of the delays associated with our development of both vaccine candidates. We expect to continue discussions with HHS BARDA during 2016 and to present plans for continued clinical and product development, although there can be no guarantee that the HHS BARDA contract will not be terminated early or will be extended beyond September 2016.

### *Pandemic H7N9 Influenza Vaccine*

#### *Burden of Disease*

Prevention 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 influenza 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. Industry and health experts have focused attention on developing a monovalent influenza vaccine against either the H5N1 strain or the H7N9 strain as potential key defenses against future pandemic disease threats.

#### *Clinical Trial Update*

We have developed and delivered compelling safety and immunogenicity data on two pandemic vaccine candidates, H5N1 and H7N9. In September 2014, we announced positive results from a Phase 1/2 clinical trial of our H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M in 610 healthy adults. The Phase 1/2 clinical trial was designed as a dose-ranging, randomized, observer-blinded, placebo-controlled clinical trial, to determine the contribution of Matrix-M to potential antigen dose sparing regimens. Our H7N9 influenza vaccine candidate, with and without Matrix-M, was highly immunogenic and well-tolerated. Matrix-M adjuvanted formulations demonstrated

immunogenicity and dose-sparing benefits relative to unadjuvanted antigen. Hemagglutination-inhibiting antibody titers were comparable to those reported in prior clinical trials, and the vaccine elicited significant anti-neuraminidase antibodies. In October 2014, the FDA granted Fast Track designation to our H7N9 influenza vaccine candidate with Matrix-M.

Our pandemic influenza vaccine program is supported by our HHS BARDA contract. Like our seasonal influenza vaccine program, we expect to continue discussions with HHS BARDA during 2016 and to present plans for continued clinical and product development of our pandemic influenza vaccine candidate, although there can be no guarantee that the HHS BARDA contract will not be terminated early or will be extended beyond September 2016.

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

Given the ongoing development of our seasonal influenza vaccine candidate and our RSV F Vaccine, we see an important opportunity to develop a combination respiratory vaccine candidate. Early preclinical development efforts have given us confidence that such a combination vaccine is viable, and in animal models, provides acceptable immunogenicity. We expect to initiate a Phase 1 clinical trial of a combination respiratory vaccine in the first half of 2017.



## **Ebola Virus (EBOV)**

EBOV, formerly known as Ebola hemorrhagic fever, is a severe, often fatal illness in humans. Multiple strains of EBOV have been identified, the most recent of which, the Makona EBOV strain, is associated with a case fatality rate of 50% to 90%.<sup>38</sup> There are currently no licensed treatments proven to neutralize the virus, but a range of blood, immunological and drug therapies are under development. Despite the development of such therapies, current vaccine approaches target either a previous strain of the virus or were initially developed to be delivered by genetic vectors. In contrast, our EBOV glycoprotein vaccine candidate (“Ebola GP Vaccine”) was developed using the Makona EBOV strain.

In July 2015, we announced data from our Phase 1 clinical trial of our Ebola GP Vaccine in ascending doses, with and without our Matrix-M adjuvant, in 230 healthy adults. Participants received either one or two intramuscular injections ranging from 6.5µg to 50µg of antigen, with or without adjuvant, or placebo. Immunogenicity was assessed at multiple time points, including days 28 and 35. These Phase 1 data demonstrated that our Ebola GP Vaccine is highly immunogenic, well-tolerated and, in conjunction with our proprietary Matrix-M adjuvant, resulted in significant antigen dose-sparing. Although the adjuvanted Ebola GP Vaccine was highly immunogenic at all dose levels, the adjuvanted two-dose regimens induced Ebola anti-GP antibody geometric mean responses between 45,000 and 70,000 ELISA units, representing a 500 to 750-fold rise over baseline at day 35. In 2015, we also announced successful data from two separate non-human primate challenge studies of our Ebola GP Vaccine in which, in both cases, the challenge was lethal for the control animal, whereas 100% of the immunized animals were protected.

## **CPLB Programs (India)**

CPL Biologicals Private Limited (“CPLB”), our joint venture company with Cadila Pharmaceuticals Limited (“Cadila”) in India, is actively developing a number of vaccine candidates that were genetically engineered by us. CPLB is owned 20% by us and 80% by Cadila. CPLB operates a manufacturing facility in India for the production of vaccines.

## ***Seasonal Influenza***

CPLB received marketing authorization, the Indian equivalent of approval of a Biologics License Application (“BLA”), for its recombinant trivalent seasonal VLP influenza vaccine in 2015. Because the market for seasonal influenza in India is limited and highly competitive, CPLB is currently evaluating its marketing strategy for this vaccine.

***Rabies***

CPLB successfully completed Stage II of its 2-stage Phase 1/2 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered. The objective was to select a dose and regimen for a recombinant vaccine that can be administered both as a pre-exposure prophylaxis for residents of certain higher-risk geographies and travelers to such locations, and as a post-exposure prophylaxis using fewer doses than the current standard of care. In October 2014, CPLB presented clinical results from Stage I of the Phase 1/2 clinical trial, demonstrating that vaccine recipients, at various doses levels and schedules, showed seroprotective antibody levels at day 14 that were sustained through day 180. The vaccine candidate, which was found to be well-tolerated, also induced seroprotective levels with two-dose and three-dose regimens. CPLB has received permission to conduct a Phase 3 clinical trial and is considering the optimal schedule for its conduct.

<sup>38</sup> WHO. <http://www.who.int/mediacentre/factsheets/fs103/en/>

## **Discovery Programs**

Our vaccine platform technology provides an efficient system that has the potential to rapidly develop antigens to selected targets, refine manufacturing processes and optimize development across multiple vaccine candidates. In conjunction with government and/or global health authorities, we believe we can address emerging disease threats with pandemic potential. In addition to our response to the H7N9 influenza strain, we have developed a vaccine candidate to Middle East respiratory syndrome (“MERS”), caused by a novel coronavirus first identified in 2012. MERS emerged as a disease threat in 2013, and is currently being monitored by global health agencies, with the WHO reporting significant confirmed cases of infection and deaths. The MERS virus is a part of the coronavirus family that includes the severe acute respiratory syndrome coronavirus (“SARS”). Within weeks of obtaining the sequence of the circulating MERS strain, we successfully produced a vaccine candidate designed to provide protection. This vaccine candidate is based on the major surface spike protein, which we had previously identified as the antigen of choice in our work with a SARS vaccine candidate. In 2014, in collaboration with the University of Maryland, School of Medicine, we published results that showed our investigational vaccine candidates against both MERS and SARS blocked infection in laboratory studies. Although the development of a MERS vaccine candidate currently remains a preclinical program, we believe that our MERS vaccine candidate offers a viable option to interested global public health authorities.

## **Sales of Common Stock**

In March 2015, we completed a public offering of 27,758,620 shares of our common stock, including 3,620,689 shares of common stock that were issued upon the exercise in full of the option to purchase additional shares granted to the underwriters, at a price of \$7.25 per share resulting in net proceeds of approximately \$190 million.

In 2012, we entered into an At Market Issuance Sales Agreement (“Sales Agreement”), under which we sold an aggregate of \$50 million in gross proceeds of our common stock. During 2015, we sold 1.4 million shares at an average sales price of \$10.63 per share, resulting in approximately \$15 million in net proceeds. The Sales Agreement was fully utilized at that time.

## **Convertible Senior Notes**

In 2016, we issued \$325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (the “Notes”). The Notes will bear cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year, beginning on August 1, 2016. The Notes are not redeemable prior to maturity and are convertible into shares of Novavax common stock. The initial conversion rate for the Notes is 146.8213 shares of Novavax’ common

stock per \$1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately \$6.81 per share of Novavax' common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of Novavax' common stock of \$5.56 per share on January 25, 2016.

In connection with the issuance of the Notes, we paid approximately \$38 million to enter into privately negotiated capped call transactions with certain financial institutions (the "capped call transactions"). The capped call transactions are expected generally to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. The cap price of the capped call transactions will initially be \$9.73 per share, which represents a premium of approximately 75% based on the last reported sale price of our common stock of \$5.56 per share on January 25, 2016, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of Novavax' common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price of the capped call transactions.

#### ***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 and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. These estimates, particularly estimates relating to accounting for revenue, the valuation of our marketable securities, stock-based compensation, long-lived assets and goodwill have a material impact on our consolidated financial statements and are discussed in detail throughout our analysis of the results of operations discussed below.

We base our estimates on historical experience and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets, liabilities and equity that are not readily apparent from other sources. Actual results and outcomes could differ from these estimates and assumptions.

### ***Revenue***

We recognize revenue under research contracts when a contract has been executed, the contract price is fixed or 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.

We are currently performing a research and development contract for a U.S. Government agency under a cost reimbursable fixed price contract. Under such 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 research and development expenses. Our HHS BARDA contract provides the U.S. government 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 the HHS BARDA contract for convenience, 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, such as the HHS BARDA contract, 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 was completed in the first quarter of 2014, which resulted in \$7.7 million revenue recognized in 2015 relating to the recovery of additional costs for the settlement of indirect rates for such fiscal years as collection of the amount became reasonably assured. An audit of fiscal years 2013 and 2014 has been initiated, but has not 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 in the period that the adjustment is known.

Under our Grant Agreement with BMGF, we are reimbursed for certain costs that support development activities, including our global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and WHO prequalification of our RSV F Vaccine. Payments received under the Grant Agreement are recognized as revenue in the period in which such research and development activities are performed.

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 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.

### ***Marketable Securities***

Our marketable securities are classified as available-for-sale securities and are carried at fair value. Unrealized gains and losses on these securities, if determined not to be “other-than-temporary,” are included in accumulated other comprehensive income (loss) in stockholders’ 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 marketable securities carried at fair value, we disclose the level within the fair value hierarchy as prescribed by Accounting Standard Codification (“ASC”) Topic 820, *Fair Value Measurements and Disclosures*. We evaluate the types of securities in our investment portfolio to determine the proper classification in the fair value hierarchy based on trading activity and market inputs. We generally obtain information from an independent third-party to help us determine the fair value of securities in Level 2 of the fair value hierarchy. Investment income is recorded when earned and included in investment income.

### ***Stock-Based Compensation***

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



### *Impairments of Long-Lived Assets*

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

### *Goodwill*

Goodwill was 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 has one 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, 2015 and 2014. The income approach is used as a confirming look to the market approach, if considered necessary. Goodwill impairment may exist if the carrying value of a reporting unit exceeds its estimated fair value, which we test annually at December 31. If the carrying value of the reporting unit exceeds its fair value, step two of the impairment analysis is performed. In step two of the analysis, an impairment loss is recorded equal to the excess of the carrying value of the reporting unit's goodwill over its implied fair value should such a circumstance arise.

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 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 impairment charges in future periods.

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

We have considered the applicability and impact of all Financial Accounting Standards Board's ("FASB") Accounting Standards Updates (ASUs).

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under Topic 605, *Revenue Recognition*. The new standard requires a company to recognize revenue when it transfers goods and services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014-09 defines a five-step process that includes identifying the contract with the customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. In July 2015, the FASB approved a one-year deferral of the effective date of the new standard to 2018 for public companies, with an option that would permit companies to adopt the new standard as early as the original effective date of 2017. Early adoption prior to the original effective date is not permitted. We are evaluating the potential impact that ASU 2014-09 will have on our consolidated financial position and results of operations.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* (“ASU 2015-03”). The new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU is effective for the Company beginning January 1, 2016. The adoption of ASU 2015-03 will not have a material effect of the Company’s financial statements.

**Results of Operations for Fiscal Years 2015, 2014 and 2013** (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, including 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:**

	2015	2014	2013	<b>Change 2014 to 2015</b>	<b>Change 2013 to 2014</b>
Revenue:					
Total revenue	\$36,250	\$30,659	\$20,915	\$ 5,591	\$ 9,744

Revenue for 2015 was \$36.3 million as compared to \$30.7 million for 2014, an increase of \$5.6 million, or 18%. Revenue for 2015 and 2014 was primarily comprised of services performed under the HHS BARDA contract, and to a much lesser extent, the Grant Agreement, PATH clinical development agreement and revenue from Novavax AB. The increase in revenue is primarily due to \$7.7 million from the recovery of additional costs for the settlement of indirect rates for fiscal years 2011 and 2012 under the HHS BARDA contract and \$3.1 million relating to our Phase 2 clinical trial of our quadrivalent seasonal influenza VLP vaccine candidate in Australia (“205 Trial”) as collection of the amount became reasonably assured in 2015. These increases in revenue were partially offset by a lower level of activity in 2015 associated with our Phase 2 quadrivalent seasonal influenza VLP vaccine candidate clinical trial as compared to our Phase 1/2 clinical trial of our pandemic H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M in 2014 under the HHS BARDA contract and a decrease in revenue under the prior PATH clinical development agreement.

Revenue for 2014 was \$30.7 million as compared to \$20.9 million for 2013, an increase of \$9.7 million, or 47%. Revenue for 2014 and 2013 was primarily comprised of services performed under the HHS BARDA contract, and to a much lesser extent, the PATH clinical development agreement and revenue from Novavax AB. The increase in revenue is primarily due to the higher level of activity in 2014 associated with our Phase 1/2 clinical trial of our pandemic H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M and manufacturing work for our Phase 2 quadrivalent seasonal influenza VLP vaccine candidate clinical trial under the HHS BARDA contract, as compared to 2013. We also had increased revenue in 2014 associated with Novavax AB resulting from twelve months of activity in 2014 as compared to only five months in 2013.

For 2016, we expect our revenue, relative to 2015, to be driven by the outcome of our ongoing discussions with HHS BARDA relating to the next steps in the development of our quadrivalent seasonal and pandemic influenza vaccine candidates. We also expect revenue in 2016 under the Grant Agreement to be significantly higher than in 2015.

**Expenses:**

	2015	2014	2013	<b>Change 2014 to <u>2015</u></b>	<b>Change 2013 to <u>2014</u></b>
Expenses:					
Research and development	\$ 162,644	\$ 94,422	\$ 58,530	\$ 68,222	\$ 35,892
General and administrative	30,842	19,928	14,819	10,914	5,109
Total expenses	\$ 193,486	\$ 114,350	\$ 73,349	\$ 79,136	\$ 41,001

***Research and Development Expenses***

Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with our process development, manufacturing, clinical, regulatory and quality assurance activities for our programs. In addition, indirect costs such as fringe benefits and overhead expenses, are also included in research and development expenses. Research and development expenses increased to \$162.6 million for 2015 from \$94.4 million for 2014, an increase of \$68.2 million, or 72%. The increase in research and development expenses was primarily due to increased costs associated with our RSV F Vaccine clinical trials and higher employee-related costs, including non-cash stock-based compensation. This increase was partially offset by a lower level of activity in 2015 associated with our Phase 2 quadrivalent seasonal influenza VLP vaccine candidate clinical trial as compared to our Phase 1/2 clinical trial of our pandemic H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M in 2014. At December 31, 2015, we had 369 employees dedicated to our research and development programs versus 261 employees as of December 31, 2014. For 2016, we expect a significant increase in research and development expenses primarily due to our ongoing RSV F Vaccine candidate clinical trials and employee-related and facility costs to support product development of our RSV F Vaccine candidate and other potential vaccine candidates.

Research and development expenses increased to \$94.4 million for 2014 from \$58.5 million for 2013, an increase of \$35.9 million, or 61%. Excluding the increase in research and development expenses of \$3.6 million from Novavax AB resulting from twelve months of activity in 2014 as compared to only five months in 2013, the increase in research and development expenses was primarily due to higher employee-related costs, the preparation and initiation of three RSV F Vaccine candidate clinical trials in 2014, the initiation of our EBOV GP Vaccine candidate program and a \$3.0 million milestone payment accrued under the Wyeth agreement. The increase also resulted from the costs of our Phase 1/2 clinical trial of our pandemic H7N9 influenza VLP vaccine candidate adjuvanted with Matrix-M and manufacturing work for our Phase 2 quadrivalent seasonal influenza VLP vaccine candidate clinical trial.

***Expenses by Functional Area***

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

The following summarizes our research and development expenses by functional area for the years ended December 31, 2015, 2014 and 2013 (in millions).

	2015	2014	2013
Manufacturing	\$81.2	\$53.5	\$31.0
Vaccine Discovery	6.2	6.2	5.6
Clinical and Regulatory	75.2	34.7	21.9
Total research and development expenses	\$162.6	\$94.4	\$58.5

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

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

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

### ***General and Administrative Expenses***

General and administrative expenses increased to \$30.8 million for 2015 from \$19.9 million for 2014, an increase of \$10.9 million, or 55%. The increase was primarily due to higher employee-related costs, including non-cash stock-based compensation, driven by the administrative requirements needed to support our expanding research and development activities, and professional fees for pre-commercialization activities. At December 31, 2015, we had 49 employees dedicated to general and administrative functions versus 35 employees as of December 31, 2014. For 2016, we expect general and administrative expenses to continue to increase primarily due to increased employee costs and activities related to the anticipated commercialization of our RSV F Vaccine.

General and administrative expenses increased to \$19.9 million for 2014 from \$14.8 million for 2013, an increase of \$5.1 million, or 34%. Excluding the increase in general and administrative expenses of approximately \$0.7 million from Novavax AB resulting from twelve months of activity in 2014 as compared to only five months in 2013, the increase was primarily due to higher employee-related costs.

### **Other Income (Expense):**

	2015	2014	2013	<b>Change 2014 to 2015</b>	<b>Change 2013 to 2014</b>
Other Income (Expense):					
Investment income	\$660	\$286	\$187	\$ 374	\$ 99
Interest expense	(241)	(157)	(160)	(84 )	3
Other income (expense), net	(120)	—	182	(120 )	(182 )

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Realized gains on marketable securities	—	615	—	(615 )	615
Change in fair value of warrant liability	—	—	267	—	(267 )
Total other income, net	\$299	\$744	\$476	\$ (445 )	\$ 268

We had total other income, net of \$0.3 million for 2015 compared to total other income, net of \$0.7 million for 2014, a decrease of \$0.4 million. Our investment income increased in 2015 as compared to 2014 due to higher cash, cash equivalents and marketable securities balances. For 2014, we sold our auction rate security and received proceeds of \$1.8 million resulting in a realized gain of \$0.6 million.

We had total other income, net of \$0.7 million for 2014 compared to total other income, net of \$0.5 million for the same period in 2013. For 2014, we sold our auction rate security and received proceeds of \$1.8 million resulting in a realized gain of \$0.6 million. The change in fair value of our warrant liability resulted in a \$0.3 million decrease in total other income, net for 2014, as compared to the same period in 2013. The warrants expired unexercised on July 31, 2013.



**Net Loss:**

	2015	2014	2013	<b>Change 2014 to 2015</b>	<b>Change 2013 to 2014</b>
Net Loss:					
Net loss	\$(156,937)	\$(82,947)	\$(51,983)	\$(73,990)	\$(30,964)
Net loss per share	\$(0.60)	\$(0.37)	\$(0.31)	\$(0.23)	\$(0.06)
Weighted average shares outstanding	262,248	225,848	169,658	36,400	56,190

Net loss for 2015 was \$156.9 million, or \$0.60 per share, as compared to \$82.9 million, or \$0.37 per share, for 2014, an increased net loss of \$74.0 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to clinical trials of our RSV F Vaccine and higher employee-related costs, as compared to 2014.

Net loss for 2014 was \$82.9 million, or \$0.37 per share, as compared to \$52.0 million, or \$0.31 per share, for 2013, an increased net loss of \$31.0 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to our RSV F Vaccine candidate and higher employee-related costs, as compared to 2013.

The increase in weighted average shares outstanding for 2015 and 2014 is primarily a result of sales of our common stock in 2015 and 2014.

**Liquidity Matters and Capital Resources**

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

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As of December 31, 2015, we had \$230.7 million in cash and cash equivalents and marketable securities as compared to \$168.1 million as of December 31, 2014. These amounts consisted of \$93.1 million in cash and cash equivalents and \$137.5 million in marketable securities as of December 31, 2015 as compared to \$32.3 million in cash and cash equivalents and \$135.7 million in marketable securities as of December 31, 2014.

The following table summarizes cash flows for 2015 and 2014 (in thousands):

	2015	2014	<b><u>Change 2014 to 2015</u></b>
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(126,090)	\$(67,014 )	\$ (59,076 )
Investing activities	(21,270 )	(129,833)	108,563
Financing activities	208,283	109,717	98,566
Effect on exchange rate on cash and cash equivalents	(150 )	(6 )	(144 )
Net increase (decrease) in cash and cash equivalents	60,773	(87,136 )	147,909
Cash and cash equivalents at beginning of year	32,335	119,471	(87,136 )
Cash and cash equivalents at end of year	\$93,108	\$32,335	\$ 60,773

Net cash used in operating activities increased to \$126.1 million for 2015, as compared to \$67.0 million for 2014. The increase in cash usage was primarily due to increased research and development expenses relating to our RSV F Vaccine, higher employee-related costs and timing of customer and vendor payments.

During 2015 and 2014, our investing activities consisted primarily of purchases and maturities of marketable securities and capital expenditures. Capital expenditures for 2015 and 2014 were \$18.3 million and \$7.3 million, respectively. The increase in capital expenditures was primarily due to the purchase of laboratory equipment for process development, analytical development and manufacturing scale-up required to support our maturing product portfolio. In 2016, we expect our level of capital expenditures to be significantly higher than our 2015 spending as we continue to invest in our core operational infrastructure. If we receive positive data from our ongoing RSV F Vaccine Phase 3 clinical trial in older adults (Resolve), expected in the third quarter of 2016, this may result in a significant increase in capital expenditures as we prepare for initial commercialization and plan ahead for the additional manufacturing capacity necessary to meet expected demand in the upcoming years.

Our financing activities consisted primarily of sales of our common stock, our issuance of the Notes, which occurred in 2016, subsequent to our year-end, and to a lesser extent, stock option exercises and purchases under our employee stock purchase plan. In 2015, we received net proceeds of approximately \$190 million through our public offering at \$7.25 per share and approximately \$15 million through our Sales Agreement at an average sales price of \$10.63 per share. In 2014, we received net proceeds of approximately \$108 million through our public offering at \$4.00 per share. We sold the remaining common stock under the Sales Agreement in July 2015. The Sales Agreement has now been fully utilized. In 2016, we received net proceeds of approximately \$315 million, before deducting offering expenses, through the issuance of the Notes, and used approximately \$38 million of such proceeds in connection with our entry into the capped call transactions.

In August 2015, we amended the lease for our new facility located in Gaithersburg, Maryland to increase the amount of space leased by us to now include the entire facility. Under the terms of the amended lease, the landlord shall provide us with a tenant improvement allowance of approximately \$3.9 million. In 2015, we were funded \$1.4 million under this tenant improvement allowance. Under the terms of another facility lease, we were reimbursed \$1.4 million in the fourth quarter of 2015 for facility improvements made at the facility, and such reimbursement will be repaid back to the landlord during the remaining term of the lease through additional rent payments.

In 2007, we entered into an agreement to license certain rights from Wyeth. The Wyeth license is a non-exclusive, worldwide license to a family of patents and patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. The Wyeth license provides for us to make an upfront payment (previously made), ongoing annual license fees, sublicense payments, milestone payments on certain development and commercialization activities and royalties on any product sales. Except in certain circumstances in which we continuously market multiple products in a country within the same vaccine program, the milestone payments are one-time only payments applicable to each related vaccine program. At present, our seasonal influenza VLP vaccine program (including CPLB's seasonal influenza program) and our pandemic influenza VLP vaccine program are the only two programs to which the Wyeth license applies. The license may be terminated by Wyeth only for cause and may be terminated by us only after we have provided ninety (90) days' notice that we have absolutely and finally ceased activity, including through any affiliate or sublicense, related to the manufacturing, development, marketing or sale of products covered by the license. In September 2015, we amended the license agreement with Wyeth. Among other things, the amendment restructured the \$3 million milestone payment ("Milestone") owed as a result of CPLB's initiation of a Phase 3 clinical trial for its recombinant trivalent seasonal VLP influenza vaccine

candidate in 2014. Under the amendment, the milestone payment, which may increase slightly over time, shall be due in connection with the initiation of a Phase 3 clinical trial for the initial seasonal influenza VLP vaccine candidate being developed outside India, but in any case no later than December 31, 2017. The amendment also restructured the final milestone payment to apply to the initial seasonal influenza VLP vaccine candidate being developed outside India. Thus, the aggregate milestone payments for a seasonal influenza VLP vaccine candidate developed and commercialized was increased from \$14 million to up to \$15 million. In connection with the execution of the amendment, we agreed to pay a one-time only payment to Wyeth. The amendment also increased annual license maintenance fees associated with VLP vaccine candidates from \$0.2 million to \$0.3 million per year. Payments under the agreement to Wyeth as of December 31, 2015 aggregated \$7.3 million. The Milestone was accrued for on the consolidated balance sheet in other current liabilities at December 31, 2014. As a result of the September 2015 amendment discussed above, the Milestone payment is not expected to occur within the next 12 months. Therefore, the Milestone has been accrued for, on a discounted basis calculated based on the probable future payment date, in other non-current liabilities at December 31, 2015. The milestone was recorded as a research and development expense in the third quarter of 2014.

Based on our December 31, 2015 cash and cash equivalents and marketable securities balances, the proceeds from our Notes, along with anticipated revenue under the contract with HHS BARDA and Grant Agreement and other resources, we believe we have adequate capital to fund our operating plans for a minimum of twelve months. Additional capital may be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our ability to perform and thus generate revenue under the HHS BARDA contract and Grant Agreement, our overall business performance and market conditions.

Any capital raised by an equity offering or convertible securities has the potential to be substantially dilutive to the existing stockholders and any licensing or development arrangement may require us to give up rights to a product or technology at less than its full potential value. We cannot provide any assurance that new financing will be available on commercially acceptable terms, if at all. If we are unable to perform under the HHS BARDA contract and Grant Agreement or obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, and/or downsize our organization, including our general and administrative infrastructure.

### Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2015 (in thousands):

Contractual Obligations:	Total	<b>Less than One Year</b>	<b>1 – 3 Years</b>	<b>3 – 5 Years</b>	<b>More than 5 Years</b>
Operating leases	\$40,699	\$ 6,159	\$9,641	\$9,428	\$ 15,471
Capital lease	108	71	37	—	—
Notes payable	395	395	—	—	—
Research funding payment	1,527	1,527	—	—	—
Accrued milestone payment	4,000	—	4,000	—	—
Total contractual obligations	\$46,729	\$ 8,152	\$13,678	\$9,428	\$ 15,471

Our research funding payment includes the research funding received under the Genocea agreement (see Note 4 to consolidated financial statements in Item 8) and accrued milestone payment includes the milestone payment incurred in 2014 under the Wyeth agreement (see above for further discussion).

### Off-Balance Sheet Arrangements

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

#### **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is preservation of capital, with the secondary objective of maximizing income. As of December 31, 2015, we had cash and cash equivalents of \$93.1 million, marketable securities of \$137.5 million, all of which are short-term, and working capital of \$210.8 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of December 31, 2015, our investments were classified as available-for-sale. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our marketable securities when they mature and the proceeds are reinvested into new marketable securities and, therefore, could impact our cash flows and results of operations.

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

We are headquartered in the U.S. where we conduct the vast majority of our business activities. We have one foreign consolidated subsidiary, Novavax AB, which is located in Sweden. A 10% decline in the exchange rate between the U.S. dollar and Swedish Krona would result in a reduction of stockholders' equity of approximately \$2.8 million at December 31, 2015.

At December 31, 2015, we did not have material debt and, as such, do not believe that we are exposed to any material interest rate risk as a result of our borrowing activities.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this item is set forth on pages F-1 to F-28.

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

None.

**Item 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

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

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

*Management’s Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, the Company's principal executive officer and principal financial officer and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States ("GAAP"). Such internal control includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- provide reasonable assurance regarding prevention or timely detection of an unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, our management used the criteria set forth in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, our management has determined that, as of December 31, 2015, our internal controls over financial reporting are effective based on those criteria.



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

***Changes in Internal Control over Financial Reporting***

Our management, including our chief executive officer and chief financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2015, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2015 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

None.

**PART III**

**Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item is incorporated by reference from our definitive Proxy Statement for our 2016 Annual Meeting of Stockholders scheduled to be held in June 2016 (the “2016 Proxy Statement”). We expect to file the 2016 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2015.

**Item 11. EXECUTIVE  
COMPENSATION**

We incorporate herein by reference the information required by this item concerning executive compensation to be contained in the 2016 Proxy Statement.

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

We incorporate herein by reference the information required by this item concerning security ownership of certain beneficial owners and management and related stockholder matters to be contained in the 2016 Proxy Statement.

The following table provides our equity compensation plan information as of December 31, 2015. Under these plans, our common stock may be issued upon the exercise of options and purchases under our Employee Stock Purchase Plan (“ESPP”). See also the information regarding our stock options and ESPP in Note 12 to the financial statements included herewith.

**Equity Compensation Plan Information**

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights  (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))  (c)
Equity compensation plans approved by security holders(1)	23,807,545	\$ 5.29	17,733,007
Equity compensation plans not approved by security holders	N/A	N/A	N/A

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

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

We incorporate herein by reference the information required by this item concerning certain related party transactions set forth in Note 16 to our financial statements included herewith. We incorporate herein by reference other information required by this item concerning certain other relationships and related transactions and director independence to be contained in the 2016 Proxy Statement.

**Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

We incorporate herein by reference the information required by this item concerning principal accountant fees and services to be contained in the 2016 Proxy Statement.

**PART IV**

**Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

(1) *Index to Financial Statements*

Reports of Independent Registered Public Accounting Firms	F-2
Consolidated Balance Sheets as of December 31, 2015 and 2014	F-5
Consolidated Statements of Operations and Statements of Comprehensive Loss for the years ended December 31, 2015, 2014 and 2013	F-6
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013	F-7
Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013	F-8
Notes to Consolidated Financial Statements	F-9

(2) *Financial Statement Schedules*

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

(3)

Exhibits

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

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

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

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

Exhibit

Number Description

- 3.1 Second Amended and Restated Certificate of Incorporation of the Registrant dated June 18, 2015 (Incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015)
- 3.2 Amended and Restated By-Laws of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 12, 2013)
- 4.1 Specimen stock certificate for shares of common stock of the Registrant, par value \$.01 per share (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 10, File No. 0-26770, filed on September 14, 1995)
- 4.2 Registration Rights Agreement between Novavax, Inc. and Satellite Overseas (Holdings) Limited, dated March 31, 2009 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, filed on May 11, 2009)
- 4.3 Indenture (including form of Notes) with respect to Novavax' 3.75% Convertible Senior Notes due 2023, dated as of January 29, 2016, between Novavax and The Bank of New York Mellon Trust Company, N.A., as trustee (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on January 29, 2016)
- 10.1†† Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 12, 2013)
- 10.2†† Amendment to Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Appendix 1 of the Registrant's Definitive Proxy Statement filed April 30, 2014 in connection with the Annual Meeting held on June 12, 2014)
- 10.3†† Form of Non-Statutory Stock Option Award Agreement granted under the Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 27, 2015)
- 10.4†† Form of Incentive Stock Option Award Agreement granted under the Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 27, 2015)
- 10.5†† 2013 Employee Stock Purchase Plan (Incorporated by reference to Appendix C to the Registrant's Definitive Proxy Statement filed on April 30, 2013 in connection with the Annual Meeting held on June 13, 2013)
- 10.6†† Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Appendix B of the Company's Definitive Proxy Statement filed April 30, 2015 in connection with the Annual Meeting held on June 18, 2015)

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10.7†† Form of Non-Statutory Stock Option Award Agreement granted under the Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015)

10.8†† Form of Incentive Stock Option Award Agreement granted under the Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015)

10.9†† Form of Restricted Stock Award Agreement granted under the Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report for the quarter ended June 30, 2015, filed on August 10, 2015)

10.10††† Form of Director Deferred Fee Agreement

Employment Agreement between Novavax, Inc. and Stanley C. Erck, dated as of February 15, 2010

10.11††† (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 1, 2010)

Employment Agreement between Novavax, Inc. and Stanley C. Erck, dated as of June 22, 2011 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed on August 9, 2011)

10.12†††

10.13††† Employment Agreement between Novavax, Inc. and Gregory M. Glenn dated July 1, 2010 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 6, 2010)

10.14††† Employment Agreement between Novavax, Inc. and Russell P. Wilson dated November 7, 2011 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on November 14, 2011)

10.15††† Employment Agreement between Novavax, Inc. and Timothy J. Hahn dated June 22, 2011 (Incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 14, 2012)

10.16††† Employment agreement between Novavax, Inc. and Barclay A. Phillips dated June 24, 2013 (Incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed on June 28, 2013)

10.17††† Novavax, Inc. Amended and Restated Change in Control Severance Benefit Plan, (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 5, 2009)

10.18††† Form of Indemnification Agreement entered into between the Registrant and its directors and officers (Incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 16, 2010)

10.19 Lease Agreement between GP Rock One, LLC and Novavax, Inc., dated as of May 7, 2007 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 11, 2008)

10.20 First Amendment to Lease Agreement between GP Rock One, LLC and Novavax, Inc., dated as of May 30, 2008 (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 11, 2008)

10.21 Second Amendment to Lease Agreement between BMR-9920 Belward Campus Q, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated as of June 26, 2008 (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 11, 2008)

10.22 Lease Agreement for space at 20 Firstfield between ARE-20/22/1300 Firstfield Quince Orchard, LLC and Novavax, Inc., dated as of November 18, 2011 (Incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 14, 2012)

10.23

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Lease Agreement for space at 22 Firstfield between ARE-20/22/1300 Firstfield Quince Orchard, LLC and Novavax, Inc., dated as of November 18, 2011 (Incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 14, 2012)



- 10.24 Lease Agreement for space at 21 Firstfield Road between Firstfield Holdco, LLC and Novavax, Inc., dated as of February 4, 2015 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on August 21, 2015)
- 10.25 First Amendment to Lease Agreement for space at 21 Firstfield Road between Firstfield Holdco, LLC and Novavax, Inc., dated as of August 17, 2015 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on August 21, 2015)
- 10.26\*\* Contract, effective as of February 24, 2011, between Novavax, Inc. and HHS/OS/ASPR/BARDA (Incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A for the quarter ended on March 31, 2011, filed on November 4, 2011)
- 10.27\*\* Contract Amendment/Modification No. 5 between Novavax, Inc. and HHS/OS/ASPR/BARDA, dated February 21, 2014 (Incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 12, 2014)
- 10.28\*\* Contract Amendment/Modification No. 6 between Novavax, Inc. and HHS/OS/ASPR/BARDA, dated September 22, 2014 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed on November 6, 2014)
- 10.29\*\* Contract Amendment/Modification No. 8 between Novavax, Inc. and HHS/OS/ASPR/BARDA, dated June 5, 2015 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed on August 10, 2015)
- 10.30\*\* License Agreement, entered in February 25, 2011, effective as of December 9, 2010, between Novavax, Inc. and LG Life Sciences, Ltd. (Incorporated by reference to Exhibit 10.2 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2011, filed on November 4, 2011)
- 10.31\*\* License Agreement, dated July 5, 2007, between Novavax, Inc. and Wyeth Holdings Corporation (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007)
- 10.32\*\* Amendment No. 1 to License Agreement, effective as of March 17, 2010, between Novavax, Inc. and Wyeth Holdings Corporation (Incorporated by reference to Exhibit 10.49 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, filed on August 6, 2010)
- 10.33\*\* Second Amendment to License Agreement between Wyeth Holdings LLC and Novavax, Inc., dated as of September 1, 2015 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 8, 2015)
- 10.34 Stock Purchase Agreement between Novavax, Inc. and Satellite Overseas (Holdings) Limited, dated March 31, 2009 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, filed on May 11, 2009)
- 10.35\*\* Amended and Restated Joint Venture Agreement between Novavax Inc. and Cadila Pharmaceuticals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)

Amended and Restated Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals  
10.36\*\* Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly  
Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)

- 10.37 Amendment No. 1 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Limited dated July 27, 2011 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, filed on November 8, 2011)
- 10.38 Amendment No. 2 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Limited dated March 7, 2013 (Incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 12, 2013)
- 10.39 Amendment No. 3 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Ltd. dated October 29, 2013 (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 8-K, filed on October 30, 2013)
- 10.40 Amendment No. 4 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Ltd. dated March 5, 2014 (Incorporated by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 12, 2014)
- 10.41 Amendment No. 5 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Ltd. dated February 25, 2015 (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, filed on February 27, 2015)
- 10.42\*\* Amended and Restated Supply Agreement between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
- 10.43\*\* Amended and Restated Technical Services Agreement between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
- 10.44\*\* Amended and Restated Seasonal / Other License Agreement between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
- 10.45\*\* Amended and Restated Option to Obtain License between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
- 10.46\*\* H1N1 License to Agreement between Novavax, Inc. and CPL Biologicals Private Limited, dated October 6, 2009 (Incorporated by reference to Exhibit 10.45 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 16, 2010)
- 10.47\*\* Grant Agreement between Bill and Melinda Gates Foundation and Novavax, Inc., dated as of September 25, 2015 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 9, 2015)
- 10.48\*\* Global Access Commitments Agreement between Bill and Melinda Gates Foundation and Novavax, Inc., dated as of September 25, 2015 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on November 9, 2015)

10.49 Base Call Option Transaction Confirmation, dated as of January 25, 2016, between Novavax and JPMorgan Chase Bank, National Association, London Branch (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed January 29, 2016)

10.50 Base Call Option Transaction Confirmation, dated as of January 25, 2016, between Novavax and Morgan Stanley & Co. LLC (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed January 29, 2016)

- 10.51\* Additional Base Call Option Transaction Confirmation, dated as of February 2, 2016, between Novavax and JPMorgan Chase Bank, National Association, London Branch
- 10.52\* Additional Base Call Option Transaction Confirmation, dated as of February 2, 2016, between Novavax and Morgan Stanley & Co. LLC
- 14 Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed on August 9, 2011)
- 21\* Subsidiaries of the Registrant
- 23.1\* Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
- 23.2\* Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm
- 31.1\* Certification of chief executive officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 31.2\* Certification of chief financial officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 32.1\* Certification of chief executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\* Certification of chief financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101\* The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of December 31, 2015 and 2014, (ii) the Consolidated Statements of Operations for the three years in the period ended December 31, 2015, (iii) the Consolidated Statements of Comprehensive Loss for the three years in the period ended December 31, 2015, (iv) the Consolidated Statements of Changes in Stockholders' Equity for the three years in the period ended December 31, 2015, (v) the Consolidated Statements of Cash Flows for the three years in the period ended December 31, 2015, and (vi) the Notes to Consolidated Financial Statements.

**SIGNATURES**

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

**NOVAVAX, INC.**

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

Date: February 29, 2016

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

<b>Name</b>	<b>Title</b>	<b>Date</b>
/s/ Stanley C. Erck Stanley C. Erck	President and Chief Executive Officer and Director (Principal Executive Officer)	February 29, 2016
/s/ Barclay A. Phillips Barclay A. Phillips	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Principal Accounting Officer)	February 29, 2016
/s/ James F. Young James F. Young	Chairman of the Board of Directors	February 29, 2016
/s/ Gail K. Boudreaux Gail K. Boudreaux	Director	February 29, 2016
/s/ Richard H. Douglas Richard H. Douglas	Director	February 29, 2016

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/s/ Gary C. Evans Gary C. Evans	Director	February 29, 2016
/s/ Michael A. McManus Michael A. McManus	Director	February 29, 2016
/s/ Rajiv I. Modi Rajiv I. Modi	Director	February 29, 2016

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***Report of Ernst & Young LLP,  
Independent Registered Public Accounting Firm,  
on the Audited Consolidated Financial Statements***

The Board of Directors and Stockholders of  
Novavax, Inc.

We have audited the accompanying consolidated balance sheets of Novavax, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Novavax, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2015 in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Novavax Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, MD

February 29, 2016

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***Report of Ernst & Young LLP,  
Independent Registered Public Accounting Firm,  
Regarding Internal Control Over Financial Reporting***

The Board of Directors and Stockholders of

Novavax, Inc.

We have audited Novavax Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Novavax Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Item 9A, Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, Novavax Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Novavax Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2015 of Novavax Inc. and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, MD

February 29, 2016

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders of

Novavax, Inc.

We have audited the accompanying consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows of Novavax Inc. (a Delaware corporation) and subsidiary (the "Company") for the year ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of Novavax, Inc. and its subsidiary's operations and their cash flows for the year ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

McLean, Virginia

March 12, 2014

**NOVAVAX, INC.****CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2015	2014
	(in thousands, except share and per share information)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$93,108	\$32,335
Marketable securities	137,548	135,721
Restricted cash	34,964	297
Accounts receivable – billed	1,449	7,510
Accounts receivable – unbilled	871	3,100
Prepaid expenses and other current assets	19,317	9,195
Total current assets	287,257	188,158
Restricted cash	1,537	—
Property and equipment, net	32,342	19,737
Intangible assets, net	10,793	12,577
Goodwill	53,065	54,612
Other non-current assets	1,044	918
Total assets	\$386,038	\$276,002
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$11,889	\$12,908
Accrued expenses	26,734	19,397
Deferred revenue	34,469	—
Current portion of notes payable	395	603
Deferred rent	1,409	1,138
Other current liabilities	1,598	70
Total current liabilities	76,494	34,116
Deferred revenue	4,171	2,500
Non-current portion of notes payable	—	395
Deferred rent	9,534	7,734
Other non-current liabilities	3,170	1,639
Total liabilities	93,369	46,384
Commitments and contingencies	—	—
Stockholders' equity:	—	—

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Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding at December 31, 2015 and 2014		
Common stock, \$0.01 par value, 600,000,000 shares authorized at December 31, 2015 and 300,000,000 shares authorized at December 31, 2014; and 270,426,662 shares issued and 269,971,232 shares outstanding at December 31, 2015 and 239,287,294 shares issued and 238,831,864 shares outstanding at December 31, 2014	2,704	2,393
Additional paid-in capital	951,569	729,373
Accumulated deficit	(650,030)	(493,093)
Treasury stock, 455,430 shares, cost basis at both December 31, 2015 and 2014	(2,450 )	(2,450 )
Accumulated other comprehensive loss	(9,124 )	(6,605 )
Total stockholders' equity	292,669	229,618
Total liabilities and stockholders' equity	\$386,038	\$276,002

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

## NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years ended December 31,		
	2015	2014	2013
	(in thousands, except per share information)		
Revenue:			
Government contracts	\$33,344	\$26,213	\$17,708
Research and development collaborations	2,906	4,446	3,207
Total revenue	36,250	30,659	20,915
Expenses:			
Research and development	162,644	94,422	58,530
General and administrative	30,842	19,928	14,819
Total expenses	193,486	114,350	73,349
Loss from operations	(157,236)	(83,691)	(52,434)
Other income (expense):			
Investment income	660	286	187
Interest expense	(241)	(157)	(160)
Other income (expense), net	(120)	—	182
Realized gains on marketable securities	—	615	—
Change in fair value of warrant liability	—	—	267
Loss from operations before income tax expense	(156,937)	(82,947)	(51,958)
Income tax expense	—	—	25
Net loss	\$(156,937)	\$(82,947)	\$(51,983)
Basic and diluted net loss per share	\$(0.60)	\$(0.37)	\$(0.31)
Basic and diluted weighted average number of common shares outstanding	262,248	225,848	169,658

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

For the Years ended December  
31,  
2015            2014            2013



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(in thousands)

Net loss	\$ (156,937)	\$ (82,947)	\$ (51,983)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities available-for-sale	42	(65 )	186
Reclassification adjustment for gains included in net loss	—	(615 )	—
Foreign currency translation adjustment	(2,561 )	(6,764 )	223
Other comprehensive income (loss)	(2,519 )	(7,444 )	409
Comprehensive loss	\$ (159,456)	\$ (90,391)	\$ (51,574)

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

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## NOVAVAX, INC.

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**For the Years ended December 31, 2015, 2014 and 2013**

	Common Stock Shares	Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income(Loss)	Total Stockholders' Equity
Balance at December 31, 2012	148,398,747	\$ 1,484	\$ 438,939	\$ (358,163 )	\$ (2,450 )	\$ 430	\$ 80,240
Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	2,480	—	—	—	2,480
Exercise of stock options	667,867	7	1,491	—	—	—	1,498
Issuance of common stock, net of issuance costs of \$6,067	60,044,130	600	169,990	—	—	—	170,590
Unrealized gain on marketable securities	—	—	—	—	—	186	186
Foreign currency translation adjustment	—	—	—	—	—	223	223
Net loss	—	—	—	(51,983 )	—	—	(51,983 )
Balance at December 31, 2013	209,110,744	2,091	612,900	(410,146 )	(2,450 )	839	203,234
Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	6,090	—	—	—	6,090
Exercise of stock options/Purchase under ESPP	1,411,550	14	2,776	—	—	—	2,790
Restricted stock issued as compensation	15,000	—	—	—	—	—	—
Issuance of common stock, net of issuance costs of \$7,105	28,750,000	288	107,607	—	—	—	107,895
Unrealized loss on marketable securities	—	—	—	—	—	(680 )	(680 )
Foreign currency translation adjustment	—	—	—	—	—	(6,764 )	(6,764 )
Net loss	—	—	—	(82,947 )	—	—	(82,947 )
Balance at December 31, 2014	239,287,294	2,393	729,373	(493,093 )	(2,450 )	(6,605 )	229,618

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Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	13,431	—	—	—	13,431
Exercise of stock options/Purchase under ESPP	1,950,748	19	4,782	—	—	—	4,801
Restricted stock issued as compensation	25,000	—	—	—	—	—	—
Issuance of common stock, net of issuance costs of \$11,912	29,163,620	292	203,983	—	—	—	204,275
Unrealized gain on marketable securities	—	—	—	—	—	42	42
Foreign currency translation adjustment	—	—	—	—	—	(2,561 )	(2,561 )
Net loss	—	—	—	(156,937 )	—	—	(156,937 )
Balance at December 31, 2015	270,426,662	\$2,704	\$951,569	\$(650,030 )	\$(2,450 )	\$(9,124 )	\$292,669

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

## NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years ended December 31,		
	2015	2014	2013
	(in thousands)		
<b>Operating Activities:</b>			
Net loss	\$(156,937)	\$(82,947 )	\$(51,983 )
Reconciliation of net loss to net cash used in operating activities:			
Change in fair value of warrant liability			(267 )
Depreciation and amortization	5,983	4,424	2,591
Loss (Gain) on disposal of property and equipment	681	534	(32 )
Amortization of net premiums on marketable securities	1,217	415	507
Deferred rent	(721 )	(552 )	897
Non-cash stock-based compensation	13,431	6,090	2,480
Realized gains on marketable securities		(615 )	
Other	243	60	(200 )
Changes in operating assets and liabilities:			
Restricted cash	(36,204 )	1,120	(431 )
Accounts receivable – billed	6,250	(5,705 )	(451 )
Accounts receivable – unbilled	2,229	1,888	(3,418 )
Prepaid expenses and other assets	(10,269 )	(5,904 )	402
Accounts payable and accrued expenses	9,075	13,979	4,184
Deferred revenue	36,140	(253 )	(341 )
Lease incentives received	2,792	452	703
Net cash used in operating activities	(126,090)	(67,014 )	(45,359 )
<b>Investing Activities:</b>			
Capital expenditures	(18,286 )	(7,268 )	(5,785 )
Proceeds from disposal of property and equipment	18	39	116
Net cash received from acquisition			3,034
Purchases of marketable securities	(228,521)	(176,469)	(14,754 )
Proceeds from sales, maturities and redemptions of marketable securities	225,519	53,865	33,781
Net cash provided by (used in) investing activities	(21,270 )	(129,833)	16,392
<b>Financing Activities:</b>			
Principal payments of capital leases	(67 )	(124 )	(87 )
Principal payments of notes payable	(600 )	(671 )	(473 )
Proceeds from notes payable			1,450
Changes in restricted cash	(126 )	(2 )	(1 )
Cash paid with acquisition		(171 )	
	204,275	107,896	128,648

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Net proceeds from sales of common stock, net of offering costs of \$11.9 million, \$7.1 million and \$6.1 million, respectively

Proceeds from the exercise of stock options and employee stock purchases	4,801	2,789	1,498
Net cash provided by financing activities	208,283	109,717	131,035
Effect of exchange rate on cash and cash equivalents	(150 )	(6 )	4
Net increase (decrease) in cash and cash equivalents	60,773	(87,136 )	102,072
Cash and cash equivalents at beginning of year	32,335	119,471	17,399
Cash and cash equivalents at end of year	\$93,108	\$32,335	\$119,471

Supplemental disclosure of non-cash activities:

Common stock issued in connection with acquisition	\$.	\$.	\$41,942
Capital expenditures included in accounts payable and accrued expenses	\$2,797	\$2,615	\$379

Supplemental disclosure of cash flow information:

Cash interest payments	\$96	\$179	\$177
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The accompanying notes are an integral part of these financial statements.

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2015, 2014 and 2013**

**Note 1 – Organization**

Novavax, Inc. (“Novavax,” and together with its wholly owned subsidiary, “Novavax AB,” the “Company”) is a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine platform technology, the Company produces vaccine candidates to efficiently and effectively respond to both known and emerging disease threats. The Company’s vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate recombinant protein antigens critical to disease pathogenesis. The Company’s product pipeline targets a variety of infectious diseases with vaccine candidates currently in clinical development for respiratory syncytial virus (“RSV”), seasonal influenza, pandemic influenza and Ebola virus (“EBOV”).

**Note 2 – Operations**

The Company’s vaccine candidates currently under development, some of which include adjuvants, will require significant additional research and development efforts that include extensive preclinical studies and clinical testing, and regulatory approval prior to commercial use.

As a clinical-stage vaccine company, the Company has primarily funded its operations from proceeds through the sale of its common stock in equity offerings, convertible debt issuance (in 2016) and revenue under its contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”) and, to a lesser degree, revenue under its prior contract with PATH Vaccine Solutions (“PATH”) and the grant agreement with the Bill & Melinda Gates Foundation (“BMGF”). Management regularly reviews the Company’s cash and cash equivalents and marketable securities relative to its operating budget and forecast to monitor the sufficiency of the Company’s working capital, and anticipates continuing to draw upon available sources of capital to support its product development activities.

**Note 3 – Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements include the accounts of Novavax, Inc. and its wholly owned subsidiary, Novavax AB, since July 31, 2013. All intercompany accounts and transactions have been eliminated in consolidation.

***Use of Estimates***

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

*Cash and Cash Equivalents*

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

	2015	2014
Cash	\$29,569	\$4,481
Money market funds	14,950	20,354
Government-backed security	20,000	7,500
Asset-backed securities	8,185	
Corporate debt securities	20,404	
Cash and cash equivalents	\$93,108	\$32,335

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

*Marketable Securities*

Marketable securities consist of commercial paper, asset-backed securities and corporate notes. Classification of marketable securities between current and non-current is dependent upon the maturity date at the balance sheet date taking into consideration the Company's ability and intent to hold the investment to maturity.

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

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



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

### ***Concentration of Credit Risk***

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

### ***Fair Value Measurements***

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

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

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

***Restricted Cash***