

NOVAVAX INC  
Form 10-K  
February 27, 2017

**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, 2016**

**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  Smaller reporting company   
(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (based on the last reported sale price of Registrants common stock on June 30, 2016 on the NASDAQ Global Select Market) was approximately \$1,646,900,000.

As of February 23, 2017, there were 271,947,036 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, 2016 in connection with the Registrant's 2017 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 wholly-owned 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**

#### **Overview**

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

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

Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate recombinant proteins critical to disease pathogenesis. Our product pipeline targets a variety of infectious diseases, with clinical vaccine candidates for respiratory syncytial virus (“RSV”) and Ebola virus (“EBOV”), and preclinical programs for Zika virus (“ZIKV”), seasonal influenza and a combination respiratory vaccine candidate, as well as other infectious disease vaccine candidates.

We are also developing immune stimulating saponin-based adjuvants through Novavax AB. Our lead adjuvant, Matrix-M™, has been shown to enhance immune responses and was well-tolerated in a Phase 1/2 clinical trial for our pandemic H7N9 influenza vaccine candidate, as well as in a Phase 1 clinical trial for our EBOV vaccine candidate. Genocea Biosciences, Inc. has licensed rights to our Matrix technology and has conducted Phase 2 clinical trials with its herpes simplex 2 vaccine candidate using Matrix-M.

#### **Product Pipeline**

Our product pipeline includes vaccine candidates engineered to elicit differentiated immune responses with the potential to provide increased protection. Our nanoparticle technology 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.

**Current**

<b>Program</b>	<b>Development Stage</b>
<b>Respiratory Syncytial Virus (“RSV”)</b>	
· <b>Infants via Maternal Immunization</b>	Phase 3*
· <b>Older Adults</b>	Phase 2
· <b>Pediatrics</b>	Phase 1
<b>Emerging Viruses</b>	
· <b>Ebola Virus (“EBOV”)</b>	Phase 1
· <b>Zika Virus (“ZIKV”)</b>	Preclinical
<b>Seasonal Influenza Nanoparticle</b>	Preclinical
<b>Combination Respiratory</b>	Preclinical

\*Supported by the \$89.1 million grant from the Bill and Melinda Gates Foundation (“BMGF”)

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



## **Respiratory Syncytial Virus**

We are developing our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) for three susceptible target populations: infants via maternal immunization, older adults (60 years of age and older) and children six months to five years of age (“pediatrics”). We believe our RSV F Vaccine represents a multi-billion dollar revenue opportunity, 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 to be in excess of \$88 billion.<sup>1</sup> Despite decades of effort to develop an RSV vaccine, there are currently no licensed vaccines. Although the monoclonal antibody palivizumab (Synagis®) is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease, it is not indicated for use in other populations. We made a breakthrough in developing a vaccine that targets the fusion protein, or F-protein, of the virus. The F-protein has highly conserved amino acid sequences, called antigenic sites, which we believe are ideal vaccine targets. Palivizumab, which targets one such site, antigenic site II, has demonstrated protection in five randomized clinical trials. We genetically engineered a novel F-protein antigen resulting in enhanced immunogenicity by exposing these antigenic sites. The RSV F Vaccine assembles into a recombinant protein nanoparticle optimized for F-protein antigen presentation. We are seeking to bring the first RSV vaccine to market to combat the 64 million RSV infections that occur globally each year.<sup>2,3</sup>

### ***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>4,5</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*

##### *Prepare Phase 3 Trial (Ongoing)*

We initiated Prepare™, a global pivotal Phase 3 clinical trial of our RSV F Vaccine, using aluminum phosphate as an adjuvant, 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 a minimum of the first 90 days of life. The Prepare trial utilizes a group sequential design and is expected to take between three and four years to complete. We are currently in discussion with the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (“FDA”) about conducting an informational analysis of the Prepare trial in late 2017. These discussions lead us to believe we will be allowed to conduct an informational analysis that would provide an indication of the vaccine’s potential efficacy against the primary endpoint.

The Prepare trial is supported by a grant (the “Grant”) of up to \$89.1 million from BMGF. The Grant supports development activities, product licensing efforts and World Health Organization (“WHO”) prequalification of our RSV F Vaccine. In 2015, along with the Grant agreement (the “Grant Agreement”), we concurrently entered into a Global Access Commitments Agreement with BMGF, under which we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

<sup>1</sup> Estimated value of life lost, future health implications and lost earnings; Preliminary data based on Novavax research of available epidemiology and health outcomes data

<sup>2</sup> Nair, H., et al., (2010) Lancet. 375:1545 - 1555

<sup>3</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>4</sup> Nair, H., et al., (2010) Lancet. 375:1545 - 1555

<sup>5</sup> CDC: <https://www.cdc.gov/rsv/research/us-surveillance.html>

<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

*Phase 2 Safety and Immunogenicity Trial (Completed)*

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.

*Fast Track Designation*

The FDA has 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 Older Adults Program*

*Burden of Disease*

Adults 60 years of age and older are at increased risk for RSV disease due to immunosenescence, the age-related decline in the human immune system. In this population, RSV is an important respiratory virus, distinct from influenza, that is frequently 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. In the U.S., the incidence rate is approximately 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>10,11</sup> Based on our analysis of published literature applied to 2014 U.S. population estimates, the disease causes 207,000 hospitalizations and 16,000 deaths among adults older than 65.<sup>12,13</sup> Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease

across all populations.<sup>14,15</sup>

<sup>10</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>11</sup> Falsey, A.R. *et al.* (1995) JID.172:389-94

<sup>12</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>13</sup> W.W. Thompson et al. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA 2003; 289(2): 179-186

<sup>14</sup> K. Widmer et al. Rates of hospitalizations for respiratory syncytial virus, human metapneumovirus, and influenza virus in older adults. J Infect Dis. 2012; 206: 56-62

<sup>15</sup> K. Widmer et al. Respiratory syncytial virus & human metapneumovirus-associated emergency department and hospital burden in adults. Influenza and Other Respiratory Viruses. 2014; 8(3): 347-352.

*Clinical Trial Update*

*Phase 2 Safety and Immunogenicity Trial (Ongoing)*

In January 2017, we announced the initiation of a Phase 2 clinical trial of the RSV F Vaccine in older adults. The objective of this Phase 2 trial is to assess safety and immunogenicity to one and two dose regimens of the RSV F Vaccine, with and without aluminum phosphate or Novavax' proprietary Matrix-M adjuvant, in older adults. The trial is a randomized, observer-blinded, placebo-controlled trial which has enrolled 300 older adults in the Southern Hemisphere. Participants were enrolled and vaccinated outside of the RSV season to best assess immunogenicity, with top-line data expected in the third quarter of 2017.

*Resolve Phase 3 Trial (Completed)*

In September 2016, we announced top-line data from the Phase 3 clinical trial of our RSV F Vaccine in older adults, known as Resolve™. Resolve was a randomized, observer-blinded, placebo-controlled trial that began in November 2015, and was fully enrolled with 11,856 older adult subjects at 60 sites in the U.S. by December 2015. Historically, annual seasonal attack rates for all symptomatic respiratory disease due to RSV ("RSV ARD") of between 3% and 7% have been observed in older adults.<sup>16</sup>

In our Phase 2 trial conducted during the 2014-2015 RSV season, we observed an RSV ARD attack rate of 4.9%, with an attack rate of 1.8% for moderate-severe RSV-associated lower respiratory tract disease ("RSV msLRTD"), which aligns with peer-reviewed literature.<sup>17</sup> In the Resolve trial, in contrast, we observed an RSV ARD attack rate of 2.0% and an RSV msLRTD attack rate of 0.4%. These unexpectedly low attack rates indicated a mild 2015-2016 RSV season in older adults. The trial did not meet the pre-specified primary or secondary efficacy objectives and did not demonstrate vaccine efficacy. The primary objective of the Resolve trial was to demonstrate efficacy in the prevention of RSV msLRTD, as defined by the presence of multiple lower respiratory tract symptoms. The secondary objective of the trial was to demonstrate efficacy of the RSV F Vaccine in reducing the incidence of all symptomatic respiratory disease due to RSV ARD. The trial also evaluated the safety of the unadjuvanted, 135 microgram dose of the RSV F Vaccine compared to placebo and consistent with our previous clinical experience, the vaccine was well-tolerated. We continue to analyze data from the Resolve trial in order to better understand these results and to map a path forward for this important program. Our efforts include analyses of existing immunogenicity and efficacy data, and application of new assays to archived samples. We have also undertaken external epidemiology studies to further understand the attack rate, healthcare burden and seasonality of RSV disease in older adults. We expect these analyses to provide important information and context when we review the results from the Phase 2 clinical trial in older adults that we initiated in January 2017 and evaluate our next steps.

*Phase 2 Rollover Trial (Completed)*

In September 2016, we also announced positive top-line data from the Phase 2 rollover clinical trial of our RSV F Vaccine in older adults. The trial was a randomized, observer-blinded, placebo-controlled rollover trial which enrolled 1,329 older adults from the prior Phase 2 trial, conducted at the same 10 sites in the U.S. as our completed Phase 2 clinical trial in older adults. The primary objectives of the trial evaluated safety and serum anti-F IgG antibody concentrations in response to immunization with the RSV F Vaccine. The exploratory objectives of the trial evaluated the efficacy of a second annual dose of the RSV F Vaccine in the prevention of RSV ARD and RSV msLRTD. Participants previously randomized to receive 135 microgram RSV F Vaccine or placebo were re-enrolled and re-randomized in the current trial to receive either 135 microgram RSV F Vaccine or placebo. This resulted in analysis of four separate trial arms: a) participants receiving a placebo in both the first trial and second trial (“Placebo-Placebo”); b) participants receiving RSV F Vaccine in the first trial and placebo in the second trial (“Vaccine-Placebo”); c) participants receiving placebo in the first trial and RSV F Vaccine in the second trial (“Placebo-Vaccine”); and d) participants receiving RSV F Vaccine in both the first trial and second trial (“Vaccine-Vaccine”).

<sup>16</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>17</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59

The rollover trial demonstrated immunogenicity in all active vaccine recipients, with a 6-fold increase in anti-F IgG in the Placebo-Vaccine arm, consistent with the Phase 2 efficacy trial. There was higher anti-F IgG at baseline in the Vaccine-Vaccine arm compared to the Placebo-Vaccine arm and the Vaccine-Vaccine arm showed a greater than 2-fold increase in anti-F IgG from the higher baseline. The rollover trial confirmed the low attack rates witnessed during the Resolve trial.

#### *Phase 2 Trial in Older Adults (Completed)*

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.

#### *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>18</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.<sup>19,20,21,22,23</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 2014-2015 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 next steps in the development of our RSV F Vaccine for pediatrics.

## **Emerging Disease**

### ***Ebola Virus***

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>24</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.

<sup>18</sup> U.S. Census. [www.census.gov/population/international/data/idb/informationGateway.php](http://www.census.gov/population/international/data/idb/informationGateway.php)

<sup>19</sup> Stockman, L.J. et al (2012) *Pediatr Infect Dis J.* 31: 5-9

<sup>20</sup> CDC update May 5, 2015. <http://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>21</sup> Boyce, T.G. et al (2000) *Pediatrics*; 137: 865-870

<sup>22</sup> Hall, C.B. et al (2009) *NEJM*; 360(6): 588-98

<sup>23</sup> Hall, C.B. et al (2013) *Pediatrics*; 132(2): E341-8

<sup>24</sup> WHO: <http://www.who.int/mediacentre/factsheets/fs103/en/>



In July 2015, we announced top-line 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.

### ***ZIKV EnvD Vaccine***

We initiated development of a vaccine against the Zika virus (“ZIKV”) in response to the unmet global medical need for a response to this serious disease. Beginning in 2015, ZIKV spread in South, Central and North America, via mosquito-borne and sexual transmission. Although acute ZIKV infections in adults are generally either asymptomatic or associated with mild symptoms (fever, joint pains and skin rash), more serious outcomes can occur, including Guillain-Barré syndrome in adults and, microcephaly in infants of women infected during pregnancy. There is no approved vaccine against ZIKV, although a number of companies have announced vaccine development efforts. We are currently conducting IND-enabling preclinical studies, including studies in non-human primates and other animal models, with the goal of initiating a Phase 1 clinical trial of our ZIKV envelope dimer nanoparticle vaccine candidate (“ZIKV EnvD Vaccine”) in 2017.

### **Seasonal 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 largely because of unique strains of influenza for which most humans have not developed protective antibodies. 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 2012-2013 season to \$5.3 billion by the 2021-2022 season.<sup>25</sup>

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>26</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>27</sup> Recombinant seasonal influenza vaccines, like the

candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of such vaccine can potentially be manufactured quickly and in a cost-effective manner, without the use of either the live influenza virus or eggs.

<sup>25</sup> Influenza Vaccines Forecasts. Datamonitor (2013)

<sup>26</sup> Resolution of the World Health Assembly. (2003) WHA56.19. 28

<sup>27</sup> WHO position paper (2012) Weekly Epidemiol Record;87(47):461–76

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After many years of developing virus-like particle (“VLP”)-based seasonal influenza vaccine candidates, we have identified advantages of developing nanoparticle-based seasonal influenza vaccines. In particular, influenza nanoparticles can display conserved antigenic regions, which have the potential to elicit broadly neutralizing antibodies that may offer protection against a range of drifted strains. Additionally, nanoparticles offer improved purity and manufacturability and advantages for co-formulation with other nanoparticle-based vaccines. We expect to continue to develop our nanoparticle influenza vaccine program in 2017 with an ongoing goal of generating additional proof-of-concept data.

### **Combination Respiratory Vaccine**

Given the ongoing development of our RSV F Vaccine and our desire to develop a combination respiratory vaccine with the potential to protect against both RSV and seasonal influenza, we made the decision to shift our seasonal influenza vaccine development focus from VLP-based seasonal influenza vaccines to nanoparticle-based seasonal influenza vaccines. Early preclinical development efforts give us confidence that such a combination vaccine is feasible.

### **CPLB Joint Venture (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, for its trivalent seasonal VLP influenza vaccine and is currently manufacturing with limited sales in 2016 and limited expected sales in 2017.

### ***Rabies***

In October 2016, CPLB initiated its Phase 3 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered, and that can be administered both as a pre-exposure and a post-exposure prophylactic regimen. The post-exposure regimen has the potential to use fewer doses (three doses) than the current standard of care (five doses).

## **Vaccine Technology**

Our recombinant protein nanoparticle vaccine technology is based on self-assembly of surface protein antigens from pathogenic organisms including viruses, bacteria or parasites. The conformations of these nanoparticles are similar but not identical to the natural structure of surface antigens of disease organisms, and lack the genetic material required for replication and therefore are not infectious. Potential immunological advantages of protein nanoparticles may be associated with the nanoparticle conformation and the presentation of key functional epitopes that are often immunologically hidden in the native pathogen. This leads to efficient recognition by the immune system's antigen presenting cells that trigger robust immune responses. Recognition of the nanoparticle vaccine's repeating protein patterns by the antigen presenting cells' toll-like receptors to stimulate innate immunity and the high purity and lack of synthetic material adds to the potential safety of recombinant nanoparticle vaccines. Protein nanoparticle vaccine technology has expanded our early-stage vaccines in development to include both virus and non-virus disease targets. Our most advanced protein nanoparticle vaccine candidate is our RSV F Vaccine, which self-assembles from our highly purified F-protein antigen.

## **Matrix Adjuvants**

Adjuvants are predominantly used to enable a vaccine to increase the amplitude of the immune response and qualitatively change it, 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 significant value when there is inadequate vaccine manufacturing capacity during an emerging disease threat such as an influenza pandemic.

### **Competition in RSV, EBOV, ZIKV, Influenza 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 RSV and influenza vaccines, as well as vaccines against a number of other infectious diseases.

There is currently no approved RSV vaccine for sale in the world; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. 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 ("MedImmune"), 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. In older adults, MedImmune also conducted a Phase 2 trial of MEDI-7510 (recombinant F subunit with an adjuvant administered intramuscularly). In both MedImmune vaccine programs, the trials did not report complete success. Additional entities have also entered into early clinical trials including GlaxoSmithKline, Sanofi, Bavarian Nordic, J&J/Crucell, Immunovaccine, Mucosis, Vaxart and the National Institute of Allergy and Infectious Diseases, an institute under the U.S. National Institutes of Health ("NIAID").

Vaccine candidates against EBOV have been in development for more than a decade; however, with the recent epidemic in West Africa (now subsided), focus on viable vaccine candidates has intensified. The WHO has reported two 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 ("Merck") and the Public Health Agency of Canada. The Merck vaccine is the only one to have completed some human trials before the epidemic

faded, published their data, and now filing for licensure. While these and 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.

Although we are not aware of all our competitors' efforts, we believe there are over 25 vaccines in development for ZIKV, which include candidates from large vaccine companies, smaller biotech companies and governmental research institutions. Many of these programs have external funding from a third party source. At least three vaccines are currently in Phase 1 clinical trials (Inovio, NIAID and WRAIR/Sanofi), while others, including Novavax, are in preclinical development. We believe that Inovio initiated the first ZIKV vaccine clinical trial in July 2016; however, additional clinical trials are expected to start with candidates from Takeda, Moderna/Valera, Baharat (India), NIAID (various live attenuated formulations) and Themis (EU). There are at least six primary vaccine technology platforms being applied, including DNA, mRNA, inactivated whole virus, live attenuated, recombinant proteins/subunit and vector-based genetics with some novel variations within each platform. Our ZIKV vaccine candidate is based on highly purified ZIKV envelope protein dimers ("EnvD") stabilized with a proprietary formulation. In addition, our ZIKV vaccine has a highly conserved quaternary neutralizing epitope that appears, in animal studies, to induce neutralizing antibody responses against multiple stains of ZIKV and other flaviviruses. While we have not yet tested our ZIKV vaccine candidate in humans, we believe that its development profile suggests broad protection, high efficacy and good stability.

There are a number of companies developing and selling vaccines for seasonal influenza employing both traditional and new vaccine technologies. Many seasonal influenza vaccines are currently approved and marketed, and most of these are marketed by major pharmaceutical companies that have significantly greater financial and technical resources, experience and expertise. Competition in the sale of seasonal influenza vaccines is intense. Therefore, newly developed and approved products must be differentiated from existing vaccines in order to have commercial success. In order to show differentiation in the seasonal influenza market, a product may need to be more efficacious and/or be less expensive and quicker to manufacture. Many of our competitors are working on new products and new generations of current products, some by adding an adjuvant that is used to increase the immunogenicity of that product, each of which is intended to be more efficacious than currently marketed products. 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 nanoparticle seasonal influenza product could be as efficacious as, or more so than, current products or products being developed by our competitors, and that our manufacturing system provides savings in both time and money; however, there can be no guarantee that our seasonal influenza vaccine will prove to be efficacious or that our manufacturing system will prove to be sufficiently effective and differentiated to ensure commercial success.

In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also may depend upon our ability to show differentiation with a product that is more efficacious 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 biotechnology and pharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. Our success will depend, in part, on whether we can:

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

*Patent Rights; Licenses.*

We have intellectual property (patents, licenses, know-how) related to our vaccines, manufacturing processes and other technologies. Currently, we have or have rights to over 250 U.S. patents and corresponding foreign patents and patent applications relating to vaccines and vaccine-related technologies.

Since 2007, we have maintained a non-exclusive license arrangement with Wyeth Holdings LLC, 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.

In 2016, U.S. Patent Nos. 9,381,239, 9,464,276, and 9,474,799, related to the influenza VLP program, were issued by the U.S. Patent & Trademark Office. In addition, European Patent No. 237009, related to the RSV F vaccine program issued in Europe.

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

*Trade Secrets.*

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

## Government Regulations

The development, production and marketing of biological products, which 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 expect to first submit an investigational new drug application (“IND”) that explains to the FDA, among other things, the results of preclinical toxicology testing conducted in laboratory animals, the method of manufacture, quality control tests for release, the stability of the investigational product and what we propose to do for human testing. At this stage, the FDA decides whether it is reasonably safe to move forward with testing the vaccine candidate in humans. We must then conduct Phase 1 clinical trials and larger-scale Phase 2 and 3 clinical trials that demonstrate the safety, immunogenicity and efficacy of our vaccine candidate to the satisfaction of the FDA. Once these trials are complete, a 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 seasonal influenza vaccine, but have not ruled out the potential use of accelerated approval for specific populations and/or for potential 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 and laboratory 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 24,000 square foot facility comprised of GMP manufacturing, laboratory and office space.

## **Sources of Supply**

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

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

## Business Development

We believe our proprietary vaccine technology affords us a range of traditional and non-traditional commercialization options 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 agreement with BMGF to fund our RSV program, that would allow for:

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

In addition to our aforementioned agreement with BMGF, another example of a strategic relationship 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 23, 2017, we have 355 full-time employees, of whom 65 hold M.D. or Ph.D. degrees and 107 of whom hold other advanced degrees. Of our total workforce, 304 are engaged primarily in research, development and manufacturing activities and 51 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; 33 of our 34 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, 2016 was \$930.0 million. Our revenue for the last three fiscal years was \$15.4 million in 2016, \$36.3 million in 2015, and \$30.7 million in 2014. 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 \$280.0 million in 2016, \$156.9 million in 2015, and \$82.9 million in 2014.

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 over time, as a result of continuing research and development efforts to support the development of our vaccine candidates. For example, we experienced a significant increase in research and development expenses in 2016 over prior years primarily due to additional RSV F Vaccine clinical trials in 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 RSV maternal vaccine may be reimbursed under our contract with BMGF, we expect to continue to incur significant operating expenses and anticipate that our losses will increase over time as we seek to:

- conduct clinical trials for RSV and other 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, biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our vaccine candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. There is no certainty that the capital and credit markets will be available to raise additional capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, 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.

***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;

existing, new or changes in interpretations of existing trade protections measures, including tariffs, 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 new, changes in or changes in interpretations of tax laws;
- political instability and actual or anticipated military or potential conflicts;
- economic instability, inflation, recession and interest rate fluctuations;
- minimal or diminished protection of intellectual property; 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 biotechnology company and face significant risk in developing, manufacturing and commercializing our products.***

We focus our research and development activities on vaccines, an area in which we 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, among others, compete in the vaccine market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products.

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

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.

We believe there are over two dozen vaccines in development for ZIKV, which include candidates from large pharmaceutical companies and governmental agencies. Many of these programs have obtained external funding from third party sources, which we have yet to obtain. At least three vaccines have initiated Phase 1 clinical trials while others are in preclinical development. Although we believe our ZIKV EnvD Vaccine has significant advantages over other candidates in development, there can be no assurance that we will be able to develop our candidate successfully or that ZIKV will continue to pose a health threat.



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 nanoparticle seasonal influenza vaccine candidate may not prove to be more efficacious than current products or products under development by our competitors. Further, our manufacturing system may not provide enough savings of time or money to provide the required differentiation for commercial success.

Regardless of the disease, smaller or early-stage companies and research institutions 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 may have 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 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, given the November 2016 workforce reduction, 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. The November 2016 workforce reduction may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause our remaining employees to seek alternative employment. Although we have implemented a retention plan, that plan may not be successful in incentivizing our current employees to continue their employment with us.

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.

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



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

- difficulties with production costs, scale up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations that vary in each country where 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, but we cannot predict when, if at all, this relationship will lead to additional approved products, sales, or otherwise provide revenue to the Company or become profitable.

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

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

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

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

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

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

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

Our success may depend, in part, on the extent to which reimbursement for the costs of vaccines will be available from third-party payers, such as government health administration authorities, private health insurers, 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 biotechnology and product development industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing.

Regulatory agencies may require us or our collaborators to delay, restrict or discontinue clinical trials on various grounds, including a finding that the 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 material applicable environmental and occupational health and safety regulations.

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

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

government health administration authorities such as the Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (“CDC”);

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”). These healthcare reform laws contain several cost containment measures that could adversely affect our future revenue, including, for example, increased drug rebates under Medicaid for brand name prescription drugs, extension of Medicaid rebates to Medicaid managed care plans, and extension of so-called 340B discounted pricing on pharmaceuticals sold to certain healthcare providers. Additional provisions of the healthcare reform laws that may negatively affect our future revenue and prospects for profitability include the assessment of an annual fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, as well as mandatory discounts on pharmaceuticals sold to certain Medicare Part D beneficiaries. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. In addition, we face uncertainties because there may be federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of

potential legislation on us.

## **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 250 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. 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 biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. From January 1, 2016 through December 31, 2016, the closing sale price of our common stock has been as low as \$1.18 per share and as high as \$8.34 per share. The market price of our common stock may be influenced by many factors, including:

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

clinical trial results;

depletion of our cash reserves;

sale of equity securities or issuance of additional debt;

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

changes in government regulations;

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

developments in our relationships with our collaboration partners;

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

sales of substantial amounts of our stock by existing stockholders (including stock by insiders or 5% stockholders);

development, spread or new announcements related to pandemic diseases;

litigation;

public concern as to the safety of our products;

significant set-backs or concerns with the industry or the market as a whole;

regulatory inquiries, reviews and potential action, including from the FDA or the SEC;

recommendations by securities analysts or changes in earnings estimates; and

the other factors described in this Risk Factors section.

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

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

<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
1201CR Gaithersburg, MD	147,000	Vaccine research and development, manufacturing, laboratory facility and offices
Uppsala, Sweden	24,000	Adjuvant manufacturing facility and research and development and offices
Total square footage	355,000	

**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, 2016	\$2.08	\$1.18
September 30, 2016	\$8.34	\$1.29
June 30, 2016	\$7.27	\$4.33
March 31, 2016	\$7.89	\$4.36
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

On February 23, 2017, the last sale price reported on the NASDAQ Global Select Market for our common stock was \$1.38. Our common stock was held by approximately 381 stockholders of record as of February 23, 2017, one of which is Cede & Co., a nominee for Depository Trust Company (“DTC”). All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder. We 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, 2011, and reinvestments of all dividends.

Value of \$100 invested on December 31, 2011 in stock or index, including reinvestment of dividends, for fiscal years ended December 31:

	12/31/11	12/31/12	12/31/13	12/31/14	12/31/15	12/31/16
Novavax, Inc.	\$ 100.00	\$ 150.00	\$ 406.35	\$ 470.64	\$ 665.87	\$ 100.00
NASDAQ Composite Index	\$ 100.00	\$ 116.41	\$ 165.47	\$ 188.69	\$ 200.32	\$ 216.54
RUSSELL 2000 Growth Biotechnology Index	\$ 100.00	\$ 114.85	\$ 179.38	\$ 222.91	\$ 247.82	\$ 197.52

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, 2016, 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,				
	2016(1)	2015(2)	2014(3)	2013(4)	2012
	(in thousands, except per share amounts)				
<b>Statements of Operations Data:</b>					
Revenue	\$ 15,353	\$ 36,250	\$ 30,659	\$ 20,915	\$ 22,076
Net loss	(279,966)	(156,937)	(82,947 )	(51,983 )	(28,507 )
Basic and diluted net loss per share	(1.03 )	(0.60 )	(0.37 )	(0.31 )	(0.22 )
Weighted average shares used in computing basic and diluted net loss per share	270,802	262,248	225,848	169,658	131,726
	<b>As of December 31,</b>				
	2016(1)	2015(2)	2014(3)	2013(4)	2012
	<b>(in thousands, except per share amounts)</b>				
<b>Balance Sheet Data:</b>					
Cash and marketable securities(5)	\$ 235,479	\$ 230,656	\$ 168,056	\$ 133,068	\$ 50,344
Total current assets	287,830	287,257	188,158	145,001	50,408
Working capital(6)	221,424	210,763	154,042	126,879	38,733
Total assets	394,301	386,038	276,002	235,125	102,345
Long-term debt, less current portion(7)	316,339	37	503	1,199	990
Accumulated deficit	(929,996)	(650,030)	(493,093)	(410,146)	(358,163)
Total stockholders’ equity (deficit)	(5,546 )	292,669	229,618	203,234	80,240

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

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

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

In 2013, we completed the acquisition of Novavax AB and had sales of 44,452,343 shares of common stock resulting in net proceeds of approximately \$129 million.

- (5) Includes non-current marketable securities of \$6,233 at December 31, 2012.
- (6) Working capital is computed as the excess of current assets over current liabilities.
- (7) Includes non-current portion of capital leases.



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

## **Overview**

We are a clinical-stage biotechnology company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine 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 clinical vaccine candidates for respiratory syncytial virus (“RSV”) and Ebola virus (“EBOV”), and preclinical programs for Zika virus (“ZIKV”), seasonal influenza and a combination respiratory vaccine candidate, as well as other infectious disease vaccine candidates.

We are also developing immune stimulating saponin-based adjuvants through our wholly owned Swedish subsidiary, Novavax AB. Our lead adjuvant, Matrix-M™, has been shown to enhance immune responses and was well-tolerated in a Phase 1/2 clinical trial for our pandemic H7N9 influenza vaccine candidate, as well as in a Phase 1 clinical trial for our EBOV vaccine candidate. Genocea Biosciences, Inc. has licensed rights to our Matrix technology and has conducted Phase 2 clinical trials with its herpes simplex 2 vaccine candidate using Matrix-M.

Following the results of the top-line data from the Phase 3 clinical trial of our RSV F Vaccine in older adults, on November 9, 2016, we announced a restructuring plan that included an immediate reduction in workforce of approximately 30% and one-time restructuring costs of \$3.6 million, including cash severance expenses, in the fourth quarter of 2016. These restructuring costs were recorded as \$2.9 million in research and development expenses and \$0.7 million in general and administrative expenses. At December 31, 2016, \$1.1 million remains unpaid, which we expect to pay in the first quarter of 2017.

## Product Pipeline

Our product pipeline includes vaccine candidates engineered to elicit differentiated immune responses with the potential to provide increased protection. Our nanoparticle technology 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.

	<b>Current</b>
<b>Program</b>	<b>Development Stage</b>
<b>Respiratory Syncytial Virus (“RSV”)</b>	
· <b>Infants via Maternal Immunization</b>	Phase 3*
· <b>Older Adults</b>	Phase 2
· <b>Pediatrics</b>	Phase 1
<b>Emerging Viruses</b>	
· <b>Ebola Virus (“EBOV”)</b>	Phase 1
· <b>Zika Virus (“ZIKV”)</b>	Preclinical
<b>Seasonal Influenza Nanoparticle</b>	Preclinical
<b>Combination Respiratory</b>	Preclinical

\*Supported by the \$89.1 million grant from the Bill and Melinda Gates Foundation (“BMGF”)

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

### **Respiratory Syncytial Virus**

We are developing our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate (“RSV F Vaccine”) for three susceptible target populations: infants via maternal immunization, older adults (60 years of age and older) and children six months to five years of age (“pediatrics”). We believe our RSV F Vaccine represents a multi-billion dollar revenue opportunity, 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 to be in excess of \$88 billion.<sup>28</sup> Despite decades of effort to develop an RSV vaccine, there are currently no licensed vaccines. Although the monoclonal antibody palivizumab (Synagis®) is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease, it is not indicated for use in other populations. We made a breakthrough in developing a vaccine that targets the fusion protein, or F-protein, of the virus. The F-protein has highly conserved amino acid sequences, called antigenic sites, which we believe are ideal vaccine targets. Palivizumab, which targets one such site, antigenic site II, has demonstrated protection in five randomized clinical trials. We genetically engineered a novel F-protein antigen resulting in enhanced immunogenicity by exposing these antigenic sites. The Novavax RSV F Vaccine assembles into a recombinant protein nanoparticle optimized for F-protein antigen presentation. We are seeking to bring the first RSV vaccine to market to combat the 64 million RSV infections that occur globally each year.<sup>29,30</sup>

### ***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>31,32</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>33,34</sup> Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.<sup>35,36</sup>

#### *Clinical Trial Update*

##### *Prepare Phase 3 Trial (Ongoing)*

We initiated Prepare™, a global pivotal Phase 3 clinical trial of our 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 a minimum of the first 90 days of life. The Prepare trial utilizes a group sequential design and is expected to take between three and four years to complete. We are currently in discussion with the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (“FDA”) about conducting an informational analysis of the Prepare trial in late 2017. These discussions lead us to believe we will be allowed to conduct an

informational analysis that would provide an indication of the vaccine's potential efficacy against the primary endpoint.

The Prepare trial is supported by a grant (the "Grant") of up to \$89.1 million from BMGF. The Grant supports development activities, product licensing efforts and World Health Organization ("WHO") prequalification of our RSV F Vaccine. In 2015, along with the Grant agreement (the "Grant Agreement"), we concurrently entered into a Global Access Commitments Agreement with BMGF, under which we agreed to make the RSV F Vaccine available and accessible at affordable pricing to people in certain low and middle income countries.

<sup>28</sup> Estimated value of life lost, future health implications and lost earnings; Preliminary data based on Novavax research of available epidemiology and health outcomes data

<sup>29</sup> Nair, H., et al., (2010) Lancet. 375:1545 - 1555

<sup>30</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>31</sup> Nair, H., et al., (2010) Lancet. 375:1545 - 1555

<sup>32</sup> CDC: <https://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>33</sup> Hall, C.B. et al. (2013) Pediatrics; 132(2):E341-348

<sup>34</sup> Oxford Vaccine Group: <http://www.ovg.ox.ac.uk/rsv>

<sup>35</sup> Glezen, W.P. et al. (1986) Am J Dis Child; 140:543-546

<sup>36</sup> Glenn, G.M. et al. (2016) JID; 213(3):411-12

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*Phase 2 Safety and Immunogenicity Trial (Completed)*

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.

*Fast Track Designation*

The 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 Older Adults Program*

*Burden of Disease*

Adults 60 years of age and older are at increased risk for RSV disease due to immunosenescence, the age-related decline in the human immune system. In this population, RSV is an important respiratory virus, distinct from influenza, that is frequently 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. In the U.S., the incidence rate is approximately 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>37,38</sup> Based on our analysis of published literature applied to 2014 U.S. population estimates, the disease causes 207,000 hospitalizations and 16,000 deaths among adults older than 65.<sup>39,40</sup> Annually, we estimate that there are approximately 900,000 medical interventions directly caused by RSV disease

across all populations.<sup>41,42</sup>

*Clinical Trial Update*

*Phase 2 Safety and Immunogenicity Trial (Ongoing)*

In January 2017, we announced the initiation of a Phase 2 clinical trial of the RSV F Vaccine in older adults. The objective of this Phase 2 trial is to assess safety and immunogenicity to one and two dose regimens of the RSV F Vaccine, with and without aluminum phosphate or Novavax' proprietary Matrix-M adjuvant, in older adults. The trial is a randomized, observer-blinded, placebo-controlled trial which has enrolled 300 older adults in the Southern Hemisphere. Participants were enrolled and vaccinated outside of the RSV season to best assess immunogenicity, with top-line data expected in the third quarter of 2017.

<sup>37</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>38</sup> Falsey, A.R. *et al.* (1995) JID.172:389-94

<sup>39</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>40</sup> W.W. Thompson et al. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA 2003; 289(2): 179-186

<sup>41</sup> K. Widmer et al. Rates of hospitalizations for respiratory syncytial virus, human metapneumovirus, and influenza virus in older adults. J Infect Dis. 2012; 206: 56-62

<sup>42</sup> K. Widmer et al. Respiratory syncytial virus & human metapneumovirus-associated emergency department and hospital burden in adults. Influenza and Other Respiratory Viruses. 2014; 8(3): 347-352.

*Resolve Phase 3 Trial (Completed)*

In September 2016, we announced top-line data from the Phase 3 clinical trial of our RSV F Vaccine in older adults, known as Resolve™. Resolve was a randomized, observer-blinded, placebo-controlled trial that began in November 2015, and was fully enrolled with 11,856 older adult subjects at 60 sites in the U.S. by December 2015. Historically, annual seasonal attack rates for all symptomatic respiratory disease due to RSV (“RSV ARD”) of between 3% and 7% have been observed in older adults.<sup>43</sup>

In our Phase 2 trial conducted during the 2014-2015 RSV season, we observed an RSV ARD attack rate of 4.9%, with an attack rate of 1.8% for moderate-severe RSV-associated lower respiratory tract disease (“RSV msLRTD”), which aligns with peer-reviewed literature.<sup>44</sup> In the Resolve trial, in contrast, we observed an RSV ARD attack rate of 2.0% and an RSV msLRTD attack rate of 0.4%. These unexpectedly low attack rates indicated a mild 2015-2016 RSV season in older adults. The trial did not meet the pre-specified primary or secondary efficacy objectives and did not demonstrate vaccine efficacy. The primary objective of the Resolve trial was to demonstrate efficacy in the prevention of moderate-severe RSV msLRTD, as defined by the presence of multiple lower respiratory tract symptoms. The secondary objective of the trial was to demonstrate efficacy of the RSV F Vaccine in reducing the incidence of all symptomatic respiratory disease due to RSV ARD. The trial also evaluated the safety of the unadjuvanted, 135 microgram dose of the RSV F Vaccine compared to placebo and consistent with our previous clinical experience, the vaccine was well-tolerated. We continue to analyze data from the Resolve trial in order to better understand these results and to map a path forward for this important program. Our efforts include analyses of existing immunogenicity and efficacy data, and application of new assays to archived samples. We have also undertaken external epidemiology studies to further understand the attack rate, healthcare burden and seasonality of RSV disease in older adults. We expect these analyses to provide important information and context when we review the results from the Phase 2 clinical trial in older adults that we initiated in January 2017 and evaluate our next steps.

*Phase 2 Rollover Trial (Completed)*

In September 2016, we also announced positive top-line data from the Phase 2 rollover clinical trial of our RSV F Vaccine in older adults. The trial was a randomized, observer-blinded, placebo-controlled rollover trial, which enrolled 1,329 older adults from the prior Phase 2 trial, conducted at the same 10 sites in the U.S. as our completed Phase 2 clinical trial in older adults. The primary objectives of the trial evaluated safety and serum anti-F IgG antibody concentrations in response to immunization with the RSV F Vaccine. The exploratory objectives of the trial evaluated the efficacy of a second annual dose of the RSV F Vaccine in the prevention of RSV ARD and RSV msLRTD. Participants previously randomized to receive 135 microgram RSV F Vaccine or placebo were re-enrolled and re-randomized in the current trial to receive either 135 microgram RSV F Vaccine or placebo. This resulted in analysis of four separate trial arms: a) participants receiving a placebo in both the first trial and second trial (“Placebo-Placebo”); b) participants receiving RSV F Vaccine in the first trial and placebo in the second trial (“Vaccine-Placebo”); c) participants receiving placebo in the first trial and RSV F Vaccine in the second trial (“Placebo-Vaccine”); and d) participants receiving RSV F Vaccine in both the first trial and second trial

(“Vaccine-Vaccine”).

The rollover trial demonstrated immunogenicity in all active vaccine recipients, with a 6-fold increase in anti-F IgG in the Placebo-Vaccine arm, consistent with the Phase 2 efficacy trial. There was higher anti-F IgG at baseline in the Vaccine-Vaccine arm compared to the Placebo-Vaccine arm and the Vaccine-Vaccine arm showed a greater than 2-fold increase in anti-F IgG from the higher baseline. The rollover trial confirmed the low attack rates witnessed during the Resolve trial.

*Phase 2 Trial in Older Adults (Completed)*

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.

<sup>43</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59 extrapolated to 2015 census population

<sup>44</sup> Falsey, A.R. *et al.* (2005) NEJM. 352:1749–59

## ***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>45</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.<sup>46,47,48,49,50</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 2014-2015 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 next steps in the development of our RSV F Vaccine for pediatrics.

## **Emerging Disease**

### ***Ebola Virus***

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>51</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 top-line 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>45</sup> U.S. Census. [www.census.gov/population/international/data/idb/informationGateway.php](http://www.census.gov/population/international/data/idb/informationGateway.php)

<sup>46</sup> Stockman, L.J. et al (2012) *Pediatr Infect Dis J.* 31: 5-9

<sup>47</sup> CDC update May 5, 2015. <http://www.cdc.gov/rsv/research/us-surveillance.html>

<sup>48</sup> Boyce, T.G. et al (2000) *Pediatrics*; 137: 865-870

<sup>49</sup> Hall, C.B. et al (2009) *NEJM*; 360(6): 588-98

<sup>50</sup> Hall, C.B. et al (2013) *Pediatrics*; 132(2): E341-8

<sup>51</sup> WHO: <http://www.who.int/mediacentre/factsheets/fs103/en/>

### ***ZIKV EnvD Vaccine***

We initiated development of a vaccine against the Zika virus (“ZIKV”) in response to the unmet global medical need for a response to this serious disease. Beginning in 2015, ZIKV spread in South, Central and North America via mosquito-borne and sexual transmission. Although acute ZIKV infections in adults are generally either asymptomatic or associated with mild symptoms (fever, joint pains and skin rash), more serious outcomes can occur, including Guillain-Barré syndrome in adults and, microcephaly in infants of women infected during pregnancy. There is no approved vaccine against ZIKV, although a number of companies have announced vaccine development efforts. We are currently conducting IND-enabling preclinical studies, including studies in non-human primates and other animal models, with the goal of initiating a Phase 1 clinical trial of our ZIKV envelope dimer nanoparticle vaccine candidate (“ZIKV EnvD Vaccine”) in 2017.

### **Seasonal 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 largely because of unique strains of influenza for which most humans have not developed protective antibodies. 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 2012-2013 season to \$5.3 billion by the 2021-2022 season.<sup>52</sup>

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>53</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>54</sup> Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of such vaccine can potentially be manufactured quickly and in a cost-effective manner, without the use of either the live influenza virus or eggs.

After many years of developing virus-like particle (“VLP”)-based seasonal influenza vaccine candidates, we have identified advantages of developing nanoparticle-based seasonal influenza vaccines. In particular, influenza nanoparticles can display conserved antigenic regions, which have the potential to elicit broadly neutralizing antibodies that may offer protection against a range of drifted strains. Additionally, nanoparticles offer improved purity and manufacturability and advantages for co-formulation with other nanoparticle-based vaccines. We expect to continue to develop our nanoparticle influenza vaccine program in 2017 with an ongoing goal of generating additional proof-of-concept data.

### **Combination Respiratory Vaccine**

Given the ongoing development of our RSV F Vaccine and our desire to develop a combination respiratory vaccine with the potential to protect against both RSV and seasonal influenza, we made the decision to shift our seasonal influenza vaccine development focus from VLP-based seasonal influenza vaccines to nanoparticle-based seasonal influenza vaccines. Early preclinical development efforts give us confidence that such a combination vaccine is feasible.

<sup>52</sup> Influenza Vaccines Forecasts. Datamonitor (2013)

<sup>53</sup> Resolution of the World Health Assembly. (2003) WHA56.19. 28

<sup>54</sup> WHO position paper (2012) Weekly Epidemiol Record;87(47):461–76



### **CPLB Joint Venture (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, for its trivalent seasonal VLP influenza vaccine and is currently manufacturing with limited sales in 2016 and limited expected sales in 2017.

### ***Rabies***

In October 2016, CPLB initiated its Phase 3 clinical trial in India of a rabies G protein vaccine candidate that we genetically engineered, and that can be administered both as a pre-exposure and a post-exposure prophylactic regimen. The post-exposure regimen has the potential to use fewer doses (three doses) than the current standard of care (five doses).

### **Convertible Senior Notes**

In the first quarter of 2016, we issued \$325 million aggregate principal amount of convertible senior unsecured notes that will mature on February 1, 2023 (the “Notes”). The Notes bear cash interest at a rate of 3.75%, payable on February 1 and August 1 of each year, beginning on August 1, 2016. The Notes are not redeemable prior to maturity and are convertible into shares of the Company’s common stock. The initial conversion rate for the Notes is 146.8213 shares of the Company’s 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 the Company’s common stock, representing an approximate 22.5% conversion premium based on the last reported sale price of the Company’s common stock of \$5.56 per share on January 25, 2016. In addition, the holders of the Notes may require us to repurchase the Notes at par value plus accrued and unpaid interest following the occurrence of a Fundamental Change (as described in the Indenture). If a holder of the Notes converts upon a Make-Whole Adjustment Event (as described in the Indenture), they may be eligible to receive a make-whole premium through an increase to the conversion rate up to a maximum of 179.8561 shares per \$1,000 principal amount of Notes (subject to other adjustments as described in the Indenture).

In connection with the issuance of the Notes, we paid \$38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the “capped call transactions”). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of 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 represented 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 the Company’s common stock, as measured under the terms of the capped call transactions, exceeds the cap price, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price.

*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 have historically performed research and development for U.S. Government agencies under cost reimbursable fixed-fee contracts. Under such cost reimbursable fixed-fee contracts, we were reimbursed and recognized revenue as allowable costs were 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 were 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. Payments to us under cost reimbursable contracts, such as the HHS BARDA contract, are provisional payments subject to adjustment upon audit by the government. An audit of indirect rates 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 indirect rates of fiscal years 2013 and 2014 was completed in the first quarter of 2017. When the final determination of the additional costs for fiscal years 2013 and 2014 has been made, and such amount is known and collection of the amount is reasonably assured, revenue and billings will be adjusted accordingly.

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 our 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.

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

At December 31, 2016 and 2015, the Company used the market approach to determine if the Company had an impairment of its goodwill. Step one of the impairment test states that if the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not to be impaired. The fair value of the Company's reporting unit was substantially higher than the carrying value, resulting in no impairment to goodwill at December 31, 2016 and 2015.

***Recent Accounting Pronouncements Not Yet Adopted***

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

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718)* that simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. We adopted this standard on the effective date, January 1, 2017, and the adoption will not have a material impact on our consolidated financial statements and related disclosure.



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. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. We have completed an initial assessment of the potential changes from adopting ASU 2014-09, primarily by reviewing our current revenue streams and deferred revenue balances. Based on our initial assessment, we do not expect any material changes to the recognition of our revenue. We have not yet completed our final review of the impact of this guidance, and in 2017, we will continue to evaluate the impacts of adoption. We currently expect to apply ASU 2014-09 on a modified retrospective basis as of January 1, 2018. We will continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current evaluation.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* that increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The standard will be effective January 1, 2019 for us, with early adoption permitted. The standard will be applied using a modified retrospective approach to the beginning of the earliest period presented in the financial statements. We are currently evaluating when we will adopt the standard and the expected impact to our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other (Topic 350)* (“ASU 2017-04”), which will simplify the goodwill impairment calculation, by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. We will continue to perform our quantitative goodwill impairment test by comparing the fair value of our reporting unit to its carrying amount, but if we are required to recognize a goodwill impairment charge, under the new standard, the amount of the charge will be calculated by subtracting the reporting unit’s fair value from its carrying amount. Under the current standard, if we are required to recognize a goodwill impairment charge, Step 2 requires us to calculate the implied value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination and the amount of the charge is calculated by subtracting the reporting unit’s implied fair value of goodwill from the goodwill carrying amount. The standard will be effective January 1, 2020 for us, with early adoption permitted, and should be applied prospectively from the date of adoption. We are currently evaluating when we will adopt ASU 2017-04 and its expected impact to our related disclosures.

**Results of Operations for Fiscal Years 2016, 2015 and 2014** (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, 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:**

	2016	2015	2014	Change 2015 to 2016	Change 2014 to 2015
Revenue:					
Total revenue	\$ 15,353	\$ 36,250	\$ 30,659	\$ (20,897	) \$ 5,591

Revenue for 2016 was \$15.4 million as compared to \$36.3 million for 2015, a decrease of \$20.9 million, or 58%. Revenue for 2016 and 2015 was primarily comprised of services performed under the Grant Agreement and the HHS BARDA contract, and to a much lesser extent, the PATH clinical development agreement and revenue from Novavax AB. The decrease in revenue is primarily due to a reduction of revenue under the HHS BARDA contract of \$31.2 million due to a lower level of activity during 2016 as compared to 2015, \$7.7 million recognized in 2015 from the recovery of additional costs for the settlement of indirect rates for fiscal years 2011 and 2012 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. This decrease in revenue was partially offset by an increase of \$9.4 million in revenue recorded under the Grant Agreement relating to our ongoing RSV F Vaccine Phase 3 clinical trial for the protection of infants via maternal immunization.

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 was 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 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 candidate adjuvanted with Matrix-M in 2014 under the HHS BARDA contract and a decrease in revenue under the prior PATH clinical development agreement.

We expect revenue in 2017 under the Grant Agreement to be significantly higher than in 2016 as we continue to enroll participants in Prepare.

**Expenses:**

	2016	2015	2014	Change 2015 to 2016	Change 2014 to 2015
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## Expenses:

Research and development	\$237,939	\$162,644	\$94,422	\$ 75,295	\$ 68,222
General and administrative	46,527	30,842	19,928	15,685	10,914
Total expenses	\$284,466	\$193,486	\$114,350	\$ 90,980	\$ 79,136

***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 related to research and development activities, are also included in research and development expenses. Research and development expenses increased to \$237.9 million for 2016 from \$162.6 million for 2015, an increase of \$75.3 million, or 46%. 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 increased non-cash stock-based compensation of \$4.4 million. At December 31, 2016, we had 322 employees dedicated to our research and development programs versus 369 employees as of December 31, 2015. For 2017, we expect a significant decrease in research and development expenses primarily due to lower anticipated RSV F Vaccine candidate clinical trials and employee-related costs to support product development of our RSV F Vaccine candidate and other potential vaccine candidates.

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 increased non-cash stock-based compensation of \$3.9 million. 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.

### *Expenses by Functional Area*

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

The following summarizes our research and development expenses by functional area for the years ended December 31, 2016, 2015 and 2014 (in millions).

	2016	2015	2014
Manufacturing	\$115.6	\$81.2	\$53.5
Vaccine Discovery	6.1	6.2	6.2
Clinical and Regulatory	116.2	75.2	34.7
Total research and development expenses	\$237.9	\$162.6	\$94.4

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 \$46.5 million for 2016 from \$30.8 million for 2015, an increase of \$15.7 million, or 51%. The increase in general and administrative expenses was primarily due to higher employee-related costs driven by the administrative requirements needed to support our expanding research and development activities, and professional fees for pre-commercialization activities. At December 31, 2016, we had 53 employees dedicated to general and administrative functions versus 49 employees as of December 31, 2015. For 2017, we expect general and administrative expenses to decrease primarily due to employee headcount reductions resulting in lower anticipated employee costs and reduced activities related to the anticipated commercialization of our RSV F Vaccine.

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 increased non-cash stock-based compensation of \$3.4 million, driven by the administrative requirements needed to support our expanding research and development activities, and professional fees for pre-commercialization activities.

**Other Income (Expense):**

	2016	2015	2014	Change 2015 to 2016	Change 2014 to 2015
Other Income (Expense):					
Investment income	\$2,143	\$660	\$286	\$ 1,483	\$ 374
Interest expense	(12,965)	(241)	(157)	(12,724 )	(84 )
Other income	(31 )	(120)	—	89	(120 )
Realized gains on marketable securities	—	—	615	—	(615 )
Total other income (expense)	\$(10,853)	\$299	\$744	\$ (11,152 )	\$ (445 )

We had total other expense of \$10.9 million for 2016 compared to total other income of \$0.3 million for 2015, a decrease of \$11.2 million. Our investment income increased in 2016 as compared to 2015 due to higher cash, cash equivalents and marketable securities balances. Our interest expense increased due to the issuance of the Notes in the first quarter of 2016.

We had total other income of \$0.3 million for 2015 compared to total other income 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.

**Net Loss:**

	2016	2015	2014	Change 2015 to 2016	Change 2014 to 2015
Net Loss:					
Net loss	\$(279,966)	\$(156,937)	\$(82,947 )	\$ (123,029 )	\$ (73,990 )
Net loss per share	\$(1.03 )	\$(0.60 )	\$(0.37 )	\$ (0.43 )	\$ (0.23 )
Weighted average shares outstanding	270,802	262,248	225,848	8,554	36,400

Net loss for 2016 was \$280.0 million, or \$1.03 per share, as compared to \$156.9 million, or \$0.60 per share, for 2015, an increased net loss of \$123.0 million. The increased net loss was primarily due to higher research and development spending relating to our RSV F Vaccine and overall higher employee-related costs as compared to 2015.

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.

The increase in weighted average shares outstanding for 2016 and 2015 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.



As of December 31, 2016, we had \$235.5 million in cash and cash equivalents and marketable securities as compared to \$230.7 million as of December 31, 2015. These amounts consisted of \$144.4 million in cash and cash equivalents and \$91.1 million in marketable securities as of December 31, 2016 as compared to \$93.1 million in cash and cash equivalents and \$137.5 million in marketable securities as of December 31, 2015.

The following table summarizes cash flows for 2016 and 2015 (in thousands):

	2016	2015	Change 2015 to 2016
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(255,467)	\$(126,090)	\$(129,377 )
Investing activities	28,017	(21,270 )	49,287
Financing activities	279,030	208,283	70,747
Effect on exchange rate on cash and cash equivalents	(335 )	(150 )	(185 )
Net increase (decrease) in cash and cash equivalents	51,245	60,773	(9,528 )
Cash and cash equivalents at beginning of year	93,108	32,335	60,773
Cash and cash equivalents at end of year	\$144,353	\$93,108	\$ 51,245

Net cash used in operating activities increased to \$255.5 million for 2016, as compared to \$126.1 million for 2015. The increase in cash usage was primarily due to increased research and development expenses relating to our RSV F Vaccine and overall higher employee-related costs. We expect our 2017 net cash used in operating activities to be lower than 2016 due to the implementation of our previously announced restructuring efforts, resulting in lower anticipated RSV F Vaccine candidate clinical trials and overall employee-related costs to support product development of our RSV F Vaccine candidate and other potential vaccine candidates (see Note 2 to the financial statements included in this Annual Report).

During 2016 and 2015, our investing activities consisted primarily of purchases and maturities of marketable securities and capital expenditures. Capital expenditures for 2016 and 2015 were \$18.2 million and \$18.3 million, respectively. Capital expenditures were primarily due to facility improvements and the purchase of laboratory equipment for process development, analytical development and manufacturing scale-up required to support the development of our product portfolio. In 2017, we expect our level of capital expenditures to be significantly lower than our 2016 spending primarily due to the timelines being extended for the commercialization of our RSV F Vaccine.

Our financing activities consisted primarily of sales of our common stock, our issuance of the Notes, and to a lesser extent, stock option exercises and purchases under our employee stock purchase plan. In 2016, we received net proceeds of \$276.5 million through the issuance of our Notes and payments of capped call transactions (see Note 9 to

the financial statements included herewith). In 2015, we received net proceeds of approximately \$190 million through our public offering at \$7.25 per share and approximately \$15 million from our At Market Issuance Sales Agreement dated October 1, 2012 at an average sales price of \$10.63 per share. In January 2017, we entered into an At Market Issuance Sales Agreement, which allows us to issue and sell up to \$75 million in gross proceeds of our common stock, and no sales have occurred yet.

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 \$3.9 million. Through 2016, we were funded \$3.4 million under this tenant improvement allowance. In May 2016, we entered into a new lease for a facility located in Gaithersburg, Maryland and under the terms of the lease the landlord shall provide us with a tenant improvement allowance of up to \$9.6 million, none of which has been funded as of December 31, 2016.

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 has increased 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, 2016 aggregated \$7.6 million. The Milestone was accrued for on the consolidated balance sheet in other current liabilities at December 31, 2014. At the time of the September 2015 amendment discussed above, the Milestone payment was 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, and at December 31, 2016, the Milestone is recorded in accrued expenses. The Milestone was recorded as a research and development expense in 2014.

Based on our December 31, 2016 cash and cash equivalents and marketable securities balances, along with anticipated revenue under the Grant Agreement and other resources, we believe we have adequate capital to fund our operating plans for a minimum of twelve months from the date that this Annual Report is filed. 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 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 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, 2016 (in thousands):

Contractual Obligations:	Total	Less than One Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Operating leases	\$81,315	\$6,986	\$19,414	\$17,555	\$37,360
Capital lease	37	37	—	—	—
Accrued milestone payment	4,000	4,000	—	—	—
Total contractual obligations	\$85,352	\$11,023	\$19,414	\$17,555	\$37,360

Our accrued milestone payment includes the milestone payment incurred in 2014 under the Wyeth agreement and is the expected payment amount that is due in 2017 (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, 2016, we had cash and cash equivalents of \$144.4 million, marketable securities of \$91.1 million, all of which are short-term, and working capital of \$221.4 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of December 31, 2016, 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 \$2.9 million at December 31, 2016.

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

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

The information required by this item is set forth on pages F-1 to F-27.

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

None.

**Item 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

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

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

### ***Management's Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, the Company's principal executive officer and principal financial officer and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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, 2016. 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, 2016, 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 (a) (1).

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

Our management, including our chief executive officer and chief financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2016, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2016 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 2017 Annual Meeting of Stockholders scheduled to be held in June 2017 (the “2017 Proxy Statement”). We expect to file the 2017 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2016.

**Item 11. EXECUTIVE  
COMPENSATION**

We incorporate herein by reference the information required by this item concerning executive compensation to be contained in the 2017 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 2017 Proxy Statement.

The following table provides our equity compensation plan information as of December 31, 2016. 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 11 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)	39,232,732	\$ 4.30	7,487,335
Equity compensation plans not approved by security holders	N/A	N/A	N/A

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

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

We incorporate herein by reference the information required by this item concerning certain related party transactions set forth in Note 15 to our 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 2017 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 2017 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 Firm	F-2
Consolidated Balance Sheets as of December 31, 2016 and 2015	F-4
Consolidated Statements of Operations and Statements of Comprehensive Loss for the years ended December 31, 2016, 2015 and 2014	F-5
Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the years ended December 31, 2016, 2015 and 2014	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014	F-7
Notes to Consolidated Financial Statements	F-8

(2)

Financial Statement Schedules

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

(3)Exhibits

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

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

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

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

Exhibit

Description

Number

- |     |   |
|-----|---|
| 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 |   |

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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 on 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†† Amended and Restated 2013 Employee Stock Purchase Plan (Incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement filed on April 20, 2016 in connection with the Annual Meeting held on June 9, 2016)

10.6†† Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Incorporated by reference to Appendix A of the Company's Definitive Proxy Statement filed on April 20, 2016 in connection with the Annual Meeting held on June 9, 2016)

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 Incentive Stock Option Award Agreement granted under the Novavax, Inc. 2015 Stock Incentive Plan

10.10†† Form of Incentive Stock Option Agreement granted under the Amended and Restated Novavax, Inc. 2015 Stock Incentive Plan (Performance- and Time-Based Vesting) (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on November 16, 2016)

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

10.12†† Form of Director Deferred Fee Agreement (Incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 29, 2016)

10.13†† 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)

10.14†† 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)

10.15†† Employment Agreement between Novavax, Inc. and John A. Herrmann dated April 1, 2012 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016)

10.16†† Employment Agreement between Novavax, Inc. and John J. Trizzino dated March 3, 2014 (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016)

10.17†† 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)

Novavax, Inc. Amended and Restated Change in Control Severance Benefit Plan

10.18††

\*

Form of Indemnification Agreement entered into between the Registrant and its directors and  
10.19†† 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)

Lease Agreement for space at 9920 Belward Campus Drive between GP Rock One, LLC and Novavax, Inc.,  
10.20 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)

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- 10.21 First Amendment to Lease Agreement for space at 9920 Belward Campus Drive 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)
- 10.22 Second Amendment to Lease Agreement for space at 9920 Belward Campus Drive between BMR-9920 Belward Campus Q, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated as of June 26, 2008 (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 11, 2008)
- 10.23 Third Amendment to Lease Agreement for space at 9920 Belward Campus Drive between BMR-9920 Belward Campus, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated February 29, 2016 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016)
- 10.24 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)
- 10.25 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)
- 10.26 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)
- 10.27 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)
- 10.28 Lease Agreement for space at 1201 Clopper Road between IP9 1201 Clopper Road, LLC and Novavax, Inc., dated May 3, 2016 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed on May 5, 2016)
- 10.29\*\* 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)
- 10.30\*\* 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)
- 10.31\*\* 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)
- 10.32\*\* 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)

License Agreement, dated July 5, 2007, between Novavax, Inc. and Wyeth Holdings Corporation  
10.33\*\* (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)



- Amendment No. 1 to License Agreement, effective as of March 17, 2010, between Novavax, Inc. and Wyeth
- 10.34\*\* 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)
- Second Amendment to License Agreement between Wyeth Holdings LLC and Novavax, Inc., dated as of
- 10.35\*\* 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)
- 10.36\* At Market Issuance Sales Agreement, dated January 19, 2017 between Novavax, Inc. and FBR Capital Markets & Co.
- Stock Purchase Agreement between Novavax, Inc. and Satellite Overseas (Holdings) Limited, dated March
- 10.37 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)
- Amended and Restated Joint Venture Agreement between Novavax Inc. and Cadila Pharmaceuticals Limited,
- 10.38\*\* 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 Technical Services Agreement between Novavax, Inc. and CPL Biologicals Limited,
- 10.39\*\* 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)
- Amended and Restated Seasonal / Other License Agreement between Novavax, Inc. and CPL Biologicals
- 10.40\*\* 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)
- H1N1 License to Agreement between Novavax, Inc. and CPL Biologicals Private Limited, dated October 6,
- 10.41\*\* 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)
- Grant Agreement between Bill and Melinda Gates Foundation and Novavax, Inc., dated as of September 25,
- 10.42\*\* 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)
- Global Access Commitments Agreement between Bill and Melinda Gates Foundation and Novavax, Inc.,
- 10.43\*\* 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)
- Base Call Option Transaction Confirmation, dated as of January 25, 2016, between Novavax and JPMorgan
- 10.44 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)
- Base Call Option Transaction Confirmation, dated as of January 25, 2016, between Novavax and Morgan
- 10.45 Stanley & Co. LLC (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed January 29, 2016)

10.46 Additional Base Call Option Transaction Confirmation, dated as of February 2, 2016, between Novavax and JPMorgan Chase Bank, National Association, London Branch (Incorporated by reference to Exhibit 10.51 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 29, 2016)

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- Additional Base Call Option Transaction Confirmation, dated as of February 2, 2016, between Novavax and Morgan Stanley & Co. LLC (Incorporated by reference to Exhibit 10.52 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 29, 2016)
- 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
- 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

The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of December 31, 2016 and 2015, (ii) the Consolidated Statements of Operations for the three years in the period ended December 31, 2016, (iii) the Consolidated Statements of Comprehensive Loss for the three years in the period ended December 31, 2016, (iv) the Consolidated Statements of Changes in Stockholders' Equity for the three years in the period ended December 31, 2016, (v) the Consolidated Statements of Cash Flows for the three years in the period ended December 31, 2016, and (vi) the Notes to Consolidated Financial Statements.

## Item 16. FORM 10-K SUMMARY

Not applicable.

**SIGNATURES**

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

**NOVAVAX, INC.**

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

Date: February 27, 2017

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><u>Name</u></b>	<b><u>Title</u></b>	<b><u>Date</u></b>
<u>/s/ Stanley C. Erck</u> Stanley C. Erck	President and Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2017
<u>/s/ Barclay A. Phillips</u> Barclay A. Phillips	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Principal Accounting Officer)	February 27, 2017
<u>/s/ James F. Young</u> James F. Young	Chairman of the Board of Directors	February 27, 2017
<u>/s/ Gail K. Boudreaux</u> Gail K. Boudreaux	Director	February 27, 2017
<u>/s/ Richard H. Douglas</u> Richard H. Douglas	Director	February 27, 2017

/s/ Gary C. Evans

Director

February 27, 2017

Gary C. Evans

/s/ Michael A. McManus

Director

February 27, 2017

Michael A. McManus

/s/ Rajiv I. Modi

Director

February 27, 2017

Rajiv I. Modi

## INDEX TO FINANCIAL STATEMENTS

Years ended December 31, 2016, 2015 and 2014

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*Report of*  
*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, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. 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, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016 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, 2016, 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 27, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, Maryland

February 27, 2017

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***Report of***

***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, 2016, 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 the accompanying *Management's Report on Internal Control over Financial Reporting* included in Item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We 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, 2016, 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, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016 of Novavax Inc. and our report dated February 27, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Baltimore, Maryland

February 27, 2017

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## NOVAVAX, INC.

## CONSOLIDATED BALANCE SHEETS

	December 31,	
	2016	2015
	(in thousands, except share and per share information)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 144,353	\$ 93,108
Marketable securities	91,126	137,548
Restricted cash	30,314	34,964
Accounts receivable	233	2,320
Prepaid expenses and other current assets	21,804	19,317
Total current assets	287,830	287,257
Restricted cash	4,590	2,422
Property and equipment, net	40,184	32,342
Intangible assets, net	9,225	10,793
Goodwill	51,673	53,065
Other non-current assets	799	159
Total assets	\$ 394,301	\$ 386,038
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 5,685	\$ 11,889
Accrued expenses	24,508	26,734
Accrued interest	5,078	—
Deferred revenue	30,079	34,469
Notes payable	—	395
Other current liabilities	1,056	3,007
Total current liabilities	66,406	76,494
Deferred revenue	2,500	4,171
Convertible notes payable	316,339	—
Other non-current liabilities	14,602	12,704
Total liabilities	399,847	93,369
Commitments and contingencies	—	—
Stockholders' equity (deficit):		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding at December 31, 2016 and 2015	—	—
	2,717	2,704

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Common stock, \$0.01 par value, 600,000,000 shares authorized at December 31, 2016 and 2015; and 271,701,397 shares issued and 271,245,967 shares outstanding at December 31, 2016 and 270,426,662 shares issued and 269,971,232 shares outstanding at December 31, 2015

Additional paid-in capital	935,997		951,569	
Accumulated deficit	(929,996)	)	(650,030)	)
Treasury stock, 455,430 shares, cost basis at both December 31, 2016 and 2015	(2,450)	)	(2,450)	)
Accumulated other comprehensive loss	(11,814)	)	(9,124)	)
Total stockholders' equity (deficit)	(5,546)	)	292,669	)
Total liabilities and stockholders' equity (deficit)	\$ 394,301		\$ 386,038	

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

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## NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years ended December 31,		
	2016	2015	2014
	(in thousands, except per share information)		
Revenue:			
Government contracts	\$ 2,184	\$ 33,344	\$ 26,213
Research and development collaborations	13,169	2,906	4,446
Total revenue	15,353	36,250	30,659
Expenses:			
Research and development	237,939	162,644	94,422
General and administrative	46,527	30,842	19,928
Total expenses	284,466	193,486	114,350
Loss from operations	(269,113 )	(157,236 )	(83,691 )
Other income (expense):			
Investment income	2,143	660	286
Interest expense	(12,965 )	(241 )	(157 )
Other income	(31 )	(120 )	—
Realized gains on marketable securities	—	—	615
Net loss	\$ (279,966 )	\$ (156,937 )	\$ (82,947 )
Basic and diluted net loss per share	\$ (1.03 )	\$ (0.60 )	\$ (0.37 )
Basic and diluted weighted average number of common shares outstanding	270,802	262,248	225,848

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

For the Years ended December  
31,  
2016      2015      2014  
(in thousands)

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Net loss	\$ (279,966)	\$ (156,937)	\$ (82,947)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities available-for-sale	54	42	(65 )
Reclassification adjustment for gains included in net loss	—	—	(615 )
Foreign currency translation adjustment	(2,744 )	(2,561 )	(6,764 )
Other comprehensive loss	(2,690 )	(2,519 )	(7,444 )
Comprehensive loss	\$ (282,656)	\$ (159,456)	\$ (90,391)

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

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## NOVAVAX, INC.

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**For the Years ended December 31, 2016, 2015 and 2014**

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income(Loss)	Total Stockholders' Equity (Deficit)
(in thousands, except share information)							
Balance at December 31, 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
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

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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
Non-cash compensation cost for stock options, ESPP and restricted stock	—	—	19,160	—	—	—	19,160
Exercise of stock options/Purchase under ESPP	1,254,735	13	3,789	—	—	—	3,802
Restricted stock issued as compensation	20,000	—	—	—	—	—	—
Payment of capped call transactions and costs	—	—	(38,521 )	—	—	—	(38,521 )
Unrealized gain on marketable securities	—	—	—	—	—	54	54
Foreign currency translation adjustment	—	—	—	—	—	(2,744 )	(2,744 )
Net loss	—	—	—	(279,966 )	—	—	(279,966 )
Balance at December 31, 2016	271,701,397	\$ 2,717	\$ 935,997	\$(929,996 )	\$(2,450 )	\$(11,814 )	\$(5,546 )

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



## NOVAVAX, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years ended December 31,		
	2016	2015	2014
	(in thousands)		
<b>Operating Activities:</b>			
Net loss	\$(279,966)	\$(156,937)	\$(82,947 )
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	8,505	5,983	4,424
Loss on disposal of property and equipment	374	681	534
Amortization of net premiums on marketable securities	257	1,217	415
Amortization of debt issuance costs	1,305		
Lease incentives received	1,963	2,792	452
Non-cash stock-based compensation	19,160	13,431	6,090
Realized gains on marketable securities			(615 )
Other	406	243	60
Changes in operating assets and liabilities:			
Restricted cash	3,301	(36,204 )	1,120
Accounts receivable	2,072	8,479	(3,817 )
Prepaid expenses and other assets	(3,191 )	(10,269 )	(5,904 )
Accounts payable and accrued expenses	(4,808 )	9,075	13,979
Deferred revenue	(6,057 )	36,140	(253 )
Other liabilities	1,212	(721 )	(552 )
Net cash used in operating activities	(255,467)	(126,090)	(67,014 )
<b>Investing Activities:</b>			
Capital expenditures	(18,213 )	(18,286 )	(7,268 )
Proceeds from disposal of property and equipment	11	18	39
Purchases of marketable securities	(356,556)	(228,521)	(176,469)
Proceeds from sales, maturities and redemptions of marketable securities	402,775	225,519	53,865
Net cash provided by (used in) investing activities	28,017	(21,270 )	(129,833)
<b>Financing Activities:</b>			
Principal payments of capital leases	(71 )	(67 )	(124 )
Principal payments of notes payable	(395 )	(600 )	(671 )
Changes in restricted cash	(819 )	(126 )	(2 )
Cash paid with acquisition			(171 )
Proceeds from issuance of convertible notes	325,000		
Payments of costs related to issuance of convertible notes	(9,966 )		
Payments for capped call transactions and costs	(38,521 )		
Net proceeds from sales of common stock		204,275	107,896

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Proceeds from the exercise of stock options and employee stock purchases	3,802	4,801	2,789
Net cash provided by financing activities	279,030	208,283	109,717
Effect of exchange rate on cash and cash equivalents	(335 )	(150 )	(6 )
Net increase (decrease) in cash and cash equivalents	51,245	60,773	(87,136 )
Cash and cash equivalents at beginning of year	93,108	32,335	119,471
Cash and cash equivalents at end of year	\$144,353	\$93,108	\$32,335
Supplemental disclosure of non-cash activities:			
Capital expenditures included in accounts payable and accrued expenses	\$697	\$2,797	\$2,615
Supplemental disclosure of cash flow information:			
Cash interest payments	\$6,189	\$96	\$179

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

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2016, 2015 and 2014**

**Note 1 – Organization**

Novavax, Inc. (“Novavax,” and together with its wholly owned subsidiary, “Novavax AB,” the “Company”) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants. Using innovative proprietary recombinant nanoparticle vaccine 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 proteins critical to disease pathogenesis. The Company’s product pipeline targets a variety of infectious diseases, with clinical vaccine candidates for respiratory syncytial virus (“RSV”) and Ebola virus (“EBOV”), and preclinical programs for Zika virus (“ZIKV”), seasonal influenza and a combination respiratory vaccine candidate, as well as other infectious disease vaccine candidates.

**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 biotechnology company, the Company has primarily funded its operations from proceeds through the sale of its common stock in equity offerings, the issuance of convertible debt and revenue under its prior contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (“HHS BARDA”) and, to a lesser degree, revenue under the grant agreement with the Bill & Melinda Gates Foundation (“BMGF”) and its prior contract with PATH Vaccine Solutions (“PATH”). 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.

Following the results of the top-line data from the Phase 3 clinical trial of its RSV F Vaccine in older adults, on November 9, 2016, the Company announced a restructuring plan that included an immediate reduction in workforce of approximately 30% and one-time restructuring costs of \$3.6 million, including cash severance expenses, in the fourth quarter of 2016. These restructuring costs were recorded as \$2.9 million in research and development expenses and \$0.7 million in general and administrative expenses. At December 31, 2016, \$1.1 million remains unpaid, which is expected to be paid in the first quarter of 2017.

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

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

***Use of Estimates***

The preparation of the consolidated financial statements in conformity with 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 December 31 (in thousands):

	2016	2015
Cash	\$17,481	\$29,569
Money market funds	95,896	14,950
Government-backed securities	19,000	20,000
Asset-backed securities		8,185
Corporate debt securities	11,976	20,404
Cash and cash equivalents	\$144,353	\$93,108

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) 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 funds, places restrictions on maturities and concentrations in certain industries and requires the Company to maintain a certain level of liquidity. At times, the Company maintains cash balances in financial institutions, which may exceed federally insured limits. The Company has not experienced any losses relating to such accounts and believes it is not exposed to a significant credit risk on its cash and cash equivalents.

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

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

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

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

### ***Restricted Cash***

The Company’s current and noncurrent restricted cash includes payments received under the Grant Agreement (see Note 7) and cash collateral accounts under letters of credit that serve as security deposits for certain facility leases. The Company will utilize the Grant Agreement funds as it incurs expenses for services performed under the agreement. At December 31, 2016 and 2015, the restricted cash balances consist of payments received under the Grant Agreement of \$33.2 million and \$36.5 million and security deposits of \$1.7 million and \$0.9 million, respectively.

### ***Accounts Receivable***

Accounts receivable includes amounts billed and unbilled for which work has been performed, though invoicing has not yet occurred. Historically, receivables arose primarily from the Company’s contract with HHS BARDA and were reported at amounts expected to be collected in future periods. No allowance for doubtful accounts is deemed necessary.

### ***Property and Equipment***

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

### ***Impairment of Long-Lived Assets***

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

### ***Goodwill***

Goodwill is subject to impairment tests annually or more frequently should indicators of impairment arise.



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

At December 31, 2016 and 2015, the Company used the market approach to determine if the Company had an impairment of its goodwill. Step one of the impairment test states that if the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not to be impaired. The fair value of the Company's reporting unit was substantially higher than its carrying value, resulting in no impairment to goodwill at December 31, 2016 and 2015.

#### ***Other Intangible Assets***

The Company's intangible assets include proprietary adjuvant technology and collaboration agreements, which were measured at their estimated fair values as of their acquisition dates. Amortization expense for intangible assets is recorded on a straight-line basis over the expected useful lives of the assets, ranging from seven to 20 years. Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable. The Company's evaluation of intangible assets completed during the years ended December 31, 2016 and 2015 resulted in no impairment losses.

#### ***Equity Method Investment***

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

#### ***Revenue Recognition***

The Company performs research and development for U.S. Government agencies and other collaborators under cost reimbursable and fixed price contracts, including license, grant and clinical development agreements. The Company recognizes 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.

Under cost reimbursable contracts with U.S. Government agencies, the Company is reimbursed and recognizes revenue as allowable costs are incurred plus a portion of the fixed-fee earned. The Company considers 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 its HHS BARDA contract (see Note 7), certain activities were 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. Payments to the Company under cost reimbursable contracts with agencies of the U.S. Government, such as the HHS BARDA contract, are provisional payments subject to adjustment upon audit by the government. An audit of indirect rates of fiscal years 2013 and 2014 was completed in the first quarter of 2017. When the final determination of the additional costs for fiscal years 2013 and 2014 has been made, and such amount is known and collection of the amount is reasonably assured, revenue and billings will be adjusted accordingly.

Under its Grant Agreement with BMGF (see Note 7), the Company is reimbursed for certain costs that support development activities, including the Company's global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and World Health Organization ("WHO") prequalification of the 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.

The Company's collaborative research and development agreements may include upfront payments, 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 control of the Company. 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 the Company's 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, the Company analyzes its 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 the Company is principal under the arrangement, and whether the arrangement is significant to, and part of, the Company's core operations. Historically, payments received under its contracts and collaborative agreements have been recognized as revenue since the Company acts as a principal in the arrangement and the activities are core to its 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.

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, the Company 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.

### *Stock-Based Compensation*

The Company accounts for stock-based compensation related to grants of stock options, restricted stock awards and purchases under its Employee Stock Purchase Plan (the “ESPP”) at fair value. The Company recognizes compensation expense related to such awards on a straight-line basis over the requisite service period (generally the vesting period) of the equity awards that are expected to vest, which typically occurs ratably over periods ranging from six months to four years. See Note 11 for a further discussion on stock-based compensation.

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

Restricted stock awards have been recorded as compensation expense over the expected vesting period based on the fair value at the award date and the number of shares ultimately expected to vest using the straight-line method of amortization.

The Company accounts for share-based awards issued to non-employees by determining the fair value of equity awards given as consideration for services rendered to be recognized as compensation expense over the shorter of the vesting or service periods. In cases where an equity award is not fully vested, such equity award is revalued on each subsequent reporting date until vesting is complete with a cumulative catch-up adjustment recognized for any changes in its estimated fair value.

### ***Research and Development Expenses***

Research and development expenses include salaries, laboratory supplies, consultants and subcontractors and other expenses associated with the Company's process development, manufacturing, clinical, regulatory and quality assurance activities for its programs. In addition, related indirect costs such as, fringe benefits and overhead expenses, are also included in research and development expenses.

### ***Income Taxes***

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

realized.

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

Interest and penalties related to income tax matters are recorded as income tax expense. At December 31, 2016 and 2015, the Company had no accruals for interest or penalties related to income tax matters.

### *Net Loss per Share*

Net loss per share is computed using the weighted average number of shares of common stock outstanding. At December 31, 2016, 2015 and 2014, the Company had outstanding stock options and unvested restricted stock awards totaling 39,277,732, 23,832,545 and 16,978,098 shares, respectively. As of December 31, 2016, the Company's Notes were initially convertible into approximately 47,716,900 shares of the Company's common stock. These and any shares due to the Company upon settlement of its capped call transactions are excluded from the computation, as their effect is antidilutive.

### *Foreign Currency*

The accompanying consolidated financial statements are presented in U.S. dollars. The functional currency of Novavax AB, which is located in Sweden, is the local currency (Swedish Krona). The translation of assets and liabilities of Novavax AB to U.S. dollars is made at the exchange rate in effect at the consolidated balance sheet date, while equity accounts are translated at historical rates. The translation of the statement of operations data is made at the average exchange rate in effect for the period. The translation of operating cash flow data is made at the average exchange rate in effect for the period, and investing and financing cash flow data is translated at the exchange rate in effect at the date of the underlying transaction. Translation gains and losses are recognized as a component of accumulated other comprehensive loss in the accompanying consolidated balance sheets. The foreign currency translation adjustment balance included in accumulated other comprehensive loss was \$11.8 million and \$9.1 million at December 31, 2016 and 2015, respectively.

### ***Segment Information***

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

### ***Recent Accounting Pronouncements***

In April 2015, the Financial Accounting Standards Board (“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 became effective for the Company beginning January 1, 2016. The adoption of ASU 2015-03 did not have a material effect on the Company’s financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40)*, to provide guidance on management’s responsibility in evaluating whether there is substantial doubt about a company’s ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about the Company’s ability to continue as a going concern within one year from the date the financial statements are issued. This guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company adopted this standard at December 31, 2016 and the adoption had no impact on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718)* that simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted this standard on the effective date, January 1, 2017, and the adoption will not have a material impact on its consolidated financial statements and related disclosure.

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. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. The Company has completed an initial assessment of the potential changes from adopting ASU 2014-09, primarily by reviewing its current revenue streams and deferred revenue balances. Based on the Company's initial assessment, it does not expect any material changes to the recognition of its revenue. The Company has not yet completed its final review of the impact of this guidance, and in 2017, the Company will continue to evaluate the impacts of adoption. The Company currently expects to apply ASU 2014-09 on a modified retrospective basis as of January 1, 2018. The Company will continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its current evaluation.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* that increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The standard will be effective January 1, 2019 for the Company, with early adoption permitted. The standard will be applied using a modified retrospective approach to the beginning of the earliest period presented in the financial statements. The Company is currently evaluating when it will adopt the standard and the expected impact to its consolidated financial statements and related disclosures.



In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other (Topic 350)* (“ASU 2017-04”), which will simplify the goodwill impairment calculation, by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. The Company will continue to perform its quantitative goodwill impairment test by comparing the fair value of its reporting unit to its carrying amount, but if the Company is required to recognize a goodwill impairment charge, under the new standard, the amount of the charge will be calculated by subtracting the reporting unit’s fair value from its carrying amount. Under the current standard, if the Company is required to recognize a goodwill impairment charge, Step 2 requires it to calculate the implied value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination and the amount of the charge is calculated by subtracting the reporting unit’s implied fair value of goodwill from the goodwill carrying amount. The standard will be effective January 1, 2020 for the Company, with early adoption permitted, and should be applied prospectively from the date of adoption. The Company is currently evaluating when it will adopt ASU 2017-04 and its expected impact to related disclosures.

### ***Reclassifications***

At December 31, 2015, accounts receivable - unbilled of \$0.9 million has been reclassified to accounts receivable, restricted cash of \$0.9 million has been reclassified from other non-current assets to restricted cash (non-current) and current deferred rent of \$1.4 million and non-current deferred rent of \$9.5 million have been reclassified to other current liabilities and non-current liabilities, respectively. These reclassifications have been made to conform to the current year presentation.

### **Note 4 – Fair Value Measurements**

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

	Fair Value at December 31, 2016			Fair Value at December 31, 2015		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds	\$ 95,896	\$	\$	\$ 14,950	\$	\$
Government-backed securities		19,000			20,000	
Asset-backed securities(1)		23,632			28,924	
Corporate debt securities(2)		79,470			137,213	
Total cash equivalents and marketable securities	\$ 95,896	\$ 122,102	\$	\$ 14,950	\$ 186,137	\$

Liabilities

Convertible notes payable	\$	\$ 141,989	\$	\$	\$	\$
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(1) Includes \$8,185 classified as cash and cash equivalents as of December 31, 2015 (see Note 3).

(2) Includes \$11,976 and \$20,404 classified as cash and cash equivalents as of December 31, 2016 and 2015, respectively (see Note 3).

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

During the years ended December 31, 2016 and 2015, the Company did not have any transfers between levels.

The amounts in the Company's consolidated balance sheets for accounts receivable and accounts payable approximate fair value due to their short-term nature. Based on borrowing rates available to the Company, the fair value of capital lease and notes payable approximates their carrying value. The Company's milestone payment due to Wyeth (see Note 14) approximates its fair value at December 31, 2016, as the liability has been calculated based on an anticipated future payment date discounted at borrowing rates available to the Company.

### Note 5 – Marketable Securities

Marketable securities classified as available-for-sale as of December 31, 2016 and 2015 were comprised of (in thousands):

	December 31, 2016				December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$23,636	\$	\$ (4 )	\$23,632	\$20,748	\$ —	\$ (9 )	\$20,739
Corporate debt securities	67,457	43	(6 )	67,494	116,821	29	(41 )	116,809
Total	\$91,093	\$ 43	\$ (10 )	\$91,126	\$137,569	\$ 29	\$ (50 )	\$137,548

In 2014, the Company sold its remaining auction rate security and received proceeds of \$1.8 million resulting in a realized gain of \$0.6 million, all of which resulted from reclassification adjustments out of accumulated other comprehensive loss in 2014.

#### *Marketable Securities – Unrealized Losses*

The Company owned 27 available-for-sale securities as of December 31, 2016. Of these 27 securities, 16 had combined unrealized losses of less than \$0.1 million as of December 31, 2016. The Company did not have any investments in a loss position for greater than 12 months as of December 31, 2016. The Company has evaluated its marketable securities and has determined that none of these investments has an other-than-temporary impairment, as it has no intent to sell securities with unrealized losses and it is not more likely than not that the Company will be required to sell any securities with unrealized losses, given the Company's current and anticipated financial position.

**Note 6 – Goodwill and Other Intangible Assets***Goodwill*

The changes in the carrying amounts of goodwill for the years ended December 31, 2016 and 2015 were as follows (in thousands):

	Year Ended December 31,	
	2016	2015
Beginning balance	\$53,065	\$54,612
Currency translation	(1,392 )	(1,547 )
Ending balance	\$51,673	\$53,065

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**Identifiable Intangible Assets**

Purchased intangible assets consisted of the following as of December 31, 2016 and 2015 (in thousands):

	December 31, 2016			December 31, 2015		
	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
Finite-lived intangible assets:						
Proprietary adjuvant technology	\$8,222	\$ (1,404)	) \$ 6,818	\$8,858	\$ (1,070)	) \$ 7,788
Collaboration agreements	3,713	(1,306)	) 2,407	3,999	(994)	) 3,005
Total identifiable intangible assets	\$11,935	\$ (2,710)	) \$ 9,225	\$12,857	\$ (2,064)	) \$ 10,793

Amortization expense for the years ended December 2016, 2015 and 2014 was \$0.8 million, \$0.9 million and \$1.1 million, respectively. Estimated amortization expense for existing intangible assets for each of the five succeeding years ending December 31, is as follows (in thousands):

Year	Amount
2017	\$ 793
2018	793
2019	793
2020	677
2021	472

**Note 7 – Collaboration, U.S. Government Agreement and Joint Venture****Bill & Melinda Gates Foundation Grant Agreement**

In support of the Company's development of its RSV F Vaccine for infants via maternal immunization, in September 2015, the Company entered into an agreement ("Grant Agreement") with BMGF, under which it was awarded a grant totaling up to \$89.1 million (the "Grant"). The Grant will support development activities, including the Company's global Phase 3 clinical trial in pregnant women in their third trimester, product licensing efforts and World Health Organization ("WHO") prequalification of the RSV F Vaccine. The Company concurrently entered into a Global Access Commitments Agreement ("GACA") with BMGF as a part of the Grant Agreement. Under the terms of the GACA, among other things, the Company agreed to make the RSV F Vaccine available and accessible at affordable pricing to

people in certain low and middle income countries. Unless terminated earlier by BMGF, the GACA will continue in effect until the latter of 15 years from its effective date, or 10 years after the first sale of a product under defined circumstances. The term of the GACA may be extended in certain circumstances, by a period of up to five additional years. Payments received under the Grant Agreement are being recognized in the period in which the research and development activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research and development activities are performed. Cash payments received under the Grant are restricted as to their use until expenditures contemplated in the Grant are incurred. The Company recognized revenue from the Grant of \$10.9 million in 2016, and has recognized approximately \$12.5 million in revenue since the inception of the contract. At December 31, 2016, the Company's current restricted cash and deferred revenue balances on the consolidated balance sheet represent its estimate of costs to be reimbursed and revenue to be recognized, respectively, in in the next twelve months under the Grant Agreement.

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

HHS BARDA initially awarded the Company a contract in 2011, which has funded the development of both the Company's quadrivalent seasonal and pandemic influenza virus-like particle ("VLP") vaccine candidates. The contract with HHS BARDA was a cost-plus-fixed-fee contract, which reimbursed the Company for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of its multivalent seasonal and monovalent pandemic H7N9 influenza VLP vaccine candidates. In September 2014, HHS BARDA exercised and initiated a two-year option to the contract, which included scope to support development activities leading up to planned Phase 3 clinical studies, added \$70 million of funding on top of the remainder of the \$97 million base period funding, and extended the contract until September 2016. 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. Advances in the Company's seasonal influenza nanoparticle program have resulted in a natural conclusion of its activities under the HHS BARDA contract, which expired in accordance with its terms in September 2016. During 2016, the Company recognized revenue of \$2.2 million, and has recognized approximately \$114 million in revenue since the inception of the contract. Billings under the contract are provisional billings, subject to adjustment upon audit by the government, and are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. These indirect rates are subject to audit by HHS BARDA on an annual basis. An audit of indirect rates of fiscal years 2013 and 2014 was completed in the first quarter of 2017. When the final determination of the additional costs for fiscal years 2013 and 2014 has been made, and such amount is known and collection of the amount is reasonably assured, revenue and billings will be adjusted accordingly.

***PATH Vaccine Solutions Clinical Development Agreement***

In 2012, the Company entered into a clinical development agreement with PATH to develop its RSV F Vaccine for infants via maternal immunization in certain low-resource countries. Under the terms of the PATH agreement, which expired in April 2015, the Company was awarded \$6.8 million by PATH to partially support Phase 2 clinical trials in women of childbearing age, reproductive toxicology studies and the development of a Phase 3 clinical trial strategy. The Company recognized revenue of \$0.5 million in 2015 and has recognized \$6.8 million in revenue since the inception of the agreement. Revenue under this arrangement was being 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 this agreement represented a reasonable measurement of proportional performance of the services being performed.

***CPLB Joint Venture***

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited (“Cadila”) named CPL Biologicals Private Limited (“CPLB”) to develop and manufacture vaccines, biological therapeutics and diagnostics in India. CPLB is owned 20% by the Company and 80% by Cadila. Because CPLB’s activities and operations are controlled and funded by Cadila, the Company accounts for its investment using the equity method. Since the carrying value of the Company’s initial investment was nominal and there is no guarantee or commitment to provide future funding, the Company has not recorded nor expects to record losses related to this investment in the foreseeable future. The Company has recognized as an expense the entire amount of purchases to date under the master services agreements related to CPLB as the Company has not recorded any equity income (loss) of CPLB (see Note 15).

## Note 8 – Other Financial Information

### *Prepaid Expenses and Other Current Assets*

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

	2016	2015
Laboratory supplies	\$15,736	\$12,968
Other prepaid expenses and other current assets	6,068	6,349
Prepaid expenses and other current assets	\$21,804	\$19,317

### *Property and Equipment, net*

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

	2016	2015
Machinery and equipment	\$32,596	\$26,461
Leasehold improvements	22,642	12,440
Computer software and hardware	4,285	3,091
Construction in progress	2,938	6,167
	62,461	48,159
Less accumulated depreciation and amortization	(22,277)	(15,817)
Property and equipment, net	\$40,184	\$32,342



Depreciation and amortization expense was approximately \$8.5 million, \$6.0 million and \$4.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

### *Accrued Expenses*

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

	2016	2015
Employee benefits and compensation	\$7,300	\$11,255
Research and development accruals	15,744	13,814
Other accrued expenses	1,464	1,665
Accrued expenses	\$24,508	\$26,734

### **Note 9 – Long-Term Debt**

#### *Convertible Notes*

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

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

In connection with the issuance of the Notes, the Company also paid \$38.5 million, including expenses, to enter into privately negotiated capped call transactions with certain financial institutions (the “capped call transactions”). The capped call transactions are generally expected to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of the Company’s common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. The cap price of the capped call transactions will initially be \$9.73 per share, which represented a premium of approximately 75% based on the last reported sale price of the Company’s common stock of \$5.56 per share on January 25, 2016, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company’s common stock, as measured under the terms of the capped call transactions, exceeds the cap price, there would nevertheless be dilution upon conversion of the Notes to the extent that such market price exceeds the cap price. The Company evaluated the capped call transactions under ASC 815-10, *Derivatives and Hedging - Overall* and determined that it should be accounted for as a separate transaction and that the capped call transactions will be classified as an equity instrument.

The Company incurred approximately \$10.0 million of debt issuance costs during the first quarter of 2016 relating to the issuance of the Notes, which were recorded as a reduction to the Notes on the consolidated balance sheet. The \$10.0 million of debt issuance costs is being amortized and recognized as additional interest expense over the 7 year contractual term of the Notes using the effective interest rate method. The Company also incurred \$0.9 million of expenses related to the capped call transactions, which were recorded as a reduction to additional paid-in-capital.

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

	December 31, 2016	December 31, 2015
Principal amount of Notes	\$ 325,000	\$
Unamortized debt issuance costs	(8,661	)
Total convertible notes payable	\$ 316,339	\$

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

	2016	2015
Coupon interest	\$11,240	\$
Amortization of debt issuance costs	1,305	
Total interest expense on Notes	\$12,545	\$

#### **Note 10 – Stockholders’ Equity**

In December 2016, the Company filed a \$200 million universal shelf registration statement that allows the Company to issue and sell common stock, preferred stock, warrants and/or units in one or more offerings up to an aggregate maximum offering amount of \$125 million and up to \$75 million in gross proceeds of its common stock pursuant to an At Market Issuance Sales Agreement, which the Company entered into in January 2017.

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

On June 18, 2015, the Company's stockholders of record as of April 20, 2015 approved the amendment to the Company's Amended and Restated Certificate of Incorporation (the "Charter Amendment") to increase the total number of shares of common stock that the Company is authorized to issue from 300,000,000 shares to 600,000,000 shares.

In March 2015, the Company completed a public offering of 27,758,620 shares of its 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 proceeds, net of offering costs of \$11.6 million, of approximately \$190 million.

In June 2014, the Company completed a public offering of 28,750,000 shares of its common stock, including 3,750,000 shares of common stock that were issued upon the exercise in full of an option to purchase additional shares granted to the underwriters, at a price of \$4.00 per share resulting in proceeds, net of offering costs of \$7.1 million, of approximately \$108 million.

In 2012, the Company entered into an At Market Issuance Sales Agreement ("2012 Sales Agreement"), under which Company sold an aggregate of \$50 million in gross proceeds of its common stock. During 2015, the Company sold 1.4 million shares at an average sales price of \$10.63 per share, resulting in \$14.6 million in net proceeds. The 2012 Sales Agreement was fully utilized at that time.

**Note 11 – Stock-Based Compensation***Stock Options*

The Amended and Restated 2005 Stock Incentive Plan (“2005 Plan”) expired in February 2015 and no new awards may be made under such plan, although awards will continue to be outstanding in accordance with their terms. The Board adopted the 2015 Stock Incentive Plan (“2015 Plan”) in March 2015, which was approved at the Company’s annual meeting of stockholders in June 2015. Under the 2015 Plan, equity awards may be granted to officers, directors, employees and consultants of and advisors to the Company and any present or future subsidiary.

The 2015 Plan authorizes the issuance of up to 31,000,000 shares of common stock under equity awards granted under the plan, including an increase of 6,000,000 shares approved at the Company’s 2016 annual meeting of stockholders. All such shares authorized for issuance under the 2015 Plan have been reserved. The 2015 Plan will expire on March 4, 2025.

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

*Stock Options Awards*

The following is a summary of option activity under the 2015 Plan and the 2005 Plan for the year ended December 31, 2016:

	2015 Plan	Weighted-	2005 Plan	Weighted-
	Stock	Average	Stock	Average
	Options	Exercise	Options	Exercise
		Price		Price
Outstanding at January 1, 2016	8,357,003	\$ 8.97	15,450,542	\$ 3.31

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Granted	19,343,937	\$ 3.37	—	\$ —
Exercised	—	\$ —	(701,663 )	\$ 2.14
Canceled	(2,596,337 )	\$ 6.85	(620,750 )	\$ 4.80
Outstanding at December 31, 2016	25,104,603	\$ 4.87	14,128,129	\$ 3.30
Vested and expected to vest at December 31, 2016	22,625,915	\$ 5.06	14,075,419	\$ 3.29
Shares exercisable at December 31, 2016	2,417,574	\$ 8.50	10,643,754	\$ 2.86
Shares available for grant at December 31, 2016	5,850,397			

The fair value of stock options granted under the 2015 Plan and 2005 Plan was estimated at the date of grant or the date upon which the 2015 Plan was approved by the Company's stockholders for stock options granted prior to that time using the Black-Scholes option-pricing model with the following assumptions:

	<b>2016</b>	<b>2015</b>	<b>2014</b>
Weighted average fair value of options granted	\$1.88	\$4.38	\$2.39
Risk-free interest rate	0.97%-1.78%	1.19%-2.13%	1.24%-2.22%
Dividend yield	0%	0%	0%
Volatility	57.86%-108.88%	53.58%-68.39%	52.47%-67.93%
Expected term (in years)	4.22-7.28	3.98-7.34	4.04-6.96
Expected forfeiture rate	0%-16.33%	0%-16.33%	0%-23.15%

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

The total aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable under the 2015 Plan and 2005 Plan as of December 31, 2016 was less than \$0.1 million and 5.8 years, respectively. The total aggregate intrinsic value and weighted-average remaining contractual term of stock options vested and expected to vest under the 2015 Plan and 2005 Plan as of December 31, 2016 was less than \$0.1 million and 7.9 years, respectively. The aggregate intrinsic value represents the total intrinsic value (the difference between the Company’s closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2016. This amount is subject to change based on changes to the closing price of the Company’s common stock. The aggregate intrinsic value of options exercised and vesting of restricted stock awards for 2016, 2015 and 2014 was \$2.4 million, \$9.7 million and \$3.4 million, respectively.

### ***Employee Stock Purchase Plan***

In 2013, the Company adopted an Employee Stock Purchase Plan (the “ESPP”), which currently authorizes an aggregate of 3,300,000 shares of common stock to be purchased, and the aggregate amount of shares will continue to increase 5% on each anniversary of its adoption up to a maximum of 4,000,000 shares. The number of authorized shares and the maximum number of shares both include an increase of 1,000,000 shares approved at the Company’s 2016 annual meeting of stockholders. The ESPP allows employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15% of their compensation, at 85% of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period (or, if later, the date during the option period when the employee was first eligible to participate). At December 31, 2016, there were 1,636,938 shares available for issuance under the ESPP.

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

	<b>2016</b>	<b>2015</b>	<b>2014</b>
Range of Black-Scholes fair values of ESPP shares granted	\$1.86-\$4.76	\$1.06-\$3.38	\$0.78-\$2.08
Risk-free interest rate	0.22%-0.61%	0.05%-0.35%	0.04%-0.24%
Dividend yield	0%	0%	0%
Volatility	43.03%-86.75%	40.79%-64.24%	50.80%-67.57%

Expected term (in years)	0.5-2.0	0.5-2.0	0.5-1.5
Expected forfeiture rate	5%	5%	5%

***Restricted Stock Awards***

The following is a summary of restricted stock awards activity for the year ended December 31, 2016:

	Number of Shares	Per Share Weighted- Average Grant-Date Fair Value
Outstanding and Unvested at January 1, 2016	25,000	\$ 8.72
Restricted stock granted	45,000	\$ 4.99
Restricted stock vested	—	\$ —
Restricted stock forfeited	(25,000 )	\$ 8.72
Outstanding and Unvested at December 31, 2016	45,000	\$ 4.99



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

	Years ended December 31,		
	2016	2015	2014
Research and development	\$11,168	\$6,771	\$2,843
General and administrative	7,992	6,660	3,247
Total stock-based compensation expense	\$19,160	\$13,431	\$6,090

As of December 31, 2016, which is prior to the adoption of ASU 2016-09 (see Note 3), there was approximately \$43.6 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested stock options, ESPP and restricted stock awards. This unrecognized non-cash compensation expense is expected to be recognized over a weighted-average period of 1.5 years, and will be allocated between research and development and general and administrative expenses accordingly. This estimate does not include the impact of other possible stock-based awards that may be made during future periods.

#### **Note 12 – Employee Benefits**

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

The Company matches 100% of the first 3% of the participants' deferral, and 50% on the next 2% of the participants' deferral, up to a potential 4% Company match. The Company's matching contributions to the 401(k) plan vest immediately. The Company has recorded expense of approximately \$1.5 million, \$0.8 million and \$0.5 million in 2016, 2015 and 2014, respectively.

The Company's foreign subsidiary has a pension plan under local tax and labor laws and is obligated to make contributions to this plan. Contributions and other expenses related to this plan were approximately \$0.5 million, \$0.5 million and \$0.4 million in 2016, 2015 and 2014, respectively.

#### **Note 13 – Income Taxes**

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

	2016	2015	2014
Domestic	\$(273,134)	\$(150,227)	\$(76,742)
Foreign	(6,832 )	(6,710 )	(6,205 )
Total net loss	\$(279,966)	\$(156,937)	\$(82,947)

As a result of current and historical losses, there is no income tax provision for the years ended December 31, 2016, 2015 and 2014.

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

	2016	2015
Net operating losses U.S.	\$286,619	\$203,284
Net operating losses foreign	9,011	8,360
Research tax credits	23,260	16,491
Deferred revenue	10,121	922
Original discount interest	12,445	
Other	17,981	11,981
Total deferred tax assets	359,437	241,038
Intangibles	(2,090 )	(2,415 )
Other	(2,817 )	(1,767 )
Total deferred tax liabilities	(4,907 )	(4,182 )
Net deferred tax assets	354,530	236,856
Less valuation allowance	(354,530)	(236,856)
Deferred tax assets, net	\$—	\$—

The valuation allowance increased by \$117.7 million, \$63.9 million and \$30.4 million for the years ended December 31, 2016, 2015 and 2014, respectively, due to increases in net deferred tax assets.

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

	2016	2015	2014
Statutory federal tax rate	(34 )%	(34 )%	(34 )%
State income taxes, net of federal benefit	(3 )%	(3 )%	(3 )%
Research and development and other tax credits	(2 )%	(3 )%	(2 )%
Release of FIN 48 liability	0 %	(2 )%	0 %
Other	2 %	1 %	2 %
Change in valuation allowance	37 %	41 %	37 %
	0 %	0 %	0 %

Realization of net deferred tax assets is dependent on the Company's ability to generate future taxable income, which is uncertain. Accordingly, a full valuation allowance was recorded against these assets as of December 31, 2016 and 2015 as management believes it is more likely than not that the assets will not be realizable. The increase in the valuation allowance was due to increased continued losses and credits in the current year.

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As of December 31, 2016, the Company had tax return reported federal net operating losses and tax credits available as follows (in thousands):

	Amount
Federal net operating losses expiring through the year 2036	\$781,019
Foreign net operating losses (no expiration)	40,957
Research tax credits expiring through the year 2036	23,166
Alternative-minimum tax credit (no expiration)	94

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

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## Tabular Reconciliation of Unrecognized Tax Benefits (in thousands):

	Amount
Unrecognized tax benefits as of January 1, 2015	\$ 4,801
Gross increases — tax positions in prior period	
Gross decreases — tax positions in prior period	4,587
Gross increases — current-period tax positions	—
Increases (decreases) from settlements	—
Unrecognized tax benefits as of December 31, 2015	\$ 214
Gross increases — tax positions in prior period	—
Gross decreases — tax positions in prior period	214
Gross increases — current-period tax positions	—
Increases (decreases) from settlements	—
Unrecognized tax benefits as of December 31, 2016	\$ —

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

The Company files income tax returns in the U.S. federal jurisdiction and in various states, as well as in Sweden. The Company had tax net operating losses and credit carryforwards that are subject to examination from 1998 through 2016. The statute extends for a number of years beyond the year in which the losses were generated for tax purposes. Since a portion of these carryforwards may be utilized in the future, many of these attribute carryforwards remain subject to examination. The returns in Sweden are subject to examination from 2010 through 2016.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2016 and 2015, the Company had no accruals for interest or penalties related to income tax matters.

**Note 14 – Commitments and Contingencies*****Operating Leases***

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The Company conducts its operations from leased facilities, under operating leases with terms expiring through 2030, unless terminated early at the Company's discretion through 2026. The leases contain provisions for future rent increases and periods in which rent payments are reduced (abated). Also, the leases obligate the Company to pay building operating costs. In May 2016, the Company signed a new lease for a facility of approximately 150,000 square feet located in Gaithersburg, Maryland with a term expiring in 2030, unless terminated early by the Company in 2026. Under the terms of the lease, the landlord shall provide the Company with a tenant improvement allowance of up to \$9.6 million, none of which has been funded as of December 31, 2016. In addition, the Company extended its Rockville, Maryland lease with a term expiring in 2020, unless terminated early by the Company in 2019. Novavax AB also extended its lease in Uppsala, Sweden with a term expiring in 2026, unless terminated early by the Company in 2023. The Company records a deferred rent liability to account for the funding under the improvement allowance and to record rent expense on a straight-line basis for these operating leases.

Future minimum rental commitments under non-cancelable leases as of December 31, 2016 are as follows (in thousands):

Year	<b>Operating Leases</b>
2017	\$ 6,986
2018	10,290
2019	9,124
2020	8,690
2021	8,865
Thereafter	37,360
Total minimum lease payments	\$ 81,315

Total rent expenses approximated \$7.0 million, \$4.2 million and \$3.6 million for the years ended December 31, 2016, 2015 and 2014, respectively.

### *Contingencies*

In 2007, the Company entered into an agreement to license certain rights from Wyeth Holdings Corporation, a subsidiary of Pfizer Inc. (“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 the Company 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 the Company continuously markets 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, the Company’s seasonal influenza VLP vaccine program (including CPLB’s seasonal influenza program) and its 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 the Company only after it has provided ninety (90) days’ notice that the Company has 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, the Company entered into an amendment to 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, which may increase slightly over time, would 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, the Company 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, 2016 aggregated to \$7.6 million. At the time of September 2015 amendment discussed above, the Milestone was 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, and at December 31, 2016, the Milestone is recorded in accrued expenses. The Milestone was recorded as a research and development expense in 2014.

### **Note 15 – Related Party Transactions**

Dr. Rajiv Modi, a director of the Company, is also the managing director of Cadila. The Company and Cadila have formed a joint venture, CPLB (see Note 7). A subsidiary of Cadila owns 2.5 million shares of the Company’s outstanding common stock as of December 31, 2016. The Company and Cadila have also entered into master services

agreements, pursuant to which Cadila or CPLB may perform certain research, development and manufacturing services for the Company. For 2016 and 2015, the Company incurred \$0.4 million and \$2.2 million, respectively, in expenses under the master services agreements. The amount due and unpaid for services performed under the master services agreements at December 31, 2016 and 2015 was \$0.1 million and \$0.7 million, respectively.

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**Note 16 – Quarterly Financial Information (Unaudited)**

The Company's unaudited quarterly information for the years ended December 31, 2016 and 2015 is as follows:

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
2016:				
Revenue	\$4,218	\$2,505	\$ 3,231	\$ 5,399
Net loss	\$(77,252)	\$(79,351)	\$ (66,254 )	\$ (57,109 )
Net loss per share	\$(0.29 )	\$(0.29 )	\$ (0.24 )	\$ (0.21 )

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
2015:				
Revenue	\$9,877	\$13,996	\$ 6,525	\$ 5,853
Net loss	\$(24,370)	\$(20,641)	\$ (33,120 )	\$ (78,806 )
Net loss per share	\$(0.10 )	\$(0.08 )	\$ (0.12 )	\$ (0.29 )

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