

NOVAVAX INC  
Form 10-K  
March 12, 2013

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, 2012**

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                      9920 Belward Campus Drive,                      22-2816046**  
**Rockville, Maryland 20850**  
*(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

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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 29, 2012 on the NASDAQ Global Select Market) was \$185,200,000.

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As of March 4, 2013, there were 147,944,817 shares of the Registrant's common stock outstanding.

Portions of the Registrant's Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2012 in connection with the Registrant's 2013 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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

PART I

**Item 1. BUSINESS**

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

**Program Overview**

Novavax, Inc. (“Novavax,” the “Company,” “we” or “us”) is a clinical-stage biopharmaceutical company focused on developing recombinant protein nanoparticle vaccines to address a broad range of infectious diseases. Our technology platform is based on proprietary recombinant vaccine technology that includes virus-like particles (VLPs) and recombinant protein micelle vaccines. Our vaccine candidates are genetically engineered three-dimensional nanostructures, which incorporate immunologically important recombinant proteins. Our product pipeline targets a variety of infectious diseases and our vaccine candidates are currently in or have completed clinical trials that target seasonal influenza, pandemic (H5N1) influenza, and respiratory syncytial virus (RSV). Further, CPL Biologics Private Limited (the JV), our joint venture company in India, is actively developing a number of vaccine candidates that were genetically engineered by Novavax; its seasonal and pandemic influenza candidates began Phase I clinical trials in 2012, and its rabies vaccine candidate is expected to begin a Phase I clinical trial in India in 2013.

*Influenza Vaccines*

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

- eight clinical trials for our seasonal and pandemic influenza vaccine candidates;

administering our seasonal and pandemic influenza VLPs (multiple distinct strains, including both influenza A and B and strains of avian and swine origin) to approximately 5,000 subjects demonstrating vaccine tolerability and immunogenicity;

- fifty (50) distinct batches of VLP vaccine produced under current good manufacturing practices (cGMP); and
- scaled up vaccine production to 1,000 liter single-use bioprocessing capacity.

We believe our influenza VLP vaccines have potential immunological advantages over currently available products because our influenza VLPs contain three of the major structural virus proteins that are important for fighting influenza: hemagglutinin (HA) and neuraminidase (NA), both of which stimulate the body to produce antibodies that neutralize the influenza virus and prevent its spread through the cells in the respiratory tract, and matrix 1 (M1), which stimulates cytotoxic T lymphocytes to kill cells that may already be infected. Our VLPs are not made from live viruses and have no genetic nucleic material in their inner core, which render them incapable of replicating and causing disease.

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

Our current influenza vaccine candidates, both seasonal and pandemic (H5N1), are being developed with a goal of seeking accelerated approval by the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA). The FDA has published criteria for granting accelerated approval of a Biologics License Application (BLA, the biologic equivalent to a New Drug Application or NDA) for a new seasonal influenza vaccine. FDA guidance allows developers to demonstrate results that meet or exceed certain specified endpoint criteria in their clinical trials; at the FDA's discretion, such vaccines may be granted a license to market prior to conducting a traditional efficacy clinical trial. In adult populations under 65 years of age, these criteria are based on demonstration of seroconversion rates (the proportion of subjects with a four-fold rise in HAI titers or attaining titers of  $\geq 1:40$  from a negative baseline) and seroprotection rates (the proportion of subjects with HAI titers  $\geq 1:40$  post-vaccination) that are  $\geq 40\%$  and  $\geq 70\%$ , respectively, at the lower of the 95% confidence interval of the estimate. Accelerated approval may be available as long as there is a shortage of seasonal influenza vaccine relative to the total population recommended by the FDA's Advisory Committee for Immunization Practices to receive the vaccine, a situation that persists. FDA expects that developers seeking accelerated approval of a BLA will diligently conduct post-marketing efficacy studies. Novavax continues to use and reference these accelerated approval seroconversion and seroprotection endpoints in developing its seasonal influenza vaccine candidates. FDA has articulated the same immunogenicity criteria for accelerated approval of vaccines that address potential pandemic influenza strains. Because controlled efficacy trials of pandemic vaccine candidates are not logistically or ethically possible, vaccine developers seeking accelerated approval of a pandemic vaccine candidate will be required to provide evidence that a seasonal vaccine made by the same manufacturing process is efficacious. Thus, the demonstration of efficacy with a seasonal vaccine product provides a key link between the seasonal and pandemic programs.

### Seasonal Influenza Vaccine

The Advisory Committee for Immunization Practices of the Center for Disease Control and Prevention (CDC) recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with this universal recommendation, attention from the 2009 influenza A/H1N1 pandemic has increased public health awareness of the importance of seasonal influenza vaccination, the market for which is expected to continue to grow worldwide in both developed and developing global markets.

In the coming years, many seasonal influenza vaccines are expected to be produced in a quadrivalent formulation (four influenza strains, two influenza A strains and two influenza B strains), as opposed to the current trivalent formulation (two influenza A strains and one influenza B strain). With two distinct lineages of influenza B viruses circulating, governmental health authorities have advocated for the addition of a second influenza B strain to provide added coverage. Current estimates for seasonal influenza vaccines growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from the current market of approximately \$3.6 billion to \$4.7 billion over the next ten years<sup>1</sup>. Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage: once licensed for commercial sale, large quantities of vaccine can be quickly and cost-effectively manufactured without use of either the live influenza virus or eggs.



Top-line data from our most recent Phase II clinical trial for our quadrivalent influenza vaccine candidate were announced in July 2012. In that clinical trial, our quadrivalent VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, and was also well-tolerated with no vaccine-related serious adverse events observed and had acceptable reactogenicity. Our vaccine candidate met the FDA accelerated approval seroprotection rates criterion for all four viral strains. The potential to fulfill the seroconversion rates criterion was demonstrated for three of the four viral strains. The fourth strain, B/Brisbane/60/08, despite fulfilling the seroprotection criterion, failed to demonstrate a satisfactory seroconversion rate. Our activities with respect to our seasonal influenza vaccine candidate have been, and are, focused on identifying the manufacturing process to ensure consistent and enhanced immune responses in all strains. Over the last six months we've made significant progress and expect to finalize our manufacturing process by mid-year 2013. During the second half of 2013, we expect to begin manufacturing product for our next Phase II clinical trial.

<sup>1</sup> Market Forecasts: Seasonal Influenza Vaccines. Datamonitor (2012)

Pandemic Influenza Vaccine

Pandemic influenza refers to a situation where there is a significant disease outbreak in humans resulting from an influenza virus for which the majority of the population has little or no immunity. Pandemic influenza strains are a major concern to world health groups because such diseases can quickly and easily spread worldwide and can cause serious illness or death before vaccines are available to limit the spread of the disease. There have been notorious examples of pandemic influenza crises; in 2009, the World Health Organization (WHO) declared a pandemic of the H1N1 strain of influenza. In the aftermath of the 2009 H1N1 influenza pandemic, recognition of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 pandemic led to the production of approximately 126 million doses of monovalent (single strain) vaccine. Public health awareness and government preparedness for the “next” potential influenza pandemic is driving development of vaccines that can be quickly manufactured against a potentially threatening influenza strain.

Our own activities during the 2009 H1N1 pandemic have provided valuable experience in developing our current pandemic (H5N1) influenza vaccine program. During the H1N1 pandemic, we successfully demonstrated our ability to develop a vaccine by producing a first batch of non-cGMP H1N1 vaccine that was made available to the CDC for analysis three (3) weeks after the genetic sequence was released, followed by manufacturing of our cGMP H1N1 vaccine eleven (11) weeks after the sequence release. Additionally, our H1N1 vaccine exceeded immunogenicity criteria for licensure at all dose levels, including the lowest 5µg dose. Thus, while H1N1 influenza is no longer a pandemic strain, and industry and health experts have focused on developing monovalent H5N1 avian influenza vaccines as a potential key defense against the next pandemic threat, many of our H1N1 vaccine activities and results are readily translatable to our current pandemic (H5N1) influenza vaccine development.

During 2012, we made significant progress in the development of our pandemic (H5N1) influenza vaccine. In May 2012, we launched two Phase I clinical trials of our H5N1 vaccine candidate in combination with two different adjuvants, both of which are designed to improve the immunogenicity of vaccines at lower doses and thus provide antigen dose-sparing. These clinical trials evaluated the safety and tolerability of the vaccines and the ability of VLP vaccine antigens with and without adjuvants to generate antibody levels that fulfill the FDA’s criteria for accelerated approval, and the ability of these vaccines to provide an expanded number of doses, with possible cross-protection against other virus strains to the U.S. population. In October 2012, we reported positive results from these clinical trials with top-line data demonstrating safety and immunogenicity of varying dose-levels of the vaccine, with and without adjuvant, and further demonstrating statistically significant robust adjuvant effects on immune response. Notably, our unadjuvanted vaccine candidate elicited HAI titers  $\geq 40$  in  $>82\%$  of subjects at a dose of 45µg. This response would fulfill the FDA’s influenza criteria for accelerated approval of a BLA as further described under the heading “Influenza Vaccines” above.

HHS BARDA Contract for Recombinant Influenza Vaccines

The Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA) awarded us a contract in February 2011 which funds the development of both our seasonal and pandemic influenza vaccine candidates. The contract, valued at \$97 million for the first three-year base-period and \$82 million for an HHS BARDA optional two-year period, is a cost-plus-fixed-fee contract in which HHS BARDA reimburses us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines. We recognized revenue of approximately \$20.1 million in 2012, and have recognized approximately \$34.8 million in revenue since the inception of the contract in 2011.

In December 2012, HHS BARDA completed a contractually-defined In-Process Review (IPR) of our contract. This IPR was conducted by an inter-governmental-agency panel of experts from government agencies including HHS BARDA, FDA, CDC and the National Institutes of Health, who provided input on our progress during the contract base-period and plans for further development, including both near-term process development and manufacturing activities and longer-term clinical efforts. HHS BARDA subsequently notified us in January 2013 that the milestone decision had been made to continue to support our vaccine advanced development contract.

Respiratory Syncytial Virus (RSV)

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

We are developing a vaccine candidate to prevent RSV and are looking at susceptible target populations that include the elderly, young children, and newborns who may receive protection through antibodies transferred from their mothers, who may be immunized during the last trimester of pregnancy. In October 2011, we announced the results of our first Phase I clinical trial to assess the safety and tolerability of our RSV vaccine candidate, and to evaluate total and neutralizing anti-RSV antibody responses and the impact of an aluminum phosphate adjuvant. Along with positive safety results, the antibody response to the RSV F protein was significantly increased compared to placebo ( $p < 0.001$ ) in all doses groups and increased by 19-fold in the highest-dose adjuvant group at day 60. A significant dose-response pattern was observed with high rates of seroconversion at all doses including a rate of 100% at the highest-dose-adjuvant group. In October 2012, we initiated two separate dose-ranging clinical trials, one in women of child bearing age, which initiates our goal of developing a vaccine for maternal immunization of pregnant women, and the other in elderly adults, which initiates our goal of developing a vaccine for the elderly. The first clinical trial is a randomized, blinded, placebo-controlled Phase II clinical trial that will evaluate the safety and immunogenicity of two dose levels of our RSV vaccine candidate with and without an aluminum phosphate adjuvant, enrolling 330 women of childbearing age. The second clinical trial is a randomized, blinded, placebo-controlled Phase I clinical trial that will evaluate the safety and immunogenicity results of 220 enrolled adults, 60 years of age and older, who received a single intramuscular injection of our RSV vaccine candidate (with and without an aluminum phosphate adjuvant) or placebo plus a single dose of licensed influenza vaccine or placebo at days 0 and 28. Top-line results from both clinical trials are expected to be reported in the first half of 2013. The design and timing of subsequent clinical trials will be determined after these data are analyzed. Our expected path forward in maternal immunization would include a dose-confirmation clinical trial in women of child-bearing age. In parallel, and in consultation with the FDA, we would expect to initiate a reproductive toxicology study to confirm the safety of our proposed formulation in advance of vaccinating pregnant women. For the elderly, the path forward would likely be to design a Phase II clinical trial.

Rabies

Rabies is a disease that causes acute encephalitis, or swelling of the brain, in warm-blooded animals, including humans. The disease can be transmitted from one species of animal to another, such as from dogs to humans, most commonly by a bite from an infected animal. For humans, rabies left untreated is almost invariably fatal. WHO has estimated that the highest public health financial expenditure in any country is the cost of rabies post-exposure

prophylaxis.<sup>3</sup> In Asia and Africa, estimates show a combined 55,000 annual human deaths from endemic canine rabies, with annual treatment costs approaching \$600 million, although human deaths from rabies may be underreported in a number of countries, particularly in the youngest age groups. In India alone, 20,000 deaths are estimated to occur annually. Internal market data of vaccine manufacturers suggest that at the global level,  $\geq 15$  million people receive rabies prophylaxis annually, the majority of whom live in China and India. It is estimated that in the absence of post-exposure prophylaxis, about 327,000 persons would die from rabies in Asia and Africa each year. Marketed rabies vaccine is mostly used for post-exposure prophylaxis that requires generally between four and five administrations of vaccine. Pre-exposure prophylaxis is recommended for anyone who will be at increased risk to the rabies virus, including travelers with extensive outdoor exposure in rural high-risk areas.<sup>4</sup>

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

<sup>3</sup> WHO Technical Report Series (2004)

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

The JV is currently developing a rabies vaccine candidate that we genetically engineered. The JV expects to initiate a Phase I clinical trial in India in 2013. The JV's objective is to develop a recombinant vaccine that can be administered as a pre-exposure prophylaxis for residents of certain higher-risk geographies, as well as travelers to such locations, and with the potential to provide post-exposure prophylaxis with fewer doses. Preliminary pre-clinical results indicate that this vaccine candidate may successfully prevent the rabies virus from entering the central nervous system and, thus, prevent death.

#### Foot-and-Mouth Disease (FMD)

In October 2011, we were awarded a \$1.3 million contract with the U.S. Department of Homeland Security to fund the development of a VLP vaccine countermeasure to protect the U.S. from foot-and-mouth disease (FMD), a highly contagious viral disease of livestock and a potential threat to U.S. agriculture. The Company is using these funds to develop a Novavax recombinant VLP-based vaccine which, unlike current FMD vaccines, would not require the use of infectious FMD virus to be manufactured. If successful, this would address the potential risk of releasing infectious virus during vaccine production and stockpiling in the U.S. or other FMD-free countries.

#### **Vaccine Platform Technologies**

We believe that our platform technology offers time-saving advantages both in terms of production time against traditional egg-base vaccine manufacturing, but also in terms of establishing a vaccine production facility (either as a new green-field project or through a retrofit of an existing facility). Currently approved influenza vaccines are typically produced by growing virus in chicken eggs, from which the virus is extracted and further processed. This 50-year-old egg-based production method requires four to six months of lead time for production of a new strain of virus and significant investment in fixed production facilities. Moreover, there can be additional delays because manufacturers must modify the selected influenza virus strain in order for it to be produced efficiently in the egg. The vaccine shortage during the 2004 influenza season (caused in part by a contamination issue at a facility in the United Kingdom) highlighted the limitations of current production methods and the need for increased vaccine manufacturing capacity. It also heightened concerns regarding manufacturers' capacity to respond to a pandemic, when the number of vaccine doses required will be higher than the number required for seasonal influenza vaccines and manufacturing lead times will be even shorter. This concern was borne out again in the 2009 H1N1 influenza pandemic as, "despite an intensive effort to develop a pandemic vaccine, the 2009 H1N1 vaccine arrived too late to have a significant effect on the dynamics of the fall disease wave."<sup>9</sup> Compared with traditional vaccine production, we believe our processes allow for faster production of vaccine. Because our process uses genetic information and not the virus itself, we can quickly construct clones of the virus as soon as the genetic information is available. This factor alone can shorten the time for creating new vaccine by several weeks compared to traditional egg-based manufacturing.

Importantly, we also believe that a manufacturing facility that produces our vaccines can be implemented and validated in significantly less time than traditional cell-based vaccine manufacturing facilities and without the costly

containment features associated with handling live viruses. We produce our vaccine candidates using a baculovirus expression system in insect cells with low-cost equipment that can be readily deployed both nationally and internationally. By not requiring significant production batch sizes, production capacity can be employed quickly. We estimate the time to qualify a facility that utilizes our processes can be six to nine months faster than a fixed-pipe bioreactor facility used in cell-based manufacturing.

### *Virus-Like Particles*

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

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

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

#### Recombinant Protein Micelle Vaccines

Our recombinant protein micelle vaccine technology is also based on self-assembling protein structures, which differ from traditional VLPs in that these particles do not generally occur in nature and can be made from proteins from any pathogenic organism including viruses, bacteria, parasites or even cancer cells. Protein micelle nanoparticles closely resemble the natural structure of surface antigens of disease organisms, but lack the genetic material required for replication and therefore are not infectious. An advantage of this technology is that the formation of nanoparticles is done *in vitro* thereby making it possible to assemble nanoparticles from one or more highly purified proteins. This results in high purity vaccines with certain manufacturing advantages over more traditional products. Potential immunological advantages of protein micelle vaccines are presentation of epitopes (antibody binding sites) in a more native configuration for improved efficacy, efficient recognition by the immune system's antigen presenting cells (APCs) and triggering robust immune responses. Recognition of the nanoparticle vaccine's repeating protein patterns by the APCs toll-like receptors to stimulate innate immunity and the high purity and lack of synthetic material adds to the potential safety of recombinant nanoparticle vaccines. Recombinant protein micelle vaccine technology has expanded our early-stage vaccines in development to include both virus and non-virus disease targets. Our most advanced recombinant protein micelle vaccine candidate is our RSV fusion (F) protein vaccine candidate, which is manufactured from highly purified F protein.

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

The biopharmaceutical industry and the vaccine market are intensely competitive and are characterized by rapid technological progress. Our technology is based upon utilizing the baculovirus expression system in insect cells to make VLPs and recombinant protein micelle vaccines. We believe this system offers many advantages when compared to other technologies and is uniquely suited for developing seasonal and pandemic influenza vaccines, as well as other infectious diseases, including our vaccine candidate against RSV.



There are a number of companies developing and selling vaccines for seasonal and pandemic influenza employing historic vaccine technology, as well as new technologies. The table below provides a list of major vaccine competitors and corresponding licensed influenza vaccine technologies.

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

There are many seasonal influenza vaccines currently approved and marketed, and most of these are marketed by major pharmaceutical companies that have significantly greater financial and technical resources, experience and expertise than we have. Competition in the sale of these seasonal influenza vaccines is intense. Therefore, newly developed and approved products must be differentiated from existing vaccines in order to have commercial success. In order to show differentiation in the seasonal influenza market, a product should be more efficacious and/or be less expensive and quicker to manufacture. Many of our competitors are working on new products and new generations of current products, some by adding an adjuvant that is used to increase the immunogenicity of that product, each of which is intended to be more efficacious than currently marketed products. Another differentiating factor is recombinant manufacturing, which we believe can be quicker and less-expensive than traditional egg-based manufacturing. In January 2013, the FDA approved the first recombinant seasonal influenza vaccine called “Flublok” manufactured by Protein Sciences Corporation.

Despite the significant competition and advancing technologies, some of which are similar to our own, we believe that our seasonal influenza product will be as efficacious as, or more so than, current products or products being developed by our competitors, and that our manufacturing system provides savings in both time and money; however, there can be no guarantee that our seasonal influenza vaccine will prove to be efficacious or that our manufacturing system will prove to be sufficiently differentiated to ensure commercial success.

Unlike influenza, there is no currently 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 to prevent disease caused by RSV. 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 virus-like particle technologies. Although early in clinical development, we believe that our RSV vaccine candidate, which utilizes recombinant F-protein antigens, could be more effective than RSV vaccine candidates in development by our competitors; however, such efficaciousness cannot be guaranteed. Although we aren't aware of all our competitors efforts, we believe that MedImmune, a subsidiary of AstraZeneca PLC, has the most advanced RSV vaccine program, as it has reported testing in Phase I clinical trials, 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 general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also depends upon our ability to show differentiation with a product that is more efficacious, particularly in the relevant target populations and/or be less expensive and quicker to manufacture. It also depends upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often substantial period between technological conception and commercial sale.

## Patents and Proprietary Rights

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

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

*Patent rights; licenses.* We have intellectual property (patents, licenses, know-how) related to our vaccines, manufacturing process and other technologies. Currently, we have or have rights to over 100 U.S. patents and corresponding foreign patents and patent applications relating to vaccines and biologics. Our core vaccine-related intellectual property extends beyond the year 2025.

In July 2007, we entered into a non-exclusive license agreement with Wyeth Holdings Corporation, a subsidiary of Pfizer Inc. (Wyeth), to obtain rights to a family of patents and patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022.

In July 2010, U.S. Patent No. 7,763,450 for Functional Influenza Virus-Like Particles was issued by the U.S. Patent & Trademark Office. The patent covers, in part, the use of influenza gene sequences for high-yield production of consistent influenza VLP vaccines to protect against current and future seasonal and pandemic strains of influenza viruses. In December 2011, European Patent No. 1644037 was issued by the European Patent Office covering this technology.

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, a method 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.

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

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

## **Government Regulations**

The development, production and marketing of biological products, which included the vaccine candidates being developed by Novavax or our collaborators, are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. As a U.S. based company, we focus on the U.S. regulatory process and the standards imposed by the FDA and other agencies because we believe, for the most part, meeting U.S. standards will allow us to meet other international standards and satisfy regulatory agencies in other countries where we intend to do business. In the U.S., the development, manufacturing and marketing of human pharmaceuticals and vaccines are subject to extensive regulation under the Federal Food, Drug, and Cosmetic Act, and biological products are subject to regulation under provisions of that Act and the Public Health Service Act. The FDA not only assesses the safety and efficacy of these products but it also regulates, among other things, the testing, manufacture, labeling, storage, record-keeping, advertising and promotion of such products. The process of obtaining FDA approval for a new vaccine is costly and time-consuming.

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

During the FDA's review of a BLA, the proposed manufacturing facility undergoes a pre-approval inspection during which the FDA examines in detail the production of the vaccine as it is in progress. Vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public. Until a vaccine is given to the general population, all potential adverse events cannot be anticipated. Thus, many vaccines are required by the FDA to undergo Phase IV confirmatory clinical trials after the BLA has been approved and the vaccine is on the market.

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

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

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

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, can considerably shorten the time development time leading up to FDA approval. 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 verify and describe its clinical benefit in Phase IV confirmatory clinical trials. Based on commentary from the FDA, we expect that our seasonal influenza vaccine candidate should qualify for accelerated approval using surrogate endpoints described in published FDA guidance documents. We would thus expect to perform Phase IV confirmatory clinical trials that will

demonstrate the clinical benefit of our seasonal influenza vaccine candidate after the BLA is approved. However, there can be no guarantee that the FDA will grant accelerated approval of our seasonal influenza vaccine candidate.

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

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

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

## **Manufacturing**

In November 2011, we announced that we had entered into a long-term lease arrangement to occupy 74,000 square feet of manufacturing, laboratory and office space in two facilities in Gaithersburg, Maryland. The main facility, located at 20 Firstfield Road in Gaithersburg, Maryland, will become the primary commercial-scale manufacturing facility for production of our vaccines in 2013, following modifications that were completed in late 2012 and validation occurring in 2013. Also in 2013, our corporate offices will relocate to the same campus at 22 Firstfield Road.

Our current 10,000 square foot cGMP pilot facility produces clinical trial material at our current corporate headquarters in Rockville, Maryland. Construction for the pilot plant facility was completed in 2007, within 120 days of ground breaking. The total cost of the project, including demolition, construction and installation of laboratory and production equipment, was approximately \$5 million. The facility had existing mechanical systems in place that were not included in the total cost. We are currently considering our plans for the Rockville, Maryland facility subsequent to relocation to the Gaithersburg, Maryland facilities. These plans may include remarketing the facility through the end of the remaining lease term of January 31, 2017.

## **Sources of Supply**



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

## **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 for ultimately conducting Phase III clinical trials for both seasonal and pandemic influenza, to continue development of our vaccine candidates until such vaccines can be licensed on a regional basis, to retain commercial rights in major markets and generate product sales revenue and, in certain markets, to commercialize our products through partners and other strategic relationships.

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

Our relationship with GEHC started in December 2007, when we entered a co-marketing agreement for a pandemic influenza vaccine solution for select international countries. The collaboration uses GEHC's bioprocessing/manufacturing solutions and design expertise in conjunction with Novavax' VLP manufacturing platform.

The JV, known as CPL Biologicals Private Limited, is owned 20% by us and 80% by Cadila. It was established in March 2009 to develop and manufacture certain vaccine candidates, biogeneric products and diagnostic products for the territory of India. The JV operates a state-of-the-art manufacturing facility for the production of influenza vaccine and other vaccine candidates. The JV is actively developing a number of vaccine candidates that were genetically engineered by Novavax. The JV's seasonal and pandemic influenza vaccine candidates began Phase I clinical trials in 2012. Also in 2012, the JV formed a new collaboration to develop a novel malaria vaccine in India with the International Centre for Genetic Engineering and Biotechnology. The JV's rabies vaccine candidate is expected to begin a Phase I clinical trial in India in 2013.

In February 2011, we entered into a license agreement with LGLS that allows LGLS to use our technology to develop and commercially sell our influenza vaccines in South Korea and certain other emerging-market countries. LGLS received an exclusive license to our influenza VLP technology in South Korea and a non-exclusive license in the other specified countries. At its own cost, LGLS is responsible for funding its clinical development of the influenza VLP vaccines and completing a manufacturing facility in South Korea. We received an upfront payment and may receive reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments at a rate of 10% from LGLS's future commercial sales of influenza VLP vaccines, which royalty rate is subject to reduction if certain timelines for regulatory licensure are not met.

In July 2012, we entered into a clinical development agreement with PATH to develop our vaccine candidate to protect against RSV through maternal immunization in low-resource countries (the RSV Collaboration Program). We were awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support our Phase II dose-ranging clinical trial in women of childbearing age as described above. The agreement expires July 31, 2013, unless we and PATH decide to continue the RSV Collaboration Program. We retain global rights to commercialize the product and have made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH has continued to fund 50% of our external clinical development costs for the RSV Collaboration Program, but we do not continue development, we would then grant PATH a fully-paid license to our RSV vaccine technology for use in pregnant women in such low-resource countries.

## **Employees**

As of March 4, 2013, we had 137 full-time employees, of whom 29 hold M.D. or Ph.D. degrees and 37 of whom hold other advanced degrees. Of our total workforce, 109 are engaged primarily in research, development and manufacturing activities and 28 are engaged primarily in executive, business development, finance and accounting,

legal and administrative functions. None of our employees are represented by a labor union or covered by a collective bargaining agreement and we consider our employee relations to be good.

## Executive Officers

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

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

### Principal Occupation and Other Business Experience

Name	Age	During the Past Five Years
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Stanley C. Erck	64	<b>President and Chief Executive Officer and Director</b> of Novavax since April 2011, formerly Executive Chairman since February 2010, and a Director since June 2009. From 2000 to 2008, Mr. Erck served as President and Chief Executive Officer of Iomai Corporation, a developer of vaccines and immune system therapies, which was acquired in 2008 by Intercell AG. He also previously held leadership positions at Procept, a publicly traded immunology company, Integrated Genetics, now known as Genzyme and Baxter International. Mr. Erck also serves on the Board of Directors of BioCryst Pharmaceuticals, MaxCyte, Inc. and MdBio Foundation.
Frederick W. Driscoll	62	<b>Vice President, Chief Financial Officer and Treasurer</b> of Novavax since August 2009. Prior to joining the Company, Mr. Driscoll served as Chief Executive Officer of Genelabs Technologies, Inc. from September 2008 to January 2009, as Interim Chief Executive Officer from February 2008 to August 2008 and as Chief Financial Officer from September 2007 to February 2008. Prior to that, from 2000 to 2006, Mr. Driscoll was employed by OXIGENE, Inc., where he served as President and Chief Executive Officer from 2002 to 2006.
Gregory Glenn, M.D.	59	<b>Senior Vice President, Chief Medical Officer</b> of Novavax since January 2011. Senior Vice President and Chief Scientific Officer from July 2010 to January 2011. Prior to joining the Company, Dr. Glenn was the Chief Scientific Officer and founder of Iomai Corporation, which was acquired in 2008 by Intercell AG, an associate in international health at Johns Hopkins University's School of Public Health and a clinical and basic research scientist at Walter Reed Army Institute of Research.
Timothy J. Hahn, Ph.D.	49	<b>Senior Vice President, Manufacturing and Process Development</b> of Novavax since June 2011. Prior to joining the Company, Dr. Hahn was Vice President of Antibody Manufacturing and later Vice President of Vaccine Manufacturing at MedImmune, LLC, with responsibilities for both U.S. and non-U.S. manufacturing sites. Dr. Hahn spent more than 15 years in vaccine manufacturing with Merck & Co.

Russell P.  
Wilson

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**Senior Vice President, Business Development** of Novavax since November 2011. Mr. Wilson was most recently the Chief Financial Officer at Supernus Pharmaceuticals beginning in 2009. He was previously Senior Vice President, Chief Financial Officer and General Counsel of Iomai Corporation, which was acquired in 2008 by Intercell AG. He was the Acting General Counsel of North American Vaccine, Inc. until its acquisition by Baxter International in 2000.

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## Availability of Information

Novavax was incorporated in 1987 under the laws of the State of Delaware. Our principal executive offices are located at 9920 Belward Campus Drive, Rockville, Maryland, 20850. Our telephone number is (240) 268-2000 and our website address is [www.novavax.com](http://www.novavax.com). The contents of our website are not part of this Annual Report on Form 10-K.

We make available, free of charge and through our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after filed with or furnished to the SEC.

## Item 1A. RISK FACTORS

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

### RISKS RELATED TO OUR BUSINESS

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

Our expenses have exceeded our revenue since our formation in 1987, and our accumulated deficit at December 31, 2012 was \$358.2 million. Our revenue for the last three fiscal years was \$22.1 million in 2012, \$14.7 million in 2011 and \$0.3 million in 2010. Prior to 2011, we recorded limited revenue from research contracts, licenses and agreements to provide vaccine candidates, services and technologies. We cannot be certain that we will be successful in entering into strategic alliances or collaborative arrangements with other companies and government agencies that will result in significant revenue to offset our expenses. Our net losses for the last three fiscal years were \$28.5 million in 2012, \$19.4 million in 2011 and \$35.7 million in 2010.

Our recent historical losses have predominantly resulted from research and development expenses for our vaccine candidates, manufacturing-related expenses, costs related to protection of our intellectual property and for other general operating expenses. Our expenses have exceeded our revenue since inception. We believe our expenses will continue to increase, as a result of higher research and development efforts to support the development of our vaccine candidates.

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

- conduct clinical trials for RSV;

- conduct pre-clinical studies for other early-stage vaccine candidates;

- comply with the FDA's manufacturing facility requirements;

- scale-up our manufacturing process for commercial-scale and cost-efficiency (not including technology transfer to our new manufacturing facility in Gaithersburg, Maryland that may be partially reimbursed by HHS BARDA); and

- maintain, expand and protect our intellectual property portfolio.

As a result, we expect our cumulative operating losses to increase until such time, if ever, that product sales, licensing fees, royalties, milestones, contract research and other sources generate sufficient revenue to fund our operations. We cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

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

We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in an amount sufficient to fully fund our operations for the foreseeable future, and we will therefore use our cash resources and expect to require additional funds to maintain our operations, continue our research and development programs, commence future pre-clinical studies and clinical trials, seek regulatory approvals and manufacture and market our products. We will seek such additional funds through public or private equity or debt financings, collaborative licensing and development arrangements, non-dilutive government contracts and grants and other sources. While we continue to apply for contracts or grants from academic institutions, non-profits and governmental entities, there are no assurances that we would be successful. We cannot be certain that adequate additional funding will be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or vaccine candidates. If we raise additional funds through future offerings of shares of our common stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our common stock.

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

Access to capital markets is critical to our ability to operate. Traditionally, biopharmaceutical companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our vaccine candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. There is no certainty that the capital and credit markets will be available to raise additional capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, our inability to access the capital markets on favorable terms due to our low stock price, could affect our ability to execute our business plan as scheduled. Moreover, we rely and intend to rely on third-parties, including our clinical research organizations and certain other important vendors and consultants. As a result of the global economic situation, there may be a disruption or delay in



the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

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

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

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

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

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

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

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

The HHS BARDA contract anticipates that we file BLAs for licensure of both a seasonal influenza vaccine and a pandemic influenza vaccine; however, the contract is for a base-period of three years plus an option-period of two additional years, and there is no guarantee that we will successfully complete all of the tasks required to file these BLAs during the anticipated contract period. For example, while we have made significant progress during the last six months in addressing our goal of consistent and enhanced immune responses in all strains of our seasonal influenza vaccine candidate, including B/Brisbane/60/08, and expect to finalize our manufacturing process by mid-year 2013, there is no guarantee that we will meet this timeframe, or that we will ever be successful in having all the strains meet the immunogenicity criteria for accelerated approval by the FDA. The inability to meet such timeframes and goals could cause delays in our influenza vaccine candidate programs.

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

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

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

FDA regulations allow for the accelerated approval of a seasonal influenza vaccine based on surrogate endpoint criteria for products that treat serious diseases and fill an unmet medical need, which can allow developers to obtain licensure well ahead of the timeline for demonstrating clinical results in a traditional efficacy trial. There is no guarantee the FDA will view the development of our seasonal influenza vaccine as meeting an unmet medical need, nor is there any guarantee the FDA will agree to our proposal for utilizing our surrogate endpoints as a basis for BLA approval. If our seasonal influenza vaccine does not receive accelerated approval from the FDA, it is likely that we will need to conduct larger and more expensive efficacy clinical trials and that licensure of our seasonal vaccine will be materially delayed for a year or more, assuming such licensure occurs at all.

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

As is the case with seasonal influenza, FDA has articulated the immunogenicity criteria for accelerated approval of vaccines that address potential pandemic influenza strains. Because a controlled efficacy clinical trial of a pandemic vaccine candidate is not logistically or ethically possible, accelerated approval will require evidence that a seasonal vaccine made by the same manufacturing process as the pandemic vaccine is efficacious. There is no guarantee the FDA will view the development of our seasonal influenza vaccine as meeting an unmet medical need, nor is there any guarantee the FDA will agree to our proposal for utilizing our surrogate endpoints as a basis for BLA approval. If our seasonal influenza vaccine does not get accelerated approval from the FDA, it is likely that we will need to conduct larger and more expensive efficacy clinical trials and that licensure of our seasonal vaccine will be materially delayed for a year or more, assuming such licensure occurs at all.

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

We have formed a joint venture with Cadila in India, entered into a license agreement with LGLS in South Korea, a clinical development agreement with PATH and have entered into other agreements and arrangements with companies in other countries. We plan to continue to enter into collaborations or partnerships with companies, non-profit organizations and local governments in other parts of the world. Risks of conducting business outside the U.S. include:

multiple regulatory requirements could affect our ability to develop, manufacture and sell products in such local markets;

compliance with anti-bribery laws such as the United States Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;

trade protections measures and import and export licensing requirements;

different labor regulations;

changes in environmental, health and safety laws;

exchange rates;

potentially negative consequences from changes in or interpretations of tax laws;

political instability and actual or anticipated military or potential conflicts;

economic instability, inflation, recession and interest rate fluctuations;

minimal or diminished protection of intellectual property in some countries; and

possible nationalization and expropriation.

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

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

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

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

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

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

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

research and development;

pre-clinical testing;

designing and implementing clinical trials;

regulatory processes and approvals;

production and manufacturing; and

sales and marketing of approved products.

Principal competitive factors in our industry include:

the quality and breadth of an organization's technology;

management of the organization and the execution of the organization's strategy;

the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees;

an organization's intellectual property portfolio;

the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and

the availability of substantial capital resources to fund discovery, development and commercialization activities.

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

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

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

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

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. There is no assurance that we will be successful in gaining significant market share for any vaccine. Our technologies and vaccines also may be rendered obsolete or non-competitive as a result of products introduced by our competitors to the marketplace more rapidly and



at a lower cost.

*If we are unable to attract or retain key management or other personnel, we may experience delays in product development.*

We depend on our senior executive officers, as well as key scientific and other personnel. The loss of these individuals could harm our business and significantly delay or prevent the achievement of research, development or business objectives. We have had several turnover situations in key executive positions and the lack of management continuity and resulting lack of long-term history with our Company along with the learning curve that executives experience when they join our management team could result in operational and administrative inefficiencies and added costs. If we were to experience additional turnover at the executive level, these risks would be exacerbated.

We may not be able to attract qualified individuals for other key management or other personnel positions on terms acceptable to us. Competition for qualified employees is intense among pharmaceutical and biotechnology companies, and the loss of qualified employees, or an inability to attract, retain and motivate additional highly skilled employees required for the expansion of our activities, could hinder our ability to complete clinical trials successfully and develop marketable products.

We also rely from time to time on outside advisors who assist us in formulating our research and development and clinical strategy. We may not be able to attract and retain these individuals on acceptable terms, which could have a material adverse effect on our business, financial condition and results of operations.

*We may have product liability exposure.*

The administration of drugs or vaccines to humans, whether in clinical trials or after marketing clearances are obtained, can result in product liability claims. We maintain product liability insurance coverage in the total amount of \$20 million aggregate for all claims arising from the use of products in clinical trials prior to FDA approval. Coverage is relatively expensive, and the market pricing can significantly fluctuate. Therefore, we may not be able to maintain insurance at a reasonable cost. There can be no assurance that we will be able to maintain our existing insurance coverage or obtain coverage for the use of our other products in the future. This insurance coverage and our resources may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace and would likely divert management's attention.

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

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

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

From time to time, we may apply for contracts or grants from academic institutions, government agencies and non-profit entities. Such contracts or grants can be highly attractive because they provide capital to fund the ongoing development of our technologies and vaccine candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for or to otherwise be eligible to receive certain contracts or grants that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded and the size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, there is no guarantee that we will be a successful awardee. Therefore, we may not be able to win any contracts or grants in a timely manner, if at all.

***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.

## 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. Commercialization of our vaccines could fail for a variety of reasons, and include the possibility that:

- our recombinant nanoparticle vaccine technologies, any or all of the products based on such technologies or our proprietary manufacturing process will be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances or commercial viability;

- we are unable to scale-up our manufacturing capabilities in a cost-effective manner;

- the products, if safe and effective, will be difficult to manufacture on a large-scale or uneconomical to market;

- our manufacturing facility will fail to continue to pass regulatory inspections;

- proprietary rights of third-parties will prevent us or our collaborators from exploiting technologies, and manufacturing or marketing products; and

- third-party competitors will gain greater market share due to superior products or marketing capabilities.

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

The development, manufacture and marketing of our pharmaceutical and biological products are subject to government regulation in the U.S. and other countries. In the U.S. and most foreign countries, we must complete rigorous pre-clinical testing and extensive clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. None of our vaccine candidates have yet gained regulatory approval in the U.S. or elsewhere. We also have vaccine candidates in clinical trials and pre-clinical laboratory or animal studies.

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

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

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

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

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

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

Influenza vaccines are seasonal in nature. If a vaccine is not available early enough in the influenza season, we would likely have difficulty selling the vaccine. Further, pandemic outbreaks present only short-term opportunities for us. There is no way to predict when there will be a pandemic outbreak, the strain of the influenza or how long the pandemic will last. For these reasons, any delay in the delivery of an influenza vaccine could result in lower sales volumes, lower sale prices, or no sales. Because the strain of the seasonal influenza changes annually, inventory of

seasonal vaccine cannot be sold during a subsequent influenza season. Any delay in the manufacture of our influenza vaccines could adversely affect our ability to sell the vaccines.

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

- difficulties with production costs, scale-up and yields;

- availability of raw materials and supplies;

- quality control and assurance;

- shortages of qualified personnel;

- compliance with strictly enforced federal, state and foreign regulations that vary in each country where product might be sold; and

- lack of capital funding.

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

***Our new manufacturing facility may not be available during 2013, which may impede or delay our ability to manufacture one or more vaccine candidates for subsequent clinical trials or obtain BLA for such vaccines.***

Although our new manufacturing facility in Gaithersburg, Maryland, designed to manufacture Phase III vaccine candidates under our influenza program, has completed refurbishment, the new facility requires relocation of equipment from our Belward facility and new equipment and validation in order to begin manufacturing. This work is expected to be completed in 2013; however, there are risks associated with bringing such a facility online, that include but are not limited to contractor issues and delays, licensing and permitting delays or rejections, limitations and delays on the installation of new or custom-ordered equipment, issues associated with validating equipment, processes or other aspects of insuring cGMP manufacturing and delays associated with moving equipment from our current facility to the new facility. Even if we meet all the scheduled activities associated with bringing the new facility online, there are many aspects of the project that rely on third party contractors and subcontractors, and there can be no guarantee that they will meet expected timeframes.

***We may not utilize our current manufacturing facility, and if so, we may not be able to defray the lease payments and operating expenses of that facility.***

With our new manufacturing facility in Gaithersburg, Maryland, we have the opportunity to relocate from our current facility in Rockville, Maryland. We do not yet know whether and to what extent we may need to utilize some portion of the Rockville facility after we move. The expenses of leasing two manufacturing facilities are significant and while we have structured our new facility arrangement to limit our financial exposure over the next year, we plan to sublease all or a portion of the Rockville facility prior to the end of our lease on January 31, 2017. However, there is no guarantee that we will be able to defray the expense of leasing two manufacturing facilities long-term. Subleasing the Rockville facility may prove difficult and even if we do so, the sublease payments may not fully cover our lease payments and operating expenses.

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

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



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

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

such partners may not devote sufficient resources to our vaccine candidates or properly maintain or defend our intellectual property rights;

any failure on the part of our partners to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our vaccine candidates and affect our ability to realize product revenue; and

disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time-consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals and commercialization activities.

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

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

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

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

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

obtain regulatory approval of, or commercially manufacture, our vaccine candidates.

*Our collaborations may not be profitable.*

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

We have formed the JV with Cadila in India and, in connection with it, entered into a master services agreement pursuant to which we may request certain services from Cadila in the areas of biologics research, pre-clinical development, clinical development, process development, manufacturing scale-up and general manufacturing related services in India. We and Cadila amended the master services agreement first in July 2011, and subsequently in March 2013, in each case to extend the term by one year for which services can be provided by Cadila under this agreement. Under the revised terms, if, by March 2014, the amount of services provided by Cadila under the master services agreement is less than \$7.5 million, we will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. Through December 31, 2012, we have purchased \$0.6 million in services from Cadila pursuant to this agreement.

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

We cannot predict when, if at all, these relationships will lead to approved products, sales, or otherwise provide revenue to the Company or become profitable.

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

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

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

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

· our ability to provide acceptable evidence of safety and efficacy;

· the prevalence and severity of adverse side effects;

- whether our vaccines are differentiated from other vaccines based on immunogenicity;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy;
- publicity concerning our products or competing products and treatments; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

In particular, there are significant challenges to market acceptance for seasonal influenza vaccines. For our seasonal vaccine to be accepted in the market, we must demonstrate differentiation from other seasonal vaccines that are currently approved and marketed. This can mean that the vaccine is more effective in certain populations, such as in older adults, or cheaper and quicker to produce. There are no assurances that our vaccine will be more efficacious than other vaccines.

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

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

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

## **REGULATORY RISKS**

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

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

- our ability to manufacture or obtain sufficient quantities of materials for use in necessary pre-clinical studies and clinical trials;

- prior regulatory agency review and approval;

- approval of the protocol and the informed consent form by the review board of the institution conducting the clinical trial;

- the rate of subject or patient enrollment and retention, which is a function of many factors, including the size of the subject or patient population, the proximity of subjects and patients to clinical sites, the eligibility criteria for the

clinical trial and the nature of the protocol;

negative test results or side effects experienced by clinical trial participants;

analysis of data obtained from pre-clinical and clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit or prevent further studies or regulatory approval;

the availability of skilled and experienced staff to conduct and monitor clinical trials and to prepare the appropriate regulatory applications; and

changes in the policies of regulatory authorities for drug or vaccine approval during the period of product development.

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

Regulatory agencies may require us or our collaborators to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, we or our collaborators may be unable to submit applications to regulatory agencies within the time frame we currently expect. Once submitted, applications must be approved by various regulatory agencies before we or our collaborators can commercialize the product described in the application. All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated costs or delays in our clinical trials could delay our ability to generate revenue and harm our financial condition and results of operations.

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

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

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

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



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

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

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

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

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

government health administration authorities;

private health insurers;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

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

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines. Some of these proposed and implemented reforms could result in reduced reimbursement rates for medical products, and while we have no current vaccines available for commercial sale, the impact of such reform could nevertheless adversely affect our business strategy, operations and financial results. In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010 (PPACA). As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. The long-term ramifications of PPACA remain unclear and many details regarding implementation of PPACA are yet to be determined, however the cost-containment measures that healthcare providers are instituting and the results of healthcare reforms may negatively impact the commercial prospects of one or more of our vaccine candidates currently in development.

## **INTELLECTUAL PROPERTY RISKS**

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

Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third-parties or allowing third-parties to infringe our rights. We currently have or have rights to over 100 U.S. patents and corresponding foreign patents and patent applications covering our technologies. However, patent issues relating to pharmaceuticals and biologics involve complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the U.S. Patent and Trademark Office or enforced by the federal courts. Therefore, we do not know whether our patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

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

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

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

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

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

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

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

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

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

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

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

Our license agreement with Wyeth, which gives us rights to a family of patents and patent applications that are expected to expire in early 2022, covering VLP technology for use in human vaccines in certain fields of use, is non-exclusive. These applications are very significant to our business. If each milestone is achieved for any particular vaccine candidate, we would likely be obligated to pay an aggregate of \$14 million to Wyeth for each vaccine candidate developed and commercialized under the agreement. Achievement of each milestone is subject to many risks, including those described in these Risk Factors. Annual license fees under the Wyeth agreement aggregate to \$0.2 million per year.

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

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

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

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

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

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

Our stock price has been highly volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. From January 1, 2012 through December 31, 2012, the closing sale price of our common stock has been as low as \$1.16 per share and as high as \$2.39 per share. The market price of our common stock may be influenced by many factors, including:

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



clinical trial results;

depletion of our cash reserves;

sale of equity securities or issuance of additional debt;

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

changes in government regulations;

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

developments in our relationships with our collaboration partners;

announcements relating to health care reform and reimbursement levels for new vaccines;

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

development, spread or new announcements related to pandemic influenza;

litigation;

public concern as to the safety of our products;

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

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

the other factors described in this Risk Factors section.

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

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

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

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

Any delay or prevention of a change of control transaction or changes in our Board of Directors 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 2. PROPERTIES**

We lease approximately 51,200 square feet in Rockville, Maryland, which serves as our corporate headquarters and includes administrative offices, vaccine research and development, as well as a manufacturing facility. In 2011, we entered into a long-term lease arrangement for 74,000 square feet of manufacturing, laboratory and office space in two facilities in Gaithersburg, Maryland. We continue to lease approximately 32,900 square feet of administrative office and research and development space at our former corporate headquarters in Malvern, Pennsylvania, all of which is currently subleased. A summary of our current facilities is set forth below.

Property Location	Approximate Square Footage	
Rockville, MD	51,200	Current corporate headquarters and vaccine research and development and manufacturing facility
20FF Gaithersburg, MD	53,000	Future vaccine research and development and manufacturing facility
22FF Gaithersburg, MD	21,000	Future corporate headquarters
Malvern, PA	32,900	Former corporate headquarters and research and development facility
Total square footage	158,100	
Malvern, PA sublease	(32,900)	)
Net square footage	125,200	

**Item 3. LEGAL PROCEEDINGS**

We currently have no legal proceedings underway.

**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, 2012	\$2.39	\$1.57
September 30, 2012	\$2.23	\$1.71
June 30, 2012	\$1.56	\$1.16
March 31, 2012	\$1.52	\$1.23
December 31, 2011	\$1.71	\$1.25
September 30, 2011	\$2.13	\$1.18
June 30, 2011	\$2.61	\$1.97
March 31, 2011	\$2.96	\$2.15

On March 4, 2013, the last sale price reported on The NASDAQ Global Select Market for our common stock was \$1.79. Our common stock was held by approximately 463 stockholders of record as of March 4, 2013, one of which is Cede & Co., a nominee for Depository Trust Company (or DTC). All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder. We have not paid any cash dividends on our common stock since our inception. We do not anticipate declaring or paying any cash dividends in the foreseeable future.

**Securities Authorized for Issuance under our Equity Compensation Plans**

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

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, the NASDAQ Pharmaceutical Index (which includes Novavax), 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, the NASDAQ Pharmaceutical Index, and the Russell 2000 Growth Biotechnology Index on December 31, 2007, and reinvestments of all dividends. The addition of the Russell 2000 Growth Biotechnology Index was made in order to reflect a group of companies that better compares with our Company.

Value of \$100 invested on December 31, 2007 in stock or index, including reinvestment of dividends, for fiscal years ended December 31:

	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12
Novavax, Inc.	\$ 100.00	\$ 56.76	\$ 79.88	\$ 72.97	\$ 37.84	\$ 56.76
NASDAQ Composite Index	\$ 100.00	\$ 59.03	\$ 82.25	\$ 97.32	\$ 98.63	\$ 110.78
NASDAQ Pharmaceutical Index	\$ 100.00	\$ 97.45	\$ 104.75	\$ 111.47	\$ 123.06	\$ 164.89
RUSSELL 2000 Growth Biotechnology Index	\$ 100.00	\$ 69.84	\$ 91.58	\$ 102.12	\$ 98.92	\$ 113.60

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, 2012, 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,				
	2012	2011	2010	2009	2008
	(in thousands, except per share amounts)				
Statements of Operations Data:					
Revenue	\$22,076	\$14,688	\$343	\$325	\$1,064
Loss from continuing operations	(28,507)	(19,364)	(35,708)	(40,346)	(34,784)
Income from discontinued operations	—	—	—	—	273
Net loss	\$(28,507)	\$(19,364)	\$(35,708)	\$(40,346)	\$(34,511)
Basic and diluted net loss per share:					
Loss per share from continuing operations	\$(0.22)	\$(0.17)	\$(0.34)	\$(0.47)	\$(0.51)
Income per share from discontinued operations	—	—	—	—	—
Basic and diluted net loss per share	\$(0.22)	\$(0.17)	\$(0.34)	\$(0.47)	\$(0.51)
Weighted average shares used in computing basic and diluted net loss per share	131,726	113,610	104,768	85,555	68,174

	As of December 31,				
	2012	2011	2010	2009	2008
	(in thousands)				
Balance Sheet Data:					
Cash and investments(1)	\$50,344	\$18,309	\$31,676	\$42,950	\$33,900
Total current assets	50,408	26,109	33,337	44,503	35,096
Working capital(2)	38,733	18,530	23,071	36,476	7,379
Total assets	102,345	66,576	74,844	85,605	76,625
Long-term debt, less current portion	990	300	320	406	480
Accumulated deficit	(358,163)	(329,656)	(310,292)	(274,584)	(234,238)
Total stockholders’ equity	80,240	53,849	59,050	69,952	42,948

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

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

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

Certain statements contained or incorporated by reference herein constitute forward-looking statements. In some cases, these statements can be identified by the use of forward-looking terminology such as “expect(s),” “intends,” “plans,” “seeks,” “estimates,” “could,” “should,” “feel(s),” “believe(s),” “will,” “would,” “may,” “can,” “anticipate(s),” “potential” and expressions or the negative of these terms. Such forward-looking statements are subject to risks and uncertainties that may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from those expressed or implied by such forward-looking statements.

Forward-looking statements in this Annual Report include, without limitation, statements regarding:

- potential benefits, regulatory approval and commercialization of our vaccine candidates;

our expectation that we will have adequate capital resources available to operate at planned levels for approximately the next 24 months;

- our expected 2013 capital expenditures;



our expectations for future revenue under the contract with HHS BARDA, funding requirements and capital raising activity, including possible proceeds from our At Market Issuance Sales Agreement entered into in October 2012, and funding under the Improvement Allowance and Loan Agreement;

our expectations on financial or business performance, conditions or strategies and other financial and business matters, including expectations regarding operating expenses, use of cash, and the fluctuations in expenses and capital requirements associated with pre-clinical studies, clinical trials and other research and development activities;

our expectations on clinical development and anticipated milestones, including contracts with HHS BARDA, LGLS and PATH, our planned clinical trials and regulatory filings, including receipt of accelerated approval status from the FDA, as necessary for our vaccine candidates;

our expectations that our vaccine candidates will prove to be safe and effective;

our expectations that our multivalent seasonal influenza VLP vaccine could potentially address an unmet medical need in two vulnerable populations – the pediatric and elderly;

our expectation that our pandemic (H5N1) influenza vaccine could potentially be developed without an adjuvant for population segments that are sensitive to adjuvant use;

our expectations that our RSV vaccine could potentially address unmet medical needs;

our expectations regarding the development by the JV, in India, of a rabies vaccine, including a planned Phase I clinical trial in 2013;

our expectation that we will utilize the amount of services that is required to be provided by Cadila under the master services agreement;

our expectations regarding payments to Wyeth;

our expectations concerning payments under existing license agreements; and

other factors referenced herein.

Any or all of our forward-looking statements in this Annual Report may turn out to be inaccurate. These forward-looking statements may be affected by inaccurate assumptions or by known or unknown risks and

uncertainties, including the risks, uncertainties and assumptions identified under the heading "Risk Factors" in this Annual Report. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

The Company assumes no obligation to update any such forward-looking statements, except as specifically required by law. We caution readers not to place considerable reliance on the forward-looking statements contained in this Annual Report.

## **Overview – Introduction**

Novavax, Inc., a Delaware corporation (Novavax, the Company, we, or us), is a clinical-stage biopharmaceutical company focused on developing recombinant protein nanoparticle vaccines to address a broad range of infectious diseases. Our technology platform is based on proprietary recombinant vaccine technology that includes VLPs and recombinant protein micelle vaccines combined with a single-use bioprocessing production system. Our vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. Our product pipeline targets a variety of infectious diseases and our vaccine candidates are currently in or have completed clinical trials that target seasonal influenza, pandemic (H5N1) influenza and RSV.

CPL Biologicals Private Limited (the JV), which is owned 20% by us and 80% by Cadila, was established to develop and manufacture certain vaccine candidates, biogeneric products and diagnostic products for the territory of India. The JV operates a state-of-the-art manufacturing facility for the production of influenza vaccine and other vaccine candidates. The JV is actively developing a number of vaccine candidates that were genetically engineered by Novavax. The JV's seasonal influenza and pandemic influenza candidates began Phase I clinical trials in 2012. Also in 2012, the JV formed a new collaboration to develop a novel malaria vaccine in India with the International Centre for Genetic Engineering and Biotechnology. The JV's rabies vaccine candidate is expected to begin a Phase I clinical trial in India in 2013. We continue to account for our investment in the JV using the equity method. Since the carrying value of our initial investment was nominal and there is no guarantee or commitment to provide future funding, we have not recorded nor do we expect to record losses related to this investment in the future.

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

<b>Program</b>	<b>Development Phase</b>	<b>Collaborator</b>
Seasonal Quadrivalent Influenza	Phase II	HHS BARDA/LGLS
Pandemic (H5N1) Influenza	Phase I	HHS BARDA/LGLS
RSV	Phase II	PATH <sup>1</sup>
Seasonal Trivalent Influenza	Phase I	JV
Pandemic (H1N1) Influenza	Phase I	JV
Rabies	Pre-clinical	JV

<sup>1</sup>PATH is collaborating with us on a Phase II clinical trial to develop our RSV vaccine to protect newborn infants in low-resource countries from RSV through maternal immunization.

## **Influenza**

The FDA has published criteria for granting accelerated approval of a BLA for a new seasonal influenza vaccine. Under this guidance, developers that can demonstrate results that meet or exceed certain specified endpoint criteria in their clinical trials may, at the FDA's decision, be granted a license to market prior to conducting a traditional efficacy clinical trial. In adult populations under 65 years of age, these criteria are based on demonstration of seroconversion rates (the proportion of subjects with a four-fold rise in HAI titers or attaining titers of  $\geq 1:40$  from a negative baseline) and seroprotection rates (the proportion of subjects with HAI titers  $\geq 1:40$  post-vaccination) that are  $\geq 40\%$  and  $\geq 70\%$ , respectively, at the lower bound of the 95% confidence interval. Accelerated approval may be available as long as there is a shortage of seasonal influenza vaccine relative to the total population recommended to receive the vaccine, a situation that persists. The FDA expects that developers seeking accelerated approval of a BLA will diligently conduct postmarketing efficacy studies. Novavax continues to use and reference these accelerated approval seroconversion and seroprotection endpoints in developing its influenza vaccine candidates. The FDA has articulated the same immunogenicity criteria for accelerated approval of vaccines that address potential pandemic influenza strains. Because a controlled efficacy clinical trial of a pandemic vaccine candidate is not logistically or ethically possible,

vaccine developers seeking accelerated approval will be required to provide evidence that a seasonal vaccine made by the same manufacturing process is efficacious. Thus, the demonstration of efficacy with a seasonal vaccine product provides a key link between the seasonal and pandemic programs.

### *Seasonal Influenza Vaccine*

The CDC recommends that all persons aged six months and older should be vaccinated annually against seasonal influenza. In conjunction with these universal recommendations, attention from the 2009 influenza H1N1 pandemic has increased public health awareness of the importance of seasonal influenza vaccination, the market for which is expected to continue to grow worldwide in both developed and developing global markets.

In the coming years, many seasonal influenza vaccines are expected to be produced in a quadrivalent formulation (four influenza strains, two influenza A strains and two influenza B strains), as opposed to the current trivalent formulation (two influenza A strains and one influenza B strain). With two distinct lineages of influenza B viruses circulating, governmental health authorities have advocated for the addition of a second influenza B strain to provide added coverage. Current estimates for seasonal influenza vaccines growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show potential growth from the current market of approximately \$3.6 billion to \$4.7 billion over the next ten years. Recombinant seasonal influenza vaccines, like the candidate we are developing, have an important advantage; once licensed for commercial sale, large quantities of vaccine can be quickly and cost-effectively manufactured without the use of either the live influenza virus or eggs.

Top-line data from our most recent Phase II clinical trial for our quadrivalent influenza vaccine candidate were announced in July 2012. In that clinical trial, our quadrivalent VLP vaccine candidate demonstrated immunogenicity against all four viral strains based on HAI responses at day 21, and was also well-tolerated with no vaccine-related serious adverse events observed and had acceptable reactogenicity. Our vaccine candidate met the FDA accelerated approval seroprotection rates criterion for all four viral strains. The potential to fulfill the seroconversion rates criterion was demonstrated for three of the four viral strains. The fourth strain, B/Brisbane/60/08, despite fulfilling the seroprotection criterion, failed to demonstrate a satisfactory seroconversion rate. Our activities with respect to our seasonal influenza vaccine candidate have been, and are, focused on identifying the manufacturing process to ensure consistent and enhanced immune responses in all strains. Over the last six months we've made significant progress and expect to finalize our manufacturing process by mid-year 2013. During the second half of 2013, we expect to begin manufacturing product for our next Phase II clinical trial.

### ***Pandemic (H5N1) Influenza Vaccine***

In the aftermath of the 2009 H1N1 influenza pandemic, recognition of the potential devastation of a human influenza pandemic remains a key priority with both governmental health authorities and influenza vaccine manufacturers. In the U.S. alone, the 2009 H1N1 pandemic led to the production of approximately 126 million doses of monovalent (single strain) vaccine. Public health awareness and government preparedness for the "next" potential influenza pandemic is driving development of vaccines that can be quickly manufactured against a potentially threatening influenza strain. Industry and health experts have focused attention on developing a monovalent H5N1 influenza vaccine as a potential key defense of the next pandemic threat.

During 2012, we made significant progress in the development of our pandemic (H5N1) influenza vaccine candidate. In May 2012, we launched two Phase I clinical trials of our pandemic (H5N1) vaccine candidate in combination with two different adjuvants, both of which are designed to improve the immunogenicity of vaccines at lower doses and thus provide antigen dose-sparing. These clinical trials evaluated the safety and tolerability of the vaccines and the ability of VLP vaccine antigens with and without adjuvants to generate antibody levels that we believe fulfill the FDA's criteria for accelerated approval, and the ability of these vaccines to provide an expanded number of doses, with possible cross-protection against other virus strains to the U.S. population. In October 2012, we reported positive results from these clinical trials with top-line data demonstrating safety and immunogenicity of varying dose-levels of the vaccine, with and without adjuvant, and further demonstrating statistically significant robust adjuvant effects on immune response. Notably, our unadjuvanted vaccine candidate elicited HAI titers  $\geq 40$  in  $>82\%$  of subjects at a dose of 45 $\mu\text{g}$ . This response would fulfill the FDA's influenza criteria for accelerated approval of a BLA as further described under the heading "Influenza" above.

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

HHS BARDA awarded us a contract in February 2011, which funds the development of both our seasonal and pandemic (H5N1) influenza vaccine candidates. The contract, valued at \$97 million for the first three-year base-period and \$82 million for an HHS BARDA optional two-year period, is a cost-plus-fixed-fee contract in which HHS BARDA reimburses us for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the ongoing clinical development and product scale-up of our multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines. We recognized revenue of approximately \$20.1 million in 2012, and have recognized approximately \$34.8 million in revenue since the inception of the contract in 2011.

In December 2012, HHS BARDA completed a contractually-defined IPR of our contract. This IPR was conducted by an inter-governmental-agency panel of experts from government agencies including HHS BARDA, FDA, CDC and the National Institutes of Health, who provided input on our progress during the contract base-period and plans for further development, including both near-term process development and manufacturing activities and longer-term clinical efforts. HHS BARDA subsequently notified us in January 2013 that the milestone decision has been made to continue to support our vaccine advanced development contract.

Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, we decided to conduct a Phase II clinical trial of our quadrivalent influenza vaccine candidate (the 205 Trial) under our existing U.S. investigational new drug application (IND) for our trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for our quadrivalent vaccine candidate (Quadrivalent IND). Based on our discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by us after we submit the clinical trial data in a future Quadrivalent IND. The filing of the Quadrivalent IND is expected shortly before we initiate the next Phase II dose-confirmatory clinical trial, which has been delayed due to the development activity associated with improving the seroconversion response of one of the four strains. The outside clinical trial costs of the 205 Trial are approximately \$3.1 million in total, of which \$3.0 million was incurred through December 31, 2012. These costs have been recorded as an expense and are included in cost of government contracts revenue.

### ***LGLS License Agreement***

In February 2011, we entered into a license agreement with LGLS that allows LGLS to use our technology to develop and commercially sell our influenza vaccines in South Korea and certain other emerging-market countries. LGLS received an exclusive license to our influenza VLP technology in South Korea and a non-exclusive license in the other specified countries. At its own cost, LGLS is responsible for funding its clinical development of the influenza VLP vaccines and completing a manufacturing facility in South Korea. We received an upfront payment and may receive reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments at a rate of 10% from LGLS's future commercial sales of influenza VLP vaccines, which royalty rate is subject to reduction if certain timelines for regulatory licensure are not met.

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

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

We are developing a vaccine candidate to prevent RSV and are looking at susceptible target populations that include the elderly, young children and newborns who may receive protection through antibodies transferred from their mothers who may be immunized during the last trimester of pregnancy. In October 2011, we announced the results of our first Phase I clinical trial to assess the safety and tolerability of our RSV vaccine candidate, and to evaluate total and neutralizing anti-RSV antibody responses and the impact of an aluminum phosphate adjuvant. Along with positive safety results, the antibody response to the RSV F protein was significantly increased compared to placebo ( $p < 0.001$ ) in all dose groups and increased by 19-fold in the highest-dose adjuvant group at day 60. A significant dose-response pattern was observed with high rates of seroconversion at all doses including a rate of 100% at the highest-dose adjuvant group. In October 2012, we initiated two separate dose-ranging clinical trials, one in women of child bearing age, which initiates our goal of developing a vaccine for maternal immunization of pregnant women, and the other in elderly adults, which initiates our goal of developing a vaccine for the elderly. The first clinical trial is a randomized, blinded, placebo-controlled Phase II clinical trial that will evaluate the safety and immunogenicity of two dose levels of our RSV vaccine candidate with and without an aluminum phosphate adjuvant, enrolling 330 women of childbearing age. The second clinical trial is a randomized, blinded, placebo-controlled Phase I clinical trial that will evaluate the safety and immunogenicity results of 220 enrolled adults, 60 years of age and older, who received a single intramuscular injection of our RSV vaccine candidate (with and without an aluminum phosphate adjuvant) or

placebo plus a single dose of licensed influenza vaccine or placebo at days 0 and 28. Top-line results from both clinical trials are expected to be reported in the first half of 2013. The design and timing of subsequent clinical trials will be determined after these data are analyzed. Our expected path forward in maternal immunization would include a dose-confirmation clinical trial in women of child-bearing age. In parallel, and in consultation with the FDA, we would expect to initiate a reproductive toxicology study to confirm the safety of our proposed formulation in advance of vaccinating pregnant women. For the elderly, the path forward would likely be to design a Phase II clinical trial.



### ***PATH Clinical Development Agreement***

In July 2012, we entered into a clinical development agreement with PATH to develop our vaccine candidate to protect against RSV through maternal immunization in low-resource countries (the “RSV Collaboration Program”). We were awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support our Phase II dose-ranging clinical trial in women of childbearing age as described above. The agreement expires July 31, 2013, unless we and PATH decide to continue the RSV Collaboration Program. We retain global rights to commercialize the product and have made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH has continued to fund 50% of our external clinical development costs for the RSV Collaboration Program, but we do not continue development, we would then grant PATH a fully-paid license to our RSV vaccine technology for use in pregnant women in such low-resource countries.

### **Rabies**

Rabies is a disease that causes acute encephalitis, or swelling of the brain, in warm-blooded animals including humans. The disease can be transmitted from one species of animal to another, such as from dogs to humans, most commonly by a bite from an infected animal. For humans, rabies left untreated is almost invariably fatal. WHO has estimated that the highest public health financial expenditure in any country is the cost of rabies post-exposure prophylaxis. In Asia and Africa, estimates show a combined 55,000 annual human deaths from endemic canine rabies, with annual treatment costs approaching \$600 million, although human deaths from rabies are likely to be grossly underreported in a number of countries, particularly in the youngest age groups. In India alone, 20,000 deaths are estimated to occur annually. Internal market data of vaccine manufacturers suggest that at the global level,  $\geq 15$  million people receive rabies prophylaxis annually, the majority of whom live in China and India. It is estimated that in the absence of post-exposure prophylaxis, about 327,000 persons would die from rabies in Africa and Asia each year. Marketed rabies vaccine is mostly used for post-exposure prophylaxis that requires generally between four and five administrations of vaccine. Pre-exposure prophylaxis is recommended for anyone who will be at increased risk to the rabies virus, including travelers with extensive outdoor exposure in rural high-risk areas.

The JV is currently developing a rabies vaccine candidate that we genetically engineered. The JV expects to initiate Phase I clinical trial in India in 2013. Our objective is to develop a recombinant vaccine that can be administered as a pre-exposure prophylaxis for residents of certain higher-risk geographies, as well as travelers to such locations, and with the potential to provide post-exposure prophylaxis with fewer doses. Preliminary pre-clinical results have demonstrated that this vaccine candidate successfully prevents the rabies virus from entering the central nervous system, thus preventing death.

### **Sales of Common Stock**

In 2012, we completed two separate offerings to sell over 12 million and 10 million shares of common stock. In October 2012, we sold 12,385,321 shares of its common stock to RA Capital Management, LLC (RA Capital), Camber Capital Management LLC and Ayer Capital Management LLC at a price of \$2.18 per share, resulting in approximately \$27 million in net proceeds. In May 2012, we sold 10,000,000 shares of our common stock to RA Capital at a price of \$1.22 per share, resulting in approximately \$12.2 million in net proceeds. In both cases, the shares were offered under an effective shelf registration statement previously filed with the SEC.

The Board of Directors of the Company (the “Board”) has appointed a standing Finance Committee (the “Committee”) to assist the Board with its responsibilities to monitor, provide advice to senior management of the Company and approve all capital raising activities. The Committee has been authorized by the Board to approve all At Market Issuance sales transactions. In doing so, the Committee sets the amount of shares to be sold, the period of time during which such sales may occur and the minimum sales price per share. In October 2012, the Company entered into an At Market Issuance Sales Agreement (2012 Sales Agreement), under which the Company may sell an aggregate of \$50 million in gross proceeds of its common stock. This agreement replaces the previous and terminated At Market Issuance Sales Agreement entered in March 2010 (2010 Sales Agreement), which also allowed for the sale of an aggregate of \$50 million in gross proceeds of its common stock, but had recently met its limitation of sales of shares. The shares of common stock are being offered pursuant to a shelf registration statement filed with the SEC. During 2012, the Company sold 8.4 million shares at an average sales price of \$1.70 per share, resulting in \$14.0 million in net proceeds; this amount excludes \$0.8 million received in early 2012 for 0.7 million shares traded in late December 2011. The Company sold a total 24,957,715 shares of its common stock and received gross proceeds of \$49.9 million under the 2010 Sales Agreement.

### ***Critical Accounting Policies and Use of Estimates***

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

The preparation of our 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 investments, stock-based compensation, long-lived assets, goodwill and estimated recovery of our net deferred tax assets have a material impact on our 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 primarily derive revenue from a cost-plus-fixed-fee contract in which HHS BARDA will reimburse us for allowable direct contract costs incurred plus allowable indirect costs and a fee earned in the further development of our seasonal and pandemic (H5N1) influenza vaccines. Revenue on this cost-plus-fixed-fee contract is recognized as such costs are incurred plus a portion of the fixed-fee earned. Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses not exceeding certain limits. Payments to the Company under cost reimbursable contracts with agencies of the U.S. Government, including our contract with HHS BARDA, are provisional payments subject to adjustment upon annual audit by the government. An audit by the government of fiscal year 2011 has been initiated, but has not been completed as of the date of this filing; however, management believes that revenue for periods subject to audit has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly.

### ***Investments***

Our investments are classified as available-for-sale securities and are carried at fair value. Unrealized gains and losses on these securities, if determined to be “other-than-temporary,” are included in accumulated other comprehensive income (loss) in stockholders’ equity. Investments are evaluated periodically to determine whether a decline in value is other-than-temporary. Management reviews criteria, such as the magnitude and duration of the decline, as well as the Company’s ability to hold the securities until market recovery, to predict whether the loss in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the security is reduced and the impairment is recorded in the statements of operations. For investments carried at fair value, we disclose the level within the fair value hierarchy as prescribed by Accounting Standard Codification (ASC) 820, *Fair Value Measurements and Disclosures*. We evaluate the types of securities in our investment portfolio to determine the proper classification in the fair value hierarchy based on trading activity and market inputs. We generally obtain information from an independent third-party to help us determine the fair value of securities in Level 2 of the fair value hierarchy. Investment income is recorded when earned and included in interest income.

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

We account for our stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. This standard requires us to measure the cost of employee services received in exchange for equity share options granted based on the grant-date fair value of the options. 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 stock options are granted and adjustments are made for stock option cancellations.

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

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

### ***Goodwill***

Our goodwill is not amortized, but is subject to impairment tests annually, or more frequently should indicators of impairment arise. We have determined since the Company's only business is the development of recombinant vaccines that the Company operates as a single operating segment and reporting unit. We utilize the market approach and, if considered necessary, the income approach to determine if we have an impairment of our goodwill. The market approach serves as the primary approach and is based on market value of invested capital. The concluded fair value significantly exceeded the carrying value of our goodwill at December 31, 2012 and 2011. The income approach is used as a confirming look to the market approach. Goodwill impairment is deemed to exist if the carrying value of a reporting unit exceeds its estimated fair value, which we test annually at December 31.

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

### *Income Taxes*

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

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

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

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

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

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

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

#### **Results of Operations for Fiscal Years 2012, 2011 and 2010** (amounts in tables are presented in thousands, except per share information)

The following is a discussion of the historical financial condition and results of operations of Novavax, Inc. and should be read in conjunction with the 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 Item 1A. Risk Factors of this Annual Report.

**Revenue:**

	2012	2011	2010	<b>Change 2011 to 2012</b>	<b>Change 2010 to 2011</b>
Revenue:					
Total revenue	\$22,076	\$14,688	\$343	\$7,388	\$14,345

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

Revenue for 2011 was \$14.7 million as compared to \$0.3 million for 2010, an increase of \$14.3 million. Revenue for 2011 is comprised of services performed under the HHS BARDA contract and revenue for 2010 resulted from work under other government contracts.



Revenue for 2012 was negatively impacted due to the Company electing to conduct the 205 Trial without immediate HHS BARDA reimbursement of its outside clinical trial costs, which are expected to total approximately \$3.1 million, of which \$2.8 million was incurred during 2012 (see discussion of the 205 Trial in Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview on page 38). For 2013, we expect a slight increase in revenue associated with our increased product development activities under the HHS BARDA contract to support the initiation of later-stage clinical trials of our seasonal influenza and pandemic (H5N1) influenza vaccine candidates.

**Costs and Expenses:**

	2012	2011	2010	Change 2011 to 2012	Change 2010 to 2011
Costs and Expenses:					
Cost of government contracts revenue	\$14,692	\$7,003	\$—	\$7,689	\$7,003
Research and development	26,061	17,885	28,032	8,176	(10,147)
General and administrative	10,988	11,379	10,805	(391 )	574
Total costs and expenses	\$51,741	\$36,267	\$38,837	\$15,474	\$(2,570 )

***Cost of Government Contracts Revenue***

Cost of government contracts revenue includes direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with our process development, manufacturing, clinical, regulatory and quality assurance activities under research contracts. Cost of government contracts revenue increased to \$14.7 million for 2012 from \$7.0 million for 2011, an increase of \$7.7 million, or 110%. The increase in cost of government contracts revenue is primarily due to the seasonal influenza and pandemic (H5N1) influenza clinical trials and product development activities that occurred during 2012 under the HHS BARDA contract.

Cost of government contracts revenue increased to \$7.0 million for 2011 due to the development work performed under the HHS BARDA contract that was awarded in February 2011.

Cost of government contracts revenue for 2012 includes \$2.8 million of direct clinical trial costs of our 205 Trial. For 2013, we expect the cost of government contracts revenue to remain flat due to fewer clinical trials in 2013 as compared to 2012, offset by increased product development activities under the HHS BARDA contract.

***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 internally funded programs. In addition, indirect costs such as, fringe benefits and overhead expenses, are also included in research and development expenses. Research and development expenses increased to \$26.1 million for 2012 from \$17.9 million for 2011, an increase of \$8.2 million, or 46%. The increase in research and development expenses was primarily due to increased costs relating to our RSV clinical trials (an internally funded program at this time), higher employee-related costs and expenses associated with our new manufacturing facility. For 2013, we expect a significant increase in research and development expenses primarily due to additional employee-related costs to support product development of RSV and other potential vaccine candidates.

Research and development expenses decreased to \$17.9 million for 2011 from \$28.0 million for 2010, a decrease of \$10.1 million, or 36%. The decrease in research and development expenses was primarily due to work performed under the HHS BARDA contract and as such, is being recorded as cost of government contracts revenue, and, to a lesser extent, lower outside-testing costs (including outsourced clinical trial costs, sponsored research and consulting agreements) as a result of fewer clinical trials in 2011.

*Costs and Expenses by Functional Area*

We track our cost of government contracts revenue and 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. At December 31, 2012, we had 102 employees dedicated to our research and development programs versus 88 employees as of December 31, 2011. 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 cost of government contracts revenue and research and development expenses by functional area for the year ended December 31 (in millions).

	2012	2011
Manufacturing	\$18.6	\$14.7
Vaccine Discovery	3.5	3.2
Clinical and Regulatory	18.7	7.0
Total cost of government contracts revenue and research and development expenses	\$40.8	\$24.9

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. As we obtain data from pre-clinical 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 decreased to \$11.0 million in 2012 from \$11.4 million for 2011, a decrease of \$0.4 million, or 3%. The decrease in expenses was primarily due to lower employee-related costs, including severance expenses, and lower professional fees, partially offset by higher expenses associated with our new office facility. For 2013, we expect general and administrative expenses to remain relatively flat.

General and administrative expenses increased to \$11.4 million in 2011 from \$10.8 million for 2010, an increase of \$0.6 million, or 5%. The increase in expenses was primarily due to higher employee-related costs, including severance expenses, partially offset by lower professional fees.

**Other Income (Expense):**

	2012	2011	2010	Change 2011 to 2012	Change 2010 to 2011
Other Income (Expense):					
Interest income	\$ 165	\$ 136	\$ 189	\$ 29	\$ (53 )
Interest expense	(32 )	(9 )	(9 )	(23 )	—
Other income	45	26	485	19	(459 )
Realized gains on short-term investments	879	—	—	879	—
Change in fair value of warrant liability	101	2,474	1,671	(2,373 )	803
Total other income (expense)	\$ 1,158	\$ 2,627	\$ 2,336	\$(1,469 )	\$ 291

We had total other income of \$1.2 million for 2012 compared to total other income of \$2.6 million for 2011, a decrease of \$1.5 million. In 2012, two of our auction rate securities were redeemed at approximately par value and resulted in \$0.9 million in realized gains as we had recorded other than temporary impairments on these securities in previous periods. Additionally, we are required to calculate the fair value of our warrant liability at each reporting period. For 2012, the change in fair value of the warrant liability resulted in a \$2.4 million decrease in total other income as compared to 2011. We will continue to mark the warrant liability to fair value at each reporting period until the warrants are either exercised or otherwise expire on July 31, 2013.

We had total other income of \$2.6 million for 2011 compared to total other income of \$2.3 million for 2010, an increase of \$0.3 million. Other income decreased to less than \$0.1 million for 2011 primarily resulting from the receipt of grants under our application of qualifying therapeutic discovery project credits in 2010. For 2011, the change in fair value of the warrant liability resulted in a \$0.8 million increase in total other income as compared to 2010.

**Income Tax:**

	2012	2011	2010	Change 2011 to 2012	Change 2010 to 2011
Income Tax:					
Income tax expense (benefit)	\$ —	\$ 412	\$(450)	\$(412 )	\$ 862

In 2011, we incurred a \$0.4 million foreign withholding tax related to a payment received in accordance with a license agreement. In 2010, we recorded a deferred income tax benefit of \$0.5 million related to a refundable income tax credit received and grants received as a result of qualifying therapeutic discovery projects under Internal Revenue

Code Section 48D.

Net Loss:

	2012	2011	2010	<b>Change 2011 to 2012</b>	<b>Change 2010 to 2011</b>
Net Loss:					
Net loss	\$(28,507 )	\$(19,364 )	\$(35,708 )	\$(9,143 )	\$16,344
Net loss per share	\$(0.22 )	\$(0.17 )	\$(0.34 )	\$(0.05 )	\$0.17
Weighted average shares outstanding	131,726	113,610	104,768	18,116	8,842

Net loss for 2012 was \$28.5 million, or \$0.22 per share, as compared to \$19.4 million, or \$0.17 per share, for 2011, an increased net loss of \$9.1 million. The increased net loss was primarily due to higher research and development spending, including increased costs relating to our RSV clinical trials, higher employee-related costs and expenses associated with our new manufacturing facility.

Net loss for 2011 was \$19.4 million, or \$0.17 per share, as compared to \$35.7 million, or \$0.34 per share, for 2010, a decreased net loss of \$16.3 million. The decreased net loss was primarily due to revenue recognized under the HHS BARDA agreement, as well as lower research and development spending as a result of fewer clinical trials in 2011.

The increase in weighted average shares outstanding for 2012 and 2011 is primarily a result of sales of our common stock in the aggregate of 30,827,346 shares in 2012, 6,001,841 shares in 2011 and 10,513,849 shares in 2010.

## 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 pre-clinical 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 pre-clinical studies and clinical trials and other research and development activities.

As of December 31, 2012, we had \$50.3 million in cash and cash equivalents and investments as compared to \$18.3 million as of December 31, 2011. These amounts consisted of \$17.4 million in cash and cash equivalents and \$32.9 million in investments as of December 31, 2012 as compared to \$14.1 million in cash and cash equivalents and \$4.2 million in investments at December 31, 2011.

The following table summarizes cash flows for the years ended December 31, 2012 and 2011 (in thousands):

	2012	2011	Change 2011 to 2012
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(18,229)	\$(23,629)	\$ 5,400
Investing activities	(32,262)	18,543	(50,805 )
Financing activities	53,786	11,129	42,657
Net increase (decrease) in cash and cash equivalents	3,295	6,043	(2,748 )
Cash and cash equivalents at beginning of year	14,104	8,061	6,043
Cash and cash equivalents at end of year	\$17,399	\$14,104	\$ 3,295

Net cash used in operating activities decreased to \$18.2 million for 2012 as compared to \$23.6 million for 2011, a reduction of 23%. The decrease in cash usage was primarily due to funds received under our Improvement Allowance (as described below) and the timing of our customer and vendor payments, partially offset by our increased net loss in 2012.

During 2012 and 2011, our investing activities primarily included purchases and maturities of investments and capital expenditures. In 2012, we purchased investments to increase our rate of return on available cash. In 2011, we utilized our investments to fund operations and increase our cash balances. Capital expenditures for 2012 and 2011 were \$4.3 million and \$0.6 million, respectively. The increase in capital expenditures was primarily due to the purchase of laboratory equipment and tenant improvements necessary to modify our new manufacturing facility. For 2013, we expect our level of capital expenditures to decrease due to the scale-up work performed in 2012 on our new manufacturing facility.

The increase in our financing activities consists primarily of increased sales of our common stock. We received net proceeds of \$54.0 million from the direct sale of our common stock and through our 2010 Sales Agreement, as compared to \$11.0 million in 2011.

In November 2011, we entered into lease agreements, under which we lease our new manufacturing, laboratory and office space in Gaithersburg, Maryland. The lease agreements provide that, among other things, as of January 1, 2012, we sublease from the previous tenant, and subsequently lease directly from the landlord, approximately 74,000 total square feet, with rent payments for such space to the landlord commencing April 1, 2014. Under the terms of the arrangement, the landlord provided us with a tenant improvement allowance of \$2.5 million and an additional tenant improvement allowance of \$3 million (collectively, the Improvement Allowance). The additional tenant improvement allowance is to be paid back to the landlord over the remaining term of the lease agreement through additional rent payments. During 2012, we were funded \$4.3 million under the Improvement Allowance.



In September 2012, we entered into a master security agreement, whereby we can borrow up to \$2.0 million to finance the purchases of equipment (Equipment Loan). During 2012, we financed \$0.5 million under the Equipment Loan.

We have entered into agreements with outside providers to support our clinical development. As of December 31, 2012, \$6.2 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2013. However, under the terms of the agreements, we have the option to terminate for convenience pursuant to notification, but we would be obligated to pay the provider for all costs incurred through the effective date of termination.

We have licensed certain rights from Wyeth. The Wyeth license, which provides for an upfront payment (previously made), ongoing annual license fees, milestone payments and royalties on any product sales, is a non-exclusive, worldwide license to a family of patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022; 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. Payments under the agreement to Wyeth from 2007 through 2012 totaled \$5.7 million, of which \$0.6 million was paid in 2012. We do not expect to make a milestone payment to Wyeth in the next 12 months.

In connection with our JV with Cadila, we entered into a master services agreement, which we and Cadila amended first in July 2011, and subsequently in March 2013, in each case to extend the term by one year for which services can be provided by Cadila under this agreement. Under the revised terms, if, by March 2014, the amount of services provided by Cadila under the master services agreement is less than \$7.5 million, we will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. Through December 31, 2012, we have purchased \$0.6 million in services from Cadila pursuant to this agreement.

Based on our current cash and cash equivalents and investments, including our recent private equity offerings, anticipated revenue under the contract with HHS BARDA, possible proceeds from the sales of our common stock under our 2012 Sales Agreement and our current business operations, we believe we have adequate capital resources available to operate at planned levels for approximately the next 24 months. Additional capital will be required in the future to develop our vaccine candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital is subject to various factors:

generating revenue under the HHS BARDA contract is subject to our performance under the contract, including our ability to collect on delayed reimbursement situations, such as the 205 Trial costs; and

·raising funds under our 2012 Sales Agreement is subject to both our business performance and market conditions.

Further, we may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, non-dilutive government contracts, collaborative arrangements or some combination of these financing alternatives. Any capital raised by an equity offering will likely 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. Other than our 2012 Sales Agreement, Improvement Allowance and Equipment Loan, we have not secured any additional commitments for new financing nor can we provide any assurance that new financing will be available on commercially acceptable terms, if at all. If we are unable to perform under the HHS BARDA contract or obtain additional capital, we will assess our capital resources and will likely 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, 2012 (in thousands):

Contractual Obligations:	Total	Less than One Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating leases	\$31,629	\$2,431	\$7,968	\$6,713	\$14,517
Capital lease	341	69	152	120	—
Notes payable	910	357	514	39	—
Purchase obligations	6,900	3,000	3,900	—	—
Total contractual obligations	\$39,780	\$5,857	\$12,534	\$6,872	\$14,517

Our purchase obligations include our anticipated timing of future purchases for services pursuant to the master services agreement with Cadila. We are required to purchase from Cadila, through March 2014, services for biologic research, pre-clinical development, clinical development, process development, manufacturing scale-up and general manufacturing related services. As of December 31, 2012, our remaining obligation to Cadila under the master services agreement was \$6.9 million.

## 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 to preserve our capital until it is required to fund operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of December 31, 2012, we had cash and cash equivalents of \$17.4 million, investments of \$32.9 million, of which \$26.7 million are short-term, and working capital of \$38.7 million.

Our exposure to market risk is primarily confined to our investment portfolio. As of December 31, 2012, 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 investments when they mature and the proceeds are reinvested into new investments and, therefore, could impact our cash flows and results of operations.

Interest and dividend income is recorded when earned and included in interest income. Premiums and discounts, if any, on investments are amortized or accreted to maturity and included in interest 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. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

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

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

The information required by this item is set forth on pages F-1 to F-25.

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

None.

Item 9A. CONTROLS AND PROCEDURES

*Evaluation of Disclosure Controls and Procedures*

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

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

*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 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, 2012. In making this assessment, our management used the criteria set forth in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, our management had determined that, as of December 31, 2012, our internal controls over financial reporting is effective based on those criteria.

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

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

Our management, including our chief executive officer and chief financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2012, and has concluded that there was no change that occurred during the quarterly period ended December 31, 2012 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**

We incorporate herein by reference the information concerning our directors, officers and corporate governance to be included in our definitive Proxy Statement for our 2013 Annual Meeting of Stockholders scheduled to be held on June 13, 2013 (the 2013 Proxy Statement). We expect to file the 2013 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2012.

**Item 11. EXECUTIVE COMPENSATION**

We incorporate herein by reference the information concerning executive compensation to be contained in the 2013 Proxy Statement.

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

We incorporate herein by reference the information concerning security ownership of certain beneficial owners and management and related stockholder matters to be contained in the 2013 Proxy Statement.

The following table provides our equity compensation plan information as of December 31, 2012. Under these plans, our common stock may be issued upon the exercise of options. See also the information regarding our stock options in Note 13 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)	9,355,725	\$ 1.95	5,752,361
Equity compensation plans not approved by security holders	N/A	N/A	N/A

(1) Includes our 2005 Stock Incentive Plan and 1995 Stock Option Plan.



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

We incorporate herein by reference the information concerning certain related party transactions set forth in Note 17 to our financial statements included herewith. We incorporate herein by reference the information concerning certain other relationships and related transactions and director independence to be contained in the 2013 Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

We incorporate herein by reference the information concerning principal accountant fees and services to be contained in the 2013 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
Balance Sheets as of December 31, 2012 and 2011	F-4
Statements of Operations and Statements of Comprehensive Loss for the years ended December 31, 2012, 2011 and 2010	F-5
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Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010	F-7
Notes to Financial Statements	F-8

(2) Financial Statement Schedules

Schedule II – Valuation and Qualifying Accounts

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

(3) *Exhibits*

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

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

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

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

- 3.1 Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1996, filed March 21, 1997), as amended by the Certificate of Amendment dated December 18, 2000 (Incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, filed March 29, 2001), as further amended by the Certificate of Amendment dated July 8, 2004 (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed August 9, 2004), as further amended by the Certificate of Amendment dated May 13, 2009 (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed August 10, 2009)
- 3.2\* Amended and Restated By-Laws of the Company
- 4.1 Specimen stock certificate for shares of common stock, par value \$.01 per share (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 10, File No. 0-26770, filed 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 Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009)
- 4.3 Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed July 30, 2008)
- 10.1† Novavax, Inc. 1995 Stock Option Plan, as amended (Incorporated by reference to Appendix A of the Company's Definitive Proxy Statement filed March 31, 2003 in connection with the Annual Meeting held on May 7, 2003) (File No. 000-26770)
- 10.2\* Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan
- 10.3† Employment Agreement of Stanley C. Erck, dated as of February 15, 2010 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed June 1, 2010)
- 10.4† Employment Agreement of Stanley C. Erck, dated as of June 22, 2011 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report for the quarter ended June 30, 2011, filed August 9, 2011)
- 10.5† Employment Agreement between Novavax, Inc. and Frederick Driscoll dated August 6, 2009 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed August 7, 2009)
- 10.6† Employment Agreement of Gregory Glenn dated July 1, 2010 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed July 6, 2010)
- 10.7† Employment Agreement of Russell Wilson dated November 7, 2011 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed November 14, 2011)
- 10.8† Employment Agreement of Timothy Hahn dated June 22, 2011 (Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed March 14, 2012)
- 10.9† Novavax, Inc. Amended and Restated Change in Control Severance Benefit Plan, (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed January 5, 2009)

10.10 Form of Indemnity Agreement, as of January 1, 2010 (Incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, filed March 16, 2010)

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- 10.11 Lease Agreement, dated as of July 15, 2004, between Liberty Property Limited Partnership and the Company (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report in Form 10-Q for the quarter ended June 30, 2004, filed August 9, 2004)
- 10.12 Sublease Agreement, dated April 28, 2006, by and between the Company and Sterilox Technologies, Inc. (now PuriCore, Inc.) (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, filed August 14, 2006)
- 10.13 Amendment dated as of October 25, 2006 to the Sublease Agreement, dated April 28, 2006, by and between the Company and Sterilox Technologies, Inc. (now PuriCore, Inc.) (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, filed November 14, 2006)
- 10.14 Second Amendment to Sublease Agreement between Novavax, Inc. and PuriCore, Inc., dated April 22, 2009 (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report for the quarter ended June 30, 2009, filed August 10, 2009)
- 10.15 Third Amendment to Sublease Agreement between Novavax, Inc. and PuriCore, Inc., dated December 29, 2010 (Incorporated by reference to Exhibit 10.24 to the Company's Annual Report for the year ended December 31, 2010, filed March 28, 2011)
- 10.16 Lease Agreement between GP Rock One, LLC and Novavax, Inc., dated as of May 7, 2007 (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report for the quarter ended June 30, 2008, filed August 11, 2008)
- 10.17 First Amendment to Lease Agreement between GP Rock One, LLC and Novavax, Inc., dated as of May 30, 2008 (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report for the quarter ended June 30, 2008, filed August 11, 2008)
- 10.18 Second Amendment to Lease Agreement between BMR-9920 Belward Campus Q, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated as of June 26, 2008 (Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report for the quarter ended June 30, 2008, filed August 11, 2008)
- 10.19 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 Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed March 14, 2012)
- 10.20 Sublease Agreement for space at 20 Firstfield between Intercell USA, Inc. and Novavax, Inc., dated as of October 21, 2011 and effective as of November 18, 2011 (Incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed March 14, 2012)
- 10.21 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 Company's Annual Report on Form 10-K for the year ended December 31, 2011, filed March 14, 2012)
- 10.22\*\* Contract, effective as of February 24, 2011, between the Company and HHS/OS/ASPR/BARDA (Incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to its Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2011, filed November 4, 2011)

License Agreement, entered in February 25, 2011, effective as of December 9, 2010, between the Company 10.23\*\* and LG Life Sciences, Ltd. (Incorporated by reference to Exhibit 10.2 to the Company's Amendment No. 1 to its Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2011, filed November 4, 2011)

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- License Agreement, dated July 5, 2007, between the Company and Wyeth Holdings Corporation  
10.24\*\* (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed August 9, 2007)
- Amendment No. 1 to License Agreement, effective as of March 17, 2010, between the Company and Wyeth  
10.25\*\* Holdings Corporation (Incorporated by reference to Exhibit 10.49 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, filed August 6, 2010)
- At Market Issuance Sales Agreement, dated March 15, 2010, by and between Novavax, Inc. and McNicoll,  
10.26 Lewis and Vlak, LLC (Incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, filed March 16, 2010)
- At Market Issuance Sales Agreement, dated October 1, 2012, by and between Novavax, Inc. and MLV & Co.  
10.27 LLC (Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed October 2, 2012)
- Stock Purchase Agreement between Novavax, Inc. and Satellite Overseas (Holdings) Limited, dated  
10.28 March 31, 2009 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009)
- Amended and Restated Joint Venture Agreement between Novavax Inc. and Cadila Pharmaceuticals Limited,  
10.29\*\* dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
- Amended and Restated Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals  
10.30\*\* Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
- Amendment No. 1 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Limited  
10.31 dated July 27, 2011 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, filed on November 8, 2011)
- 10.32\* Amendment No. 2 to Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Limited dated March 7, 2013
- Amended and Restated Supply Agreement between Novavax, Inc. and CPL Biologicals Limited, dated as of  
10.33\*\* June 29, 2009 (Incorporated by reference to Exhibit 10.6 to the Company'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,  
10.34\*\* dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.7 to the Company'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  
10.35\*\* Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
- 10.36\*\*

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Amended and Restated Option to Obtain License between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.9 to the Company'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, 2009 (Incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010)



- 14 Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed on August 9, 2011)
- 23.1\* Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm
- 31.1\* Certification of chief executive officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 31.2\* Certification of chief financial officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
- 32.1\* Certification of chief executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\* Certification of chief financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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: March 12, 2013

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

<b>Name</b>	<b>Title</b>	<b>Date</b>
/s/ Stanley C. Erck Stanley C. Erck	President and Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2013
/s/ Frederick W. Driscoll Frederick W. Driscoll	Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2013
s/ James F. Young James F. Young	Chairman of the Board of Directors	March 12, 2013
/s/ Richard H. Douglas Richard H. Douglas	Director	March 12, 2013
/s/ Gary C. Evans Gary C. Evans	Director	March 12, 2013
/s/ John O. Marsh, Jr. John O. Marsh, Jr.	Director	March 12, 2013
/s/ Michael A. McManus Michael A. McManus	Director	March 12, 2013
/s/ Rajiv Modi Rajiv Modi	Director	March 12, 2013



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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders of

Novavax, Inc.

We have audited the accompanying balance sheets of Novavax, Inc. (a Delaware corporation) (the “Company”) as of December 31, 2012 and 2011, and the related statements of operations, comprehensive loss, changes in stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2012. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Item 15(a)(2). These financial statements and financial statement schedule are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule 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 financial position of Novavax, Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company’s internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 12, 2013 expressed an unqualified opinion.

/s/ Grant Thornton LLP

McLean, Virginia

March 12, 2013

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of

Novavax, Inc.

We have audited the internal control over financial reporting of Novavax, Inc. (a Delaware Corporation) (the “Company”) as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control Over Financial Reporting. 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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements of the Company as of and for the year-ended December 31, 2012, and our report dated March 12, 2013 expressed an unqualified opinion on those financial statements.

/s/ Grant Thornton LLP

McLean, VA

March 12, 2013

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## NOVAVAX, INC.

## BALANCE SHEETS

	December 31,	
	2012	2011
	(in thousands, except share and per share information)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,399	\$ 14,104
Short-term investments available-for-sale	26,712	4,205
Restricted cash	986	—
Accounts receivables	1,011	1,965
Unbilled receivables	1,570	1,836
Prepaid expenses	2,559	2,441
Other current assets	171	1,558
Total current assets	50,408	26,109
Investments available-for-sale	6,233	—
Property and equipment, net	11,456	6,857
Goodwill	33,141	33,141
Restricted cash	756	—
Other non-current assets	351	469
Total assets	\$ 102,345	\$ 66,576
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,228	\$ 2,645
Accrued expenses and other current liabilities	7,275	4,528
Deferred revenue	258	—
Current portion of capital lease	58	—
Current portion of notes payable	157	20
Warrant liability	267	—
Deferred rent	432	386
Total current liabilities	11,675	7,579
Deferred revenue	2,500	2,500
Non-current portion of capital lease	237	—
Non-current portion of notes payable	753	300
Warrant liability	—	368
Deferred rent	6,940	1,980
Total liabilities	22,105	12,727
Commitments and contingences	—	—
Stockholders' equity:		

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Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.01 par value, 200,000,000 shares authorized; and 148,398,747 shares issued and 147,943,317 shares outstanding at December 31, 2012 and 117,480,867 shares issued and 117,025,437 shares outstanding at December 31, 2011	1,484	1,175
Additional paid-in capital	438,939	383,948
Accumulated deficit	(358,163 )	(329,656 )
Treasury stock, 455,430 shares, cost basis	(2,450 )	(2,450 )
Accumulated other comprehensive income	430	832
Total stockholders' equity	80,240	53,849
Total liabilities and stockholders' equity	\$ 102,345	\$ 66,576

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

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NOVAVAX, INC.

## STATEMENTS OF OPERATIONS

	For the Years ended December 31,		
	2012	2011	2010
	(in thousands, except per share information)		
Revenue:			
Government contracts	\$ 20,671	\$ 14,688	\$ 343
Research and development collaborations	1,405	—	—
Total revenue	22,076	14,688	343
Costs and expenses:			
Cost of government contracts revenue	14,692	7,003	—
Research and development	26,061	17,885	28,032
General and administrative	10,988	11,379	10,805
Total costs and expenses	51,741	36,267	38,837
Loss from operations before other income (expense)	(29,665 )	(21,579 )	(38,494 )
Other income (expense):			
Interest income	165	136	189
Interest expense	(32 )	(9 )	(9 )
Other income	45	26	485
Realized gains on short-term investments	879	—	—
Change in fair value of warrant liability	101	2,474	1,671
Loss from operations before income tax	(28,507 )	(18,952 )	(36,158 )
Income tax expense (benefit)		412	(450 )
Net loss	\$ (28,507 )	\$ (19,364 )	\$ (35,708 )
Basic and diluted net loss per share:	\$ (0.22 )	\$ (0.17 )	\$ (0.34 )
Basic and diluted weighted average number of common shares outstanding	131,726	113,610	104,768

## STATEMENTS OF COMPREHENSIVE LOSS

For the Years ended December  
31,  
2012      2011      2010  
(in thousands)

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Comprehensive loss:

Net loss		\$(28,507)	\$(19,364)	\$(35,708)
Change in unrealized gain on investments available-for-sale	(402 )	60	(48 )	
Comprehensive loss		\$(28,909)	\$(19,304)	\$(35,756)

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

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NOVAVAX, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY  
For the Years ended December 31, 2012, 2011 and 2010

	Common Stock Shares	Amount	Additional Paid-in Capital	Notes Receivable From Former Directors	Accumulated Treasury Deficit	Treasury Stock	Accumulated Other Comprehensive Income	Total Stockholders' Equity
<b>(in thousands, except share information)</b>								
Balance at December 31, 2009	100,717,890	1,007	346,731	(1,572 )	(274,584 )	(2,450 )	820	69,952
Non-cash compensation cost for stock options and restricted stock	—	—	1,339	—	—	—	—	1,339
Exercise of stock options	261,942	3	423	—	—	—	—	426
Restricted stock issued as compensation	75,000	1	(1 )	—	—	—	—	—
Restricted stock cancelled	(76,667 )	(1 )	1	—	—	—	—	—
Issuance of common stock, net of issuance costs of \$468	10,513,849	105	22,984	—	—	—	—	23,089
Unrealized gain (loss) on investments	—	—	—	—	—	—	(48 )	(48 )
Net loss	—	—	—	—	(35,708 )	—	—	(35,708 )
Balance at December 31, 2010	111,492,014	1,115	371,477	(1,572 )	(310,292 )	(2,450 )	772	59,050
Non-cash compensation cost for stock options and restricted stock	—	—	2,047	—	—	—	—	2,047
Exercise of stock options	198,679	2	177	—	—	—	—	179
Restricted stock issued as compensation	50,000	1	(1 )	—	—	—	—	—
	(261,667 )	(3 )	(1,519 )	1,572	—	—	—	50

Cancellation of common stock issued to former directors								
Issuance of common stock, net of issuance costs of \$246	6,001,841	60	11,767	—	—	—	—	11,827
Unrealized gain (loss) on investments	—	—	—	—	—	—	60	60
Net loss	—	—	—	—	(19,364 )	—	—	(19,364 )
Balance at December 31, 2011	117,480,867	1,175	383,948	—	(329,656 )	(2,450 )	832	53,849
Non-cash compensation cost for stock options and restricted stock	—	—	2,091	—	—	—	—	2,091
Exercise of stock options	90,534	1	53	—	—	—	—	54
Issuance of common stock, net of issuance costs of \$365	30,827,346	308	52,847	—	—	—	—	53,155
Unrealized gain (loss) on investments	—	—	—	—	—	—	(402 )	(402 )
Net loss	—	—	—	—	(28,507 )	—	—	(28,507 )
Balance at December 31, 2012	148,398,747	\$ 1,484	\$ 438,939	\$ —	\$ (358,163 )	\$ (2,450 )	\$ 430	\$ 80,240

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

NOVAVAX, INC.

## STATEMENTS OF CASH FLOWS

	For the Years ended December 31,		
	2012	2011	2010
	(in thousands)		
<b>Operating Activities:</b>			
Net loss	\$(28,507)	\$(19,364)	\$(35,708)
Reconciliation of net loss to net cash used in operating activities:			
Change in fair value of warrant liability	(101 )	(2,474 )	(1,671 )
Depreciation and amortization	1,666	1,613	1,372
(Gain) Loss on disposal of property and equipment	(28 )		35
Impairment of long-lived assets		360	162
Amortization of net premiums on investments	(18 )	317	247
Deferred rent	660	(341 )	(282 )
Non-cash stock-based compensation	2,091	2,047	1,339
Realized gains on short-term investments	(879 )		
Changes in operating assets and liabilities:			
Restricted cash	(986 )		
Accounts receivables	954	(1,911 )	204
Unbilled receivables	266	(1,836 )	
Prepaid expenses and other assets	40	(1,854 )	(312 )
Accounts payable and accrued expenses	2,009	(2,686 )	1,912
Deferred revenue	258	2,500	(150 )
Lease incentives received	4,346		
Net cash used in operating activities	(18,229)	(23,629)	(32,852)
<b>Investing Activities:</b>			
Capital expenditures	(4,341 )	(610 )	(1,556 )
Proceeds from disposal of property and equipment	324		
Purchases of investments	(48,652)	(2,082 )	(38,717)
Proceeds from maturities and redemptions of investments	20,407	21,235	19,000
Net cash (used in) provided by investing activities	(32,262)	18,543	(21,273)
<b>Financing Activities:</b>			
Principal payments of capital lease	(104 )		
Principal payments of notes payable	(60 )	(80 )	(86 )
Proceeds from notes payable	650		
Proceeds from settlement of notes receivable from former directors		50	
Restricted cash	(756 )		
Net proceeds from sales of common stock, net of offering costs of \$0.4 million, \$0.2 million and \$0.5 million, respectively	54,002	10,980	23,089

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Proceeds from the exercise of stock options	54	179	426
Net cash provided by financing activities	53,786	11,129	23,429
Net increase (decrease) in cash and cash equivalents	3,295	6,043	(30,696)
Cash and cash equivalents at beginning of year	14,104	8,061	38,757
Cash and cash equivalents at end of year	\$17,399	\$14,104	\$8,061
Supplemental disclosure of non-cash activities:			
Deposit applied towards the purchase of equipment	\$500	\$	\$
Equipment acquired under a capital lease	\$399	\$	\$
Equipment purchases included in accounts payable and accrued expenses	\$1,321	\$14	\$418
Settlement of notes receivable from former directors	\$	\$1,522	\$
Sale of common stock under the 2010 Sales Agreement not settled at year-end	\$	\$847	\$
Supplemental disclosure of cash flow information:			
Cash interest payments	\$20	\$	\$

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

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NOVAVAX, INC.

NOTES TO FINANCIAL STATEMENTS

December 31, 2012, 2011 and 2010

Note 1 – Organization

Novavax, Inc. (the “Company”) is a clinical-stage biopharmaceutical company focused on developing recombinant protein nanoparticle vaccines to address a broad range of infectious diseases. The Company’s technology platform is based on proprietary recombinant vaccine technology that includes virus-like particles (“VLPs”) and recombinant protein micelle vaccines combined with a single-use bioprocessing production system. These vaccine candidates are genetically engineered three-dimensional nanostructures that incorporate immunologically important recombinant proteins. The Company’s product pipeline targets a variety of infectious diseases and its vaccine candidates are currently in or have completed clinical trials that target seasonal influenza, pandemic (H5N1) influenza and respiratory syncytial virus (“RSV”).

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Limited (“Cadila”) named CPL Biologicals Private Limited (the “JV”) to develop and manufacture vaccines, biological therapeutics and diagnostics in India. The JV is owned 20% by the Company and 80% by Cadila (See Note 7). The Company accounts for its investment in the JV using the equity method.

Note 2 – Operations

The Company’s vaccine candidates currently under development will require significant additional research and development efforts that include extensive pre-clinical and clinical testing, and regulatory approval prior to commercial use. The Company’s research and development efforts may not be successful and any potential vaccine candidates may not prove to be safe and effective in clinical trials. Even if developed, these vaccine candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The commercial launch of any vaccine is subject to significant risks including, but not limited to, manufacturing scale-up and market acceptance.

As a clinical-stage biopharmaceutical company, the Company has primarily funded its operations from proceeds through the sale of its common stock in equity offerings and under its At Market Issuance Sales Agreements and revenue under its contract with the Department of Health and Human Services, Biomedical Advanced Research and

Development Authority (“HHS BARDA”). Management regularly reviews the Company’s cash and cash equivalents and investments against its operating budget to ensure the Company will have sufficient working capital, and will continue to draw upon such available sources of capital to meet its operating needs.

### Note 3 – Summary of Significant Accounting Policies

#### Use of Estimates

The preparation of the 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 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.

## Investments

Investments consist of commercial paper, corporate notes and investments in auction rate securities. Classification of marketable securities between current and non-current is dependent upon the original maturity date at purchase. Those securities purchased with original maturities greater than 90 days, but less than one year are classified as current and those with greater than one year as non-current.

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

The Company has classified its investments as available-for-sale since the Company may need to liquidate these securities within the next year. The available-for-sale securities are carried at fair value and unrealized gains and losses on these securities, if determined to be 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." 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 in the 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 investments. The Company's investment policy limits investments to certain types of instruments, including auction rate securities, high-grade corporate debt securities and money market instruments, places restrictions on maturities and concentrations in certain industries and requires the Company to maintain a certain level of liquidity. At times, the Company maintains cash balances in financial institutions, which may exceed federally insured limits. The Company has not experienced any losses relating to such accounts and believes it is not exposed to a significant credit risk on its cash and cash equivalents. The carrying value of cash and cash equivalents approximates their fair value based on their short-term maturities at December 31, 2012 and 2011. As discussed below, the fair value of investments is based upon Level 2 data.

## Fair Value Measurements

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

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

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

### Restricted Cash

The Company's restricted cash includes payments received under the PATH agreement (See Note 6) until such time as the Company has paid for the work performed for the related Phase II RSV clinical trial. In addition, the Company's non-current restricted cash with respect to its new manufacturing, laboratory and office space in Gaithersburg, Maryland functions as collateral for letters of credit, which serve as security deposits for the duration of the leases.

### Accounts Receivable

Accounts receivable arise primarily from the Company's contract with HHS BARDA and are 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 ten years. Amortization of leasehold improvements is provided over the shorter of the estimated useful lives of the improvements or the term of the lease. Repairs and maintenance costs are expensed as incurred.

### Goodwill and Intangible Assets

Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are 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 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. When utilized, the income approach is used as a confirming look to the market approach. Goodwill impairment is deemed to exist if the carrying value of the reporting unit exceeds its estimated fair value.

At December 31, 2012 and 2011, 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, 2012 and 2011.

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

The Company has an equity investment in CPL Biologicals Private Limited. 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.

### ***Long-Lived Assets***

The Company accounts for the impairment of its long-lived assets in accordance with ASC 360, *Property, Plant and Equipment*. This financial standard requires a periodic evaluation of the recoverability of the carrying value of long-lived assets whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. The Company considers historical performance and anticipated future results in its evaluation of potential impairment. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of these assets in relation to the operating performance of the business and future undiscounted cash flows expected to result from the use of these assets. Impairment losses are recognized when the sum of expected future cash flows is less than the assets' carrying value, and losses are determined based upon the excess carrying value of the assets over its fair value.

## 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 and clinical development agreements. The Company recognizes revenue under research contracts when a contract has been executed, the contract price is fixed and determinable, delivery of services or products has occurred and collection of the contract price is reasonably assured. Payments received in advance of work performed are recorded as deferred revenue and losses on contracts, if any, are recognized in the period in which they become known.

Under cost reimbursable contracts, 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, certain activities must be pre-approved by HHS BARDA in order for their costs to be deemed allowable direct costs. Direct costs incurred under cost reimbursable contracts are recorded as cost of government contracts revenue. The Company's government contracts, including its HHS BARDA contract, provide the U.S. government (or agency) the ability to terminate the contract for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work. The Company believes that if the government were to terminate one of its contracts for convenience, including the HHS BARDA contract, the costs incurred through the effective date of such termination and any settlement costs resulting from such termination would be allowable costs. Payments to the Company under cost reimbursable contracts with agencies of the U.S. Government, including its contract with HHS BARDA, are provisional payments subject to adjustment upon annual audit by the government. An audit by the government of fiscal year 2011 has been initiated, but not completed as of the date of this filing; however, management believes that revenue for periods subject to audit has been recorded in amounts that are expected to be realized upon final audit and settlement.

The Company's 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 control of the Company. Deliverables that cannot be divided into separate units are combined with other units of accounting, as appropriate. 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. If the performance under a fixed price contract cannot be reasonably estimated, the Company recognizes the revenue on a straight-line basis over the contract term.

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

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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.

#### Cost of Government Contracts Revenue

Cost of government contracts revenue includes direct costs of salaries, laboratory supplies, consultants and subcontractors and other direct costs associated with the Company's process development, manufacturing, clinical, regulatory and quality assurance activities under research contracts. Cost of government contracts revenue does not include allocations of indirect costs.

#### Stock-Based Compensation

The Company accounts for stock-based compensation related to grants of stock options and restricted stock awards 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 13 for a further discussion on stock-based compensation.

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. The expected volatility of the options granted 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 of the options. 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.

Restricted stock awards to employees and directors 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 must be 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 internally funded programs. In addition, indirect costs such as, fringe benefits and overhead expenses, are also included in research and development expenses. These expenses exclude costs associated with cost of government contracts revenue.

#### ***Warrant Accounting***

The Company accounts for the Warrants in accordance with applicable accounting guidance in ASC 815, *Derivatives and Hedging*, as derivative liabilities. The term of the Warrants expire July 31, 2013, as such the Warrants have been classified accordingly in the Company's balance sheet. In compliance with applicable accounting standards, registered warrants that require the issuance of registered shares upon exercise and do not sufficiently preclude an implied right to cash settlement are accounted for as derivative liabilities. The Company uses the Monte Carlo Simulation model to determine the fair value of the Warrants, which requires the input of subjective assumptions, including the expected stock price volatility and probability of a fundamental transaction (a strategic merger or sale).

The fair value of the Warrants as of December 31 was estimated with the following assumptions:

	2012	2011
Underlying price of common stock per share	\$1.89	\$1.26
Exercise price per share	\$3.62	\$3.62
Risk-free interest rate	0.11%	0.20%
Dividend yield	0%	0%
Volatility	72.6%	72.5%
Expected term (in years)	0.58	1.58
Probability of a fundamental transaction	0%-5%	0%-5%

The revaluation of the estimated fair value of Warrants at each subsequent balance sheet date results in a change in the carrying value of the liability, which is recorded as “change in fair value of warrant liability” in the statements of operations.

### ***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 that includes the enactment date. 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, 2012 and 2011, 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. All outstanding warrants, stock options and unvested restricted stock awards totaling 12,732,383, 11,284,054 and 9,344,635 shares at December 31, 2012, 2011 and 2010, respectively, are excluded from the computation for 2012, 2011 and 2010, as their effect is anti-dilutive.

## 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 280, *Segment Reporting*.

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## Recent Accounting Pronouncements

Recently Adopted

In June 2011, the Financial Accounting Standards Board (FASB) issued ASU 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (“ASU 2011-05”). This guidance is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single-statement or two-statement approach. This ASU was effective for the Company beginning January 1, 2012. This presentation requirement was adopted January 1, 2012 and is presented herein.

In September 2011, the FASB issued ASU 2011-08, *Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment* (“ASU 2011-08”), to give both public and nonpublic entities the option to qualitatively determine whether they can bypass the two-step goodwill impairment test. Under the new guidance, if an entity chooses to perform a qualitative assessment and determines that it is more likely than not (a more than 50 percent likelihood) that the fair value of a reporting unit is less than its carrying amount, it would then perform Step 1 of the annual goodwill impairment test in ASC 350-20 and, if necessary, proceed to Step 2. Otherwise, no further evaluation would be necessary. The decision to perform a qualitative assessment is made at the reporting unit level, and an entity with multiple reporting units may utilize a mix of qualitative assessments and quantitative tests among its reporting units. The amended guidance was effective for interim and annual goodwill impairment tests performed for fiscal years beginning after December 15, 2011, although early adoption was permitted. The adoption of ASU 2011-08 on January 1, 2012 did not have a material effect on the Company’s financial statements.

## Note 4 – Fair Value Measurements

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

	Fair Value at December 31, 2012			Fair Value at December 31, 2011		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b><u>Assets</u></b>						
Corporate debt securities and auction rate securities	\$ —	\$ 32,945	\$ —	\$ —	\$ 4,205	\$ —
Total investments	\$ —	\$ 32,945	\$ —	\$ —	\$ 4,205	\$ —
<b><u>Liabilities</u></b>						

Warrant liabilities	\$ —	\$ —	\$ 267	\$ —	\$ —	\$ 368
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During the years ended December 31, 2012 and 2011, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

The following table provides a reconciliation of the beginning and ending balance of Level 3 assets and liabilities measured on a recurring basis for the year ended December 31, 2012 (in thousands):

	<b>Fair Value Measurements of</b>	
	<b>Warrants Using Significant</b>	
	<b>Unobservable Inputs</b>	
	<b>(Level 3)</b>	
Balance at December 31, 2011	\$	368
Change in fair value of Warrant liability		(101 )
Balance at December 31, 2012	\$	267

The amounts in the Company's balance sheet for accounts receivables, unbilled receivables 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.

## Note 5 – Investments

Investments classified as available-for-sale as of December 31, 2012 and 2011 were comprised of (in thousands):

	December 31, 2012				December 31, 2011			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Auction rate securities	\$ 1,175	\$ 409	\$ —	\$ 1,584	\$ 3,373	\$ 832	\$ —	\$ 4,205
Corporate debt securities	31,340	21	—	31,361	—	—	—	—
<b>Total</b>	<b>\$ 32,515</b>	<b>\$ 430</b>	<b>\$ —</b>	<b>\$ 32,945</b>	<b>\$ 3,373</b>	<b>\$ 832</b>	<b>\$ —</b>	<b>\$ 4,205</b>

Non-current investments had original maturities at purchase of greater than one year, but less than two years.

In 2012, the Company received proceeds of \$3.1 million from the redemption of two auction rate securities resulting in realized gains of \$0.9 million. Approximately \$0.3 million of these realized gains resulted from reclassification adjustments out of accumulated other comprehensive income during the period.

## Note 6 – U.S. Government Agreement and Collaborations

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

In February 2011, the Company was awarded a contract from HHS BARDA valued at \$97 million for the first three-year base-period, with an HHS BARDA option for an additional two-year period valued at \$82 million, for a total contract value of up to \$179 million. The HHS BARDA contract award provides significant funding for the Company's ongoing clinical development and product scale-up of both its seasonal and pandemic (H5N1) influenza vaccine candidates. This is a cost-plus-fixed-fee contract in which HHS BARDA will reimburse the Company for allowable direct contract costs incurred plus allowable indirect costs and a fixed-fee earned in the further development of its multivalent seasonal and monovalent pandemic (H5N1) influenza vaccines. Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses not exceeding certain limits. These indirect rates are subject to audit by HHS BARDA on an annual basis. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly. The Company recognized revenue of approximately \$20.1 million in 2012, and has recognized approximately \$34.8 million in revenue since the inception of the contract in 2011.

In December 2012, HHS BARDA completed a contractually-defined In-Process Review (“IPR”) of its contract with the Company. This IPR was conducted by an inter-governmental-agency panel of experts from government agencies including HHS BARDA, FDA, CDC and the National Institutes of Health, who provided input on the Company’s progress during the contract base-period and plans for further development, including both near-term process development and manufacturing activities and longer-term clinical efforts. HHS BARDA subsequently notified the Company in January 2013 that the milestone decision had been made to continue to support this vaccine advanced development contract.

Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, the Company decided to conduct a Phase II clinical trial of its quadrivalent influenza vaccine candidate (“205 Trial”) under its existing U.S. investigational new drug application (“IND”) for its trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for its quadrivalent vaccine candidate (“Quadrivalent IND”). Based on the Company’s discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by the Company after it submits the clinical trial data in a future Quadrivalent IND. The filing of the Quadrivalent IND is expected shortly before the Company initiates the next Phase II dose-confirmatory clinical trial, which has been delayed due to the development activity associated with improving the seroconversion response of one of the four strains. The outside clinical trial costs of the 205 Trial are approximately \$3.1 million in total, of which \$3.0 million was incurred through December 31, 2012. These costs have been recorded as an expense and are included in cost of government contracts revenue.



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

In February 2011, the Company entered into a license agreement with LGLS that allows LGLS to use the Company’s technology to develop and commercially sell influenza vaccines exclusively in South Korea and non-exclusively in certain other specified countries. At its own cost, LGLS is responsible for funding its clinical development of the influenza VLP vaccines and completing a manufacturing facility in South Korea. Under the license agreement, the Company is obligated to provide LGLS with information and materials related to the manufacture of the licensed products, provide on-going project management and regulatory support and conduct clinical trials of its influenza vaccines in order to obtain FDA approval in the U.S. The term of the license agreement is expected to terminate in 2027. Payments to the Company under the license agreement include an upfront payment of \$2.5 million, reimbursements of certain development and product costs, payments related to the achievement of certain milestones and royalty payments at a rate of 10% from LGLS’s future commercial sales of influenza VLP vaccines, which royalty rate is subject to reduction if certain timelines for regulatory licensure are not met. The upfront payment has been deferred and will be recognized when the previously mentioned obligations in the agreement are satisfied, which may not occur until the end of the term of the agreement. Payments for milestones under the agreement will be recognized on a straight-line basis over the remaining term of the research and development period upon achievement of such milestone. Any royalties under the agreement will be recognized as earned.

***PATH Vaccine Solutions (“PATH”) Clinical Development Agreement***

In July 2012, the Company entered into a clinical development agreement with PATH to develop its vaccine candidate to protect against RSV through maternal immunization in low-resource countries (the “RSV Collaboration Program”). The Company was awarded approximately \$2.0 million by PATH for initial funding under the agreement to partially support its Phase II dose-ranging clinical trial in women of childbearing age, which was launched in October 2012. The agreement expires July 31, 2013, unless the Company and PATH decide to continue the RSV Collaboration Program. The Company retains global rights to commercialize the product and has made a commitment to make the vaccine affordable and available in low-resource countries. To the extent PATH has continued to fund 50% of the Company’s external clinical development costs for the RSV Collaboration Program, but the Company does not continue development, the Company would then grant PATH a fully-paid license to its RSV vaccine technology for use in pregnant women in such low-resource countries. During 2012, the Company recognized revenue of approximately \$1.3 million under the agreement. Revenue under this arrangement is 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 represent a reasonable measurement of proportional performance of the work.

**Note 7 – Joint Venture**

In March 2009, the Company entered into a Joint Venture Agreement with Cadila pursuant to which the Company and Cadila formed CPL Biologicals Private Limited, a joint venture (the "JV"), of which 20% is owned by the Company and 80% is owned by Cadila. The JV was established to develop and manufacture certain of the Company's vaccine candidates and certain of Cadila's biogeneric and diagnostic products for the territory of India. The JV has the right to negotiate definitive license arrangements in India to certain of the Company's future vaccine products and certain of Cadila's future biogeneric and diagnostic products, prior to the Company or Cadila licensing such rights to third-parties. The Company has the right to negotiate definitive license arrangements for vaccines developed by the JV using Company technology for commercialization in every country except India and for vaccines developed by the JV using Cadila technology for commercialization in certain other countries, including the U.S. Cadila has supported and continues to support the JV's operations. The JV is actively developing a number of vaccine candidates that were genetically engineered by Novavax. The JV's seasonal and pandemic influenza vaccine candidates began Phase I clinical trials in 2012. Also in 2012, the JV formed a new collaboration to develop a novel malaria vaccine in India with the International Centre for Genetic Engineering and Biotechnology. The JV's rabies vaccine candidate is expected to begin a Phase I clinical trial in India in 2013. In connection with the Joint Venture Agreement, in March 2009, the Company also entered into additional agreements, including a master services agreement with Cadila. Because the Company does not control the JV, 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 future.

**Note 8 – Other Financial Information*****Prepaid Expenses***

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

	2012	2011
Laboratory supplies	\$1,592	\$1,616
Other prepaid expenses	967	825
Prepaid expenses	\$2,559	\$2,441

***Property and Equipment, net***

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

	2012	2011
Construction in progress	\$5,248	\$56
Machinery and equipment	8,035	7,131
Leasehold improvements	4,629	4,548
Computer software and hardware	698	669
	18,610	12,404
Less accumulated depreciation and amortization	(7,154)	(5,547)
Property and equipment, net	\$11,456	\$6,857

Depreciation and amortization expense was approximately \$1.7 million, \$1.6 million and \$1.4 million for the years ended December 31, 2012, 2011 and 2010, respectively. Machinery and equipment included \$0.4 million of equipment acquired under a capital lease (see Note 9) with accumulated depreciation of less than \$0.1 million as of December 31, 2012.

***Accrued Expenses and Other Current Liabilities***

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

	2012	2011
Employee benefits and compensation	\$3,242	\$2,283
Research and development accruals	3,396	1,213
Other accrued expenses	592	1,000
Accrued interest	45	32
Accrued expenses and other current liabilities	\$7,275	\$4,528

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**Note 9 – Capital Lease**

In August 2012, the Company leased equipment under a capital lease with an effective interest rate of 6.5% with an advance payment and monthly payments of \$6,325 starting August 2012 and over the next 59 months. The capital lease is recorded at the present value of the future minimum lease payments. Future minimum capital lease payments under the capital lease agreement at December 31, 2012 are as follows (in thousands):

Year	Amount
2013	\$ 69
2014	76
2015	76
2016	76
2017	44
	341
Less amounts representing interest	(46 )
Present value of net minimum lease payments	295
Less current portion of capital lease	(58 )
Non-current portion of capital lease	\$ 237

**Note 10 – Long-Term Debt****Notes Payable**

Notes payable consist of the following at December 31 (in thousands):

	2012	2011
Equipment loan; 12.1%, principal payments due in monthly installments of \$13,089 through March 2016	\$510	\$
Loan agreements; bear interest at 3% per annum; repayment is conditional	400	300
Opportunity Grant Fund notes payable; non-interest bearing; principal only payments due in monthly installments of \$6,667 through April 2012		20
Total	910	320
Less current portion	(157)	(20)
Long-term portion	\$753	\$300

### Equipment Loan

In September 2012, the Company entered into a Master Security Agreement with General Electric Capital Corporation (“GE”), whereby the Company can borrow up to \$2.0 million to finance the purchases of equipment (“Equipment Loan”). Each Equipment Loan bears interest at the three-year U.S. Government treasury rate plus 11.68%, provided that the rate shall not be less than 12.1%, and is to be repaid over forty-two (42) months. GE will maintain a security interest in all equipment financed under this facility. During 2012, the Company financed \$0.5 million at an interest rate of 12.1% with monthly principal payments of \$13,089, which began in October 2012. Interest accrues on the outstanding balance until paid in full.

### Loan Agreements

In May 2008, the Company entered into loan agreements with the State of Maryland and Montgomery County. The repayment of loan amounts and accrued interest, if any, is conditioned upon the Company meeting the capital investment and employment requirements during the term of the loans through 2014, as amended.

Aggregate future minimum principal payments on long-term debt at December 31, 2012 are as follows (in thousands):

Year	Amount
2013	\$ 357
2014	357
2015	157
2016	39
Total minimum principal payments	\$ 910

#### Note 11 – Warrant Liability

In July 2008, the Company completed a registered direct offering of 6,686,650 units, raising approximately \$17.5 million in net proceeds. Each unit consisted of one share of common stock and a warrant to purchase 0.5 shares of common stock (the “Warrants”) at a price of \$2.68 per unit. The Warrants represent the right to acquire an aggregate of 3,343,325 shares of common stock at an exercise price of \$3.62 per share and are exercisable through July 31, 2013.

During 2012, 2011 and 2010, the Company recorded as other income in its statements of operations a change in fair value of warrant liability of \$0.1 million, \$2.5 million and \$1.7 million, respectively. As of December 31, 2012, the warrant liability recorded on the balance sheet was \$0.3 million and all Warrants remain outstanding as of that date under this offering.

#### Note 12 – Sales of Common Stock

In 2012, the Company completed two separate offerings to sell over 12 million and 10 million shares of common stock. In October 2012, the Company sold 12,385,321 shares of its common stock to RA Capital Management, LLC (“RA Capital”), Camber Capital Management LLC and Ayer Capital Management LLC at a price of \$2.18 per share, resulting in approximately \$27 million in net proceeds. In May 2012, the Company sold 10,000,000 shares of its common stock to RA Capital at a price of \$1.22 per share, resulting in approximately \$12.2 million in net proceeds. In both cases, the shares were offered under an effective shelf registration statement previously filed with the Securities and Exchange Commission (“SEC”).

The Board of Directors of the Company (the “Board”) has appointed a standing Finance Committee (the “Committee”) to assist the Board with its responsibilities to monitor, provide advice to senior management of the Company and approve all capital raising activities. The Committee has been authorized by the Board to approve all At Market Issuance sales transactions. In doing so, the Committee sets the amount of shares to be sold, the period of time during

which such sales may occur and the minimum sales price per share. In October 2012, the Company entered into an At Market Issuance Sales Agreement (“2012 Sales Agreement”), under which the Company may sell an aggregate of \$50 million in gross proceeds of its common stock. This agreement replaces the previous and terminated At Market Issuance Sales Agreement entered in March 2010 (“2010 Sales Agreement”), which also allowed for the sale of an aggregate of \$50 million in gross proceeds of its common stock, but had recently met its limitation of sales of shares. The shares of common stock are being offered pursuant to a shelf registration statement filed with the SEC. During 2012, the Company sold 8,442,025 shares at sales prices ranging from of \$1.31 – \$2.18 per share, resulting in \$14.0 million in net proceeds; this amount excludes \$0.8 million received in early 2012 for 0.7 million shares traded in late December 2011. During 2011, the Company sold 6,001,841 shares at sales prices ranging from \$1.25 – \$2.75 per share, resulting in \$11.8 million in net proceeds (with \$0.8 million received in early 2012 for 0.7 million shares traded in late December 2011). During 2010, the Company sold 10,513,849 shares at sales prices ranging from \$2.10 – \$2.55 per share, resulting in \$23.1 million in net proceeds. The Company sold a total 24,957,715 shares of its common stock and received gross proceeds of \$49.9 million under the 2010 Sales Agreement.



## Note 13 – Stock-Based Compensation

The Company has granted equity awards under several plans. Under the 2005 Stock Incentive Plan (the “2005 Plan”), equity awards may be granted to officers, directors, employees, consultants and advisors to the Company and any present or future subsidiary. The 2005 Plan, approved in May 2005 and amended in June 2007, June 2011 and June 2012 by the Company’s stockholders, currently authorizes the grant of equity awards for up to 18,312,192 shares of common stock, which included, at the time of approval of the 2005 Plan, a maximum 5,746,468 shares of common stock subject to stock options outstanding under the Company’s 1995 Stock Option Plan (the “1995 Plan”) that may revert to and become issuable under the 2005 Plan if such options should expire or otherwise terminate unexercised. The term of the Company’s 1995 Plan has expired. Outstanding stock options remain in existence in accordance with their terms and no new awards will be made under the 1995 Plan.

Under the 2005 Plan and the 1995 Plan, incentive stock options, having a maximum term of 10 years, can be or were granted at no less than 100% of the fair value of the Company’s common stock at the time of grant and are generally exercisable over periods ranging from six months to four years. There is no minimum exercise price for non-statutory stock options.

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,		
	2012	2011	2010
Research and development	\$ 873	\$ 610	\$ 335
General and administrative	1,218	1,437	1,004
Total stock-based compensation expenses	\$ 2,091	\$ 2,047	\$ 1,339

***Stock Options Awards***

The following is a summary of option activity under the 2005 Plan and the 1995 Plan for the year ended December 31, 2012:

2005 Stock Incentive Plan		1995 Stock Option Plan	
Stock Options	Weighted-Average Exercise	Stock Options	Weighted-Average Exercise

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		Price		Price
Outstanding at January 1, 2012	7,412,746	\$ 2.22	474,650	\$ 4.38
Granted	3,483,000	\$ 1.29	—	\$ —
Exercised	(90,534 )	\$ 0.61	—	\$ —
Canceled	(1,661,387 )	\$ 2.27	(262,750 )	\$ 3.86
Outstanding at December 31, 2012	9,143,825	\$ 1.87	211,900	\$ 4.94
Vested and expected to vest at December 31, 2012	8,255,692	\$ 1.92	211,900	\$ 4.94
Shares exercisable at December 31, 2012	3,541,268	\$ 2.34	211,900	\$ 4.94
Shares available for grant at December 31, 2012	5,752,361			

The fair value of the stock options granted for the years ended December 31, 2012, 2011 and 2010, was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2012	2011	2010
Weighted average fair value of options granted	\$0.71	\$1.14	\$1.47
Risk-free interest rate	0.55%-1.54%	0.48%-1.91%	0.93%-2.89%
Dividend yield	0%	0%	0%
Volatility	75.5%-78.6%	73.3%-81.0%	97.0%-108.0%
Expected term (in years)	3.34-7.09	3.26-4.47	3.06-6.26
Expected forfeiture rate	0%-23.15%	0%-23.15%	21.07%

The aggregate intrinsic value and weighted average remaining contractual term of stock options exercisable as of December 31, 2012 was approximately \$0.7 million and 5.8 years, respectively. The aggregate intrinsic value and weighted average remaining contractual term of options vested and expected to vest as of December 31, 2012 was \$2.6 million and 7.5 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 2012 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, 2012. This amount is subject to change based on changes to the fair market value of the Company's common stock. The aggregate intrinsic value of options exercised for 2012, 2011 and 2010 was \$0.1 million, \$0.3 million and \$0.3 million, respectively.

### ***Restricted Stock Awards***

Under the 2005 Plan, the Company granted restricted stock awards subject to certain performance-based or time-based vesting conditions which, if not met, would result in forfeiture of the shares and reversal of any previously recognized related stock-based compensation expense.

The following is a summary of restricted stock awards activity for the year ended December 31, 2012:

	Number of Shares	Per Share Weighted- Average Grant-Date Fair Value
Outstanding at January 1, 2012	53,333	\$ 1.63
Restricted stock granted	—	\$ —
Restricted stock vested	(19,999 )	\$ 2.03
Restricted stock forfeited	—	\$ —
Outstanding at December 31, 2012	33,334	\$ 1.39

As of December 31, 2012, there was approximately \$3.4 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested options and restricted stock awards. This unrecognized compensation expense is expected to be recognized over a weighted average period of 1.4 years.

### **Note 14 – Employee Benefits**

The Company maintains a defined contribution 401(k) retirement plan, pursuant to which employees who have completed 90 days of service 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.

During 2012, the Company increased its match from 25% to 50% of the first 6% of the participants' deferral. Contributions to the 401(k) plan vest equally over a three-year period. The Company has expensed, net of forfeitures, approximately \$127,000, \$88,000 and \$71,000 in 2012, 2011 and 2010, respectively.

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## Note 15 – Income Taxes

The Company recorded a current income tax expense for foreign taxes of \$0.4 million in 2011, and a deferred federal income tax benefit of \$0.5 million in 2010. The components of the income tax provision (benefit) are as follows (in thousands):

	2012	2011	2010
Current U.S.	\$ —	\$ —	\$ —
Current foreign	—	412	—
Deferred	—	—	(450)
Net provision	\$ —	\$412	\$(450)

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

	2012	2011
Net operating losses	\$122,731	\$116,492
Research tax credits	5,693	5,904
Other	7,326	3,974
Total deferred tax assets	135,750	126,370
Other	(335 )	(350 )
Total deferred tax liabilities	(335 )	(350 )
Net deferred tax assets	135,415	126,020
Less valuation allowance	(135,415)	(126,020)
Deferred tax assets, net	\$—	\$—

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

	2012	2011	2010
Statutory federal tax rate	(34 )%	(34 )%	(34 )%
State income taxes, net of federal benefit	(8 )%	(9 )%	(4 )%
Research and development and other tax credits	0 %	(5 )%	(2 )%
Expiration of net operating losses	6 %	10 %	4 %
Other	3 %	(3 )%	(1 )%
Change in valuation allowance	33 %	43 %	36 %
	0 %	2 %	(1 )%

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, 2012 and 2011 as management believes it is more likely than not that the assets will not be realizable.

During 2011, the Company incurred a \$0.4 million foreign withholding tax related to a payment received in accordance with a license agreement. This withholding tax gives rise to an increase to the U.S. net operating loss for which a full valuation allowance has been recorded. During the year ended December 31, 2010, as a result of new legislation allowing for the partial refund of research and development credits, the Company requested and received a refund of approximately \$0.1 million. In addition, during the year ended December 31, 2010, the Company received grants totaling \$0.8 million for qualifying therapeutic discovery projects under Internal Revenue Code Section 48D. The combination of the refundable research and development credits and the Internal Revenue Code Section 48D grant resulted in the Company recording a deferred federal income tax benefit of \$0.5 million during the year ended December 31, 2010.

As of December 31, 2012, 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 2032	\$302,394
Research tax credits expiring through the year 2032	6,238
Alternative-minimum tax credit (no expiration)	94

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change under Section 382 of the Internal Revenue Code occurred. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards and credits attributable to periods before the change and could result in a reduction in the total net operating losses and credits available.

Beginning in 2006, the windfall equity-based compensation deductions are tracked, but will not be recorded to the balance sheet until management determines more likely than not that such amounts will be utilized. During 2012 and 2011, the Company had less than \$0.1 million and \$0.1 million, respectively, of windfall stock compensation deductions. If and when realized, the tax benefit associated with these deductions will be credited to additional paid-in capital. These excess benefit deductions are included in the total federal net operating losses disclosed above.

Tabular Reconciliation of Unrecognized Tax Benefits (in thousands):

	Amount
Unrecognized tax benefits as of January 1, 2011	\$4,910
Gross increases — tax positions in prior period	
Gross decreases — tax positions in prior period	(35 )
Gross increases — current-period tax positions	—
Increases (decreases) from settlements	—
Unrecognized tax benefits as of December 31, 2011	\$4,875
Gross increases — tax positions in prior period	
Gross decreases — tax positions in prior period	(74 )
Gross increases — current-period tax positions	—
Increases (decreases) from settlements	—
Unrecognized tax benefits as of December 31, 2012	\$4,801

To the extent these unrecognized tax benefits are ultimately recognized, it would affect the annual effective income tax rate.

The Company files income tax returns in the U.S. federal jurisdiction and in various states. The Company had tax net operating losses and credit carryforwards that are subject to examination for a number of years beyond the year in which they are 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 Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2012 and December 31, 2011, the Company had no accruals for interest or penalties related to income tax matters.



## Note 16 – Commitments and Contingencies

## Operating Leases

The Company conducts its operations from leased facilities, under operating leases with terms expiring in 2017 for its Rockville, Maryland facility and in 2023 for its Gaithersburg, Maryland facilities. The leases obligate the Company to also pay building operating costs. In November 2011, the Company entered into lease and sublease agreements, under which the Company will lease its new manufacturing, laboratory and office space in Gaithersburg, Maryland. The agreements provide that, among other things, as of January 1, 2012, the Company sublease from the previous tenant, and subsequently lease from the landlord approximately 74,000 total square feet, with rent payments for such space to the landlord commencing April 1, 2014. On April 1, 2012, one of the two subleases with the previous tenant for space totaling approximately 21,000 square feet ended and was replaced by a lease with the landlord. On April 1, 2013, the other sublease with the previous tenant for space totaling approximately 53,000 square feet will end and be replaced by a lease with the landlord. Under the terms of one lease agreement, the landlord provided the Company with a tenant improvement allowance of \$2.5 million and an additional tenant improvement allowance of \$3 million, which additional tenant improvement allowance is paid back to the landlord during the remainder of the term of such lease agreement through additional rent payments (collectively, the “Improvement Allowance”). In 2012, the Company has been funded \$4.3 million under the Improvement Allowance. 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. In addition, the Company entered into an agreement with the previous tenant to purchase certain laboratory equipment to be used at the facility. The Company is currently considering its plans for the Rockville, Maryland facility subsequent to relocation to the Gaithersburg, Maryland facilities, which plans include remarketing the facility through the end of the remaining lease term of January 31, 2017. The Company also leased space in Malvern, Pennsylvania, its former corporate headquarters, under an operating lease with a term expiring in 2014. The Company has subleased this facility under an amended sublease agreement expiring in 2014.

Future minimum rental commitments under non-cancelable leases as of December 31, 2012 are as follows (in thousands):

Year	Operating Leases	Sublease	Net Operating Leases
2013	\$ 2,431	\$ (295 )	\$ 2,136
2014	3,797	(201 )	3,596
2015	4,171	—	4,171
2016	4,271	—	4,271
2017	2,442	—	2,442
Thereafter	14,517	—	14,517
Total minimum lease payments	\$ 31,629	\$ (496 )	\$ 31,133

Total rent expenses approximated \$3.2 million, \$1.6 million and \$1.6 million for the years ended December 31, 2012, 2011 and 2010, respectively.

#### Purchase Obligations

In March 2009, the Company and Cadila entered into a master services agreement pursuant to which the Company may request services from Cadila in the areas of biologics research, pre-clinical development, clinical development, process development, manufacturing scale-up and general manufacturing related services in India. In July 2011, and subsequently in March 2013, in each case the Company and Cadila amended the master services agreement to extend the term by one year for which services can be provided by Cadila under this agreement. Under the revised terms, if, by March 31, 2014, the amount of services provided by Cadila is less than \$7.5 million, the Company will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. When calculating the shortfall, the amount of services provided by Cadila includes amounts that have been paid under all project plans, the amounts that will be paid under ongoing executed project plans and amounts for services that had been offered to Cadila, that Cadila was capable of performing, but exercised its right not to accept such project. The term of the master services agreement is five years, but may be terminated by either party if there is a material breach that is not cured within 30 days of notice or, at any time after three years, provided that 90 days prior notice is given to the other party. As of December 31, 2012, the Company's remaining obligation to Cadila under the master services agreement is \$6.9 million.

## *Contingencies*

### *License Agreement with Wyeth Holdings Corporation*

The Company entered into a license agreement in 2007 with Wyeth Holdings Corporation, a subsidiary of Pfizer Inc. (“Wyeth”). The license is a non-exclusive, worldwide license to a family of patent applications covering VLP technology for use in human vaccines in certain fields, with expected patent expiration in early 2022. The agreement provides for an upfront payment, annual license fees, milestone payments and royalties on any product sales. If each milestone is achieved for any particular vaccine candidate, the Company would likely be obligated to pay an aggregate of \$14 million to Wyeth for each product developed and commercialized under the agreement. Annual license fees under the agreement total \$0.2 million per annum. The royalty to be paid by the Company under the agreement, if a product is approved by the FDA for commercialization, will be based on single digit percentage of net sales. Payments under the agreement to Wyeth as of December 31, 2012 aggregated \$5.7 million, of which the Company paid the annual license fees during the three years ended December 31, 2012. The agreement will remain effective as long as at least one claim of the licensed patent rights cover the manufacture, sale or use of any product unless terminated sooner at the Company’s option or by Wyeth for an uncured breach by the Company.

### *Employment Agreements*

The Company has entered into employment agreements with certain of its executive officers and key employees. The employment agreements have one year terms that automatically renew annually and provide for base salaries and other incentives. The agreements include a provision whereby if the Company terminates the employment of such an employee other than for cause, including pursuant to a change of control under its severance plan, or the employee leaves the Company for good reason, such employee shall be entitled to receive payment of existing salary and benefits for a period that ranges from 12 to 24 months.

## Note 17 – Related Party Transactions

Dr. Rajiv Modi, a director of Novavax, is also the managing director of Cadila. The Company and Cadila have formed a joint venture called CPL Biologicals Private Limited, of which the Company owns 20% and Cadila owns 80%. The Company and Cadila also have entered into a master services agreement, pursuant to which Cadila may perform certain research, development and manufacturing services for the Company up to \$7.5 million. A subsidiary of Cadila owns 12.5 million shares of the Company’s outstanding common stock. Since entering into the master services agreement and through December 31, 2012, the Company has incurred \$0.6 million under the agreement.

**Note 18 – Quarterly Financial Information (Unaudited)**

The Company's unaudited quarterly information for the years ended December 31, 2012 and 2011 is as follows:

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
2012:				
Revenue	\$4,642	\$7,103	\$ 5,765	\$ 4,567
Net loss	\$(7,336)	\$(5,920)	\$ (7,217 )	\$ (8,035 )
Net loss per share	\$(0.06 )	\$(0.05 )	\$ (0.05 )	\$ (0.06 )

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
2011:				
Revenue	\$834	\$3,001	\$ 5,008	\$ 5,845
Net loss	\$(7,453)	\$(4,993)	\$ (3,212 )	\$ (3,705 )
Net loss per share	\$(0.07 )	\$(0.04 )	\$ (0.03 )	\$ (0.03 )

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.

## NOVAVAX, INC.

## SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

December 31, 2012, 2011 and 2010

(in thousands)

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Net Deferred Tax Asset				
Valuation Allowance:				
2012	\$ 126,020	\$ 9,395	\$ —	\$ 135,415
2011	108,004	18,016	—	126,020
2010	94,853	13,151	—	108,004