NOVAVAX INC
Form 10-K
March 14, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2011

OR

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

For the transition period from to .

Commission File No. 0-26770

NOVAVAX, INC.

(Exact name of Registrant as specified in its charter)

Delaware	9920 Belward Campus Drive, Rockville, Maryland 20850	22-2816046
(State of incorporation)	(Address of principal executive offices)	(I.R.S. Employer Identification No.)

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

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

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

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

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

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

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

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 x No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 o	Accelerated filer x	Non-accelerated filer o	Smaller reporting company o
	(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 o No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (based on the last reported sale price of Registrants common stock on June 30, 2011 on the NASDAQ Global Market) was $172,600,000.

As of March 8, 2012, there were 121,571,186 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, 2011 in connection with the Registrant s 2012 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

TABLE OF CONTENTS

	Page
PART I Item 1. BUSINESS	1
Item 1A. RISK FACTORS	13
Item 2. PROPERTIES	31
Item 3. LEGAL PROCEEDINGS	31
PART II Item 5. MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	32
Item 6. SELECTED FINANCIAL DATA	34
Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	35
Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	47
Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	47
Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	47
Item 9A. CONTROLS AND PROCEDURES	47
Item 9B. OTHER INFORMATION	48
PART III Item 10.	49

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE
Item 11.
49

EXECUTIVE COMPENSATION
Item 12.
49

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS
Item 13.
49

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE
Item 14.
49

PRINCIPAL ACCOUNTING FEES AND SERVICES
PART IV
Item 15.
50

EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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.

TABLE OF CONTENTS

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, that attempt to advise you of the risks and factors that may affect our future results.

Overview

Novavax, Inc. (Novavax, the Company, we or us) is a clinical-stage biopharmaceutical company focused on developing novel recombinant vaccines to address a broad range of infectious diseases. Our goal is to become a profitable vaccine company that is aggressively driving towards development, licensure and commercialization of important vaccines worldwide.

Our technology platform is based on proprietary recombinant vaccine technology that includes virus-like particles (VLPs) and recombinant nanoparticle vaccines. Our vaccine candidates are genetically engineered three-dimensional nanostructures, which incorporate immunologically important recombinant proteins. There are a number of recombinant protein-based vaccines currently marketed and widely-used, including Recombivax® HB (Merck) and Engerix® (GlaxoSmithKline), which protect against Hepatitis B, Gardasil® (Merck) and Cervarix® (GlaxoSmithKline), which protect against human papilloma virus and Provenge® (Dendreon), which treats certain types of prostate cancer. Our product pipeline targets a variety of infectious diseases and our vaccine candidates are currently in or have completed clinical trials that target pandemic influenza (H5N1), seasonal influenza and respiratory syncytial virus (RSV). Further, CPL Biologics Private Limited (the JV), our joint venture company in India, is actively developing a rabies vaccine candidate that was genetically engineered by Novavax. The JV recently completed initial pre-clinical immunogenicity studies on this new vaccine candidate and is progressing with pre-clinical toxicology studies.

Influenza Vaccines

We have a significant amount of experience in developing recombinant VLP influenza vaccines. Highlights of our experience include the following:

eight clinical trials for our seasonal and pandemic influenza vaccine candidates (including one currently ongoing seasonal influenza trial) and two imminent pandemic influenza trials scheduled to start in the second quarter of 2012;
administering our seasonal and pandemic influenza VLPs (nine distinct strains, including both influenza A and B and strains of avian and swine origin) to over 4,200 subjects demonstrating vaccine tolerability and immunogenicity;
five animal toxicology studies without any safety issues;

two ferret immunization and challenge studies demonstrating control of viral shedding with a seasonal virus strain, and prevention of clinical signs, weight loss and mortality for a highly pathogenic avian strain;

vaccine production under current good manufacturing practices (cGMP) resulting in 45 batches of VLP vaccine with over a dozen different influenza strains; and

scaled-up vaccine production with our 1,000 liter single-use bioprocessing capacity.

1

TABLE OF CONTENTS

We believe our influenza VLP vaccines have potential immunological advantages over currently available products because our influenza VLPs contain three of the major structural influenza virus proteins, which we believe are important to combat 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. Further, our VLPs are not made from a live virus and have no genetic nucleic material in their inner core, which renders them incapable of replicating and causing disease.

Novavax s 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 infrastructure, (4) competitive cost of goods and (5) the potential for advance seed production, which could provide a shorter lead time to produce vaccine than egg-based technology in the face of strain changes.

HHS BARDA Contract Award for Recombinant Influenza Vaccines

In February 2011, we were awarded a contract from the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA) of the U.S. government valued at $97 million for the first 36 month base-period, with an HHS BARDA option period of 24 months valued at $82 million, for a total contract value of up to $179 million. The HHS BARDA contract award provides significant funding for the continued ongoing clinical development and product scale-up of both our seasonal and pandemic influenza vaccine candidates. This is a cost-plus-fixed-fee contract in which HHS BARDA will reimburse us for direct contract costs incurred plus allowable indirect costs and a fee earned in the further development of our seasonal and pandemic (H5N1) influenza vaccines. During 2011, we recognized revenue of approximately $15 million, made significant progress in product characterization and production scale-up and are progressing forward with our multi-year clinical development program.

Pandemic Influenza (H1N1)

Pandemic influenza refers to a situation where there is a significant disease outbreak resulting from an influenza virus appearing in humans for which the majority have little or no immunity. Pandemic influenzas 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 (this strain has been referred to in the media as swine flu).

During 2009 and 2010, we dedicated significant resources to demonstrate our ability to develop a recombinant VLP vaccine against this latest pandemic influenza strain:

three (3) weeks after the Center for Disease Control and Prevention (CDC) announced the genetic sequence of the novel H1N1 virus, we produced a first batch of non-cGMP H1N1 VLP vaccine candidate that was made available to the CDC for analysis;
eleven (11) weeks after receiving the sequence, we manufactured our H1N1 VLP vaccine candidate under cGMP; using this vaccine candidate, we conducted a Phase II clinical trial in Mexico, in collaboration with Laboratorio Avi-Mex S.A. de C.V. and GE Healthcare (GEHC); and

final data results, published last year and presented at the World Health Organization (WHO) Meeting for the Evaluation of Pandemic Influenza Vaccines in Clinical Trials, showed that our H1N1 VLP vaccine exceeded the immunogenicity criteria for licensure at all dose levels, including the lowest 5µg dose and that a single administration of the VLP vaccine induced high levels of hemagglutinin inhibition (HAI) titers in subjects without pre-existing detectable immunity to H1N1 influenza.

TABLE OF CONTENTS

H1N1 influenza is no longer considered a pandemic (WHO categorizes H1N1 as post-pandemic) and the strain is being addressed as an active strain in WHO and CDC s determination of ongoing seasonal influenza strains. Nevertheless, we expect that the data from our H1N1 clinical trial will be used to support our active pandemic (H5N1) and seasonal influenza VLP vaccine programs in the U.S. and in other countries.

Pandemic Influenza (H5N1)

The H5N1 strain of influenza has been identified by WHO as having the potential to cause a pandemic (the H5N1 strain of influenza has commonly been referred to in the media as the avian flu). Most recently, the Center for Infectious Disease Research & Policy (CIDRAP) announced that animal health officials in Nepal reported H5N1 avian influenza outbreaks, while Vietnam and India reported more detection in poultry. In November 2011, CIDRAP also reported poultry outbreaks in Indonesia and Egypt with human fatal infections in Bali. According to the United Nations Food and Agriculture Organization (FAO), 14 countries reported H5N1 outbreaks in 2011.

We have made significant progress in the development of our vaccine that targets the H5N1 influenza strain. In 2007, we released results from an important pre-clinical study in which ferrets that received our H5N1 vaccine candidate were protected from a lethal challenge of the H5N1 virus. After filing an Investigational New Drug (IND) application, we initiated a Phase I/IIa clinical trial. We released interim human data from the first portion of this clinical trial in December 2007. These interim results demonstrated that our pandemic influenza vaccine can generate a protective immune response. We conducted the second portion of the Phase I/IIa trial in 2008 to gather additional subject immunogenicity and safety data and determine a final dose through the completion of this clinical trial. In August 2008, we reported favorable results from this clinical trial, which demonstrated strong neutralizing antibody titers across three doses tested. The vaccine was well-tolerated at all dose levels as compared with placebo, and no serious adverse events were reported. The vaccine also induced robust HAI responses, which have been shown to be important for protection against influenza disease. In conjunction with our BARDA contract, in 2012, we expect to launch two Phase I trials of our H5N1 vaccine candidate in combination with several alternative adjuvant candidates. These trials will evaluate the safety and tolerability of the vaccines in the presence and absence of adjuvants; the ability of VLP vaccine antigens with and without adjuvants to generate antibody levels that fulfill the Food and Drug Administration s (FDA) criteria for accelerated approval and the ability of these vaccines to provide an expanded number of doses and possible cross-protection against other virus strains to the U.S. population.

Seasonal Influenza

We are actively developing our VLP vaccine that targets the seasonal influenza virus. In 2008, we announced positive results from an immunogenicity study in ferrets inoculated with our seasonal influenza vaccine candidate. Subsequently, we conducted a Phase IIa clinical trial to evaluate the safety and immunogenicity of different doses of our seasonal trivalent (three strain) influenza vaccine candidate. In December 2008, we announced favorable safety and immunogenicity results from this Phase IIa seasonal trial in healthy adults (aged between 18 and 49 years) with no vaccine-related serious adverse events reported. In May 2009, we enrolled subjects in a second Phase II trial in healthy adults using our trivalent seasonal influenza vaccine candidate. In September 2009, we announced favorable safety and immunogenicity results from this Phase II trial in healthy adults that supported a Phase II dose-ranging trial in older adults (60 years of age or older), head-to-head with a marketed trivalent vaccine that we commenced in November 2009.

In April 2010, we reported the final results of our Phase II trial in older adults in a dose-ranging study comparing our trivalent seasonal influenza VLP vaccine with a commercially available inactivated trivalent influenza vaccine. The results showed that the vaccine was both safe and immunogenic against the 2009 2010 seasonal influenza virus strains in older adults. The CDC has indicated that currently approved seasonal influenza vaccines may be

suboptimally effective in preventing hospitalization for pneumonia and influenza in older adults; however, we believe that some features of our seasonal influenza VLP vaccine have the potential to address this unmet medical need.

TABLE OF CONTENTS

In 2012, we initiated a seasonal influenza Phase II dose-ranging trial using both trivalent and quadrivalent (four strain) formulations. We developed a quadrivalent formulation of our seasonal influenza vaccine candidate as many influenza vaccine manufacturers move from trivalent to quadrivalent formulations, an industry move that has been acknowledged by WHO and the FDA. At the conclusion of the trial, we will select the optimal quadrivalent dose and expect to initiate a dose-confirmatory Phase II trial in the second half of 2012. A Phase III registration trial is expected to begin in late 2013.

Respiratory Syncytial Virus (RSV)

RSV causes infection of the lungs and breathing passages. In adults, RSV generally only produce cold-like symptoms; however, it is the leading cause of bronchiolitis (inflammation of the small airways) and pneumonia in infants and children under one year of age. In premature babies and children with diseases that affect the lungs, heart or immune system, RSV can lead to more serious illnesses. It is a highly contagious virus that often causes epidemics that last from late fall through early spring in the U.S. and other northern hemisphere regions. Currently, there is no approved RSV vaccine available.

We have developed a recombinant nanoparticle vaccine for the prevention of RSV. In pre-clinical studies, we have demonstrated positive results in models designed to test the safety and efficacy of our RSV vaccine candidate. In February 2009, we announced favorable results from an RSV pre-clinical study performed in mice against the viral fusion (F) protein, which fuses with cells in the respiratory tract and causes illness. The vaccine induced neutralizing antibodies against the viral fusion protein and also protected against RSV infection. In January 2010, we announced positive pre-clinical results with a recombinant RSV fusion (F) particle vaccine in cotton rats, which are generally accepted as the best model to evaluate the safety of candidate RSV vaccines. The RSV F vaccine candidate completely protected the vaccinated animals and there was no evidence of enhanced disease in the lungs of vaccinated animals following challenge with live RSV, an effect that was observed in an earlier version of RSV vaccines developed by other companies.

In December 2010, we initiated a blinded, placebo-controlled, dose-escalating Phase I trial to assess the safety and tolerability of aluminum phosphate-adjuvanted and unadjuvanted formulations of our RSV vaccine candidate. A secondary objective of the study was to evaluate total and neutralizing anti-RSV antibody responses and assess the impact of the adjuvant. The study enrolled 150 healthy adults 18 to 49 years old who were allocated to six cohorts that included four dose levels of vaccine. The primary safety findings were local pain and tenderness at the site of injection, the majority of which were mild in nature with no dose-related increase observed. There were no observed vaccine-related serious adverse events or trends for related systemic side effects. The antibody response to the RSV F protein was significantly increased compared to placebo ($p<0.001$) in all groups and increased by 19-fold in the highest-dose group at day 60. A significant dose-response pattern was observed. High rates of seroconversion were seen at all doses including a rate of 100% at the highest-dose-adjuvant group. In 2012, we expect to initiate two separate dose-ranging Phase II trials in older adults and women of child bearing age.

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 develop to a VLP vaccine countermeasure to protect the U.S. from FMD, a highly contagious viral disease of livestock and a potential threat to U.S. agriculture. The Company will use these funds over the next two and a half years 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. 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

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, with production yields that vary from strain to strain. In addition, sometimes the influenza virus strain must be changed 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

TABLE OF CONTENTS

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 pandemic as, even with expedited regulatory approvals for companies that already had approved vaccines, production of H1N1 vaccines took six months before significant doses were distributed.

Compared with traditional egg-based influenza vaccine production, we believe our processes allow for faster production of vaccine. Because our process uses genetic information and no viral seed is required, we can quickly construct clones of the influenza virus as soon as the genetic information is available and without needing to adjust the strain. 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 validated in significantly less time than cell-based vaccine manufacturing facilities. 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 resemble viruses. 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.

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 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 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 the elderly.

Recombinant Nanoparticle Vaccines

Our recombinant nanoparticle vaccine technology is also based on self-assembling protein structures but differ from traditional VLPs in that these particles do not generally occur in nature and can be made from proteins from any pathogenic organism including viruses, bacteria, parasites or even cancer cells. Protein nanoparticles closely resemble the natural structure of surface antigens of disease organisms but lack the genetic material required for replication and therefore are not infectious. An advantage of this technology is the formation of nanoparticles is done *in vitro* or outside of cells thereby making it possible to assemble nanoparticles from one or more very higher purified proteins. This results in high purity vaccines with certain

TABLE OF CONTENTS

manufacturing advantages over more traditional products. Potential immunological advantages of protein nanoparticle vaccines are presentation of epitopes (antibody binding sites) in a more native configuration for improved efficacy, efficient recognition by the immune system s antigen presenting cells (APCs) and triggering robust immune responses, recognition of the nanoparticle vaccine s repeating protein patterns by the APCs Toll-like receptors to stimulate innate immunity and the high purity and lack of synthetic material adds to the potential safety of recombinant nanoparticle vaccines. Recombinant nanoparticle vaccine technology has expanded our early-stage vaccines in development to include both virus and non-virus disease targets. Our most advanced recombinant nanoparticle 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 nanoparticle vaccines. We believe this system offers many advantages when compared to other technologies and is uniquely suited for developing pandemic and seasonal 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 influenza vaccine technologies.

Company	Competing Technology Description
sanofi pasteur, Inc.	Inactivated sub-unit (egg-based)
MedImmune, LLC (a subsidiary of AstraZeneca PLC)	Nasal, live attenuated (egg-based)
GlaxoSmithKline plc	Inactivated (egg-based)
Novartis, Inc.	Inactivated sub-unit (cell and egg-based)
Merck & Co., Inc.	Inactivated sub-unit (egg-based)

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 should 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, some by adding an adjuvant that is used to increase the efficacy of that product, each of which is intended to be more efficacious than currently marketed products. We believe that our seasonal influenza product will be as efficacious 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 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 virus 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 as recombinant nanoparticle vaccines, 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, 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.

TABLE OF CONTENTS

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 products;
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 115 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 patent applications covering VLP technology for use in human vaccines in certain fields.

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

TABLE OF CONTENTS

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 pharmaceutical and biological products 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. 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 product 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 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 Biologics License Application (BLA) (the biologic equivalent to a New Drug Application or NDA) 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 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 new drug or 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 drug or biologic product is safe and effective, a BLA or NDA (depending on whether the product is a biologic or pharmaceutical product) is filed with the FDA to approve the marketing and commercial shipment of the drug. This process takes substantial time and effort and the FDA may not accept the BLA or NDA for filing. Even if filed and accepted, the FDA might not grant approval. FDA approval of a BLA or NDA 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.

TABLE OF CONTENTS

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 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 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 proposals during 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 what legislative proposals will be adopted or what actions federal, state or private payers for medical goods and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect medical or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

Manufacturing

We constructed a 10,000 square foot cGMP pilot facility to produce clinical trial material at our current corporate headquarters in Rockville, MD. Construction for the pilot plant facility commenced in the fourth quarter of 2007 and was completed 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.