NOVAVAX INC
Form 10-K
March 31, 2009

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

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

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 Stock Market LLC

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 þ

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 þ

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 þ 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. o

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 þ	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 þ

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, 2008 on the NASDAQ Global Market) was $108,995,283.

As of March 23, 2009, there were 68,855,091 shares of the Registrant s Common Stock, par value $0.01 per share, outstanding.

Portions of the Registrant s Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2008 in connection with the Registrant s 2009 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 undu 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., a Delaware corporation (Novavax or the Company) was incorporated in 1987, and is a clinical-stage biopharmaceutical company focused on creating differentiated, value-added vaccines that improve upon current preventive options for a range of infectious diseases. These vaccines leverage our virus-like particle (VLP) platform technology coupled with a unique, disposable production technology. In 2005, Novavax transitioned from a specialty pharmaceutical company that sold and marketed women s health products to an innovative, biopharmaceutical company focused on vaccines. The Company is now firmly focused on its VLP vaccine technology platform.

VLPs are genetically engineered three-dimensional nanostructures, which incorporate immunologically important lipids and recombinant proteins. Our VLPs resemble the virus but lack the genetic material to replicate the virus. Our proprietary production technology uses insect cells rather than chicken eggs or mammalian cells. Our current product targets include vaccines against the H5N1 and other subtypes of avian influenza with pandemic potential, human seasonal influenza, Varicella Zoster, which causes shingles, and Respiratory Syncytial Virus (RSV). This RSV vaccine was recently announced on October 30, 2008.

We made significant progress in 2008 and 2007 in the development of our vaccine that targets the H5N1 avian influenza with pandemic potential. In June 2007, we released results from an important preclinical study in which ferrets that received Novavax s pandemic vaccine were protected from a lethal challenge of the H5N1 virus. After filing an Investigational New Drug application (IND), Novavax initiated its Phase I/IIa human clinical trial in July 2007. We released interim human data from the first portion of this clinical trial in December 2007. These interim results demonstrated that Novavax s pandemic influenza vaccine can generate a protective immune response. We conducted the second portion of the Phase I/IIa trial in March 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 all three doses tested. Although the safety data is still blinded at the subject level (pending complete safety follow-up), there were no serious adverse events reported. In February 2009, we announced that the vaccine induced robust hemagglutination inhibition (HAT) responses, which have been shown to be important for protection against influenza disease. We only intend to initiate further human clinical trials for our pandemic influenza vaccine, which would be required for regulatory approval, with a collaborative partner.

We progressed development of our VLP trivalent vaccine that targets seasonal influenza virus in 2007 and 2008. In December 2007, we announced results from a preclinical study in mice. In April 2008, we announced that we received positive results from an immunogenicity study in ferrets inoculated with our trivalent seasonal influenza vaccine candidate. In September 2008, we began Phase II clinical trials to evaluate the safety and immunogenicity of different doses of our seasonal influenza vaccine. In November 2008, we announced a delay of our seasonal influenza dose ranging study in the elderly (≥65 years of age) from fourth quarter of 2008 to 2009, pending top line safety and immunogenicity results from our ongoing seasonal influenza study in healthy adults. We

had observed a slightly different safety profile (non-serious adverse events) from our Phase IIa trial of our pandemic VLP vaccine, and decided to review and analyze the dose response curve as well as the safety data from the healthy adult seasonal trial prior to commencing a study in the elderly. In December 2008, we announced favorable safety and immunogenicity results from our Phase IIa seasonal study in healthy adults. Further seasonal studies are planned in 2009 including the aforementioned study in elderly adults in the second half of 2009. We intend to seek a collaborative partner for our seasonal influenza vaccine upon completion of additional Phase II clinical studies, which are expected to be completed by the end of 2009.

We have also developed vaccine candidates for both RSV and VZV, both of which are currently being evaluated in preclinical studies. To date, preliminary data have shown that an RSV vaccine candidate has shown positive results in two separate studies with mice. In December 2008, Novavax and the University of Massachusetts jointly announced favorable results from a preclinical study to evaluate the immunogenicity and efficacy of an RSV vaccine candidate in mice. The RSV VLP vaccine induced strong antibody responses against RSV. We have licensed exclusive worldwide rights from the University of Massachusetts Medical School to certain technology for the development and commercialization of vaccines. In February 2009, we announced favorable results from an RSV preclinical 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, reducing the quantity of RSV virus found in the lungs of immunized mice after a challenge with live virus. A VZV vaccine candidate has also induced antibody and T-cell responses. We plan on moving forward with further preclinical development of both vaccines in 2009.

Importantly, we have developed a unique production process for making our recombinant VLP-based vaccines using portable, disposable manufacturing technology that has advantages over traditional egg-based vaccine manufacturing and other vaccines in development. Because the equipment is both portable and disposable, a facility to produce VLP-based vaccines can be constructed and validated for production use in 12-18 months (depending on the capacity) as compared to current egg-based facilities which can take four or more years to deploy. Our manufacturing technology requires substantially less capital costs than traditional egg-based manufacturing (currently estimated at up to 75% less capital cost). Due to the use of the Company s proprietary VLP approach in developing recombinant vaccines, the current production yields up to 10 times the yields of traditional egg-based or mammalian cell culture manufacturing are encouraging compared to currently used egg-based vaccines as well as developing mammalian cell growth approaches.

The following table shows the current stage of each product candidate in Novavax s vaccine pipeline:

	Discovery	Preclinical	Phase I/IIa	Phase IIb/III
Pandemic Influenza	ü	ü	ü	
Seasonal Influenza	ü	ü	ü	
Varicella Zoster Shingles	ü	ü		
Respiratory Syncytial Virus (RSV)	ü	ü		

We also had a drug delivery platform based on micellar nanoparticles (MNPs), proprietary oil and water nanoemulsions used for the topical delivery of drugs. The MNP technology was the basis for Novavax s first FDA-approved estrogen replacement product, Estrasorb®. In October 2005, we entered into license and supply agreements for Estrasorb with Allergan, Inc., successor-in-interest to Esprit Pharma, Inc. (Allergan), under which we manufactured Estrasorb, and Allergan had an exclusive license to sell Estrasorb in North America. In 2007, the Company and Allergan terminated the supply agreement. In April 2006, the Company entered into a License and

Development Agreement and a Supply Agreement with Allergan to co-develop, supply and commercialize our MNP-based testosterone product candidate for the treatment of female hypoactive sexual desire disorder. In October 2007, these agreements were mutually terminated. In February 2008, we entered into asset purchase and supply agreements with Graceway Pharmaceuticals, LLC related to Estrasorb and supply of additional units of Estrasorb and terminated the Estrasorb license agreement with Allergan. We engaged an investment bank to aid us in the search for potential buyers or licensees of the technology, but we were not successful in attempts to sell or license the technology in fields of use outside vaccines. In 2008, we recorded an impairment charge of the remaining MNP assets we held totaling $846,000. We may not be successful in our efforts to divest the MNP assets

and, if we are, it may not be on favorable terms. The operations related to our Estrasorb product are shown as discontinued operations in our financial statements.

Our Strategy

We are creating novel vaccines to address a broad range of infectious diseases across the globe using advanced, proprietary virus-like particle (VLP) technology. We are producing these VLP-based, highly potent, recombinant vaccines utilizing a new, efficient manufacturing solution.

In creating VLPs, our researchers genetically engineer three-dimensional nanostructures, which incorporate immunologically important lipids and recombinant proteins. Our VLPs resemble a virus but lack the genetic material that would cause infection. VLP technology is a proven technology. For example Merck s Gardasil® utilizes VLP technology. Our propriety VLPs 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 our vaccine candidates.

Our recombinant VLP platform allows us to utilize ready-to-use and disposable equipment which enable production capacity anywhere in the world for a fraction of the cost of traditional vaccine plants. Our manufacturing platform offers several significant advantages over traditional vaccine production: (1) higher yields than traditional mammalian or egg-based systems, (2) faster facility commissioning time, (3) significantly lower capital expenditures, and (4) competitive cost of goods.

Based upon our proprietary VLP platform and manufacturing system, the key components to the business strategy are as follows:

Leverage our proven technologies to develop differentiated influenza vaccines

The world-wide seasonal influenza market place is projected to exceed $6 billion by 2013. Although there are several significant companies in the vaccine market, there are unmet needs related to effectiveness in certain populations, speed to market, and reliable and cost effective supply.

An influenza pandemic is considered by experts and governments to be a critical public health threat. Governments and non-government organizations have spent billions of dollars to stockpile vaccines and anti-viral drugs and to enact a variety of other measures to prepare for a pandemic. Although these measures are important, there are opportunities to do more. Specifically, there are needs related to more effective vaccines, vaccines that can be matched to a pandemic strain in time to address or halt the first-wave of a pandemic, and vaccines that can be produced in sufficient quantities to address the needs of people in areas that do not have local or domestic vaccine supply.

We believe that our influenza vaccines are designed to address many of the significant unmet needs related to seasonal and pandemic influenza. This past year our pandemic and seasonal influenza VLP vaccines generated strong Phase IIa data. Specifically, the pandemic influenza VLP vaccine induced strong neutralizing antibody titers across all three doses tested and increasing antibody titers with escalation of dose. In addition, the vaccine induced strong hemagglutination inhibition (HAI) responses and was well tolerated with no reports of serious adverse events. The seasonal influenza VLP vaccine study also showed robust HAI responses against each of the strains in the vaccine including H3N2, H1N1, and B strains. Cross-reactivity was observed against drifted H3N2 and H1N1 strains, a

response typically not seen without an adjuvant. Safety follow-up for this study is ongoing; no vaccine-related serious adverse events have been reported to date.

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 hemagglutinin (HA), neuraminidase (NA) and matrix protein (M1). Traditional egg-based vaccines contain meaningful levels of HA but not 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 flu 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 should help provide additional protection throughout an entire flu season even as strains mutate. Finally, because of the VLPs structure and components, they may have greater immunogenicity in two vulnerable populations pediatric and elderly patients.

Our influenza VLPs may provide important time to market advantages. Once an influenza virus strain is identified, our VLP vaccines can be produced in about half the time of other influenza vaccines. This can be a critical advantage in rapidly addressing a pandemic outbreak, providing a vaccine earlier in the season (including potential availability for back-to-school doctor visits) and addressing a late-breaking influenza strain.

Build a robust pipeline of products based upon our VLP technology

Our VLP technology is a platform technology which provides an efficient system to select lead candidates, refine manufacturing processes and optimize development across product candidates. In addition to influenza, we currently have two vaccines in discovery that are ready for preclinical development. The first vaccine is for respiratory syncytial virus (RSV) and the second is for varicella zoster virus (VZV).

RSV is the leading cause of hospitalizations in children and second only to flu as the leading cause of hospitalizations for pneumonia in the elderly. VZV is the virus that causes shingles and the associated pain that may linger for up to 6 months, called post-herpetic neuralgia. Preclinical studies of these candidates have shown consistently robust antibody responses and activation of cell mediated immunity. Further, mice vaccinated with our RSV vaccine candidates and then infected with live RSV were protected, with no virus replication in the lungs. We are now in the process of selecting one or more RSV candidates for preclinical studies to support an IND and future clinical trials.

Maximize the potential of our unique and efficient manufacturing process

The baculovirus expression system manufacturing process for VLP vaccines has been developed using a portable, ready-to-use approach which requires less labor and infrastructure than egg-based vaccine manufacturing processes. In addition, using process development techniques, the vaccines under development are providing yields which will lower cost of production, and also allow the possibility of higher dose products that are commercially viable. We can maximize these advantages in the near term by producing vaccines for preclinical and clinical studies of our vaccine pipeline of products, and in the long term through potential commercialization advantages.

Seek strategic collaborations and partnerships to advance and set the stage for the commercialization of our products and technologies

We believe proprietary VLP technology affords us a range of traditional and non-traditional commercial options that are broader than those of existing vaccine companies. Our primary strategy for maximizing the value of our early vaccine candidates is to complete early to mid stage development and at the right time, partner with an organization that has complementary capabilities to maximize the commercial value of the product.

Although the primary strategy is to create major partnerships for commercialization, the manufacturing technology affords us the option to commercialize products directly or through local partnerships. These opportunities are not possible using traditional vaccine and manufacturing approaches because of the capital investment, scale and other

resources needed for industrial operations and commercialization. For example, we have a pilot launch facility capable of producing ten million-plus doses of seasonal influenza vaccines within six months of strain identification. This capacity can be used to commercialize influenza in the U.S. and other attractive markets. Another example of our strategic relationships is our collaboration with GE Healthcare (GEHC). In many countries there are significant unmet needs related to pandemic influenza.

It is highly likely that borders would close in the event of a pandemic; access to vaccine could be limited, putting populations at risk. Because of the VLP technology and the manufacturing benefits, it is cost-effective (both in terms of capital expenditures and operating costs) for a country to have an in-border solution for pandemic. Because our solution utilizes a platform technology, a country is able to adapt the manufacturing facility to create not only a seasonal vaccine, but other VLP vaccines as well. A third example is to work with government or non-government organizations (NGOs) to offer unique vaccines and vaccine solutions to countries and populations in need that currently have no or limited access.

Research and Development Technology and Activities

Vaccines

VLPs. We develop and produce biopharmaceutical proteins for use as vaccines against pandemic and seasonal influenza and other infectious diseases. These proteins, as tolerogens, are used to prevent inflammatory responses in the initiation and progression of stroke and other illnesses. Our lead vaccine technology platform is based on VLP, which are self-assembling protein structures that resemble viruses. These are noninfectious particles that, for many viral diseases, have been shown in animal and human studies 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. We have several ongoing development programs involving VLP vaccines that address urgent medical needs, including pandemic and seasonal influenza, Varicella Zoster Virus, RSV and other infectious diseases.

Pandemic Influenza VLP Vaccine. In the recent past, unexpected influenza subtypes of avian origin have resulted in severe morbidity and mortality in a limited number of people. Highly pathogenic H5N1 influenza viruses which are now widespread in poultry in Asia and have spread to some European countries, have been linked to human infection. Genetic reassortment between avian and human influenza subtypes, or genetic mutations, may lead to the emergence of a virus capable of causing worldwide illness, a pandemic. Proof-of-concept of the VLP approach in H5N1 pandemic influenza has been demonstrated by the Phase I/IIa human clinical trial interim results released by us in December 2007. We reported that our VLP vaccine for H5N1 influenza is immunogenic, that elicited immune responses at both 15 and 45 mcg doses. We began subject enrollment in the second portion of the Phase I/IIa trial in March 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 all three doses tested. Although the safety data are still blinded at the subject level (pending complete safety follow-up), there were no serious adverse events reported. In February 2009, we announced that the vaccine induced robust hemagglutination inhibition (HAI) responses, which have been shown to be important for protectioni against influenza disease. We only intend to initiate further human clinical trials for our pandemic influenza vaccine, which would be required for regulatory approval, with a collaborative partner.

Seasonal Influenza VLP Vaccine. According to the Center for Disease Control, every year between 5% and 20% of the United States population is infected by the influenza virus. While the severity of illness varies, influenza causes an estimated 36,000 deaths in the United States and 500,000 worldwide annually. These seasonal outbreaks have in recent years been caused by subtypes of influenza virus designated as H3N2 and H1N1. In December 2007, we announced results from a preclinical study in mice. In April 2008, we announced that we received positive results from an immunogenicity study in ferrets inoculated with our trivalent seasonal influenza vaccine candidate. In September 2008, we began Phase II clinical trials to evaluate the safety and immunogenicity of different doses of our seasonal influenza vaccine. In November 2008, we announced a delay of our seasonal influenza dose ranging study in the elderly (≥65 years of age) from the fourth quarter of 2008 to 2009, pending top line safety and immunogenicity results from our ongoing seasonal influenza study in healthy adults. We had observed a slightly different safety profile (non-serious adverse events) from our Phase IIa trial of our pandemic VLP vaccine, and decided to review and

analyze the dose response curve as well as the safety data from the healthy adult seasonal trial prior to commencing a study in the elderly. In December 2008, we announced favorable safety and immunogenicity results from our Phase IIa seasonal study in healthy adults. Further seasonal studies are planned in 2009 including the aforementioned study in elderly adults in the second half of 2009. We intend to seek a collaborative partner for

our seasonal influenza vaccine upon completion of additional Phase II clinical studies, which are expected to be completed by the end of 2009.

Varicella Zoster VLP Vaccine. In September 2007, we announced a new discovery-phase product indication target for the prevention of a disease associated with Varicella Zoster virus in older patients, commonly referred to as Shingles. Shingles, a skin rash often accompanied by painful blisters, is caused by the same virus that causes chickenpox. Anyone who has had chicken pox can develop Shingles because VZV remains dormant in the nerve cells and may re-emerge many years later causing the illness. Shingles most frequently occurs in patients 60 years or older and manifests itself with acute pain (post-herpetic neuralgia-PHN) occurring in 65% of affected patients. Shingles-associated pain may last months or even years and can have a negative impact on quality of life. It is also associated with high rates of hospitalization in older adults. The Advisory Committee on Immunization Practices (ACIP), a federal body of immunization experts, currently recommends vaccination for all individuals 60 years of age or older. With only one vaccine currently approved for use, the potential market for a Varicella Zoster vaccine is significant.

Respiratory Syncytial Virus (RSV). RSV is the most commonly identified cause of lower respiratory tract infection in infants and young children with repeated infections causing moderate to severe cold-like symptoms throughout their lives. High risk individuals (including the elderly over age 65 years, people with cardiovascular disease and children less than four years of age) may also develop lower respiratory tract infections leading to bronchiolitis and pneumonia. It is estimated that more than 8.5 million adults, including the elderly over age 65 years, are infected and 900,000 patients are hospitalized annually due to RSV infection in the United States and major European countries. In the United States alone there are 177,500 hospitalizations of high risk adults including the elderly over age 65, resulting in annual medicals costs exceeding $1 billion. In addition, there are up to 125,000 infants in the United States who are hospitalized annually due to RSV.

On December 9, 2008, Novavax and the University of Massachusetts Medical School announced results from a preclinical study of an RSV vaccine candidate. Novavax has licensed exclusive worldwide rights from the University of Massachusetts Medical School to certain technology for the development and commercialization of Paramyxovirus vaccines incorporating certain VLPs. This vaccine candidate is our first recombinant VLP for the prevention of RSV disease. The preclinical study evaluated the immunogenicity and efficacy of the RSV VLP vaccine candidate in mice. The RSV VLP vaccine induced strong antibody responses against RSV, protected mice against RSV replication in the lungs, and did not lead to enhanced inflammation of the airways. These data support continued development of this and additional RSV VLP vaccine candidates containing other proteins (i.e., Gb and F) important for immunity.

VLP Vaccine Manufacturing. All currently approved influenza vaccines are 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 a minimum of a six-month lead time for production of a new strain of virus and significant investment in fixed production facilities, with relatively low production yields. The vaccine shortage during the 2004 flu 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 flu vaccines and manufacturing lead times will be even shorter. We produce VLPs using a baculovirus expression system in insect cells with disposable, low-cost equipment that can be readily dispersed both nationally and internationally. By not requiring significant production batch sizes, production capacity can be employed quickly; estimated to be built and validated within twelve to eighteen months compared to the current approved manufacturing technology that can take four years or more to deploy. Lead times for production against new virus strains are measured in weeks, not months.

In 2007, we streamlined operations by consolidating our offices and laboratories into our new corporate headquarters in Rockville, Maryland where we leased a 51,000 square foot, stand-alone facility. This facility has ample office space, state of the art laboratory space, as well as utilities that allow for operating a Good Manufacturing Practice (GMP) pilot plant. In late 2007, we embarked on making leasehold improvements to create a GMP pilot plant in this facility, and in May 2008, we celebrated the opening of our new state-of-the-art vaccine facility. On January 26, 2009, we announced that all equipment in our pilot plant is installed and ready for operations supporting scale-up and validation. The 5,000 square-foot, $5.0 million pilot and commercial-scale

manufacturing plant will initially supply influenza vaccine for our current clinical programs with planned annual capacity of 10 million doses. This facility showcases the capability of our disposable production technology to create vaccine production capacity rapidly, in a low infrastructure environment, at a fraction of the cost required to bring traditional vaccine facilities on line. In addition to lower capital costs, we have made substantial improvement in our production yields during 2007 which allows us to remain highly competitive from a cost perspective even at higher vaccine doses. We continued to operate our manufacturing operations for producing Phase I/II vaccine materials at our Taft Court facility, also located in Rockville, Maryland, until October 2008, when we closed the Taft Court location.

VLP Intellectual Property Rights. In March 2007, we secured additional intellectual property through the licensing of additional VLP technology through a license agreement with the University of Massachusetts using their proprietary paramyxoviruses as a core for building VLP vaccines. In July 2007, we entered into a non-exclusive license agreement with Wyeth Holdings Corporation to obtain rights to a family of patent applications covering VLP technology for use in human vaccines in certain fields of use.

Other VLP Projects. We are working on certain other vaccine projects with sponsoring organizations. These projects, described below, are currently funded and controlled by other parties. As is typical with these research contracts, we do not currently have commercial rights to these products.

HIV-1/AIDS VLP Vaccine. The human toll of AIDS is staggering and now kills more people worldwide than any other infectious disease. Nearly 34 million people are infected with HIV-1, including 2.5 million people who were newly infected in 2007, according to the World Health Organization (WHO). Under a five-year National Institutes of Health (NIH) grant, which was awarded in 2003, we are working in collaboration with leading scientists from the University of Alabama Birmingham, Emory University and Harvard Medical School in the development of a second-generation AIDS vaccine. In January 2007, we announced that it has significantly enhanced both the quality and purity of its VLP vaccine for HIV/AIDS. This second generation AIDS vaccine is based on the HIV-1 viral envelope with a natural three-dimensional structure to trigger a protective immune response. Preclinical studies are under way using the improved HIV-1 vaccine, and planning has begun to advance this new vaccine to human clinical trials in collaboration with the United States government potentially as early as 2009. Early versions of Novavax s VLP vaccine were successful in triggering immune responses in preclinical studies, however, attempts to develop a vaccine against this disease has proven to be elusive to date. Novavax scientists and its collaborators discovered a way to optimize the expression of the HIV-1 envelope, which is a principal target for immunity in humans. We do not have commercial rights to this potential vaccine; however, the project does demonstrate the breadth of potential application of VLPs to various infectious diseases. This contract ended in the first quarter of 2008.

SARS VLP Vaccine. Severe acute respiratory syndrome (SARS) is a viral respiratory illness cased by a coronavirus and was first reported in Asia in February 2003. According to the World Health Organization (WHO), subsequent to the 2003 breakout, over 8,000 people were infected, with 774 reported deaths. While there is currently no known reported SARS transmission globally, WHO and other such agencies continue to monitor the SARS situation on a global basis as health officials remain concerned that SARS or similar disease could reemerge. In 2005, the NIH awarded us a $1.1 million, three-year grant to develop a vaccine to prevent SARS. SARS is a severe form of pneumonia, accompanied by a fever and caused by a coronavirus. Our SARS VLP vaccine is also based on the production of coronavirus-like VLPs in insect cells. In May 2008, we announced we had created a new proprietary process to develop a vaccine candidate against SARS. Novavax does not have the commercial rights to this product and continues to work with NIH funding to support its development. This contract ended in January 2009. We intend to apply for a no cost extension and to seek additional funding from NIH on the SARS grant.

E-Selectin Tolerogen. In collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), we have been developing E-selectin-based molecularly-derived products for the prevention of strokes. In September 2002, a published report in the professional journal Stroke provided experimental evidence on prevention of stroke in

stroke-prone rats. These results provided supportive evidence that E-selectin tolerization may help in the prevention of strokes and other illness where inflammatory and immune responses are involved in the initiation and progression of disease. We were awarded a government contract for the formulation development and manufacture of E-selectin for Phase I clinical trials to be run by the NINDS and the NIH. Formulation and

product has been produced by the Company for future preclinical and human clinical trials. We do not have commercial rights to this product.

Research and Development Funding

Total externally contracted research and development costs were $0.3 million in 2008, $1.0 million in 2007 and $0.9 million in 2006. Externally contracted research and development costs were primarily related to our HIV, SARS and E-Selectin project. Total internally sponsored research and development costs were $24.0 million in 2008, $16.6 million in 2007 and $10.4 million in 2006.

Competition

The biopharmaceutical industry and the vaccine market are intensely competitive and are characterized by rapid technological progress. There are a number of companies developing and selling vaccines for pandemic and seasonal influenza employing current technology with some modifications, as well as new technologies. Our technology is based upon utilizing the baculovirus expression system in insect cells to make VLPs. 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. The fact that we do not rely on the use of adjuvants, chemical substances that can boost the human immune system, leads us to believe we have a clearer regulatory path toward approval of our vaccines with regulatory agencies. 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 Vaccines, Inc. (a subsidiary of Astra-Zeneca, Inc.)	Nasal, live attenuated (cell-based)
GlaxoSmithKline Biologicals	Inactivated (egg-based)
Novartis, Inc.	Inactivated sub-unit (egg-based)
Merck & Co.	Novel vaccines

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 in the seasonal flu space with a product that is more efficacious, particularly in the elderly population, 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 United States and abroad. The patent position of biotechnology 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 its vaccine, drug delivery, adjuvant and other technologies. Currently, we have or have rights to over 99 United States patents and corresponding foreign patents and patent applications relating to vaccines and biologics. Our core vaccine

related intellectual property extends beyond 2010. On November 6, 2008, we entered into an option agreement with SGN Biopharma which allows SGN Biopharma to license certain intellectual property rights from us related to our drug delivery technology.

In March 2007, we secured additional intellectual property through the licensing of additional VLP technology through a license agreement with the University of Massachusetts using their proprietary paramyxoviruses as a core for building VLP vaccines. In July 2007, we entered into a non-exclusive license agreement with Wyeth Holdings Corporation to obtain rights to a family of patent applications covering VLP technology for use in human vaccines in certain fields of use.

Consistent with statutory guidelines issued under the Federal Technology Transfer Act of 1986 designed to encourage the dissemination of science and technology innovation and provide sharing of technology that has commercial potential, our collaborative research efforts with the United States government and with other private entities receiving federal funding provide that developments and results must be freely published, that information or materials supplied by us will not be treated as confidential and that we will be required to negotiate a license to any such 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 developments 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 signed 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 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 United States and other countries. In the United States, 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 both under provisions of that Act and under the Public Health Service Act. The Food and Drug Administration (FDA) assesses the safety and efficacy of products and regulates, among other things, the testing, manufacture, labeling, storage, record keeping, advertising and promotion. The process of obtaining FDA approval for a new product is costly and time-consuming.

Vaccine clinical development follows the same general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug application (an IND) describing the vaccine, its method of manufacture and quality control tests for release. Before applying for FDA approval to market any new drug product candidates, we must first submit an IND that explains to the FDA the results of pre-clinical testing conducted in laboratory animals 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 drug on humans. We must then conduct Phase I human clinical trials and larger-scale Phase II and III human clinical trials that demonstrate the safety and efficacy of our products to the satisfaction of the FDA. Once these trials are complete, a Biologics License Application (BLA) (the biologic equivalent to a New Drug Application) can be filed with the FDA requesting approval of the vaccine for marketing based on the vaccine s effectiveness and safety.

If successful, the completion of all three phases of clinical development can be followed by the submission of a BLA. Also during this stage, the proposed manufacturing facility undergoes a pre-approval inspection during which production of the vaccine as it is in progress is examined in detail. 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 undergo Phase IV studies after a BLA has been approved and the vaccine is licensed and on the market.

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 current GMP regulations. To supply products for use either in the United States or outside the United States, including clinical trials, United States and foreign manufacturing establishments, including third-party facilities, must comply with GMP regulations and are subject to periodic inspection by the corresponding regulatory agencies in their home country under reciprocal agreements with the FDA and/or by the FDA.

Preclinical studies may take several years to complete and there is no guarantee that the FDA will permit an IND based on those studies to become effective and 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, 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.

In addition to regulatory approvals that must be obtained in the United States, 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 license 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 (DEA) regulations.

There have been a number of federal and state proposals during the last few years to subject the pricing of pharmaceutical and biological products to government control and to make other changes to the medical care system of the United States. 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 medical 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

During the fourth quarter of 2007, we commenced the build out of a manufacturing suite in our Rockville, Maryland corporate headquarters for a 5,000 square foot GMP facility to produce clinical trial material as well as modest commercialization quantities of our VLP vaccines. Due to our unique manufacturing platform, we believe we are able to produce vaccines at up to 10 times the yields of traditional manufacturing methods (i.e. egg-based), depending on the vaccine dose, and at significantly lower capital costs than currently available vaccine technologies. Construction for this GMP suite was completed and a ribbon cutting ceremony was held in May 2008. This facility was ready for use in January 2009, when we announced that all equipment in the pilot plant was installed and ready for operations supporting scale up and validation. Any plans to further expand our manufacturing capabilities

at our Rockville, Maryland facilities, including the facilities necessary to expand manufacturing quantities, test and package an adequate supply of finished products in order to meet any long term commercial needs, will require additional resources and will be subject to ongoing government approval and oversight.

We had a GMP facility in our other facility in Maryland which incorporated disposable cell culture equipment that supported the manufacturing requirements for early stage clinical trial materials for our VLP vaccine candidates, including pandemic and seasonal influenza vaccine candidates, and other biologic products. This facility was used through September 2008, when we consolidated our research and development and manufacturing activities into one facility.

We also had a manufacturing facility in Philadelphia, Pennsylvania. Estrasorb, our first FDA-approved commercial product, was being manufactured at this facility. In February 2008, we entered into an agreement with Graceway Pharmaceuticals, LLC (Graceway) to sell our manufacturing equipment and other assets related to Estrasorb. In addition to the sale of assets, we agreed to produce additional lots of Estrasorb on behalf of Graceway, which was completed in August 2008, at which time we closed down this operation and exited the facility.

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. We have plans in place to qualify multiple suppliers for all critical supplies before the time we would put any of our product candidates into commercial production. One of our major suppliers is GE Healthcare which supplies disposable components used in our manufacturing process. GE Healthcare utilizes a sophisticated, in depth process to qualify multiple vendors for the products that are supplied to us. All the materials and vendors that supply manufacturing materials to the Company are audited for compliance with GMP standards.

Business Development

We continue to explore opportunities for corporate alliances and partners to help develop and ultimately commercialize and market our technologies and product candidates. Our strategy is to enter into collaborative arrangements with pharmaceutical and other companies for some or all aspects of product development, manufacturing, marketing and sales of our products that will require broad marketing capabilities and overseas marketing. Specifically, we are working with GE Healthcare to engage foreign countries in discussions of in-border solutions to a pandemic threat. We also are seeking to collaborate with global vaccine and other large pharmaceutical companies for our seasonal product. These collaborators are generally expected to be responsible for funding or reimbursing all or a portion of the development costs, including the costs of later stage clinical testing necessary to obtain regulatory clearances and for commercial scale manufacturing, in exchange for rights to market specific products in particular geographic territories.

Employees

As of March 10, 2009, we had 69 full-time employees and 1 part-time employee for a total of 70 employees, 20 of whom hold M.D. or Ph.D. degrees and 15 of whom hold other advanced degrees. Of our total workforce, 51 are engaged primarily in research, development and manufacturing activities and 19 are engaged primarily in business development, finance and accounting 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.

Name	Age	Principal Occupation and Other Business Experience During the Past Five Years
Rahul Singhvi	44	President and Chief Executive Officer and Director of Novavax since August 2005. Senior Vice President and Chief Operating Officer of Novavax from April 2005 to August 2005 and Vice President, Pharmaceutical Development and Manufacturing Operations from April 2004 to April 2005. For 10 years prior to joining the Company, served in several positions with Merck & Co., culminating as Director of the Merck Manufacturing Division from 1999 to 2004.
Raymond J. Hage, Jr.	41	Senior Vice President, Commercial Operations since October 2006. Senior Vice President and Chief Operating Officer from August 2005 to October 2006 and Vice President of Marketing and Corporate Development of Novavax from January 2004 to August 2005. Prior to joining the Company, served in several positions including an independent marketing consultant with CHS, Inc. in 2003, Director of Marketing with Cephalon, Inc. from 2002 to 2003 and for 10 years held various marketing and sales roles at Eli Lilly culminating as Director of US Women s Health from 2001 to 2002.
Penny Heaton	44	Vice President, Research & Development and Chief Medical Officer of Novavax since October 2006. Prior to joining the Company, served as Sr. Director and Director of Vaccine Clinical Research at Merck & Co., Inc. from 1999 to September 2006.
James Robinson	48	Vice President, Technical Operations and Quality Operations at Novavax since March 2007. Served at sanofi pasteur, Inc. in its US Vaccine Division in various positions, most recently, as Vice President, Industrial Operations from June 1986 to December 2006.
Thomas Johnston	38	Vice President, Strategy of Novavax since April 2008. Prior to joining the Company in March 2007, and from August 2003 served as independent strategic business consultant and Gemalto employee for multiple industries including banking, government security and mobile telecommunications. Prior to this, served as VP of Emerging Technology for Fleet Bank, and additional roles within Microsoft Corporation and Comcast Corporation.
Evdoxia Kopsidas	44	Director of Finance, since October 2006. Prior to joining the Company, served as Controller of BioVeris Corporation from June 2004 through October 2006 and Controller of BioReliance Corporation between April 1998 and June 2004. Appointed as Interim Principal Accounting Officer in February 2009.

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. 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