

NOVAVAX INC  
Form 10-K  
March 16, 2010

**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, 2009**

**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

NOVAVAX, INC.

(State of Incorporation)

(I.R.S. Employer  
Identification No.)

**9920 Belward Campus Drive,  
Rockville, Maryland 20850**

(Address of Principal Executive Offices)

**(240) 268-2000**

(Registrant's Telephone Number, Including Area Code)

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: <b>Not Applicable</b>	

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☒

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Edgar Filing: NOVAVAX INC - Form 10-K

Large Accelerated Filer ☐ Accelerated Filer ☒ Non-Accelerated Filer ☐ Smaller Reporting Company ☐  
(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (based on the last reported sale price of Registrants common stock on June 30, 2009 on the NASDAQ Global Market) was \$191,100,000.

As of March 11, 2010, there were 100,277,960 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, 2009 in connection with the Registrant's 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

---

TABLE OF CONTENTS

**NOVAVAX, INC.**  
**TABLE OF CONTENTS**

	Page
PART I	
<u>Item 1.</u>	<u>1</u>
<u>Business</u>	
<u>Item 1A.</u>	<u>10</u>
<u>Risk Factors</u>	
<u>Item 1B.</u>	<u>26</u>
<u>Unresolved Staff Comments</u>	
<u>Item 2.</u>	<u>27</u>
<u>Properties</u>	
<u>Item 3.</u>	<u>27</u>
<u>Legal Proceedings</u>	
PART II	
<u>Item 5.</u>	<u>28</u>
<u>Market for Registrant's Common Equity and Related Stockholder Matters</u>	
<u>Item 6.</u>	<u>29</u>
<u>Selected Financial Data</u>	
<u>Item 7.</u>	<u>30</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	
<u>Item 7A.</u>	<u>40</u>
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	
<u>Item 8.</u>	<u>41</u>
<u>Financial Statements and Supplementary Data</u>	
<u>Item 9.</u>	<u>41</u>
<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	
<u>Item 9A.</u>	<u>41</u>
<u>Controls and Procedures</u>	
<u>Item 9B.</u>	<u>42</u>

Other Information

PART III

Item 10.

43

Directors, Executive Officers and Corporate Governance

Item 11.

43

Executive Compensation

Item 12.

43

Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Item 13.

43

Certain Relationships and Related Transactions, and Director Independence

Item 14.

43

Principal Accounting Fees and Services

PART IV

Item 15.

44

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 biopharmaceutical company focused on developing novel highly potent recombinant vaccines. Our goal is to become a profitable vaccine company that is aggressively driving towards development, licensure and commercialization of important vaccine candidates.

Our technology platform is based on proprietary virus-like particles (VLPs). Our VLPs are genetically engineered three-dimensional nanostructures, which incorporate immunologically important recombinant proteins. Recombinant protein-based vaccines are widely used and accepted. Examples of vaccines currently available that use recombinant protein particle technology include Recombivax® HB (Merck) and Engerix® (GlaxoSmithKline), which protect against Hepatitis B, and Gardasil® (Merck) and Cervarix® (GlaxoSmithKline), which protect against human papilloma virus. Our product pipeline targets several infectious diseases. Currently, we have vaccine product candidates to target pandemic influenza (both H1N1 and H5N1 strains), seasonal influenza, Respiratory Syncytial Virus (RSV) and Varicella Zoster Virus (VZV).

We have a significant amount of experience in developing recombinant VLP influenza vaccines. To date, among other things, we have:

- conducted five human clinical studies for our seasonal and pandemic influenza vaccine candidates; administered our seasonal and pandemic influenza VLPs (seven distinct strains) to over 4,200 subjects demonstrating vaccine safety and immunogenicity;

- completed four animal toxicology studies without any safety issues;

- conducted multiple ferret studies demonstrating efficacy of VLP influenza vaccine candidates; and
- conducted vaccine production under current good manufacturing practices (cGMP) and manufactured more than 35 batches of VLP vaccine with over a dozen different influenza strains.

We believe our influenza VLP vaccines have potential immunological advantages over currently available products. 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 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.

Our proprietary production technology uses insect cells rather than chicken eggs or mammalian cells. This platform offers several potential significant advantages over traditional vaccine production, including: (1) higher yields than traditional mammalian or egg-based system, (2) faster facility commissioning time, (3) significantly lower capital expenditures on infrastructure, (4) competitive cost of goods, (5) shorter lead time to produce vaccine than egg-based technology, and (6) a scalable production process that can respond rapidly to pandemic outbreaks.

1

---

## TABLE OF CONTENTS

### **Pandemic Influenza**

In May 2009, we announced that we had produced a first batch of non-cGMP influenza A (H1N1) VLP vaccine candidate three weeks after the Center for Disease Control and Protection (CDC) announced the genetic sequence of the novel H1N1 virus (the H1N1 virus is commonly referred to as the swine flu in the media). The purified H1N1 VLP vaccine candidate was sent to scientists at the CDC and an agreement was made with the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases and the National Institutes of Health for further studies. To further demonstrate the capability of recombinant VLP technology, we manufactured an H1N1 VLP vaccine candidate under cGMP at our vaccine manufacturing facility in Rockville, MD within eleven weeks after receiving the gene sequence from the CDC.

In October 2009, we initiated a two-stage clinical trial of our H1N1 vaccine candidate in Mexico in collaboration with Laboratorio Avi-Mex S.A. de C.V. (Avimex). The first stage of the study evaluated the vaccine's safety, immunogenicity and efficacy in 1,000 subjects, including 750 vaccine recipients and 250 placebo recipients. In December 2009, we reported positive results from the first stage of the study. Based on these results, the Independent Data and Safety Monitoring Board recommended that we proceed with the second stage of the study to evaluate the safety of the vaccine in a larger cohort of 3,000 subjects (2,000 vaccine and 1,000 placebo recipients). This study has been fully enrolled. With the positive data reported in December 2009, we have filed for regulatory approval of our 2009 H1N1 vaccine candidate in Mexico. These data are also expected to support our pandemic and seasonal influenza VLP vaccines in other countries. We believe this effort in Mexico represents a unique opportunity for Novavax to accelerate the development of our H1N1 vaccine candidate.

We have also made significant progress in the development of our vaccine that targets the H5N1 avian influenza with pandemic potential. In 2007, we released results from an important pre-clinical study in which ferrets that received our pandemic vaccine candidate were protected from a lethal challenge of the H5N1 virus. After filing an Investigational New Drug application (IND), we initiated a Phase I/IIa human 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 all three doses tested. A final clinical study report has been completed and the vaccine was well tolerated at all dosages as compared with placebo. No serious adverse events were reported. In February 2009, we announced that the vaccine induced robust hemagglutination inhibition (HAI) responses, which have been shown to be important for protection against influenza disease.

### **Seasonal Influenza**

We have also progressed the development of our VLP trivalent 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 influenza vaccine. In December 2008, we announced favorable safety and immunogenicity results from this Phase IIa seasonal study in healthy adults (aged between 18 and 49 years). A final clinical study report was completed and no vaccine-related serious adverse events were reported. In May 2009, we enrolled subjects in a second Phase II study in healthy adults. In September 2009, we announced favorable results from this Phase II study in healthy adults that supports a new Phase II dose range study in elderly patients (60 years of age or older), head-to-head with a marketed vaccine that we commenced in November 2009. In September 2009, we responded to the United States government (HHS BARDA) request for proposal (RFP) for a potential contract award



for the advanced development of recombinant influenza vaccines. If we receive the award it could provide significant funding for the continued ongoing clinical development of our seasonal and pandemic influenza vaccines. Based on the results of the Phase II trial in elderly subjects and our ability to potentially receive the HHS BARDA contract and receive it in a timely manner, we plan to begin Phase III studies and seek to file United States registration of this vaccine candidate.

## TABLE OF CONTENTS

### **RSV and VZV**

We have also developed vaccine candidates for both RSV and VZV, both of which are currently being evaluated in pre-clinical studies. To date, our RSV vaccine candidate has demonstrated positive results in two separate studies with mice. These studies have been confirmed in two more studies in cotton rats, which are generally accepted as the best model to evaluate the safety of candidate RSV vaccines. 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. 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. We also announced the successful scale-up and cGMP manufacturing of vaccine and the initiation of a rabbit toxicology study in preparation for submission of an RSV IND to the United States Food and Drug Administration (FDA). We plan to file an IND and launch a Phase I clinical trial in 2010.

A multi-protein VZV particle vaccine candidate is currently in development. The VZV vaccine was shown in mice to induce antibody and T-cell responses. Formulation of the VZV vaccine candidate is being finalized and tested in preparation for human trials.

### **Research and Development Technology and Activities**

*VLPs.* Our vaccine technology platform is based on VLPs, 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. 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 hemagglutinin (HA), neuraminidase (NA) and matrix protein (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 should help provide additional protection throughout an entire influenza season, even as strains mutate. Data from our Phase IIa trial in healthy adults showed that 50 to 73% of the volunteers immunized with our VLP vaccine had a 4-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 – pediatric and elderly patients.

*VLP Vaccine Manufacturing.* 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 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 United Kingdom) highlighted the limitations of current production methods and the need for increased vaccine

## TABLE OF CONTENTS

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.

Our production process involves the use of genetic information and no viral seed is required. This shortens the time of creating a new vaccine by several weeks compared to the egg-based process. Furthermore, the production process for manufacturing our VLP vaccines is also unique because the equipment we use in the cell culture process is largely portable and disposable. A facility to produce VLP-based vaccines can be constructed and validated in significantly less time as compared to traditional egg-based facilities.

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.

*Other 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.

*SARS VLP Vaccine.* Severe acute respiratory syndrome (SARS) is a viral respiratory illness caused by a corona virus. In 2005, the National Institutes of Health (NIH) awarded us a \$1.1 million, three year grant to develop a vaccine to prevent SARS. We successfully completed the NIH grant in January 2009 and successfully demonstrated that a SARS VLP vaccine candidate was effective in inducing immunity in an animal model that fully protected against a lethal challenge with SARS virus.

*E-Selectin Tolerogen.* In collaboration with the National Institute of Neurological Disorders and Stroke and the NIH, we have been developing E-selectin-based molecularly-derived products for the prevention of strokes.

## **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 (egg-based)
GlaxoSmithKline Biologicals	Inactivated (egg-based)

Novartis, Inc.

Inactivated sub-unit (cell and egg-based)

Merck & Co.

Inactivated sub-unit (egg-based)

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 influenza 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

## TABLE OF CONTENTS

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.

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 space, a product must be more efficacious, particularly in the elderly population, and/or be less expensive and quicker to manufacture. Many of our competitors are working on new products and new generations of current products, often by adding an adjuvant that is used to increase the efficacy of the current product, each of which is intended to be more efficacious than products currently being marketed. Our seasonal influenza product may not prove to be more efficacious than current products or products under development by our competitors. Further, our manufacturing system may not provide enough savings of time or money to provide the required differentiation for commercial success.

## **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 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 99 United States patents and corresponding foreign patents and patent applications relating to vaccines and biologics. Our core vaccine-related intellectual property extends beyond 2027.

In March 2007, we secured additional intellectual property 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.

TABLE OF CONTENTS

## **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 under provisions of that Act and the Public Health Service Act. The 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 drugs and other biologics. 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, the method of manufacture and 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 product in 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 (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 the BLA, 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 cGMP 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 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 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 based on those studies to become effective or 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.

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 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

## TABLE OF CONTENTS

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 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 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 have constructed a 10,000 square foot cGMP facility to produce clinical trial material as well as modest commercialization quantities of our VLP vaccines at our corporate headquarters. 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 (pharmaceutical air and water system) that were not included in the total cost. Any plans to further expand our manufacturing capabilities at our corporate headquarters, 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 have not manufactured any of our vaccine product candidates at a commercial level and the process requires further scale-up and yield improvement. In October 2009, we engaged Xcellerex, Inc. (Xcellerex) to perform scale-up activities and manufacture our 2009 H1N1 vaccine candidate for potential sale in Mexico. The agreement with Xcellerex expired by its own terms on February 15, 2010. Although the H1N1 manufacturing campaign with Xcellerex did not result in the manufacturing of acceptable vaccine to Novavax, we did achieve proof of concept by scaling up to a commercial grade bioreactor. The success in scaling up our VLPs in stir tank bioreactors potentially provides an additional path to large-scale, commercially viable vaccine production. We may encounter unexpected expenses or delays as we, or third-party vendors, work to scale-up and improve efficiencies of our manufacturing process.

## **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 (GEHC) which supplies disposable components used in our manufacturing process. GEHC 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 cGMP standards.

## **Business Development**

We believe our proprietary VLP technology affords us a range of traditional and non-traditional commercialization options that are broader than those of existing vaccine companies. We strive to create sustainable value by working to obtain non-dilutive funding for conducting Phase III trials for both seasonal and pandemic influenza, to continue development of our vaccine product candidates until such vaccines can be licensed on a regional basis, to retain commercial rights in major markets and generate product sales revenue and, in certain markets, to commercialize our products through partners and other strategic relationships.

## TABLE OF CONTENTS

Examples of our strategic relationships are our collaboration with GEHC, our joint venture with Cadila Pharmaceuticals, Ltd. and our relationship with Avimex.

We have entered into a co-marketing agreement with GEHC for a pandemic influenza vaccine solution for select international countries. The collaboration incorporates GEHC's bioprocess solutions and design expertise with Novavax's VLP manufacturing platform.

On March 31, 2009, we and Cadila Pharmaceuticals Ltd., a company incorporated under the laws of India (Cadila) entered into a Joint Venture Agreement (the JVA) pursuant to which we and Cadila formed CPL Biologicals Private Limited, a joint venture (the JV), of which 80% is ultimately owned by Cadila and 20% is owned by Novavax. The JV will develop and commercialize our H1N1 pandemic and seasonal influenza vaccine candidates and Cadila's biogeneric products and other diagnostic products for the territory of India. We also contributed to the JV technology for the development of several other VLP vaccine candidates against diseases of public health concern in the territory, such as hepatitis E and chikungunya fever. Cadila has committed to contribute approximately \$8 million over three years to support the JV's operations. The JV will be responsible for clinical testing and registration of products that will be marketed and sold in India. In October 2009, the JV began construction of a state-of-the-art manufacturing facility that may be used to produce pandemic and seasonal influenza vaccines. The facility, which is 100% funded by Cadila, is expected to open in early 2010.

On June 30, 2009, we announced that we had signed a non-binding letter of intent to license our VLP vaccine technology to ROVI Pharmaceuticals of Spain (ROVI). On February 5, 2010, we terminated negotiations with ROVI. The decision to terminate negotiations was made because of the companies' inability to agree on acceptable terms of the proposed collaboration and to obtain the necessary funding commitments for the program. We are free to seek a new partner for our pandemic and seasonal influenza vaccine development efforts in Europe in the future.

On October 19, 2009, we entered into a Materials Transfer Agreement with Avimex, pursuant to which we supplied Avimex with certain amounts of our 2009 H1N1 vaccine candidate. Avimex used the H1N1 vaccine to conduct clinical trials and is currently seeking regulatory approval in Mexico. The agreement and the option to enter into a non-exclusive distribution agreement to distribute the 2009 H1N1 vaccine in Mexico both expired on their own terms on December 31, 2009. The second phase of the clinical trial is ongoing and the parties are continuing to cooperate in seeking regulatory approval in Mexico.

## **Employees**

As of March 12, 2010, we had 93 full-time employees and 1 part-time employee for a total of 94 employees, 19 of whom hold M.D. or Ph.D. degrees and 21 of whom hold other advanced degrees. Of our total workforce, 73 are engaged primarily in research, development and manufacturing activities and 21 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.

TABLE OF CONTENTS**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
Stanley C. Erck	61	<b>Executive Chairman and Director</b> of Novavax since February 2010, and a Director since June 2009. From 2000 to 2008, Mr. Erck served as President and Chief Executive Officer of Iomai Corporation, a developer of vaccines and immune system therapies, which was acquired in 2008 by Intercell. He also previously held leadership positions at Procept, a publicly traded immunology company, Integrated Genetics, now known as Genzyme, and Baxter International. Mr. Erck also serves on the Board of Directors of BioCryst Pharmaceuticals, MaxCyte, Inc. and MdBio Foundation.
Rahul Singhvi, Sc.D.	45	<b>President and Chief Executive Officer and Director</b> 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, Dr. Singhvi served in several positions with Merck & Co., culminating as Director of the Merck Manufacturing Division from 1999 to 2004.
Frederick W. Driscoll	59	<b>Vice President, Chief Financial Officer and Treasurer</b> of Novavax since August 2009. Prior to joining the Company, Mr. Driscoll served as Chief Executive Officer of Genelabs Technologies, Inc. from September 2008 to January 2009, as Interim Chief Executive Officer from February 2008 to August 2008 and as Chief Financial Officer from September 2007 to February 2008. Prior to that, from 2000 to 2006, Mr. Driscoll was employed by OXIGENE, Inc., where he served as President and Chief Executive Officer from 2002 to 2006.
Raymond J. Hage, Jr.	42	<b>Senior Vice President, Commercial Operations</b> 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, Mr. Hage served in several positions including as 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 U.S. Women's Health from 2001 to 2002.
Thomas Johnston	39	<b>Vice President, Strategy</b> of Novavax since April 2008. From March 2007 through August 2008, Mr. Johnston served as independent strategic business consultant for multiple industries including banking, government security and mobile telecommunications. Prior to this, Mr. Johnston served as VP of Emerging Technology for Fleet Bank, and additional roles within Microsoft

Corporation and Comcast Corporation.

John Trizzino

50

**Senior Vice President, International and Government Alliances** of the Company since July 2009. Prior to joining the Company, Mr. Trizzino served as Vice President of the vaccine franchise at MedImmune, Inc. from 2006 to 2009, Senior Vice President of business development at ID Biomedical from 2004 to 2006, and served as Vice President within the Henry Schein, Inc. medical division in business development and General Manager of their GIV division from 1997 to 2004.

TABLE OF CONTENTS

## **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 Form 10-Q, Current Reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after filed with or furnished to the Securities and Exchange Commission.

## **Item 1A. Risk Factors**

You should carefully consider the following risk factors in evaluating our business. There are a number of risk factors that could cause our actual results to differ materially from those that are indicated by forward-looking statements.

Some of the risks described relate principally to our business and the industry in which we operate. Others relate principally to the securities market and ownership of our common stock. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. You should also consider the other information included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

## **Risks Related to Our Business**

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

Our expenses have exceeded our revenue since our formation in 1987, and our accumulated deficit at December 31, 2009 was \$274.2 million. Our revenue for the last three fiscal years from continuing operations was \$0.3 million in 2009, \$1.1 million in 2008 and \$1.5 million in 2007. We have recorded limited revenue from research contracts, licenses and agreements to provide vaccine candidates, services and technologies. We cannot be certain that we will be successful in entering into strategic alliances or collaborative arrangements with other companies that will result in significant revenue to offset our expenses. Our net losses for the last three fiscal years were \$38.4 million in 2009, \$36.0 million in 2008 and \$34.8 million in 2007, including discontinued operations.

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

We expect to continue to incur significant operating expenses and anticipate that our expenses and losses will increase in the foreseeable future as we seek to:

- initiate Phase III and complete Phase II clinical trials for our seasonal influenza vaccine;
- conduct additional pre-clinical studies for VZV and RSV product candidates and begin clinical trials for RSV;

comply with the FDA's manufacturing facility requirements;  
scale-up our manufacturing process for commercial scale and cost efficiency; and  
maintain, expand and protect our intellectual property portfolio.

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



TABLE OF CONTENTS

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

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

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

Access to capital markets is critical to our ability to operate. Traditionally, biopharmaceutical companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our product candidates and clinical trials. The general economic and capital market conditions, both in the United States and worldwide, have been extremely volatile over the past eighteen months and have adversely affected our access to capital and increased the cost of capital, and any recovery will likely be very slow. There is no certainty that the capital and credit markets will recover to the point where we could raise additional capital on terms similar to the terms that companies raised capital prior to the deterioration. If these economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

In addition, our inability to access the capital markets on favorable terms due to our low stock price, or upon a potential delisting from the NASDAQ Global Market if we fail to satisfy a listing requirement, could affect our ability to execute our business plan as scheduled. Moreover, we rely and intend to rely on third-parties, including our clinical research organizations, third-party manufacturers and certain other important vendors and consultants. As a result of the global economic situation, there may be a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

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

From time to time, we may apply for grants from academic institutions, government agencies and non-profit entities and, most recently, we responded to the United States Government RFP solicitation number HHS BARDA-09-32 for a contract award for the advanced development of recombinant influenza vaccines. Such grants or contracts can be highly attractive because they provide capital to fund the ongoing development of our technologies and product candidates without diluting our stockholders. However, there is often significant competition for these grants. Grantors may have requirements to apply for or to otherwise be eligible to receive certain grants that our competitors may be able to satisfy that we cannot. In addition, grantors may make arbitrary decisions as to whether to make grants, to whom the grants will be awarded and the size of the grants to each awardee. Even if we are able to satisfy the award requirements, there is no guarantee that we will be a successful awardee. Therefore, we may not be able to win any grants, including BARDA in a timely manner, if at all, which could delay the start of our Phase III program in seasonal influenza.

TABLE OF CONTENTS

**A portion of our investments are auction rate securities which present potential liquidity concerns.**

As of December 31, 2009, we had \$5.1 million invested in three auction rate securities, which were classified as short-term investments available-for-sale and carried at their estimated fair value of \$4.2 million. Auction rate securities are long-term debt instruments that provide liquidity through a competitive bidding process known as a Dutch Auction that resets the applicable interest rates at pre-determined calendar intervals. Although two auction rate securities were redeemed during the year ended December 31, 2009, as a result of the issues that presently exist in the credit markets, we may be unable to liquidate some or all of our remaining auction rate securities when we are in need of the cash to fund operations at prices that are acceptable to us. Even if we are able to liquidate the investments, the sales may be at a loss. In addition, given the complexity of auction rate securities and their valuations, our estimates of their fair value may differ from the actual amount we would be able to collect in the ultimate sale. It is uncertain as to when the liquidity issues relating to these investments will improve.

**Our collaborations with regional partners, such as Cadila and Avimex, expose us to additional risks associated with doing business outside the United States, and any adverse event could have a material negative impact on our operations.**

We have formed a joint venture with Cadila in India and have entered into other agreements and arrangements with companies in other countries. We plan to continue to enter into collaborations or partnerships with companies, non-profit organizations and local governments in other parts of the world. Risks of conducting business outside the United States include:

multiple regulatory requirements could affect the ability to develop, manufacture and sell products in such local markets;  
compliance with anti-bribery laws such as the United States Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;  
trade protections measures and import and export licensing requirements;  
different labor regulations;  
changes in environmental, health and safety laws;  
exchange rates;  
potentially negative consequences from changes in or interpretations of tax laws;  
political instability and actual or anticipated military or potential conflicts;  
economic instability, inflation, recession and interest rate fluctuations;  
minimal or diminished protection of intellectual property in some countries; and  
possible nationalization and expropriation.

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

**Our strategy to enter into regional relationships may hinder our ability to engage in a larger transaction.**

We have entered into regional collaborations to develop our product candidates in certain parts of the world. Our relationships with Cadila and Avimex are examples of this strategy. We expect that many of these relationships will involve the licensing of our technology to our partner or entering into a distribution agreement, frequently on an

exclusive basis. Generally, these exclusive agreements are restricted to certain territories. Because we have entered into exclusive license and distribution agreements, larger companies may not be interested, or able, to enter into collaborations with us on a worldwide scale. Also, these regional relationships may make us an unattractive target for an acquisition.

TABLE OF CONTENTS

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

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

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

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

research and development;  
pre-clinical testing;  
designing and implementing clinical trials;  
regulatory processes and approvals;  
production and manufacturing; and  
sales and marketing of approved products.

Principal competitive factors in our industry include:

the quality and breadth of an organization's technology;  
management of the organization and the execution of the organization's strategy;  
the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees;

an organization's intellectual property portfolio;  
the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and

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

Large and established companies such as Merck & Co., Inc., GlaxoSmithKline PLC, Novartis, Inc., sanofi pasteur,

We are a biopharmaceutical company and face significant risk in developing, manufacturing and commercializing o

Inc. and MedImmune Inc. (a subsidiary of Astra-Zeneca, Inc.), among others, compete in the vaccine market. In particular, these companies have greater experience and expertise in securing government

## TABLE OF CONTENTS

contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, and manufacturing such products on a broad scale and marketing approved products.

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

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

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

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

We depend on our senior executive officers, as well as key scientific and other personnel. The loss of these individuals could harm our business and significantly delay or prevent the achievement of research, development or business objectives. Employment with our Chief Medical Officer and Vice President of Manufacturing ended in November 2009 and January 2010, respectively. While we are searching for replacements, we may not be able to attract qualified individuals on terms acceptable to us. We appointed John J. Trizzino as Senior Vice President, International and Government Alliances, in July 2009. Our Chief Financial Officer, Frederick Driscoll, assumed this responsibility in August 2009. In February 2010 Stanley Erck was appointed Executive Chairman of the Board. This lack of management continuity, the resulting lack of long-term history with our Company and the learning curve that executives experience when they join our management team, could result in operational and administrative inefficiencies and added costs. If we were to experience additional turnover at the executive level, these risks would be exacerbated.

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

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

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



TABLE OF CONTENTS

**We do not currently have a majority of independent directors and are, therefore, not in compliance with NASDAQ's listing requirements.**

Because two independent directors resigned in 2009 and Mr. Stanley Erck was appointed Executive Chairman on February 15, 2010 rendering him no longer independent, the majority of our Board of Directors is no longer independent. After disclosing this fact to NASDAQ as required, we received a notice from NASDAQ confirming that we are no longer in compliance with the NASDAQ requirements set forth in Listing Rule 5605(b)(1), which requires that the Company's Board of Directors be comprised of a majority of independent directors. We have 45 days to submit a plan to NASDAQ to regain compliance. The notification has no immediate effect on the listing of Novavax's common stock on The NASDAQ Global Market. The Company's common stock continues to trade on the NASDAQ Global Market under the symbol NVAX.

Over recent months, the Nominating and Corporate Governance Committee of Novavax's Board of Directors has been identifying, evaluating and recruiting potential candidates for election to the Board of Directors. Novavax expects to elect two independent directors and thus cure this non-compliance before its 2010 Annual Meeting of Stockholders. We may not be able to attract and recruit qualified individuals to serve as directors. Certain qualified individuals may demand more compensation than we are willing to pay and we may not have two new independent directors on a timely basis. If we are unable to add two new independent directors and we do not receive an extension of time from the NASDAQ, our listing on The NASDAQ Global Market may be affected.

**We may have product liability exposure.**

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

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

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

**There are outstanding loans owed by certain of our former directors which may not be repaid.**

Two of our former directors have outstanding notes due to the Company. The notes were initially delivered by the

We do not currently have a majority of independent directors and are, therefore, not in compliance with NASDAQ's

former directors to us in March 2002 as payment of the exercise price of options. As security, the former directors pledged shares of our common stock as collateral. As of December 31, 2009, the outstanding principal and interest for these two notes was \$2.0 million. Both notes are currently in default.

We are uncertain about the collectability of these notes. At our current market prices, we do not expect to recover the full amount outstanding under either note upon a sale of pledged shares alone. We continue to actively work to collect the amounts outstanding and reserve our rights to seek legal remedies currently available to us. There are no assurances that the former directors will be able to repay the notes in full.

## TABLE OF CONTENTS

### **Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders or require us to relinquish rights to our technologies or product candidates.**

If we are unable to partner with a third-party to advance the development of one or more of our vaccine candidates, we will need to raise money through additional debt or equity financings. To the extent that we raise additional capital by issuing equity securities, our stockholders will experience immediate dilution which may be significant. To the extent that we raise additional capital through licensing arrangements or arrangements with collaborative partners, we may be required to relinquish, on terms that may not be favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. In addition, current economic conditions may also negatively affect the desire or ability of potential collaborators to enter into transactions with us. They may also have to delay or cancel research and development projects or reduce their overall budgets.

## **Product Development Risks**

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

Our vaccine work depends on new, rapidly evolving technologies and on the marketability and profitability of our products. Commercialization of our vaccine products could fail for a variety of reasons, and include the possibility that:

our VLP technology, any or all of the products based on VLP technology or our proprietary manufacturing process will be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances or commercial viability;

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

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

our pilot plant manufacturing facility will fail to continue to pass regulatory inspections;

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

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

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

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

The steps required by the FDA before our proposed investigational products may be marketed in the United States include:

performance of pre-clinical (animal and laboratory) tests;

submissions to the FDA of an IND which must become effective before human clinical trials may commence;  
performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the  
investigational product in the intended target population;  
performance of a consistent and reproducible manufacturing process intended for commercial use, including  
appropriate manufacturing data and regulatory inspections;

16

---

## TABLE OF CONTENTS

submission to the FDA of a BLA or a NDA; and

FDA approval of the BLA or NDA before any commercial sale or shipment of the product.

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

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

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

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

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

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk vaccines on a commercial

If we are unable to manufacture our vaccines in sufficient quantities, at sufficient yields or are unable to obtain regu

scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our vaccine. A third-party manufacturer may also encounter difficulties in production. These problems may include:

difficulties with production costs, scale-up and yields;  
availability of raw materials and supplies;  
quality control and assurance;

TABLE OF CONTENTS

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

lack of capital funding.

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

**We must identify products and product candidates for development with our VLP technology and establish successful third-party relationships.**

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

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

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

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

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

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

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

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

We must identify products and product candidates for development with our VLP technology and establish successful

We must identify products and product candidates for development with our VLP technology and establish successful



TABLE OF CONTENTS

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

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

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

**Our collaborations may not be profitable.**

We have entered into a co-marketing agreement with GEHC for a pandemic influenza vaccine solution for select international countries. The collaboration incorporates GEHC's bioprocess solutions and design expertise with Novavax's VLP manufacturing platform. We have formed a joint venture with Cadila in India. In connection with this joint venture, we agreed to a Master Services Agreement under which we will purchase \$7.5 million of services from Cadila or pay Cadila all or a portion of the shortfall before March 2012. We cannot predict when, if at all, these relationships will lead to approved products, sales, or otherwise provide revenue to the Company or become profitable.

**Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.**

The United States government, through its various agencies, has provided grants to fund certain research and development efforts. There can be no assurances that we will continue to receive the same level of funding from the United States government, if at all. For example, the grants awarded to the Company to conduct research related to HIV and SARS have expired and have not been renewed. We have responded to the United States government (HHS BARDA) RFP for advanced development of recombinant influenza vaccines. However, for various reasons, including public need, program requirements, timing and other factors beyond our control, we may not receive any funds under any government programs.

Because we depend on third-parties to conduct some of our laboratory testing, human studies, and manufacturing,

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

We currently have no sales, marketing or distribution capabilities. As a result, we will depend on collaborations with third-parties that have established distribution systems and sales forces. To the extent that we enter into co-promotion or other licensing arrangements, our revenue will depend upon the efforts of third-parties, over which we may have little or no control. If we are unable to reach and maintain agreements with one or more pharmaceutical companies or collaborators, we may be required to market our products directly.

## TABLE OF CONTENTS

Developing a marketing and sales force is expensive and time-consuming and could delay a product launch. We cannot be certain that we will be able to attract and retain qualified sales personnel or otherwise develop this capability.

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

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

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

In particular, there are significant challenges to market acceptance for seasonal influenza vaccines. For our seasonal vaccine to be accepted, we must demonstrate differentiation from other seasonal vaccines that are currently approved and marketed. This can mean that the vaccine is more effective in certain populations, such as the elderly, or cheaper and quicker to produce. While we are currently conducting Phase II trials in the elderly, we have not yet received any data and there are no assurances that our vaccine will be more efficacious than other vaccines.

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

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

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



TABLE OF CONTENTS

## Regulatory Risks

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

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

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

prior regulatory agency review and approval;

Institutional Review Board approval of the protocol and the informed consent form;

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

negative test results or side effects experienced by trial participants;

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

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

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

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

Regulatory agencies may require us or our collaborators to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition,

we or our collaborators may be unable to submit applications to regulatory agencies within the time frame we currently expect. Once submitted, applications must be approved by various regulatory agencies before we or our collaborators can commercialize the product described in the application. All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated costs or delays in our clinical studies could delay our ability to generate revenue and harm our financial condition and results of operations.

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

We intend to have our product candidates marketed outside the United States. In furtherance of this objective, we have entered into relationships with Cadila in India and Avimex in Mexico. In order to market our products in the European

Union, Mexico, India, Asia and many other non-United States jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. To date, we have filed for marketing approval for our 2009 H1N1 vaccine candidate in Mexico but may not receive the approval necessary to commercialize our vaccine candidate in Mexico or any market or may receive approval only after the commercial opportunity has passed. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain foreign regulatory

## TABLE OF CONTENTS

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

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

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

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the vaccine itself, and only if the specific event occurs with some regularity over a period of time does the vaccine become suspect as having a causal relationship to the adverse event.

Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition.

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

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

Our facility in Maryland is subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, microorganisms and various hazardous compounds used in connection with our research and development activities. In the United States, these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and

Even if regulatory approval is received for our product candidates, the later discovery of previously unknown problems

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



## TABLE OF CONTENTS

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

## **Intellectual Property Risks**

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

Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third-parties or allowing third-parties to infringe our rights. We currently have or have rights to over 99 United States patents and corresponding foreign patents and patent applications covering our technologies. However, patent issues relating to pharmaceuticals and biologics involve complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the United States Patent and Trademark Office or enforced by the federal courts. Therefore, we do not know whether our patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

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

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

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

Our research, development and commercialization activities, including any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third-parties and to which we do not

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

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

## TABLE OF CONTENTS

infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us.

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

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

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

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

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

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

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

Our license agreement with Wyeth Holdings Corporation, which gives us rights to a family of patent applications covering VLP technology for use in human vaccines in certain fields of use, is non-exclusive. These applications are very significant to our business. Payments since inception, under this agreement, have aggregated \$5.1 million as of December 31, 2009. If each milestone is achieved for any particular product candidate, we would be obligated to pay

We may become involved in lawsuits to protect or enforce our patents or the patents of our collaborators and licensors.

an aggregate of \$14 million to Wyeth Holdings for each product candidate developed and commercialized under the agreement. Achievement of each milestone is subject to many risks, including those described in these Risk Factors. Annual license maintenance fees under the Wyeth Holdings agreement aggregate \$0.3 million per year. Our license with the University of Massachusetts gives us exclusive rights to develop and commercialize vaccines incorporating certain virus-like particles for use in human vaccines.

While many of the licenses under which we have rights provide us with rights in specified fields, the scope of our rights under these and other licenses may be subject to dispute by our licensors or third-parties. In addition, our rights to use these technologies and practice the inventions claimed in the licensed patents and

## TABLE OF CONTENTS

patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. Any of our licenses may be terminated by the licensor if we are in breach of a term or condition of the license agreement, or in certain other circumstances.

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

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

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

## **Risks Related to Our Common Stock and Organizational Structure**

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

Our stock price has been highly volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. From January 1, 2009 through December 31, 2009, the closing price of our common stock has been as low as \$0.56 per share and as high as \$6.65 per share. The market price of our common stock may be influenced by many factors, including:

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

clinical trial results;

depletion of our cash reserves;

sale of equity securities or issuance of additional debt;

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

changes in government regulations;  
developments in our relationships with our collaboration partners;  
announcements relating to health care reform and reimbursement levels for new vaccines;  
sales of substantial amounts of our stock by existing stockholders (including stock by insiders or 5% stockholders);  
development, spread or new announcements related to pandemic influenza, including H1N1 (swine) influenza;  
litigation;

25

---

## TABLE OF CONTENTS

public concern as to the safety of our products;  
significant set-backs or concerns with the industry or the market as a whole; and  
the other factors described in this Risk Factors section.

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

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

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

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

Our organizational documents could hamper a third-party's attempt to acquire, or discourage a third-party from attempting to acquire control of, the Company. We have also adopted a shareholder rights plan, or "poison pill," that empowers our Board to delay or negotiate, and thereby possibly thwart, any tender offer or takeover attempt the Board opposes. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions also could limit the price investors are willing to pay in the future for our securities and make it more difficult to change the composition of our Board in any one year. These provisions include the right of the Board to issue preferred stock with rights senior to those of common stock without any further vote or action by stockholders, the existence of a staggered Board with three classes of directors serving staggered three-year terms and advance notice requirements for stockholders to nominate directors and make proposals.

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

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

## **Item 1B. Unresolved Staff Comments**

None.





TABLE OF CONTENTS

## Item 2. Properties

We have current operations in one leased facility. We lease approximately 51,200 square feet in Rockville, Maryland, which serves as our corporate headquarters and includes administrative offices, vaccine research and development, as well as a manufacturing facility. We continue to lease approximately 32,900 square feet of administrative office and research and development space at our former corporate headquarters in Malvern, Pennsylvania, all of which is currently subleased. We believe that our corporate facility in Rockville, Maryland is sufficient for our current needs. We have additional space in our current facility to accommodate our anticipated growth over the next several years.

A summary of our current facilities is set forth below.

Property Location	Approximate Square Footage	
Rockville, MD	51,200	Corporate headquarters and vaccine research and development
Malvern, PA	32,900	Former corporate headquarters and research and development
Total square footage	84,100	
Malvern, PA sublease	(32,900 )	
Net square footage	51,200	

## Item 3. Legal Proceedings

In March 2010, we instituted collection proceedings against Mr. Mitch Kelly in the state of New York and Mr. Denis O'Donnell in the Commonwealth of Massachusetts. Mr. Kelly and Mr. O'Donnell are former directors of the Company that have outstanding notes due to the Company in the aggregate principal amount of \$1,572,000. Both notes are currently in default.

TABLE OF CONTENTS**PART II****Item 5. Market for Registrant's Common Equity and Related Stockholder Matters**

Our common stock trades on The NASDAQ Global Market under the symbol NVAX. The following table sets forth the range of high and low closing sale prices for our common stock as reported on The NASDAQ Global Market for each quarter in the two most recent years:

Quarter Ended	High	Low
December 31, 2009	\$ 4.41	\$ 2.53
September 30, 2009	\$ 6.65	\$ 2.51
June 30, 2009	\$ 3.28	\$ 0.76
March 31, 2009	\$ 2.04	\$ 0.56
December 31, 2008	\$ 3.03	\$ 1.22
September 30, 2008	\$ 3.42	\$ 2.05
June 30, 2008	\$ 3.10	\$ 2.24
March 31, 2008	\$ 3.71	\$ 2.30

On March 11, 2010, the last sale price reported on The NASDAQ Global Market for our common stock was \$2.48. Our common stock was held by approximately 519 stockholders of record as of March 11, 2010, one of which is Cede & Co., a nominee for Depository Trust Company (or DTC). All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder. We have not paid any cash dividends on our common stock since our inception. We do not anticipate declaring or paying any cash dividends in the foreseeable future.

**Securities Authorized for Issuance Under Our Equity Compensation Plans**

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

The graph below compares the cumulative total stockholders return on our common stock for the last five fiscal years with the cumulative total return on the NASDAQ Stock Market (United States and Foreign) Index and the NASDAQ Pharmaceutical Index (which includes Novavax) over the same period, assuming the investment of \$100 in our common stock, the NASDAQ Stock Market (United States and Foreign) Index and the NASDAQ Pharmaceutical Index on December 31, 2004, and reinvestments of all dividends.

TABLE OF CONTENTS

Value of \$100 invested on 12/31/04 in stock or index, including reinvestment of dividends, for fiscal years ended December 31:

	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08	12/31/09
Novavax, Inc.	\$ 100	\$118.10	\$125.77	\$102.15	\$57.98	\$81.60
NASDAQ Stock Market (United States and Foreign)	\$ 100	\$101.41	\$114.05	\$123.94	\$73.43	\$105.89
NASDAQ Pharmaceutical Index	\$ 100	\$102.23	\$105.16	\$99.56	\$91.99	\$98.21

This graph is not soliciting material, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

## Item 6. Selected Financial Data

The following table sets forth selected financial data for each of the years in the five-year period ended December 31, 2009. The information below should be read in conjunction with our financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K. These historical results are not necessarily indicative of results that may be expected for future periods.

	For the Years Ended December 31,				
	2009	2008	2007	2006	2005
	(In Thousands, Except per Share Amounts)				
Statements of Operations Data:					
Revenue	\$325	\$1,064	\$1,513	\$1,738	\$5,343
Loss from continuing operations	(38,374)	(36,322)	(28,590)	(19,577)	(6,319)
(Loss) income from discontinued operations		273	(6,175)	(3,491)	(4,855)
Net loss	\$(38,374)	\$(36,049)	\$(34,765)	\$(23,068)	\$(11,174)
Basic and diluted net loss per share:					
Loss per share from continuing operations	(0.45)	(0.53)	(0.47)	(0.33)	(0.15)
Loss per share from discontinued operations			(0.10)	(0.06)	(0.11)
Basic and diluted net loss per share	\$(0.45)	\$(0.53)	\$(0.57)	\$(0.39)	\$(0.26)
Shares used in computing basic and diluted net loss per share	85,555	68,174	61,101	58,664	42,758

	As of December 31,				
	2009	2008	2007	2006	2005
Balance Sheet Data:					
Cash and short-term investments	\$42,950	\$33,900	\$46,489	\$73,595	\$31,893
Total current assets	44,503	35,096	49,016	77,342	37,611
Working capital	36,476	7,379	42,810	72,003	32,735
Total assets	85,605	76,625	91,291	121,877	84,382
Long-term debt, less current portion	406	480	21,629	22,458	29,678

Edgar Filing: NOVAVAX INC - Form 10-K

Accumulated deficit	(274,150)	(235,776)	(199,727)	(164,962)	(141,894)
Total stockholders' equity	74,465	45,489	63,065	94,001	49,652

---

TABLE OF CONTENTS

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

Certain statements contained herein or as may otherwise be incorporated by reference herein constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Forward-looking statements include, but are not limited to, statements relating to future financial or business performance, conditions or strategies and other financial and business matters, including expectations regarding operating expenses, use of cash, and clinical developments and anticipated milestones, including a BARDA contract,

Phase III studies and seeking approval in Mexico, and include words such as expect(s), intends, plans, seeks, estimates, could, should, feel(s), believe(s), will, would, may, can, anticipate(s), potential, and the negative of these terms, are based upon management's current expectations and beliefs. Such forward-looking statements are not guarantees of future performance, involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from those expressed or implied by such forward-looking statements.

Factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include, among other things, the following: our ability to progress any product candidates into pre-clinical or clinical trials; the scope, initiation, rate and progress of our pre-clinical studies and clinical trials and other research and development activities; clinical trial results; even if the data from pre-clinical studies or clinical trials is positive, the product may not prove to be safe and efficacious; regulatory approval is needed before any vaccines can be sold in or outside the United States and, to date, no governmental authority has approved any of our vaccine candidates for sale; influenza is seasonal in nature, and if approval or commercial launch after approval is not timely in relation to the influenza season, we may not be able to manufacture or sell our influenza vaccines on terms favorable to us until the next influenza season, if at all; we have not manufactured any of our vaccine candidates at a commercial level; we utilize a unique manufacturing process and the scale-up of that process may prove difficult and costly; our dependence on third parties to manufacture and distribute our vaccines; risks associated with conducting business outside of the United States; our ability to enter into future collaborations with industry partners and the terms, timing and success of any such collaboration; our ability to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity or debt financing or otherwise; the inability to win any government grants, including BARDA in a timely manner or at all and other factors referenced herein.

All forward-looking statements contained in this annual report are based on information available to the Company on the date hereof, and the Company assumes no obligation to update any such forward-looking statements, except as specifically required by law. Accordingly, past results and trends should not be used to anticipate future results or trends.

### **Overview**

Novavax, Inc., a Delaware corporation (Novavax, the Company, we, or us), was incorporated in 1987, and is a clinical-stage biopharmaceutical company focused on developing novel, highly potent recombinant vaccines. These vaccines leverage our virus-like-particle (VLP) platform technology coupled with a unique disposable production technology.

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 pandemic and seasonal influenza, including the H5N1 and H1N1 pandemic strains, Respiratory Syncytial Virus (RSV) and Varicella Zoster Virus (VZV), which causes shingles.

TABLE OF CONTENTS

## **Summary of Significant Transactions in 2009**

### **Joint Venture With Cadila**

On March 31, 2009, we entered into a Joint Venture Agreement (the JVA) with Cadila Pharmaceuticals Ltd., a private company incorporated under the laws of India (Cadila) pursuant to which we and Cadila formed CPL Biologicals Private Limited, a joint venture (the JV), of which 80% is owned by Cadila and 20% is owned by Novavax. The JV will develop and commercialize our seasonal influenza and H1N1 pandemic vaccine candidates and Cadila's biogeneric products and other diagnostic products for the territory of India. The JV has the right to negotiate a definitive agreement for rights to certain future Novavax products (other than RSV) and certain future Cadila products in India, prior to Novavax or Cadila licensing such rights to a third party. We have the right to negotiate the licensing of vaccines developed by the JV using our technology for commercialization in every country except for India and vaccines developed by the JV using Cadila's technology for commercialization in certain other countries, including the United States. Cadila has committed to contribute approximately \$8 million over three years to support the JV's operations. In connection with the JVA, on March 31, 2009, we also entered into a license agreement, an option to enter into a license agreement, a technical services agreement and a supply agreement with the JV and a master services agreement with Cadila. Because we do not control the JV, we account for our investment using the equity method. Since the carrying value of our contribution was \$0 and there is no guarantee or commitment to provide future funding, we do not expect to record losses related to this investment in the future.

Also on March 31, 2009, we entered into a stock purchase agreement with Satellite Overseas (Holdings) Limited (SOHL), a subsidiary of Cadila, pursuant to which SOHL purchased 12.5 million shares of our common stock at the market price of \$0.88 per share. We received net proceeds of approximately \$10.6 million.

### **Convertible Notes**

As of January 1, 2009, we had \$22 million of senior convertible notes outstanding (the Notes). The Notes carried a 4.75% coupon; were convertible into shares of Novavax common stock at \$4.00 per share; and matured on July 15, 2009. On April 29, 2009, we entered into amendment agreements (the 2009 Amendments) with holders of the outstanding Notes representing \$17.0 million of the outstanding principal amount of the Notes to amend the terms of the Notes to allow for early retirement by paying 70% of the principal amount plus accrued and unpaid interest in cash totaling \$12.1 million and paying the remaining 30% through issuance of 2,040,000 shares of common stock at \$2.50 per share. On July 15, 2009, we paid the \$5.0 million balance of the Notes by paying approximately \$2.6 million of principal and accrued and unpaid interest in cash and issuing 1,016,939 shares of common stock to pay the remaining \$2.6 million of principal and accrued and unpaid interest, based on a price of \$2.5163 per share. As of July 15, 2009, the Notes were fully paid and extinguished.

### **H1N1 Mexico Transaction**

On October 19, 2009, we entered into a Materials Transfer Agreement with Laboratorio Avi-Mex S.A. de C.V. (Avimex), pursuant to which we supplied Avimex with certain amounts of our 2009 H1N1 vaccine candidate and made payments to Avimex related to our clinical trial. Avimex used the H1N1 vaccine to conduct clinical trials and is currently seeking regulatory approval in Mexico. Avimex made a milestone payment to us and is obligated to pay us a transfer fee for the H1N1 vaccine based on our production cost. The agreement and the option to enter into a non-exclusive distribution agreement to distribute the 2009 H1N1 vaccine in Mexico both expired by its terms on December 31, 2009. The second phase of the clinical trial is ongoing and the parties are continuing to cooperate in

seeking regulatory approval in Mexico.

On October 20, 2009, we entered into a binding term sheet (as amended, the Xcellerex Agreement) with Xcellerex, Inc. Pursuant to the Xcellerex Agreement, Xcellerex performed scale-up and manufacturing activities related to our 2009 H1N1 vaccine candidate for potential sale in Mexico. Although the H1N1 manufacturing campaign with Xcellerex did not result in the manufacture of acceptable vaccine to Novavax, we did achieve proof of concept by scaling up to a commercial grade bioreactor. The success in scaling up our VLP s in stir tank bioreactors potentially provides an additional path to large scale, commercially viable vaccine production. As consideration, we paid Xcellerex a fixed payment and supplied materials. The Xcellerex Agreement expired by its terms on February 15, 2010.



## TABLE OF CONTENTS

### **Underwritten Public Offering**

On November 25, 2009, we issued 6,800,000 shares of our common stock at \$3.30 per share in an underwritten public offering. We received net proceeds from the sale of the shares, after underwriting discounts, commissions and estimated offering expenses, of approximately \$21 million.

### **At the Market Sales Issuances**

On January 12, 2009, we entered into an At the Market Sales Agreement (the January Sales Agreement) with Wm Smith & Co. (Wm Smith), under which we may sell an aggregate of up to \$25 million in gross proceeds of our common stock from time to time through Wm Smith, as the agent for the offer and sale of the common stock. During 2009, we sold 7,489,207 shares at a range of \$1.75 – \$5.03 and received net proceeds of approximately \$22 million under the January Sales Agreement.

On September 15, 2009, we entered into a second At Market Issuance Sales Agreement (the September Sales Agreement), with Wm Smith, under which we may sell an aggregate of up to \$10 million in gross proceeds of our common stock from time to time through Wm Smith. We have not sold any common stock under the September Sales Agreement.

On March 15, 2010, we terminated the January Sales Agreement and the September Sales Agreement and entered into a sales agreement with McNicoll, Lewis & Vlak LLC, as sales agent, under which we may sell an aggregate of \$50 million in gross proceeds of our common stock. Our Board of Directors has authorized the sale of up to 25 million shares of our common stock pursuant to this agreement.

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

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

The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and equity and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. These estimates, particularly estimates relating to accounting for the valuation of our short-term investments, stock-based compensation, long-lived assets, goodwill, and valuation of net deferred tax assets have a material impact on our financial statements and are discussed in detail throughout our analysis of the results of operations discussed below.

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

### **Short-Term Investments**

Our short-term investments are carried at fair value and unrealized gains and losses on these securities, if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders' equity. We assess the

recoverability of our short-term investments and, if an impairment is indicated, we measure the amount of such impairment by comparing the fair value to the carrying value. Other-than-temporary impairments are included in the consolidated statements of operations. We invested in auction rate securities for short periods of time as part of our cash management program. Recent uncertainties in the credit markets have prevented us from liquidating certain holdings of auction rate securities as the amount of securities submitted for sale during the auction has exceeded the amount of purchase orders. Although an event of an auction failure does not necessarily mean that a security is impaired, we consider various factors to assess the fair value and the classification of the securities as short-term assets. Fair value was determined with the assistance of an independent valuation firm using two valuation methods a discounted cash flow method and a market comparable method. Certain factors used in these methods include, but are not necessarily limited to, comparable securities traded on secondary markets, timing of the failed auction, specific security

## TABLE OF CONTENTS

auction history, quality of underlying collateral, rating of the security and the bond insurer, our ability and intent to retain the securities for a period of time to allow for anticipated recovery in the market value, and other factors.

### **Stock-Based Compensation**

We account for our stock-based compensation in accordance with Accounting Standards Codification (ASC) 718, *Compensation – Stock Compensation*. This standard requires us to measure the cost of employee services received in exchange for equity share options granted based on the grant-date fair value of the options. Employee stock-based compensation is estimated at the date of grant based on the award's fair value using the Black-Scholes option-pricing model and is recognized as expense on a straight-line basis over the requisite service period. The Black-Scholes option-pricing model requires the use of certain assumptions, the most significant of which are our estimates of the expected volatility of the market price of our stock, the expected term of the award, and the risk-free interest rate. Our estimate of the expected volatility is based on historical volatility over the look-back period corresponding to the expected life. The expected term represents the period during which our stock-based awards are expected to be outstanding. In 2009, we estimated this amount based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting exercise and forfeiture history. Our estimate of the risk-free interest rate is based on United States Treasury debt securities with maturities close to the expected term of the option as of the date of grant. We review our valuation assumptions at each grant date and, as a result, our assumptions in future periods may change. Also, the accounting estimate of stock-based compensation expense is reasonably likely to change from period to period as further stock options are granted and adjustments are made for stock option forfeitures and cancellations.

### **Research and Development**

Research and development costs are expensed as incurred. Such costs include internal research and development expenditures (such as salaries and benefits, raw materials and supplies) and contracted services (such as sponsored research, consulting and testing services) of proprietary research and development activities and similar expenses associated with collaborative research agreements.

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

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

## Goodwill

Goodwill originally resulted from a business acquisition in 2000. Assets acquired and liabilities assumed were recorded at their fair values; the excess of the purchase price over the identifiable net assets acquired is recorded as goodwill. Goodwill is not amortized, but is subject to impairment tests annually, or more frequently should indicators of impairment arise. We utilize both the market approach and the income approach to determine if we have an impairment of our goodwill. The market approach serves as the primary approach and is based on market value of invested capital. The concluded fair value significantly exceeded the carrying

## TABLE OF CONTENTS

value of our goodwill at December 31, 2009 and 2008. The income approach is used as a confirming look to the market approach. Goodwill impairment is deemed to exist if the carrying value of a reporting unit exceeds its estimated fair value. We perform the required annual impairment test as of December 31 of each year on the carrying amount of our goodwill.

Given the current economic conditions and the uncertainties regarding their impact on us, there can be no assurance that the estimates and assumptions made for purposes of our goodwill impairment testing at December 31, 2009 will prove to be accurate predictions of the future, or that any change in the assumptions or the current economic conditions will not trigger another goodwill impairment test before December 31, 2010. If our assumptions are not achieved or economic conditions deteriorate further, we may be required to record goodwill impairment charges in future periods.

## **Income Taxes**

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

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

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

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

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

## **Recently Adopted Accounting Guidance**

In June 2009, the Financial Accounting Standards Board (FASB) issued ASC 105, *Generally Accepted Accounting Principles*, which establishes the FASB Accounting Standards Codification as the sole source of authoritative generally accepted accounting principles (GAAP). Pursuant to the provisions of ASC 105, we have updated references to GAAP in our financial statements issued beginning for the period ended September 30, 2009. The adoption of ASC 105 did not impact our financial position or results of operations.

Effective January 1, 2009, we prospectively adopted ASC 820, *Fair Value Measurements and Disclosures*, with respect to fair value measurements required for our nonfinancial assets and nonfinancial liabilities. The adoption did not have a material effect on our financial position or results of operations.

In April 2009, ASC 805, *Business Combinations*, was amended for provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination. Under the amended guidance, assets acquired and liabilities assumed in a business combination that arise from contingencies should be recognized at fair value on the acquisition date if fair value can be determined during the measurement period. If fair value cannot be determined, companies should typically account for the acquired contingencies using existing guidance. This amendment did not have a material effect on our financial position or results of operations.

## TABLE OF CONTENTS

In April 2009, ASC 820 was amended to provide additional guidance for estimating fair value when the volume and level of activity for the asset or liability have significantly decreased. This amendment also includes guidance on identifying circumstances that indicate a transaction is not orderly. This amendment was effective for the quarter ended June 30, 2009 and the adoption of this amendment did not have a material effect on our financial position or results of operations.

In April 2009, ASC 320, *Investments – Debt & Equity Securities*, was amended to provide guidance for other-than-temporary impairments of debt securities. The amendment provides that financial asset impairment indicators should be based on the Company's intent to sell the security instead of the Company's ability to hold the security, and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This amendment was effective for the quarter ended June 30, 2009 and the adoption of this amendment did not have a material effect on our financial position or results of operations.

In May 2009, the FASB issued ASC 855, *Subsequent Events*. ASC 855 establishes general standards of accounting for, and disclosure of, events that occur after the balance sheet date, but before financial statements are issued or are available to be issued. In particular, ASC 855 establishes (i) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, (ii) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements and (iii) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. We have evaluated all subsequent events through the date of issuance of our financial statements. We adopted ASC 855 for the quarter ended June 30, 2009 and the adoption did not have any effect on our financial condition or results of operations.

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

In June 2009, the FASB issued authoritative guidance on the consolidation of variable interest entities, which is effective for the Company beginning January 1, 2010. The new guidance requires revised evaluations of whether entities represent variable interest entities, ongoing assessments of control over such entities, and additional disclosures for variable interests. We believe adoption of this new guidance will not have a material impact on our financial position and results of operations.

In September 2009, ASU 2009-13, *Revenue Recognition (Topic 605) – Multiple-Deliverable Revenue Arrangements*, was issued and will change the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. Specifically, this guidance amends the criteria in Subtopic 605-25, *Revenue Recognition – Multiple-Element Arrangements*, for separating consideration in multiple-deliverable arrangements. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates.

This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 with early adoption permitted. The impact of ASU 2009-13 on our consolidated financial statements will depend on the nature and terms of our revenue arrangements entered into or materially modified after the adoption date. However, based on our current customer arrangements, we do not believe the adoption of this ASU will have a material impact on our consolidated financial statements.

In January 2010, the FASB issued ASU 2010-06, *Fair Value Measurements and Disclosures (Topic 820) – Improving*

*Disclosures about Fair Value Measurements*, which amends Topic 820 to add new requirements for disclosures about transfers into and out of Levels 1 and 2 and separate disclosures about purchases, sales, issuances, and settlements related to Level 3 measurements. ASU 2010-06 also clarifies existing fair value disclosures about the level of disaggregation and about inputs and valuation techniques used to measure fair value. The ASU is effective for the first reporting period beginning after December 15, 2009, except for the requirements to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will be effective for fiscal years beginning after December 15, 2010, and for



TABLE OF CONTENTS

interim periods within those fiscal years. Early adoption is permitted. We believe the adoption of this amendment will not have a material effect on our financial position or results of operations.

**Results of Operations for Fiscal Years 2009, 2008 and 2007** (amounts in tables are presented in thousands, except per share information)

The following is a discussion of the historical consolidated financial condition and results of operations of Novavax, Inc. and its wholly owned subsidiary and should be read in conjunction with the consolidated financial statements and notes thereto set forth in this Annual Report on Form 10-K. Additional information concerning factors that could cause actual results to differ materially from those in our forward-looking statements is contained from time to time in our SEC filings. Certain reclassifications have been made to the prior years' financial statements to conform to the current year presentation.

**Revenue:**

	2009	2008	2007	Change 2008 to 2009	Change 2007 to 2008
Revenue:					
Total revenue	\$ 325	\$ 1,064	\$ 1,513	\$ (739 )	\$ (449 )

Revenue for 2009 was \$0.3 million as compared to \$1.1 million for 2008, a decrease of \$0.8 million, or 69%. The decrease in revenue in 2009, as compared to 2008, was due to lower contract research and development revenue primarily as a result of timing of work under a government contract.

Revenue for 2008 was \$1.1 million as compared to \$1.5 million for 2007, a decrease of \$0.4 million, or 30%. The decrease in revenue during 2008, as compared to 2007, was principally due to lower contract research and development revenue as a result of the completion of a government contract in 2008.

**Operating Expenses:**

	2009	2008	2007	Change 2008 to 2009	Change 2007 to 2008
Operating Expenses:					
Research and development	\$ 25,780	\$ 24,334	\$ 17,821	\$ 1,446	\$ 6,513
General and administrative	11,928	11,090	13,963	838	(2,873 )
Total operating expenses	\$ 37,708	\$ 35,424	\$ 31,784	\$ 2,284	\$ 3,640

**Research and Development Expenses**

Research and development expenses increased to \$25.8 million for 2009 from \$24.3 million for 2008, an increase of \$1.5 million, or 6%, primarily due to higher research and development spending to support our clinical trials related to our H1N1 and seasonal influenza product candidates. The increase is primarily a result of increased outside-testing costs of \$1.9 million, partially offset by a decrease in facility costs of \$0.4 million related to the exiting of our Taft Court facility in 2008.

Research and development expenses increased to \$24.3 million for 2008 from \$17.8 million for 2007, an increase of \$6.5 million, or 37%. This increase was due primarily to higher research and development spending to support our strategic focus on creating differentiated, value-added vaccines that leverage our proprietary VLP technology.

Outside-testing costs (including outsourced clinical trial costs, sponsored research and consulting agreements) associated with expanded pre-clinical testing, human clinical trials, process development, manufacturing and quality-related programs necessary to move our influenza vaccine candidates into human clinical trials and license fees paid to Wyeth account for \$2.9 million of the increase. The remaining increase of \$3.6 million can be attributed to an increase in employee-related costs of \$1.1 million, an increase in facility costs of \$1.5 million and \$0.4 million accrued in 2008 related to future lease payments for our Taft Court facility. The costs associated with our Taft Court facility resulted from our decision to consolidate our research and development and manufacturing activities into our Belward Campus Drive facility.

TABLE OF CONTENTS**General and Administrative Expenses**

General and administrative expenses were \$11.9 million in 2009 compared to \$11.1 million in 2008, an increase of \$0.8 million, or 8%. The increase in expenses is primarily due to increased employee-related costs of \$0.5 million and professional fees of \$0.4 million.

General and administrative expenses were \$11.1 million in 2008 compared to \$14.0 million in 2007, a decrease of \$2.9 million, or 21%. The decrease was primarily due to reclassification and related accounting for notes receivable due from former directors to show these notes as reductions of equity in the December 31, 2008 consolidated balance sheet. General and administrative expenses in 2008 included a \$1.2 million credit to eliminate the previously recorded allowance we established for these notes receivable. General and administrative expenses for 2008 were also favorably impacted by lower facility costs of approximately \$0.6 million and decreased employee costs of approximately \$0.3 million as we implemented our plan to consolidate all operations into our Belward Campus Drive facility.

**Other Income (Expense):**

	2009	2008	2007	Change 2008 to 2009	Change 2007 to 2008
Other Income (Expense):					
Interest income	\$ 285	\$ 959	\$ 3,287	\$ (674 )	\$ (2,328 )
Interest expense	(786 )	(1,683 )	(1,606 )	897	(77 )
Impairment of short-term investments	(1,338 )	(1,238 )		(100 )	(1,238 )
Realized gains on short-term investments	848			848	
Total other income (expense)	\$ (991 )	\$ (1,962 )	\$ 1,681	\$ 971	\$ (3,643 )

We had total other expense of \$1.0 million for 2009 compared to total other expense of \$2.0 million for 2008, a change of \$1.0 million, or 49%. Interest income decreased \$0.7 million, or 70%, to \$0.3 million in 2009 from \$1.0 million in 2008 primarily due to the decline in our cash, cash equivalents and short-term investment balances and a decrease in the rates of return on our investments. Interest expense decreased \$0.9 million, or 53%, to \$0.8 million in 2009 from \$1.7 million in 2008 as a result of our payment of the Notes in 2009. In 2009, we recorded an impairment of \$1.3 million relating to our auction rate securities, which was partially offset by realized gains of \$0.8 million relating to redemptions of several auction rate securities. At December 31, 2009, we have recorded \$0.8 million in unrealized gains on the auction rate securities held by us at year-end in other comprehensive income on the consolidated balance sheet.

We had total other expense of \$2.0 million for 2008 compared to total other income of \$1.7 million for 2007, a change of \$3.7 million, or 217%. Interest income decreased to \$1.0 million in 2008 from \$3.3 million in 2007 due in part to the correction of a matter described above (in General and Administrative Expenses) related to notes receivable from former directors along with a decrease in our cash, cash equivalents and short-term investment balances. For 2008, interest income included a \$0.5 million adjustment to reverse cumulative interest income related to the notes receivable from former directors, as discussed above. Interest expense increased to \$1.7 million in 2008 from \$1.6 million in 2007. The increase in interest expense was primarily due to the increase in the amortization of debt discount of \$0.3 million, related to an amendment of the convertible notes, which occurred in June 2007. Additionally, we recorded a \$1.2 million impairment on our short-term investments in 2008, related to an other-than-temporary impairment loss on our auction rate securities.



TABLE OF CONTENTS**Discontinued Operations:**

In February 2008, we sold certain assets related to our former Estrasorb business to Graceway Pharmaceuticals, LLC (Graceway) in exchange for an upfront payment. In connection with the sale, we agreed to manufacture and supply additional units of Estrasorb for Graceway, which we completed in August 2008. The results of operations of our former Estrasorb business are reported as discontinued operations in the consolidated statements of operations and are summarized in the table below.

	2008	2007	Change 2008 to 2007
Discontinued Operations:			
Revenue	\$ 3,776	\$ 1,913	\$ 1,863
Total operating expenses	3,503	8,088	(4,585 )
Income (loss)	\$ 273	\$ (6,175 )	\$ (6,448 )

We recorded income from discontinued operations of \$0.3 million in 2008 compared to a loss of \$6.2 million in 2007. Revenue from discontinued operations increased to \$3.8 million in 2008 from \$1.9 million in 2007, an increase of \$1.9 million, or 97%, primarily due to the recognition of revenue related to the Graceway agreements.

Operating expenses from discontinued operations decreased to \$3.5 million in 2008 from \$8.1 million in 2007 primarily due to a decrease in costs of products sold of \$3.8 million. Cost of products sold in 2007 included an additional \$1.8 million in idle plant capacity costs and a \$2.2 million impairment charge related to the fixed assets at our manufacturing facility.

**Net Loss:**

	2009	2008	2007	Change 2008 to 2009	Change 2007 to 2008
Net Loss:					
Net loss	\$(38,374)	\$(36,049)	\$(34,765)	\$(2,325 )	\$(1,284)
Net loss per share	\$(0.45 )	\$(0.53 )	\$(0.57 )	\$0.08	\$0.04
Weighted shares outstanding	85,555	68,174	61,101	17,381	7,073

Net loss for 2009 was \$38.4 million, or \$0.45 per share, as compared to \$36.0 million, or \$0.53 per share, for 2008, an increased net loss of \$2.4 million. The increased net loss was primarily due to higher research and development spending to support our clinical trials related to our H1N1 and seasonal influenza product candidates, partially offset by reduced total other expenses in 2009.

Net loss for 2008 was \$36.0 million, or \$0.53 per share, as compared to \$34.8 million, or \$0.57 per share, for 2007, an increased net loss of \$1.2 million. The increased net loss was primarily due to an increase in operating expenses of \$3.6 million, a decrease in total other income of \$3.6 million, partially offset by a loss from discontinued operations of \$6.2 million in 2007.

The increase in weighted shares outstanding for 2009 and 2008 is primarily a result of sales of our common stock in the aggregate of 27,884,098 shares and 6,686,650 shares, respectively.

## Liquidity Matters and Capital Resources

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

TABLE OF CONTENTS

As of December 31, 2009, we had \$38.8 million in cash and cash equivalents and \$4.2 million in short-term investments as compared to \$26.9 million and \$7.0 million, respectively, at December 31, 2008. The following table summarizes cash flows for the years ended December 31, 2009 and 2008 (in thousands):

	2009	2008	Change 2008 to 2009
Summary of Cash Flows:			
Net cash (used in) provided by:			
Operating activities	\$(32,830)	\$(24,310)	\$(8,520 )
Investing activities	2,355	29,906	(27,551)
Financing activities	42,294	16,992	25,302
Net increase in cash and cash equivalents	11,819	22,588	(10,769)
Cash and cash equivalents at beginning of year	26,938	4,350	22,588
Cash and cash equivalents at end of year	\$38,757	\$26,938	\$11,819

Net cash used in operating activities increased to \$32.8 million in 2009 from \$24.3 million for 2008, primarily due to our increased loss in 2009 and the receipt in 2008 of \$3.0 million in lease incentives and \$2.5 million of cash provided by our discontinued operations, both of which did not recur in 2009.

During 2009 and 2008, our investing activities consisted primarily of purchases and maturities of short-term investments, capital expenditures and \$1.4 million of cash provided by our discontinued operations in 2008. Capital expenditures for 2009 and 2008 were \$0.7 million and \$5.7 million, respectively. The decrease in capital expenditures was primarily due to the completion of our GMP pilot manufacturing facility, which was ready for use in early 2009.

We used our short-term investments in 2008 to help fund operations. For 2010, we expect the level of capital expenditures to increase modestly.

The increase in our financing activities consists primarily of increased sales of our common stock, partially offset by the repayment of our Notes in 2009.

We have entered into agreements with outside providers to support our clinical development. As of December 31, 2009, \$7.6 million remains unpaid on certain of these agreements in the event our outside providers complete their services in 2010. However, under the terms of the agreements, we have the option to terminate, but we would be obligated to pay the provider for all costs incurred through the effective date of termination.

We have licensed certain rights from Wyeth Holdings Corporation (Wyeth) and the University of Massachusetts Medical School (UMMS). The Wyeth license provides for an upfront payment, annual license fees, milestone payments and royalties on any product sales, is a non-exclusive, worldwide license to a family of patent applications covering VLP technology for use in human vaccines in certain fields of use. Payments under the agreement to Wyeth from 2007 through 2009 aggregated \$5.1 million. Based on the clinical and commercial milestones, which could possibly occur in 2010, we would make a milestone payment to Wyeth of \$4 million in the next twelve months. However, it is difficult for us to predict at this time whether such milestones will be achieved in 2010. The UMMS license, which provides for milestone payments and royalties on product sales, is an exclusive worldwide license of VLP technology to develop VLP vaccines for the prevention of any viral diseases in humans. As of December 31, 2009, our payments made to UMMS in the aggregate are not material. Also, we believe that all payments under the UMMS agreement will not be material in the next twelve months.

Based on our cash, cash equivalents and short-term investment balances as of December 31, 2009, and our current business operations, we believe we will have adequate capital resources available to operate at planned levels for at least the next twelve months. Additional capital will be required in the future to develop our product candidates through clinical development, manufacturing, and commercialization. We will seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, non-dilutive government contracts, collaborative arrangements, or some combination of these financing alternatives.

Any capital raised by an equity offering will likely be substantially dilutive to the existing stockholders and any licensing or development arrangement may require us to give up rights to



TABLE OF CONTENTS

a product or technology at less than its full potential value. Other than our At the Market Sales Agreement with McNicoll, Lewis & Vlax LLC, we have not secured any additional commitments for new financing nor can we provide any assurance that new financing will be available on commercially acceptable terms, if at all. If we are unable to obtain additional capital, we will assess our capital resources and will likely be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs, downsize our organization, or reduce our general and administrative infrastructure.

## Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2009 (in thousands):

Contractual Obligations:	Total	One Year or Less	2 3 Years	4 5 Years	More than 5 Years
Operating leases	\$ 14,840	\$ 2,043	\$ 4,219	\$ 4,330	\$ 4,248
Notes payable	486	80	106	300	
Purchase obligations	7,401	901	6,500		
Total contractual obligations	\$ 22,727	\$ 3,024	\$ 10,825	\$ 4,630	\$ 4,248

Our purchase obligations include our currently anticipated timing of future purchases for services pursuant to the master services agreement with Cadila. We are required to purchase from Cadila through March 2012 services for biologic research, pre-clinical development, clinical development, process development, manufacturing scale up, and general manufacturing related services. As of December 31, 2009, our remaining obligation to Cadila under the master services agreement is \$7.4 million.

## Off-Balance Sheet Arrangements

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

## Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital until it is required to fund operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of December 31, 2009, we had cash and cash equivalents of \$38.8 million, short-term investments of \$4.2 million and working capital of \$36.5 million.

Our exposure to market risk is confined to our investment portfolio. As of December 31, 2009, our short-term investments are classified as available-for-sale. We do not believe that a change in the market rates of interest would have any significant impact on the realizable value of our investment portfolio. Changes in interest rates may affect the investment income we earn on our investments and, therefore, could impact our cash flows and results of operations.

We had previously invested in auction rate securities for short periods of time as part of our cash management program. Short-term investments at December 31, 2009 consist of investments in three auction rate securities with a

par value of \$5.1 million and a fair value of \$4.2 million. We recorded an other-than-temporary impairment charge of \$1.3 million related to these securities in 2009, which was partially offset by realized gains of \$0.8 million relating to redemptions of several auction rate securities. At December 31, 2009, we have recorded \$0.8 million in unrealized gains on the auction rate securities held by us at year-end in other comprehensive income on the consolidated balance sheet. These investments are classified within current assets because we may need to liquidate these securities within the next year to fund our ongoing operations.

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

We are headquartered in the United States where we conduct the vast majority of our business activities. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

TABLE OF CONTENTS

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

## **Item 8. Financial Statements and Supplementary Data**

The information required by this item is set forth on pages F-1 to F-26.

## **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the assistance of our chief executive officer and chief financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of as of December 31, 2009. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives. Based on the evaluation of our disclosure controls and procedures as of December 31, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

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

Our management, including our chief executive officer and chief financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the fourth quarter of 2009, and has concluded that there was no change that occurred during the fourth quarter of 2009 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

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

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

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

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## TABLE OF CONTENTS

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making this assessment, our management used the criteria set forth in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, our management has determined that, as of December 31, 2009, our internal control over financial reporting is effective based on those criteria.

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

## **Item 9B. Other Information**

On October 6, 2009, we entered into a license agreement with CPL Biologicals Private Limited (CPLB). CPLB is a joint venture between us and Cadila Pharmaceuticals, Ltd (Cadila). Pursuant to the license agreement, we granted CPLB an exclusive, fully paid-up, royalty free license to use our technology to research, develop and commercialize a vaccine for the 2009 H1N1 influenza in the country of India. We have approval rights for all development and commercialization plans. The license will terminate upon written notice from CPLB, the mutual agreement of the parties, or upon our termination of the joint venture agreement with Cadila.

On March 15, 2010, we entered into an At Market Issuance Sales Agreement (the ATM Agreement), with McNicoll, Lewis & Vlcek LLC (MLV), under which we may sell an aggregate of \$50,000,000 in gross proceeds of our common stock from time to time through MLV, as the agent for the offer and sale of the common stock. MLV may sell the common stock by any method permitted by law, including sales deemed to be an at the market offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on The NASDAQ Global Market, on any other existing trading market for the common stock or to or through a market maker. MLV may also sell the common stock in privately negotiated transactions, subject to our prior approval. We will pay MLV a commission equal to 2% of the gross proceeds of the sales price of all common stock sold through it as sales agent under the ATM Agreement.

The ATM Agreement will terminate on the earliest of (1) the sale of all of the common stock subject to the ATM Agreement, or (2) termination of the ATM Agreement by us or MLV. MLV may terminate the ATM Agreement at any time in certain circumstances, including the occurrence of a material adverse change that, in MLV's reasonable judgment, may impair its ability to sell the common stock, our failure to satisfy any condition under of the ATM Agreement or a suspension or limitation of trading of our common stock on NASDAQ. We may terminate the ATM Agreement at any time upon 30 days prior notice, and MLV may terminate the ATM Agreement at any time upon 60 days prior notice. Our Board of Directors has authorized the sale of up to 25 million shares of our common stock under the ATM Agreement.

TABLE OF CONTENTS**PART III****Item 10. Directors, Executive Officers and Corporate Governance**

We incorporate herein by reference the information concerning our directors, officers and corporate governance to be included in our definitive Proxy Statement for our 2010 Annual Meeting of Stockholders to be held on June 16, 2010 (the 2010 Proxy Statement). We expect to file the 2010 Proxy Statement within 120 days after the close of the fiscal year ended December 31, 2009.

**Item 11. Executive Compensation**

We incorporate herein by reference the information concerning executive compensation to be contained in the 2010 Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

We incorporate herein by reference the information concerning security ownership of certain beneficial owners and management and related stockholder matters to be contained in the 2010 Proxy Statement.

The following table provides our equity compensation plan information as of December 31, 2009. Under these plans, our common stock may be issued upon the exercise of options. See also the information regarding our stock options in Note 9 to the Consolidated Financial Statements included herewith.

**Equity Compensation Plan Information**

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a) (c)
Equity compensation plans approved by security holders <sup>(1)</sup>	5,994,994	\$ 3.01	2,712,580
	N/A	N/A	N/A

Equity compensation plans not approved by  
security holders

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

## **Item 13. Certain Relationships and Related Transactions, and Director Independence**

We incorporate herein by reference the information concerning certain related party transactions set forth in Note 14 to our Consolidated Financial Statements included herewith. We incorporate herein by reference the information concerning certain other relationships and related transactions and director independence to be contained in the 2010 Proxy Statement.

## **Item 14. Principal Accounting Fees and Services**

We incorporate herein by reference the information concerning principal accountant fees and services to be contained in the 2010 Proxy Statement.

TABLE OF CONTENTS

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

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

(1) *Index to Consolidated Financial Statements*

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Consolidated Balance Sheets as of December 31, 2009 and 2008</u>	<u>F-3</u>
<u>Consolidated Statements of Operations for each of the Years in the Period Ended December 31, 2009, 2008 and 2007</u>	<u>F-4</u>
<u>Consolidated Statements of Stockholders' Equity for each of the Years in the Period Ended December 31, 2009, 2008 and 2007</u>	<u>F-5</u>
<u>Consolidated Statements of Cash Flows for each of the Three Years in the Period Ended December 31, 2009, 2008 and 2007</u>	<u>F-6</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-7</u>

(2) *Consolidated Financial Statement Schedules*

Schedule II Valuation and Qualifying Accounts

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

(3) *Exhibits*

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

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

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

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

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

- 3.1 Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1996, filed March 21, 1997), as amended by the Certificate of Amendment dated December 18, 2000 (Incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, filed March 29, 2001), as further amended by the Certificate of Amendment dated July 8, 2004 (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed August 9, 2004), as further amended by the Certificate of Amendment dated May



Edgar Filing: NOVAVAX INC - Form 10-K

13, 2009 (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009)

3.2 Amended and Restated By-Laws of the Company, as amended on August 2, 2007  
(Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed August 8, 2007)

4.1 Specimen stock certificate for shares of common stock, par value \$.01 per share (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 10, File No. 0-26770, filed September 14, 1995)

44

---

TABLE OF CONTENTS

4.2	Rights Agreement, dated as of August 8, 2002, by and between the Company and Equiserve Trust Company, which includes the Form of Summary of Rights to Purchase Series D Junior Participating Preferred Stock as Exhibit A, the Form of Right Certificate as Exhibit B and the Form of Certificate of Designation of Series D Junior Participating Preferred Stock as Exhibit C (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed August 9, 2002)
4.3	Registration Rights Agreement between Novavax, Inc. and Satellite Overseas (Holdings) Limited, dated March 31, 2009 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009)
4.4	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed July 30, 2008)
10.1	Novavax, Inc. 1995 Stock Option Plan, as amended (Incorporated by reference to Appendix A of the Company's Definitive Proxy Statement filed March 31, 2003 in connection with the Annual Meeting held on May 7, 2003)
10.2	Novavax, Inc. 1995 Director Stock Option Plan (Incorporated by reference to Exhibit 10.5 to the Company's Registration Statement in Form 10, File No. 0-26770, filed September 14, 1995)
10.3	Novavax, Inc. Amended and Restated 2005 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed January 5, 2009)
10.4	Amended and Restated Employment Agreement of Rahul Singhvi, effective July 20, 2009 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed July 22, 2009)
10.5	Employment Agreement of Penny Heaton, dated October 2, 2008 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed October 10, 2008)
10.6	Employment Agreement of Len Stigliano, dated October 2, 2008 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed October 10, 2008)
10.7	Amended and Restated Employment Agreement, dated as of August 2, 2007, originally effective November 9, 2005, by and between the Company and Raymond J. Hage, Jr. (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed August 9, 2007)
10.8	Amendment to the Amended and Restated Employment Agreement of Raymond Hage, dated October 2, 2008 (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed October 10, 2008)
10.9	Second Amendment to Amended and Restated Employment Agreement of Raymond Hage, effective July 20, 2009 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed July 22, 2009)
10.10	Employment Agreement of James Robinson, effective October 2, 2008 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed October 16, 2008)
10.11*	Severance Agreement of James Robinson dated February 1, 2010
10.12	Employment Agreement between Novavax, Inc. and Frederick Driscoll dated August 6, 2009 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed August 7, 2009)
10.13*	Employment Agreement of Thomas Johnston dated September 23, 2008
10.14*	Amendment to the Employment Agreement of Thomas Johnston dated as of July 20, 2009
10.15*	Employment Agreement of John Trizzino dated July 16, 2009
10.16	Consulting Agreement, dated as of April 27, 2007, effective as of March 7, 2007, between the Company and John Lambert (Incorporated by reference to Exhibit 10.1 to the Company's

Edgar Filing: NOVAVAX INC - Form 10-K

- 10.17 Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed May 10, 2007)  
Consulting Agreement of Len Stigliano, effective January 28, 2009 (Incorporated by reference  
to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed February 20, 2009)

45

---

TABLE OF CONTENTS

10.18	Novavax, Inc. Amended and Restated Change in Control Severance Benefit Plan, (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed January 5, 2009)
10.19*	Form of Indemnity Agreement, as of January 1, 2010
10.20	Lease Agreement, dated as of July 15, 2004, between Liberty Property Limited Partnership and the Company (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report in Form 10-Q for the quarter ended June 30, 2004, filed August 9, 2004)
10.21	Sublease Agreement, dated April 28, 2006, by and between the Company and Sterilox Technologies, Inc. (now PuriCore, Inc.) (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, filed August 14, 2006)
10.22	Amendment dated as of October 25, 2006 to the Sublease Agreement, dated April 28, 2006, by and between the Company and Sterilox Technologies, Inc. (now PuriCore, Inc.) (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, filed November 14, 2006)
10.23	Second Amendment to Sublease Agreement between Novavax, Inc. and PuriCore, Inc., dated April 22, 2009 (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report for the quarter ended June 30, 2009, filed August 10, 2009)
10.24	Lease, commencing April 1, 2005, by and between United Health Care Services, Inc. and the Company (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, filed August 9, 2005)
10.25	Lease Agreement between GP Rock One, LLC and Novavax, Inc., dated as of May 7, 2007 (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report for the quarter ended June 30, 2008, filed August 11, 2008)
10.26	First Amendment to Lease Agreement between GP Rock One, LLC and Novavax, Inc., dated as of May 30, 2008 (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report for the quarter ended June 30, 2008, filed August 11, 2008)
10.27	Second Amendment to Lease Agreement between BMR-9920 Belward Campus Q, LLC (formerly GP Rock One, LLC) and Novavax, Inc., dated as of June 26, 2008 (Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report for the quarter ended June 30, 2008, filed August 11, 2008)
10.28	License Agreement between IGEN, Inc. and the Company (Incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1995, filed April 1, 1996)
10.29***	Exclusive License Agreement, dated February 26, 2007, between the Company and the University of Massachusetts (Incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, filed March 14, 2007)
10.30***	License Agreement, dated July 5, 2007, between the Company and Wyeth Holdings Corporation (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed August 9, 2007)
10.31	Form of Investor Rights Agreement dated July 29, 2008 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed July 30, 2008)
10.32	Forbearance and Pledge Agreement among Denis O. Donnell and the Company, dated May 7, 2007, relating to Secured Promissory Note and Pledge Agreement, each dated March 21, 2002 and filed as Exhibits 10.11 and 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002 (Incorporated by reference to Exhibit 10.32 to the

Company's Amendment No. 1 on Form 10-K/A for the year ended December 31, 2007, filed on December 12, 2008)

TABLE OF CONTENTS

10.33	Amended and Restated Promissory Note by Mitchell J. Kelly to the Company, dated May 7, 2008, relating to Secured Promissory Note, dated March 21, 2002 and filed as Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002 (Incorporated by reference to Exhibit 10.33 to the Company's Amendment No. 1 on Form 10-K/A for the year ended December 31, 2007, filed on December 12, 2008)
10.34	Amended and Restated Pledge Agreement among Mitchell J. Kelly and the Company, dated May 7, 2008, relating to Pledge Agreement, dated March 21, 2002 and filed as Exhibit 10.10 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002 (Incorporated by reference to Exhibit 10.34 to the Company's Amendment No. 1 on Form 10-K/A for the year ended December 31, 2007, filed on December 12, 2008)
10.35	At Market Issuance Sales Agreement, dated January 12, 2009, by and between Novavax, Inc. and Wm. Smith & Co. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed January 13, 2009)
10.36	At Market Issuance Sales Agreement, dated September 15, 2009, by and between Novavax, Inc. and Wm. Smith & Co. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 15, 2009)
10.37*	At Market Issuance Sales Agreement, dated March 15, 2010, by and between Novavax, Inc. and McNicoll, Lewis and Vlask, LLC
10.38	Stock Purchase Agreement between Novavax, Inc. and Satellite Overseas (Holdings) Limited, dated March 31, 2009 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009)
10.39***	Amended and Restated Joint Venture Agreement between Novavax Inc. and Cadila Pharmaceuticals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
10.40***	Amended and Restated Master Services Agreement between Novavax, Inc. and Cadila Pharmaceuticals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
10.41***	Amended and Restated Supply Agreement between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
10.42***	Amended and Restated Technical Services Agreement between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
10.43***	Amended and Restated Seasonal / Other License Agreement between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
10.44***	Amended and Restated Option to Obtain License between Novavax, Inc. and CPL Biologicals Limited, dated as of June 29, 2009 (Incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 10, 2009)
10.45* **	H1N1 License to Agreement between Novavax, Inc. and CPL Biologicals Private Limited, dated October 6, 2009

Edgar Filing: NOVAVAX INC - Form 10-K

- 10.46\*\*\* Materials Transfer Agreement by and between Novavax, Inc. and Laboratorio Avi-Mex S.A. de C.V., dated October 19, 2009 (Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, filed on November 9, 2009)
- 14\* Code of Business Conduct and Ethics

47

---

TABLE OF CONTENTS

23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm
31.1*	Certification of chief executive officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
31.2*	Certification of chief financial officer pursuant to Rule 13a-14(a) or 15d-14(e) of the Securities Exchange Act
32.1*	Certification of chief financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of chief financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

48

---



TABLE OF CONTENTS

# SIGNATURES

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

**NOVAVAX, INC.**

By:

Date: March 16, 2010

/s/ Rahul Singhvi  
President and Chief Executive Officer  
and Director

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

Name	Title	Date
/s/ Rahul Singhvi Rahul Singhvi	President and Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2010
/s/ Frederick W. Driscoll Frederick W. Driscoll	Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2010
s/ Stanley Erck Stanley Erck	Executive Chairman of the Board of Directors	March 16, 2010
/s/ Gary C. Evans Gary C. Evans	Lead Independent Director	March 16, 2010
/s/ John Lambert John Lambert	Director	March 16, 2010
/s/ John O. Marsh, Jr. John O. Marsh, Jr.	Director	March 16, 2010
/s/ Michael A. McManus Michael A. McManus	Director	March 16, 2010
/s/ Rajiv Modi Rajiv Modi	Director	March 16, 2010

TABLE OF CONTENTS

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**  
**Years Ended December 31, 2009, 2008 and 2007**

**CONTENTS**

Report of Independent Registered Public Accounting Firm	F- <u>2</u>
Consolidated Balance Sheets as of December 31, 2009 and 2008	F- <u>3</u>
Consolidated Statements of Operations for each of the Three Years in the Period Ended December 31, 2009	F- <u>4</u>
Consolidated Statements of Stockholders' Equity for each of the Three Years in the Period Ended December 31, 2009	F- <u>5</u>
Consolidated Statements of Cash Flows for each of the Three Years in the Period Ended December 31, 2009	F- <u>6</u>
Notes to Consolidated Financial Statements	F- <u>7</u>
Schedule II Valuation and Qualifying Accounts	

F-1

---

TABLE OF CONTENTS

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders of  
Novavax, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of Novavax, Inc. (a Delaware corporation) and its subsidiary as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Item 15(a)(2). We also have audited Novavax, Inc. and its subsidiary's internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Novavax, Inc. and its subsidiary's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule and an opinion on Novavax Inc. and its subsidiary's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall consolidated financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Novavax, Inc. and subsidiary as of December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

In our opinion, Novavax, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by COSO.

/s/ Grant Thornton LLP

Baltimore, Maryland  
March 16, 2010

F-2

---

TABLE OF CONTENTS**NOVAVAX, INC.****CONSOLIDATED BALANCE SHEETS**

	December 31, 2009              2008 (In Thousands, Except Share and per Share Information)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$38,757	\$26,938
Short-term investments available-for-sale	4,193	6,962
Accounts and other receivables, net of allowance of \$218 as of December 31, 2008	258	290
Prepaid expenses and other current assets	1,295	774
Current assets of discontinued operations		132
Total current assets	44,503	35,096
Property and equipment, net	7,801	8,228
Goodwill	33,141	33,141
Other non-current assets	160	160
Total assets	\$85,605	\$76,625
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,098	\$1,750
Accrued expenses and other current liabilities	5,417	2,969
Current liabilities of discontinued operations		242
Current portion of notes payable	80	650
Convertible notes, current portion net of discount		21,778
Deferred revenue	150	
Deferred rent	282	328
Total current liabilities	8,027	27,717
Non-current portion of notes payable	406	480
Deferred rent	2,707	2,939
Total liabilities	11,140	31,136
Commitments and contingences (see Note 13)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized; no shares issued and outstanding		
Common stock, \$0.01 par value, 200,000,000 shares authorized; and 100,717,890 shares issued and 100,262,460 shares outstanding at December 31, 2009 and 69,220,021 shares issued and 68,764,591 shares outstanding at December 31, 2008		
	1,007	692
Additional paid-in capital	350,810	284,595

Edgar Filing: NOVAVAX INC - Form 10-K

Notes receivable from former directors	(1,572 )	(1,572 )
Accumulated deficit	(274,150)	(235,776)
Treasury stock, 455,430 shares at December 31, 2009 and 2008, cost basis	(2,450 )	(2,450 )
Accumulated other comprehensive income	820	
Total stockholders' equity	74,465	45,489
Total liabilities and stockholders' equity	\$85,605	\$76,625

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

F-3

---

TABLE OF CONTENTS**NOVAVAX, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	For the Years Ended December 31,		
	2009	2008	2007
	(In Thousands, Except per Share Information)		
Revenue	\$325	\$1,064	\$1,513
Operating expenses:			
Research and development	25,780	24,334	17,821
General and administrative	11,928	11,090	13,963
Total operating expenses	37,708	35,424	31,784
Loss from continuing operations before other income (expense)	(37,383)	(34,360)	(30,271 )
Other income (expense):			
Interest income	285	959	3,287
Interest expense	(786 )	(1,683 )	(1,606 )
Impairment of short-term investments	(1,338 )	(1,238 )	
Realized gains on short-term investments	848		
Loss from continuing operations	(38,374)	(36,322)	(28,590 )
Income (loss) from discontinued operations		273	(6,175 )
Net loss	\$(38,374)	\$(36,049)	\$(34,765 )
Basic and diluted net loss per share:			
Loss per share from continuing operations	\$(0.45 )	\$(0.53 )	\$(0.47 )
Loss per share from discontinued operations			(0.10 )
Net loss per share	\$(0.45 )	\$(0.53 )	\$(0.57 )
Basic and diluted weighted average number of common shares outstanding	85,555	68,174	61,101

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

TABLE OF CONTENTS

**NOVAVAX, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS  
EQUITY**

**For the Years Ended December 31, 2009, 2008 and  
2007**

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

F-5

---



TABLE OF CONTENTS**NOVAVAX, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Years Ended December 31,		
	2009	2008	2007
	(In Thousands)		
Operating Activities:			
Net loss:	\$(38,374)	\$(36,049)	\$(34,765 )
Plus net loss (income) from discontinued operations		(273 )	6,175
Net loss from continuing operation	(38,374)	(36,322)	(28,590 )
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	1,194	893	834
Amortization of deferred financing costs	147	258	259
Amortization of debt discount	222	409	221
Provision for bad debts			176
Loss on disposal of property and equipment	21	258	100
Impairment of long-lived assets	23	994	
Amortization of net discounts on short-term investments		(181 )	(2,320 )
Reserve for notes receivable and accrued interest		(534 )	875
Deferred rent	(279 )	(123 )	312
Non-cash expense for services			57
Non-cash stock-based compensation	1,533	2,070	1,800
Lease incentives received		3,000	
Net impairment of short-term investments	490	1,238	
Changes in operating assets and liabilities:			
Accounts and other receivables	32	438	(298 )
Prepaid expenses and other current assets	(536 )	674	219
Other non-current assets		18	432
Accounts payable and accrued expenses	2,547	141	206
Deferred revenue	150		
Net cash used in operating activities from continuing operations	(32,830)	(26,769)	(25,717 )
Net cash provided by (used in) in operating activities from discontinued operations		2,459	(1,025 )
Net cash used in operating activities	(32,830)	(24,310)	(26,742 )
Investing Activities:			
Capital expenditures	(745 )	(5,689 )	(1,961 )
Proceeds from disposal of property and equipment		121	
Purchases of short-term investments		(15,650)	(94,993 )
Proceeds from maturities of short-term investments	3,100	49,770	121,608
Net cash provided by investing activities from continuing operations	2,355	28,552	24,654
Net cash provided by (used in) investing activities from discontinued operations		1,354	(3 )
Net cash provided by investing activities	2,355	29,906	24,651

## Financing Activities:

Principal payments of notes payable	(15,043)	(1,040 )	(809 )
Proceeds from other borrowings		200	
Net proceeds from sales of common stock	56,385	17,503	
Proceeds from the exercise of stock options	952	329	89
Net cash provided by (used in) financing activities	42,294	16,992	(720 )
Net increase (decrease) in cash and cash equivalents	11,819	22,588	(2,811 )
Cash and cash equivalents at beginning of year	26,938	4,350	7,161
Cash and cash equivalents at end of year	\$38,757	\$26,938	\$4,350
Supplemental disclosure of non-cash activities:			
Conversion of convertible debt and accrued interest to common stock	\$7,660	\$	\$
Debt discount from modification of convertible debt	\$	\$	\$852
Equipment purchases included in accounts payable	\$66	\$	\$624
Financed insurance premiums	\$	\$570	\$600
Supplemental disclosure of cash flow information:			
Cash interest payments	\$817	\$1,040	\$1,073

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

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007**

**Note 1 Organization**

Novavax, Inc. (the Company), is a clinical-stage biopharmaceutical company focused on developing novel, highly potent recombinant vaccines. These vaccines leverage the Company's virus-like-particle (VLP) platform technology coupled with a unique disposable production technology. VLPs are genetically engineered three-dimensional nanostructures which incorporate immunologically important lipids and recombinant proteins. The Company's VLPs resemble the virus, but lack the genetic material to replicate the virus and its proprietary production technology uses insect cells rather than chicken eggs or mammalian cells. The Company's current product targets include vaccines against pandemic and seasonal influenza, including H5N1 and H1N1 pandemic strains, Respiratory Syncytial Virus (RSV) and Varicella Zoster Virus (VZV), which causes shingles.

In 2009, the Company formed a joint venture with Cadila Pharmaceuticals Ltd., named CPL Biologicals Private Limited, to develop and manufacture vaccines, biological therapeutics and diagnostics in India (see Note 4).

**Note 2 Liquidity Matters**

Since its inception, the Company has incurred, and continues to incur, significant losses from operations. At December 31, 2009, the Company had cash and cash equivalents of \$38.8 million and short-term investments with a fair value of \$4.2 million.

The Company's vaccine product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercial use. There can be no assurance that the Company's research and development efforts will be successful or that any potential product candidates will prove to be safe and effective in clinical trials. Even if developed, these vaccine product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The commercial launch of any vaccine product candidate is subject to certain risks including, but not limited to, manufacturing scale-up and market acceptance.

Based on the Company's cash, cash equivalents and short-term investment balances as of December 31, 2009 and its current business operations, the Company believes it will have adequate capital resources available to operate at planned levels for at least the next twelve months. Additional capital will be required in the future to develop its product candidates through clinical development, manufacturing, and commercialization. The Company will seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, non-dilutive government contracts, collaborative arrangements, or some combination of these financing alternatives. Any capital raised by an equity offering will likely be substantially dilutive to the existing stockholders and any licensing or development arrangement may require the Company to give up rights to a product or technology at less than its full potential value. Other than the Company's At the Market Sales Agreement with McNicoll, Lewis & Vlask LLC (see Note 7), we have not secured any additional commitments for new financing nor

can the Company provide any assurance that new financing will be available on commercially acceptable terms, if at all. If the Company is unable to obtain additional capital, it will assess its capital resources and will likely be required to delay, reduce the scope of, or eliminate one or more of its product research and development programs, downsize the organization, or reduce its general and administrative infrastructure.

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

### **Basis of Presentation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Fielding Pharmaceutical Company. All significant intercompany accounts and transactions have been eliminated in consolidation.

F-7

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 3 Summary of Significant Accounting Policies**  
**(continued)**

As a result of the Company's sale of its Estasorb business in 2008, the consolidated financial statements and the related note disclosures reflect the operations of the Estasorb business as a discontinued operation (see Note 11).

**Use of Estimates**

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

**Reclassifications**

Certain reclassifications have been made to the prior years' financial statements to conform to the current year presentation. In 2008, the Company corrected the classification and related accounting for notes receivable due from former directors to show these notes as a reduction to stockholders' equity in the December 31, 2008 consolidated balance sheet. As a result, the Company reduced its net loss by \$0.7 million for the accumulated amounts previously reserved and recorded as general and administrative expenses of \$1.2 million and a charge to interest income for the cumulative interest income of \$0.5 million related to the notes receivable. The Company evaluated the impact of this correction in accordance with Accounting Standards Codification (ASC) 250-10-355-1, *Materiality*. The amount of the adjustment when compared to the operating results for the year ended December 31, 2008, or any trend of income, is not considered by management to be material.

**Cash and Cash Equivalents**

Cash and cash equivalents consist of highly liquid investments with original maturities of three months or less from the date of purchase.

**Short-Term Investments**

Short-term investments at December 31, 2009 consist of investments in three auction rate securities with a par value of \$5.1 million and a fair value of \$4.2 million. In 2009 and 2008, the Company recorded other-than-temporary impairment charges related to these securities of \$1.3 million and \$1.2 million, respectively, because of the recent uncertainties in the credit markets and management's belief these securities cannot be sold at par value, but are saleable

at a discount from their par value. In 2009, the Company realized gains of \$0.8 million relating to redemptions of several auction rate securities from its portfolio.

The Company had invested in auction rate securities for short periods of time as part of its cash management program. Recent uncertainties in the credit markets have prevented the Company from liquidating certain holdings of auction rate securities as the amount of securities submitted for sale during the auction has exceeded the amount of purchase orders. Although an event of an auction failure does not necessarily mean that a security is impaired, the Company considered various factors to assess the fair value and the classification of the securities as short-term assets. Fair value was determined through an independent valuation using two valuation methods – a discounted cash flow method and a market comparable method. Certain factors used in these methods include, but are not necessarily limited to, comparable securities traded on secondary markets, timing of the failed auction, specific security auction history, quality of underlying collateral, rating of the security and the bond insurer, the Company's ability and intent to retain the securities for a period of time to allow for anticipated recovery in the market value, and other factors.

The Company has classified these securities as available-for-sale since the Company may need to liquidate these securities within the next year. The available-for-sale securities are carried at fair value and unrealized gains and losses on these securities, if determined to be temporary, are included in accumulated

TABLE OF CONTENTS**NOVAVAX, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007****Note 3 Summary of Significant Accounting Policies  
(continued)**

other comprehensive income (loss) in stockholders' equity. Investments available for sale are evaluated periodically to determine whether a decline in value is other-than-temporary. The term other-than-temporary is not intended to indicate a permanent decline in value. Rather, it means that the prospects for a near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria, such as the magnitude and duration of the decline, as well as the Company's ability to hold the securities until market recovery, to predict whether the loss in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the security is reduced and the impairment is recorded in the consolidated statements of operations. The specific identification method is used in computing realized gains and losses on sale of the Company's securities.

Short-term investments classified as available-for-sale as of December 31, 2009 were comprised of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Auction rate securities	\$ 3,373	\$ 820	\$	\$ 4,193
Total	\$ 3,373	\$ 820	\$	\$ 4,193

**Financial Instruments and Concentration of Credit Risk**

Financial instruments, which possibly expose the Company to concentration of credit risk, consist primarily of cash and cash equivalents and short-term investments. The Company's investment policy limits investments to certain types of instruments, including auction rate securities, high-grade corporate debt securities and money market instruments, places restrictions on maturities and concentrations in certain industries and requires the Company to maintain a certain level of liquidity. At times, the Company maintains cash balances in financial institutions, which may exceed federally insured limits. The Company has not experienced any losses relating to such accounts and believes it is not exposed to a significant credit risk on its cash and cash equivalents. The carrying value of cash and cash equivalents approximates their fair value based on their short-term maturities at December 31, 2009 and 2008.

**Fair Value Measurements**

The Company adopted ASC Topic 820, *Fair Value Measurements and Disclosures*, for financial assets and liabilities on January 1, 2008. The Company adopted ASC 820 for non-financial assets and liabilities on January 1, 2009.

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

*Level 1:* Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

*Level 2:* Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly.

These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

*Level 3:* Unobservable inputs that reflect the reporting entity's own assumptions.

F-9

---



TABLE OF CONTENTS**NOVAVAX, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007****Note 3 Summary of Significant Accounting Policies  
(continued)**

Financial assets and liabilities measured a fair market value on a recurring basis as of December 31, 2009 are summarized below (in thousands):

Assets	Fair Value Measurement at December 31, 2009 Using Fair Value Hierarchy			
	Level 1	Level 2	Level 3	Fair Value
Cash and cash equivalents	\$ 38,757	\$	\$	\$ 38,757
Short-term investments		4,193		4,193
Total	\$ 38,757	\$ 4,193	\$	\$ 42,950

The amounts in the Company's consolidated balance sheet for accounts receivable, accounts payable and notes payable approximate fair value due to their short-term nature.

**Accounts Receivables**

Accounts receivable are reported at their net realizable value. The Company maintains an allowance for doubtful accounts that is determined based on historical experience and management's expectations of future losses. Accounts deemed uncollectible are charged to the allowance based on specific identification. Accounts that are ultimately deemed uncollectible are written-off as a reduction of accounts receivable and the allowance for doubtful accounts.

**Property and Equipment**

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

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

	2009	2008
Construction in progress	\$ 1,351	\$ 5,394
Machinery and equipment	4,348	3,880
Leasehold improvements	4,531	637
Computer software and hardware	333	339

	10,563	10,250
Less accumulated depreciation and amortization	(2,762 )	(2,022 )
	\$ 7,801	\$ 8,228

Construction in progress is primarily related to costs incurred related to the completion of the Company's GMP pilot manufacturing facility, which was ready for use in January 2009 and the purchase of equipment that is awaiting final installation or validation prior to its use.

Depreciation expense was approximately \$1.2 million, \$0.9 million and \$0.7 million for the years ended December 31, 2009, 2008 and 2007, respectively.

## Goodwill and Intangible Assets

Goodwill originally resulted from a business acquisition in 2000. Assets acquired and liabilities assumed were recorded at their fair values; the excess of the purchase price over the identifiable net assets acquired was recorded as goodwill. Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to impairment tests annually, or more frequently should indicators of impairment arise. The Company utilizes both the market approach and the income approach to determine if it has an impairment of

F-10

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 3 Summary of Significant Accounting Policies**  
**(continued)**

its goodwill. The market approach serves as the primary approach and is based on market value of invested capital. The income approach is used as a confirming look to the market approach. Goodwill impairment is deemed to exist if the carrying value of a reporting unit exceeds its estimated fair value.

At December 31, 2009 and 2008, the Company used both the market approach and the income approach to determine if the Company had an impairment of its goodwill. The Company used a market approach to determine the market value of capitalization of its single reporting unit. Step one of the impairment test states that if the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not to be impaired. The Company's forecasts were used to create a risk adjusted discounted cash flow analysis to indicate fair value. The fair value of the Company's reporting unit was compared to the carrying amount of the reporting unit. Under both approaches, the fair value of the reporting unit was higher than the carrying value, resulting in no impairment to goodwill at December 31, 2009 and 2008. Due to a significant decrease in its stock price during the first quarter of 2009, the Company also performed a goodwill impairment test as of March 31, 2009, and determined there was no impairment to goodwill.

**Equity Method Investments**

The Company has an equity investment in CPL Biologicals Private Limited. The Company accounts for this investment using the equity method (see Note 4). Under the equity method of accounting, investments are stated at initial cost and are adjusted for subsequent additional investments and the Company's proportionate share of earnings or losses and distributions up to the amount initially invested or advanced.

**Long-Lived Assets and Discontinued Operations**

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

In 2008, the Company was unable to sell the patent related to its MNP technology, previously recorded as assets held for sale, and recorded an impairment of \$0.8 million.

## Revenue Recognition

The Company performs research and development for United States government agencies. The Company recognizes revenue under research contracts when a contract has been executed, the contract price is fixed and determinable, delivery of services or products has occurred and collection of the contract price is considered probable. Revenue is earned under cost reimbursable and fixed price contracts. Direct contract costs are expensed as incurred.

Under cost reimbursable contracts, the Company is reimbursed for allowable costs and paid a fixed fee. Revenue on cost reimbursable contracts is recognized as costs are incurred plus a portion of the fee earned. Revenue for fixed price arrangements are recognized under the proportional performance method based upon the ratio of costs incurred to achieve contract milestones to total estimated cost. Losses on contracts, if any, are recognized in the period in which they become known.

F-11

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 3 Summary of Significant Accounting Policies**  
**(continued)**

For upfront payments and licensing fees related to contract research or technology, the Company follows provisions of ASC 605, *Revenue Recognition*, in determining if these payments and fees represent the culmination of a separate earnings process or if they should be deferred and recognized as revenue over the life of the related agreement.

**Stock-Based Compensation**

The Company accounts for stock-based compensation in accordance with ASC Topic 718, *Compensation-Stock Compensation*, which requires grants of employee stock options and restricted stock awards to be recognized in the financial statements based upon their respective grant-date fair values. The Company recognizes compensation expense on a straight-line basis over the requisite service period (generally the vesting period) of the equity awards, which typically occurs ratably over periods ranging from six months to four years. See Note 9 for a further discussion on stock-based compensation.

The expected life of stock options granted was based on the Company's historical option exercise experience and post vesting forfeiture experience using the historical expected term from the vesting date. The expected volatility of the options granted was determined using historical volatilities based on stock prices over a look-back period corresponding to the expected life. The risk-free interest rate was determined using the yield available for zero-coupon United States government issues with a remaining term equal to the expected life of the options. The forfeiture rate was determined using historical pre-vesting forfeiture rates since the inception of the plans. The Company has never paid a dividend, and as such, the dividend yield is zero.

Restricted stock awards to employees and directors have been recorded as compensation expense over the expected vesting period based on the fair value at the award date and the number of shares ultimately expected to vest using the straight-line method of amortization. The Company accounts for share-based awards issued to non-employees by determining the fair value of equity awards given as consideration for services rendered to be recognized as compensation expense over the shorter of the vesting or service periods. In cases where services are not fully rendered, the equity award must be revalued on each subsequent reporting date until performance is complete with a cumulative catch-up adjustment recognized for any changes in their estimated fair value.

**Research and Development Expenses**

Research and development expenses are expensed as incurred. Such costs include internal research and development expenditures (such as salaries and benefits, raw materials, and supplies) and contracted services (such as sponsored research, testing and consulting services) of proprietary research and development activities and similar expenses associated with collaborative research agreements.

## Income Taxes

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

A valuation allowance is established when necessary to reduce net deferred tax assets to the amount expected to be realized.

F-12

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 3 Summary of Significant Accounting Policies**  
**(continued)**

On January 1, 2007, the Company adopted a new financial pronouncement that gives guidance related to the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and requires that the Company recognize in its financial statements the impact of a tax position, if that position is more likely than not to be sustained upon an examination, based on the technical merits of the position.

Interest and penalties related to income tax matters are recorded as income tax expense. At December 31, 2009 and 2008, the Company had no accruals for interest or penalties related to income tax matters.

**Net Loss per Share**

Net loss per share is computed using the weighted average number of shares of common stock outstanding. All outstanding warrants, stock options and unvested restricted stock awards totaling 9,428,319 shares at December 31, 2009 are excluded from the computation for 2009, as their effect is anti-dilutive.

**Comprehensive Income (Loss)**

The Company accounts for comprehensive income (loss) as prescribed by ASC 220, *Comprehensive Income*. Comprehensive income (loss) is the total net income (loss) plus all changes in equity during the period except those changes resulting from investment by and distribution to owners. Total comprehensive loss was \$37.6 million, \$36.0 million and \$34.8 million for the years ended December 31, 2009, 2008 and 2007, respectively.

At December 31, 2009, the Company's other comprehensive income consists of \$0.8 million related to the appreciation on previously impaired marketable securities in the later part of 2009. During 2008 and early 2009, the Company experienced a decrease in the value of these securities and recorded other-than-temporary impairment charges and adjusted the carrying value of these securities.

**Segment Information**

The Company manages its business as one operating segment: developing novel, highly potent recombinant vaccines.

The Company does not operate separate lines of business with respect to its products or product candidates. Accordingly, the Company does not have separately reportable segments as defined by ASC 280, *Segment Reporting*.

## Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board ( FASB ) issued authoritative guidance on the consolidation of variable interest entities, which is effective for the Company beginning January 1, 2010. The new guidance requires revised evaluations of whether entities represent variable interest entities, ongoing assessments of control over such entities, and additional disclosures for variable interests. The Company believes adoption of this new guidance will not have a material impact on its financial position and results of operations.

In September 2009, ASU 2009-13, *Revenue Recognition* (Topic 605) *Multiple-Deliverable Revenue Arrangements*, was issued and will change the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. Specifically, this guidance amends the criteria in Subtopic 605-25, *Revenue Recognition Multiple-Element Arrangements*, for separating consideration in multiple-deliverable arrangements. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates.

This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. ASU 2009-13 is effective

F-13

---



TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 3 Summary of Significant Accounting Policies**  
**(continued)**

prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 with early adoption permitted. The impact of ASU 2009-13 on the Company's consolidated financial statements will depend on the nature and terms of its revenue arrangements entered into or materially modified after the adoption date. However, based on the Company's current customer arrangements, the Company does not believe the adoption of this ASU will have a material impact on its consolidated financial statements.

In January 2010, the FASB issued ASU 2010-06, *Fair Value Measurements and Disclosures* (Topic 820) *Improving Disclosures about Fair Value Measurements*, which amends Topic 820 to add new requirements for disclosures about transfers into and out of Levels 1 and 2 and separate disclosures about purchases, sales, issuances, and settlements related to Level 3 measurements. ASU 2010-06 also clarifies existing fair value disclosures about the level of disaggregation and about inputs and valuation techniques used to measure fair value. The ASU is effective for the first reporting period beginning after December 15, 2009, except for the requirements to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will be effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. Early adoption is permitted. The Company believes the adoption of this amendment will not have a material effect on its financial position or results of operations.

**Note 4 Joint Venture and H1N1 Mexico Transaction**

**Joint Venture With Cadila**

On March 31, 2009, the Company entered into a Joint Venture Agreement (the "JVA") with Cadila Pharmaceuticals Ltd., a private company incorporated under the laws of India ("Cadila") pursuant to which the Company and Cadila formed CPL Biologicals Private Limited, a joint venture (the "JV"), of which 80% is owned by Cadila and 20% is owned by Novavax. The JV will develop and commercialize the Company's seasonal influenza and H1N1 pandemic vaccine candidates and Cadila's biogeneric products and other diagnostic products for the territory of India. The JV has the right to negotiate a definitive agreement for rights to certain future Novavax products (other than RSV) and certain future Cadila products in India, prior to Novavax or Cadila licensing such rights to a third party. Novavax has the right to negotiate the licensing of vaccines developed by the JV using Novavax's technology for commercialization in every country except for India and vaccines developed by the JV using Cadila's technology for commercialization in certain other countries, including the United States. Cadila has committed to contribute approximately \$8 million over three years to support the JV's operations. In connection with the JVA, on March 31, 2009, the Company also entered into a license agreement, an option to enter into a license agreement, a technical services agreement and a supply agreement with the JV and a master services agreement with Cadila. Because the Company does not control the JV, the Company accounts for its investment using the equity method. Since the carrying value of the Company's contribution was \$0

and there is no guarantee or commitment to provide future funding, the Company does not expect to record losses related to this investment in the future.

Also on March 31, 2009, the Company entered into a Stock Purchase Agreement with Satellite Overseas (Holdings) Limited ( SOHL ), a subsidiary of Cadila, pursuant to which SOHL purchased 12.5 million shares of the Company's common stock at the market price of \$0.88 per share, resulting in net proceeds of approximately \$10.6 million.

### **H1N1 Mexico Transaction**

On October 19, 2009, the Company entered into a Materials Transfer Agreement with Laboratorio Avi-Mex S.A. de C.V. ( Avimex ), pursuant to which it supplied Avimex with certain amounts of its 2009 H1N1 vaccine candidate and made payments to Avimex related to the Company's clinical trial. Avimex used the H1N1 vaccine to conduct clinical trials and is currently seeking regulatory approval in Mexico. Avimex made a milestone payment to the Company and is obligated to pay the Company a transfer fee for the H1N1

F-14

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007**

**Note 4 Joint Venture and H1N1 Mexico Transaction  
(continued)**

vaccine based on the Company's production cost. The agreement and the option to enter into a non-exclusive distribution agreement to distribute the 2009 H1N1 vaccine in Mexico both expired by its terms on December 31, 2009. The second phase of the clinical trial is ongoing and the parties are continuing to cooperate in seeking regulatory approval in Mexico.

On October 20, 2009, the Company entered into a binding term sheet (as amended, the "Xcellerex Agreement") with Xcellerex, Inc. A director of the Company was also a director of Xcellerex at the time the term sheet was negotiated.

This director did not participate in any Board of Directors meetings regarding this transaction. Pursuant to the Xcellerex Agreement, Xcellerex performed scale-up and manufacturing activities related to the Company's 2009 H1N1 vaccine candidate for potential sale in Mexico. Although the H1N1 manufacturing campaign with Xcellerex did not result in the manufacture of acceptable vaccine to the Company, the Company achieved proof of concept by scaling up to a commercial grade bioreactor. The success in scaling up its VLPs in stir tank bioreactors potentially provides an additional path to large scale, commercially viable vaccine production. As consideration, the Company paid Xcellerex a fixed payment and supplied materials. The Xcellerex Agreement expired by its terms on February 15, 2010.

**Note 5 Accrued Expenses and Other Current Liabilities**

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

	2009	2008
Employee benefits and compensation	\$ 1,726	\$ 412
Research and development accruals	2,638	1,297
Other accrued expenses	1,038	782
Interest expense	15	478
Accrued expenses and other current liabilities	\$ 5,417	\$ 2,969

**Note 6 Long-Term Debt**

**Notes Payable**

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

2009 2008

Edgar Filing: NOVAVAX INC - Form 10-K

Note payable; insurance financing; bears interest at 4.9% per annum; principal and interest due in monthly installments of \$51,677 through September 2009	\$	\$ 570
Opportunity Grant Fund notes payable; non-interest bearing; principal only payments due in monthly installments of \$6,667 through April 2012	186	260
Loan agreements; bear interest at 3% per annum; repayment is conditional	300	300
Total	486	1,130
Less current portion	(80 )	(650 )
Long-term portion	\$ 406	\$ 480

F-15

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 6 Long-Term Debt (continued)**

**Opportunity Grant Fund Note Payable**

In April 2007, the Company entered into a Settlement and Release Agreement with the Commonwealth of Pennsylvania, whereby the Company agreed to repay the original grant of \$400,000 associated with its former corporate headquarters and product development activities in Malvern, Pennsylvania in 60 monthly installments of \$6,667 each starting May 2007. Interest does not accrue on the outstanding balance.

**Loan Agreements**

In May 2008, the Company entered into loan agreements with the State of Maryland and Montgomery County whereby the repayment of the loan amounts and accrued interest is conditioned upon the Company meeting the capital investment and employment requirements during the term of the loans through 2013.

**Convertible Notes**

At December 31, 2008, the Company had convertible notes outstanding, net of a discount, totaling \$21.8 million. These notes had a face value of \$22 million, with interest at 4.75%, due July 15, 2009 and were convertible by the holders into 4,029,304 shares of the Company's common stock at \$4.00 per share.

On April 29, 2009, the Company entered into amendment agreements (the 2009 Amendments) with holders of the outstanding Notes representing \$17.0 million of the \$22 million outstanding principal amount of the Notes to amend the terms of the Notes to allow for early retirement; 70% of this principal amount plus accrued and unpaid interest was paid in cash, totaling \$12.1 million, and 30% was paid through issuance of 2,040,000 shares of common stock at \$2.50 per share.

On July 15, 2009, the Company paid the \$5.0 million balance of the Notes. Under the terms of the Notes, the Company paid approximately \$2.6 million of principal and accrued and unpaid interest in cash and issued 1,016,939 shares of common stock to pay the remaining \$2.6 million of principal and accrued and unpaid interest, based on a price of \$2.5163 per share. As of July 15, 2009, the Notes were fully paid and extinguished.

Aggregate future minimum principal payments on long-term debt at December 31, 2009 are as follows (in thousands):

Year	Amount
2010	\$ 80
2011	80

2012	26
2013	300
	\$ 486

## Note 7 Sales of Common Stock

On November 25, 2009, the Company issued 6,800,000 shares of common stock at \$3.30 per share in an underwritten public offering. The Company received net proceeds of approximately \$21 million.

On June 30, 2009, the Company entered into a stock purchase agreement with ROVI Pharmaceuticals of Spain for the purchase of \$3 million of common stock at \$2.74 per share and issued approximately 1,094,891 shares of its common stock in this transaction.

On March 31, 2009, the Company entered into a stock purchase agreement with SOHL, pursuant to which SOHL purchased 12.5 million shares of common stock at the market price of \$0.88 per share. The Company received net proceeds of approximately \$10.6 million.

F-16

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 7 Sales of Common Stock (continued)**

On January 12, 2009, the Company entered into an At the Market Sales Agreement (the January Sales Agreement) with Wm Smith & Co. (Wm Smith), under which the Company may sell an aggregate of up to \$25 million in gross proceeds of its common stock from time to time through Wm Smith, as the agent for the offer and sale of the common stock. During 2009, the Company sold 7,489,207 shares at a range of \$1.75-\$5.03 and received net proceeds of approximately \$22 million under the January Sales Agreement. On September 15, 2009, the Company entered into a second At Market Issuance Sales Agreement (the September Sales Agreement), with Wm Smith, under which the Company may sell an aggregate of up to \$10 million in gross proceeds of the Company's common stock from time to time through Wm Smith. The Company has not sold any common stock under the September Sales Agreement.

On March 15, 2010, the Company terminated the January Sales Agreement and the September Sales Agreement and entered into a sales agreement with McNicoll, Lewis & Vlask LLC, as sales agent, under which the Company may sell an aggregate of \$50 million of gross proceeds of the Company's common stock. The Company's Board of Directors has authorized the sale of up to 25 million shares of common stock pursuant to this agreement.

On July 31, 2008, the Company completed a registered direct offering of 6,686,650 units (the Units), with each unit consisting of one share of common stock and a warrant to purchase 0.5 shares of common stock at a price of \$2.68 per unit (or \$2.8425 per unit for units sold to affiliates of the Company). The warrants represent the right to acquire an aggregate of 3,343,325 shares of common stock at an exercise price of \$3.62 per share and are exercisable between January 31, 2009 and July 31, 2013. The Company received net proceeds of approximately \$17.5 million.

In connection with the sale of Units, the Company estimated the fair value attributable to the warrants of approximately \$4.1 million as of the date of grant by applying the Black-Scholes pricing valuation model. The Black-Scholes pricing valuation model utilized the following assumptions: warrant issue date stock price of \$2.52, expected volatility of 80.32%, expected term of 5.0 years, risk-free interest rate of 3.30%, and dividend yield of 0%. The fair value of the warrants was included in additional paid-in-capital on the Company's consolidated balance sheet.

**Note 8 Stockholders Equity**

On August 7, 2002, the Company adopted a Shareholder Rights Plan which provides for the issuance of rights to purchase shares of Series D Junior Participating Preferred Stock, par value \$0.01 per share (the Preferred Shares), of the Company. Under the Shareholder Rights Plan, the Company distributed one preferred share purchase right (a Right) for each outstanding share of common stock of the Company. The Rights were distributed to stockholders of record on August 16, 2002.

Each Right entitles the holder to purchase from the Company one-thousandth of a Preferred Share at a price of \$40, subject to adjustment. The Rights become exercisable, with certain exceptions, 10 business days after any party,

without prior approval of the Board of Directors, acquires or announces an offer to acquire beneficial ownership of 15% or more of the Company's outstanding common stock. In the event that any party acquires 15% or more of the Company's outstanding common stock, the Company enters into a merger or other business combination, or if a substantial amount of the Company's assets are sold after the time that the Rights become exercisable, the Rights provide that the holder will receive, upon exercise, shares of the common stock of the surviving or acquiring company, as applicable, having a market value of twice the exercise price of the Right.

The Rights expire August 7, 2012, and are redeemable by the Company at a price of \$0.00025 per Right at any time prior to the time that any party acquires 15% or more of the Company's outstanding common stock. Until the earlier of the time that the Rights become exercisable, are redeemed or expire, the Company will issue one Right with each new share of common stock issued.

F-17

---



TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007**

**Note 9 Stock-Based Compensation**

The Company has granted equity awards under several plans. Under the 2005 Stock Incentive Plan (the "2005 Plan"), approved in May 2005 and amended in June 2007 by the Company's stockholders, equity awards may be granted to officers, directors, employees, consultants and advisors to the Company and any present or future subsidiary to purchase a maximum of 5,565,724 shares of the Company's common stock. In addition, at the time of approval of the 2005 Plan, a maximum 5,746,468 shares of common stock subject to stock options outstanding under the Company's 1995 Stock Option Plan (the "1995 Plan") may revert to and become issuable under the 2005 Plan, if such options should expire or otherwise terminate unexercised. Although the term of the 1995 Plan has expired, stock options previously granted under the 1995 Plan remain in existence in accordance with their terms. No new awards will be made under the 1995 Plan.

Under the 2005 Plan, the 1995 Plan and the 1995 Director Stock Option Plan (the "1995 Director Plan") incentive stock options, having a maximum term of 10 years, can be or were granted at no less than 100% of the fair market value of the Company's stock at the time of grant and are generally exercisable over periods ranging from six months to four years. There is no minimum exercise price for non-statutory stock options. The 1995 Director Plan has expired. Stock options previously granted under the 1995 Director Plan remain in existence in accordance with their terms. No new awards will be made under the 1995 Directors Plan.

The Company recorded stock-based compensation expense in the consolidated statement of operation as follows (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Research and development	\$ 539	\$ 750	\$ 608
General and administrative	994	1,064	737
Total stock-based compensation expenses	\$ 1,533	\$ 1,814	\$ 1,345

TABLE OF CONTENTS**NOVAVAX, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007****Note 9 Stock-Based Compensation (continued)****Stock Options Awards**

The following is a summary of option activity under the 2005 Plan, the 1995 Plan and the 1995 Director Plan for the year ended December 31, 2009:

	2005 Stock Incentive Plan		1995 Stock Option Plan		1995 Director Stock Option Plan	
	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price	Stock Options	Weighted-Average Exercise Price
Outstanding at January 1, 2009	4,604,509	\$ 2.46	1,433,969	\$ 5.43	40,000	\$ 5.63
Granted	1,339,525	\$ 1.99		\$		\$
Exercised	(541,832 )	\$ 1.72	(5,000 )	\$ 4.28		\$
Canceled	(523,527 )	\$ 2.70	(342,650 )	\$ 4.45	(10,000)	\$ 5.63
Outstanding at December 31, 2009	4,878,675	\$ 2.38	1,086,319	\$ 5.72	30,000	\$ 5.63
Vested and expected to vest at December 31, 2009	4,471,134	\$ 2.38	1,086,319	\$ 5.72	30,000	\$ 5.63
Shares exercisable at December 31, 2009	2,594,887	\$ 2.38	1,086,319	\$ 5.72	30,000	\$ 5.63
Shares available for grant at December 31, 2009	2,712,580					

The fair value of the stock options granted for the years ended December 31, 2009, 2008 and 2007, was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2009		2008		2007	
Weighted average fair value of options granted	\$1.29		\$1.59		\$1.76	
Risk-free interest rate	1.56%	3.19%	1.97%	3.29%	3.93%	4.62%
Dividend yield	0%		0%		0%	
Volatility	85.68	119.53%	81.14%	87.78%	86.11%	93.80%
Expected life (in years)	3.89	7.05	3.62	6.37	4.03	5.94
Expected forfeiture rate	21.07%		21.96%		20.34%	

The aggregate intrinsic value and weighted-average remaining contractual term of stock options exercisable as of December 31, 2009 was approximately \$1.8 million and 5.1 years, respectively. The aggregate intrinsic value and

weighted-average remaining contractual term of options vested and expected to vest as of December 31, 2009 was \$3.0 million and 6.5 years, respectively. The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's closing stock price on the last trading day of 2009 and the exercise price, multiplied by the number of in-the-money options) that would have been received by

F-19

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 9 Stock-Based Compensation (continued)**

the option holders had all option holders exercised their options on December 31, 2009. This amount is subject to change based on changes to the fair market value of the Company's common stock. The aggregate intrinsic value of options exercised for 2009, 2008 and 2007 was \$0.9 million, \$0.1 million and \$40,000, respectively.

**Restricted Stock Awards**

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

The following is a summary of restricted stock awards activity for the year ended December 31, 2009:

	Number of Shares	Per Share Weighted- Average Grant-Date Fair Value
Outstanding at January 1, 2009	148,332	\$ 3.07
Restricted stock granted	10,000	\$ 5.21
Restricted stock vested	(68,332 )	\$ 3.46
Restricted stock forfeited		\$ 0.00
Outstanding at December 31, 2009	90,000	\$ 3.04

As of December 31, 2009, there was approximately \$2.0 million of total unrecognized compensation expense (net of estimated forfeitures) related to unvested options and restricted stock awards. This unrecognized compensation expense is expected to be recognized over a weighted average period of 1.4 years.

**Note 10 Employee Benefits**

The Company maintains a defined contribution 401(k) retirement plan, pursuant to which employees who have completed 90 days of service may elect to contribute up to 15% of their compensation on a tax deferred basis up to the maximum amount permitted by the Internal Revenue Code of 1986, as amended.

The Company currently matches 25% of the first 6% of the participants' deferral. Contributions to the 401(k) plan vest equally over a three-year period. The Company has expensed, net of forfeitures, approximately \$37,000, \$77,000 and \$59,000 in 2009, 2008 and 2007, respectively.

## **Note 11    Discontinued Operations**

In February 2008, the Company sold certain assets used in the production of Estrasorb, an estrogen product currently licensed by Graceway Pharmaceuticals, LLC ( Graceway ), to Graceway. In connection with the sale, the Company agreed to manufacture and supply additional units of Estrasorb for Graceway, which the Company completed and exited the facility in August 2008. The Company received an upfront payment from Graceway upon the execution of the transaction agreements. As part of the transaction, once the Company satisfied its supply obligations, the Company transferred to Graceway manufacturing equipment related to the production of Estrasorb, valued at \$1.1 million on the closing date, which had been included as assets held for sale in the Company's consolidated balance sheet.

F-20

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 11 Discontinued Operations (continued)**

Due to the operations and cash flows of the Estrasorb business being eliminated from continuing operations of the Company, and the fact that the Company does not have any significant continuing involvement in the business, the operations of the Estrasorb business have been classified as discontinued operations for the years ended December 31, 2008 and 2007. Summarized operating results from the discontinued operations included in the Company's consolidated statements of operations are as follows (in thousands):

	2008	2007
Revenue	\$ 3,776	\$ 1,913
Income (loss) from discontinued operations	\$ 273	\$ (6,175 )

The assets and liabilities of the discontinued operations in the Company's consolidated balance sheet are as follows as of December 31 (in thousands):

	2008
Prepaid expenses and other current assets	\$ 132
Current assets of discontinued operations	\$ 132
Accounts payable	\$ 209
Accrued expenses and other current liabilities	33
Current liabilities of discontinued operations	\$ 242

**Note 12 Income Taxes**

The Company incurred a current tax liability for foreign and state income taxes of approximately \$92,000 and \$0 for the years ended December 31, 2009 and 2008, respectively. There is no deferred provision as the deferred tax asset has been entirely offset by a valuation allowance.

The components of the income tax provision (benefit) are as follows (in thousands):

	2009	2008
Current	\$ 92	\$
Deferred		
Net provision	\$ 92	\$

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

Edgar Filing: NOVAVAX INC - Form 10-K

	2009	2008
Net operating losses	\$ 87,698	\$ 73,585
Research tax credits	3,880	3,278
Other	3,539	4,648
Total deferred tax assets	95,117	81,511
Other	(264 )	(712 )
Total deferred tax liabilities	(264 )	(712 )
Net deferred tax assets	94,853	80,799
Less valuation allowance	(94,853 )	(80,799 )
Deferred tax assets, net	\$	\$

F-21

---

TABLE OF CONTENTS**NOVAVAX, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007****Note 12 Income Taxes (continued)**

The differences between the United States federal statutory tax rate and the Company's effective tax rate are as follows:

	2009	2008	2007
Statutory federal tax rate	(34 )%	(34 )%	(34 )%
State income taxes, net of federal benefit	%	(6 )%	(7 )%
Research and development credit	(1 )%	(1 )%	%
Other	(4 )%	%	1 %
Change in valuation allowance	39 %	41 %	40 %
	%	%	%

Realization of net deferred tax assets is dependent on the Company's ability to generate future taxable income, which is uncertain. Accordingly, a full valuation allowance was recorded against these assets as of December 31, 2009 and 2008 as management believes it is more likely than not that the assets will not be realizable.

As of December 31, 2009, the Company had tax return reported federal net operating losses and tax credits available as follows (in thousands):

	Amount
Federal net operating losses expiring through the year 2029	\$ 237,569
Research tax credits expiring through the year 2029	4,576
Alternative-minimum tax credit (no expiration)	94

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

Beginning in 2006, the windfall equity-based compensation deductions are tracked off balance sheet in conformity with ASC 360. During 2009, 2008 and 2007, the Company recorded \$0.5 million, \$0.2 million and \$0.4 million, respectively, of windfall stock compensation deductions that are being tracked off balance sheet. If and when realized, the tax benefit associated with these deductions will be credited to additional paid-in capital. These excess benefit deductions are included in the total Federal net operating losses disclosed above.





TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007**

**Note 12 Income Taxes (continued)**

Tabular Reconciliation of Unrecognized Tax Benefits (in thousands):

	Amount
Balance as of January 1, 2008	\$ 6,113
Gross increases tax positions in prior period	
Gross decreases tax position in prior period	(193 )
Gross increases current-period tax positions	619
Increases (decreases) from settlements	
Unrecognized tax benefits as of December 31, 2008	\$ 6,539
Gross increases tax positions in prior period	
Gross decreases tax position in prior period	(2,105 )
Gross increases current-period tax positions	425
Increases (decreases) from settlements	
Unrecognized tax benefits as of December 31, 2009	\$ 4,859

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

The Company and its subsidiary file income tax returns in the United States federal jurisdiction and in various states. The Company had tax net operating losses and credits carryforwards that are subject to examination for a number of years beyond the year in which they are generated for tax purposes. Since a portion of these carryforwards may be utilized in the future, many of these attribute carryforwards remain subject to examination.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2009 and December 31, 2008, the Company had no accruals for interest or penalties related to income tax matters.

**Note 13 Commitments and Contingencies**

**Operating Leases**

The Company conducts its operations from a leased facility, under an operating lease with a term expiring in 2017, in Rockville, Maryland. The lease obligates the Company to pay building operating costs. The Company also leased space in Malvern, Pennsylvania, its former corporate headquarters, under an operating lease with a term expiring in 2014. The Company has subleased this facility, under a sublease agreement expiring in 2011 and has granted the subtenant an option to renew the sublease for an additional three year term.



TABLE OF CONTENTS**NOVAVAX, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007****Note 13 Commitments and Contingencies (continued)**

Future minimum rental commitments under non-cancelable leases as of December 31, 2009 are as follows (in thousands):

Year	Operating Leases	Sublease	Net Operating Leases
2010	\$ 2,043	\$ (339 )	\$ 1,704
2011	2,087	(259 )	1,828
2012	2,132		2,132
2013	2,179		2,179
2014	2,151		2,151
Thereafter	4,248		4,248
Total minimum lease payments	\$ 14,840	\$ (598 )	\$ 14,242

Total rent expenses approximated \$1.5 million, \$2.7 million and \$2.4 million for the years ended December 31, 2009, 2008 and 2007, respectively. Rent expense for the year ended December 31, 2008 includes an accrual of \$0.4 million related to the exit of the Taft Court facility.

**Purchase Obligations**

On March 31, 2009, the Company and Cadila entered into a master services agreement (the Master Services Agreement ) pursuant to which the Company may request services from Cadila in the areas of biologics research, pre-clinical development, clinical development, process development, manufacturing scale up and general manufacturing related services in India. If, at the third anniversary of the Master Services Agreement, the amount of services provided by Cadila is less than \$7.5 million, the Company will pay Cadila the portion of the shortfall amount that is less than or equal to \$2.0 million and 50% of the portion of the shortfall amount that exceeds \$2.0 million. When calculating the shortfall, the amount of services provided by Cadila includes amounts that have been paid under all project plans, the amounts that will be paid under ongoing executed project plans and amounts for services that had been offered to Cadila, that Cadila was capable of performing, but exercised its right not to accept such project. The term of the Master Services Agreement is five years, but may be terminated by either party if there is a material breach that is not cured within 30 days of notice or, at any time after three years, provided that 90 days prior notice is given to the other party. As of December 31, 2009, the Company's remaining obligation to Cadila under the Master Services Agreement is \$7.4 million.

## Contingencies

### License Agreement With Wyeth Holdings Corporation

The Company entered into a license agreement in 2007 with Wyeth Holdings Corporation, a subsidiary of Wyeth ( Wyeth ). The license is a non-exclusive, worldwide license to a family of patent applications covering VLP technology for use in human vaccines in certain fields of use. The agreement provides for an upfront payment, annual license fees, milestone payments and royalties on any product sales. If each milestone is achieved for any particular product candidate, the Company would be obligated to pay an aggregate of \$14.0 million to Wyeth for each product candidate developed and commercialized under the agreement. Annual license maintenance fees under the agreement total \$0.3 million per annum. The royalty to be paid by the Company under the agreement, if a product is approved by the FDA for commercialization, will be based on single digit percentage of net sales. Payments under the agreement to Wyeth as of December 31, 2009 aggregated \$5.1 million. The agreement will remain effective as long as at least one claim of the licensed patent rights cover the manufacture, sale or use of any product unless terminated sooner at the Company s option or by Wyeth for an uncured breach by the Company.

F-24

---

TABLE OF CONTENTS

**NOVAVAX, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2009, 2008 and 2007**

**Note 13 Commitments and Contingencies (continued)**

**License Agreement With University of Massachusetts Medical School**

The Company entered into an exclusive license agreement in 2007 with the University of Massachusetts ( UMMS ). The license is an exclusive, worldwide license of VLP technology to develop VLP vaccines for the prevention of any viral diseases in humans. The agreement provides for an upfront payment, annual license fees, milestone payments and royalties on any product sales. Payments under the agreement as of December 31, 2009 were not material. The agreement will remain effective as long as at least one claim of the licensed patent rights cover the manufacture, sale or use of any product unless terminated sooner at the Company's option or by either party for an uncured breach by the other party.

**Supplies Provided by GE Healthcare Bio-Sciences Corp.**

GE Healthcare Bio-Sciences Corp. ( GE ) has supplied the Company consumables free-of-charge that were to be used by Xcellerex in the manufacturing activities related to its 2009 H1N1 vaccine candidate. The Company has arranged to reimburse GE for such consumables if it receives funding for the development or manufacture or receives payment for the commercial sale or supply of the vaccine. At December 31, 2009, the Company has not recorded this contingent liability since neither event has occurred and the likelihood of occurrence is currently not determinable.

**Note 14 Related Party Transactions**

Dr. Rajiv Modi, a director of Novavax, is also a managing director of Cadila Pharmaceuticals Ltd. The Company and Cadila have formed a joint venture called CPL Biologicals Private Limited, of which the Company owns 20%. The Company and Cadila have also entered into a Master Services Agreement, pursuant to which Cadila may perform certain research, development and manufacturing services for the Company up to \$7.5 million. A subsidiary of Cadila owns 12.5 million shares of the Company's outstanding common stock. During the year ended December 31, 2009, the Company incurred \$0.1 million related to the Master Services Agreement.

Mr. John Lambert, the Company's former Executive Chairman of the Board of Directors, had a consulting agreement with the Company, pursuant to which he assisted the Company with issues regarding the development and commercialization of its vaccine product candidates. His annual compensation for these services was \$220,000. The Company also pays Mr. Lambert \$30,000 annually for his service as a board member and also has granted him equity awards. For the years ended December 31, 2009, 2008 and 2007, the Company recorded consulting expenses of \$220,000, \$220,000 and \$180,000, respectively, in accordance with the consulting agreement. On March 8, 2010, Mr. Lambert's consulting agreement expired by its terms.

On February 15, 2010, the Board of Directors elected Mr. Stanley Erck as its new Executive Chairman. Mr. Erck will

be paid a salary of \$300,000 per annum and has been granted equity awards.

Two of the Company's former directors have outstanding notes due to the Company in the aggregate principal amount of \$1,572,000, as reflected on the Company's balance sheet as of December 31, 2009. The notes, in the initial principal amount of \$1,479,268, were initially delivered by the former directors to the Company in March 2002 as payment of the exercise price of options. In May 2008, one of the Notes was amended and restated to, among other things, include accrued interest in the principal amount, bringing the aggregate principal amount outstanding to \$1,610,516. As of December 31, 2009, the Company received payments of \$65,000. As security, the former directors pledged shares of the Company's common stock as collateral. The Company has the right to sell the pledged shares. As of December 31, 2009, the outstanding principal and interest for these two notes was \$2.0 million. The Company has not accrued interest due to collection concerns. Both notes are currently in default and the Company is pursuing the collection of these promissory notes.

F-25

---

TABLE OF CONTENTS**NOVAVAX, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 2009, 2008 and 2007****Note 15 Quarterly Financial Information (Unaudited)**

The Company's unaudited quarterly information for the years ended December 31, 2009 and 2008 is as follows:

	Quarter Ended			
	March 31	June 30	September 30	December 31
(In Thousands, Except per Share Data)				
2009:				
Revenue	\$ 21	\$ 29	\$ 201	\$ 75
Net loss	\$(8,349 )	\$(8,540 )	\$(7,530 )	\$(13,955 )
Net loss per share	\$(0.12 )	\$(0.10 )	\$(0.08 )	\$(0.15 )
2008:				
Revenue	\$ 458	\$ 342	\$ 194	\$ 70
Loss from continuing operations	(7,103 )	(8,314 )	(10,330 )	(10,575 )
(Loss) income from discontinued operations	(652 )	(1,058 )	2,488	(505 )
Net loss	\$(7,755 )	\$(9,372 )	\$(7,842 )	\$(11,080 )
Basic and diluted net loss per share:				
Loss from continuing operations	\$(0.12 )	\$(0.14 )	\$(0.16 )	\$(0.11 )
(Loss) income from discontinued operations	(0.01 )	(0.01 )	0.04	(0.04 )
Net loss per share	\$(0.13 )	\$(0.15 )	\$(0.12 )	\$(0.15 )

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



TABLE OF CONTENTS

**NOVAVAX, INC.**

**SCHEDULE II VALUATION AND QUALIFYING  
ACCOUNTS**

**December 31, 2009, 2008 and 2007  
(in thousands)**

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Allowance for Doubtful Accounts:				
2009	\$ 218	\$	\$ (218 )	\$
2008	168	54	(4 )	218
2007	117	218	(167 )	168
Sales Return and Rebate Allowance:				
2009	\$ 118	\$ 68	\$ (146 )	\$ 40
2008	371	53	(306 )	118
2007	252	250	(131 )	371

---