NOVAVAX INC
Form 424B5
September 15, 2009

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-138893

Prospectus Supplement
(To Prospectus dated December 11, 2006)

Novavax, Inc.
3,400,000 SHARES
COMMON STOCK

You should carefully read this prospectus supplement and the accompanying prospectus before you invest. Both documents contain information you should consider before making your investment decision.

This prospectus supplement relates to the issuance and sale of up to 3,400,000 shares of our common stock through our sales agent, Wm Smith & Co. These sales, if any, will be made pursuant to the terms of an At Market Issuance Sales Agreement entered into between us and our sales agent, the form of which was filed with the Securities and Exchange Commission under a Current Report on Form 8-K dated September 15, 2009 and is incorporated herein by reference. Our sales agreement with Wm Smith is limited to the sale of common stock with gross proceeds aggregating $10,000,000.

Our common stock is quoted on the NASDAQ Global Market under the symbol NVAX. On September 10, 2009, the closing price of our common stock as reported on NASDAQ was $5.98 per share. Sales of shares of our common stock under this prospectus supplement, if any, may be made in privately negotiated transactions and/or any other method permitted by law, including sales deemed to be an at the market offering as defined in Rule 415 under the Securities Act of 1933, as amended, which includes sales made directly on NASDAQ Global Markets, the existing trading market for our common stock, or sales made to or through a market maker other than on an exchange. The sales agent will make all sales using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreeable terms between the sales agent and us.

Unless we and our sales agent otherwise agree, the commission to the sales agent for sales of common stock sold pursuant to the sales agreement will be 2% of the gross proceeds of the sales price per share. If different than 2%, the amount of any compensation to be received by the sales agent will be disclosed in a separate prospectus supplement for such shares. The net proceeds to us that we receive from sales of our common stock will depend on the number of shares actually sold and the offering price for such shares. Based on the closing price of our common stock on September 10, 2009, because our sales agreement with Wm Smith is limited to the sale of common stock with gross proceeds aggregating $10,000,000, the maximum number of shares we could sell is 1,672,241. If all 3,400,000 shares of common stock were sold at the September 10, 2009 closing sales price, we would receive $20,332,000 in gross proceeds, or $19,925,360 in aggregate net proceeds assuming a sales agent fee of 2%. The actual proceeds to us will vary.

In connection with the sale of common stock on our behalf, the sales agent may be deemed an underwriter within the meaning of the Securities Act of 1933, as amended, and the compensation of the sales agent may be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to the sales agent against certain liabilities, including liabilities under the Securities Act of 1933.

Investing in our common stock involves a high degree of risk. Risks associated with an investment in our common stock are described in the section titled Risk Factors beginning on page S-5 of this prospectus supplement, which supercede in their entirety the risk factors beginning on page 4 of the accompanying prospectus. You should carefully consider these risk factors before making an investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Wm Smith & Co.

The date of the Prospectus Supplement is September 15, 2009.

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Prospectus Supplement

Prospectus

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information contained in this prospectus supplement and the accompanying prospectus, as well as the information that we have filed with the Securities and Exchange Commission, or the SEC, and incorporated by reference herein and therein, is accurate only as of the date of the applicable document. This prospectus supplement and the accompanying prospectus do not constitute an offer or solicitation by anyone in any jurisdiction in which an offer or solicitation is not authorized or in which the person making an offer or solicitation is not qualified to do so, or to anyone to whom it is unlawful to make an offer or solicitation.

This prospectus supplement contains the terms of this offering. This prospectus supplement, along with the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, may add, update or change information in the accompanying prospectus. If information in this prospectus supplement, or the documents incorporated by reference in this prospectus supplement,

and the accompanying prospectus, is inconsistent with the accompanying prospectus, this prospectus supplement, or the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, will apply and will supersede the information in the accompanying prospectus.

The information contained in this prospectus supplement and the accompanying prospectus is correct only as of the date on the cover, regardless of the date this prospectus supplement was delivered to you or the date on which you acquired any of the shares.

SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents we have filed with the Securities and Exchange Commission, or SEC, that are incorporated herein by reference and that are referenced under the section entitled Where You Can Find More Information , contain 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 regarding future product development and related clinical trials and future research and development, including Food and Drug Administration approval and product sales. Such forward-looking statements 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. Such factors 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 preclinical studies and clinical trials and other research and development activities; clinical trial results; even if the data from preclinical 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 US; the rate and progress of manufacturing scale-up; Novavax s pilot plant facility is subject to extensive validation and FDA inspections, which may result in delays and increased costs; the success of the Company s joint ventures and licensing agreements; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; our ability to obtain rights to technology; competition for clinical resources and patient enrollment from drug candidates in development by other companies with greater resources and visibility; our ability to enter into future collaborations with industry partners and the terms, timing and success of any such collaboration; the cost, timing and success of regulatory filings and approvals; our ability to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity or debt financing or otherwise; general business conditions; competition; business abilities and judgment of personnel; availability of qualified personnel; and other factors referenced herein.

You should also consider carefully the statements set forth in the section entitled Risk Factors and other sections of this prospectus supplement, in the accompanying prospectus, and in the other documents we have filed with the SEC and that are incorporated herein by reference, which address these and additional factors that could cause results or events to differ from those set forth in the forward-looking statements. All subsequent written and oral forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements. We have no plans to update these forward-looking statements.

PROSPECTUS SUPPLEMENT SUMMARY

This summary only highlights the more detailed information appearing elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein. It may not contain all of the information that may be important to you. To fully understand the investment you are contemplating, you should read carefully this entire prospectus supplement, the accompanying prospectus and the detailed information incorporated into each of them by reference before you decide to make an investment. You should pay special attention to the Risk Factors section of this prospectus supplement beginning on page S-5 to determine whether an investment in our common stock is appropriate for you. Unless the context otherwise requires, the terms Novavax, we, us, the company and our refer to Novavax , Inc., a Delaware corporation, together with its subsidiary.

NOVAVAX, INC.

Novavax, Inc. is a clinical-stage biopharmaceutical company focused on creating differentiated, value-added vaccines that improve upon current preventive options for a range of infectious diseases. These vaccines leverage 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. Novavax s proprietary production technology uses insect cells rather than chicken eggs or mammalian cells. The Company s current product targets include vaccines against the H5N1 and other subtypes of avian influenza with pandemic potential, human seasonal influenza, influenza A (H1N1) virus, Varicella Zoster, which causes shingles, and Respiratory Syncytial Virus (RSV).

Novavax has made significant progress in the development of its vaccine that targets the H5N1 avian influenza with pandemic potential. In June 2007, the Company released results from an important preclinical study in which ferrets that received Novavax s pandemic vaccine were protected from a lethal challenge of the H5N1 virus. After filing an Investigational New Drug application (IND), Novavax initiated its Phase I/IIa human clinical trial in July 2007. Novavax released interim human data from the first portion of this clinical trial in December 2007. These interim results demonstrated that Novavax s pandemic influenza vaccine can generate a protective immune response. The Company conducted the second portion of the Phase I/IIa trial in March 2008 to gather additional subject immunogenicity and safety data and determine a final dose through the completion of this clinical trial. In August 2008, we reported favorable results from this clinical trial, which demonstrated strong neutralizing antibody titers across all three doses tested. A final Clinical Study Report has been completed. The vaccine was well tolerated at all dosages as compared with placebo. No serious adverse events were reported. In February 2009, Novavax announced that the vaccine induced robust hemagglutination inhibition (HAI) responses, which have been shown to be important for protection against influenza disease.

Novavax also progressed development of its VLP trivalent vaccine that targets seasonal influenza virus. In December 2007, Novavax announced results from a preclinical study in mice. In April 2008, we announced that we received positive results from an immunogenicity study in ferrets inoculated with our trivalent seasonal influenza vaccine candidate. In September 2008, we began Phase II

clinical trials to evaluate the safety and immunogenicity of different doses of our seasonal influenza vaccine. In December 2008, we announced favorable safety and immunogenicity results from our Phase IIa seasonal study in healthy adults. We had observed a slightly different safety profile (non-serious adverse events) from our Phase IIa trial of our pandemic VLP vaccine, and thus renewed and analyzed the dose response curve as well as the safety data from the healthy adult seasonal trial. A final Clinical Study Report has been completed. No vaccine-related serious adverse events were reported. In May 2009, the Company enrolled subjects in the second Phase II study of its trivalent seasonal influenza VLP vaccine candidate. In September 2009, the Company announced favorable results from a Phase II human clinical trial of its trivalent seasonal influenza VLP vaccine candidate that supports a planned study in elderly patients in Q4 2009. The Company intends to initiate further clinical trials for its pandemic influenza vaccine, which would be required for regulatory approval, with collaborative partners. The Company entered into a letter of intent with ROVI Pharmaceuticals which, among other things, will support Phase III clinical development, however, a definitive agreement is yet to be finalized.

The Company has also developed vaccine candidates for both RSV and VZV, both of which are currently being evaluated in preclinical studies. To date, preliminary data have shown that an RSV vaccine candidate has shown positive results in two separate studies with mice. In December 2008, Novavax and the University of Massachusetts jointly announced favorable results from a preclinical study to evaluate the immunogenicity and efficacy of an RSV vaccine candidate in mice. The RSV VLP vaccine induced strong antibody responses against RSV. The Company has licensed exclusive worldwide rights from the University of Massachusetts Medical School to certain technology for the development and commercialization of vaccines. In February 2009, Novavax announced favorable results from an RSV preclinical study performed in mice against the viral fusion (F) protein, which fuses with cells in the respiratory tract and causes illness. The vaccine induced neutralizing antibodies against the viral fusion protein and also protected against RSV infection, reducing the quantity of RSV virus found in the lungs of immunized mice after a challenge with live virus. A VZV vaccine candidate has also induced antibody and T-cell responses. The Company is moving forward with further preclinical development of both vaccines in 2009. In July 2009, the Company announced final selection of a RSV vaccine candidate that will be advanced into additional preclinical studies to support an Investigational New Drug application and can be produced at sufficient yields to allow commercial manufacture.

The Company has recently announced that it produced a first batch of the influenza A (H1N1) VLP vaccine candidate three weeks after the Centers for Disease Control and Prevention (CDC) announced the genetic sequence of the novel H1N1 virus (the H1N1 virus is commonly referred to as the swine flu in the media). Novavax has further announced that the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases, National Institutes of Health have signed an agreement to cooperate in the evaluation of the VLP vaccine candidate. The purified H1N1 VLP vaccine candidate has been sent to scientists at the CDC and there are discussions with DMID for further studies. In August 2009, the Company announced that it had manufactured a VLP vaccine candidate against the H1N1 virus under current good-manufacturing practices at its new vaccine manufacturing facility in Rockville, MD.

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

cell culture manufacturing are encouraging compared to currently used egg-based vaccines as well as developing mammalian cell growth approaches.

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

	Discovery	Preclinical	Phase I/IIa	Phase IIb/III
Pandemic Influenza (avian)	√	√	√	
Seasonal Influenza	√	√	√	
Varicella Zoster (Shingles)	√	√		
Respiratory Syncytial Virus (RSV)	√	√		
Influenza A (H1N1) (swine)	√	√		

CORPORATE 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 prospectus supplement or accompanying prospectus.

THE OFFERING

Issuer	Novavax, Inc.
Common Stock offered by us pursuant to this prospectus supplement	Up to 3,400,000 shares
Common Stock to be outstanding after this offering if all shares are sold	Up to 96,742,178[1] shares
Maximum Gross Proceeds	$10,000,000
Manner of Offering	Sales of shares of our common stock under this prospectus supplement, if any, may be made in privately negotiated transactions and/or any other method permitted by law, including sales deemed to be an at the market offering as defined in Rule 415 under the Securities Act of 1933, as amended, which includes sales made directly on NASDAQ Global Markets, the existing trading market for our common stock, or sales made to or through a market maker other than on an exchange. The sales agent will make all sales using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreeable terms between the sales agent and us. See Plan of Distribution.
Sales agent	Wm Smith & Co.
NASDAQ Symbol	NVAX
Use of Proceeds	The net proceeds of this offering will be added to our general funds and used for pre-clinical studies and clinical trials of our VLP-based vaccines, internal research and development programs, working capital, capital expenditures and other general corporate purposes as further described in this prospectus supplement under the heading Use of Proceeds.

1. The number of shares of common stock to be outstanding after this offering is based on 93,342,178 shares outstanding as of September 10, 2009.

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. Additional risks and uncertainties that are not yet identified or that we currently deem immaterial may materially harm our business, operating results and financial condition and could result in a complete loss of your investment. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected.

RISKS RELATED TO OUR BUSINESS

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

Our expenses have exceeded our revenues since our formation in 1987, and our accumulated deficit at June 30, 2009 was $253 million. Our net revenues for the last three fiscal years from continuing operations were $1.1 million in 2008, $1.5 million in 2007 and $1.7 million in 2006. We have received a limited amount of related 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 revenues to offset our expenses. Our net losses for the last three fiscal years were $36.0 million in 2008, $34.8 million in 2007 and $23.1 million in 2006, including discontinued operations.

Our historical losses have resulted from research and development expenses for our vaccine and drug delivery product candidates, sales and marketing expenses, and manufacturing expenses for Estrasorb, protection of our intellectual property and other general operating expenses. Our losses increased due to the launch of Estrasorb since 2004 as we expanded our manufacturing capacity and sales and marketing capabilities. More recently, our losses have increased, and 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:

complete Phase II clinical trials for our seasonal flu vaccine;

complete our human Phase I/IIa clinical trial for our pandemic flu vaccines;

conduct additional preclinical studies for Varicella Zoster and RSV product candidates using our VLP vaccine technology platform;

obtain validation from the Food and Drug Administration, as a product manufacturing facility and comply with the FDA s manufacturing facility requirements;

scale up of 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.

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

We do not expect to generate revenues 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 preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our products. We will seek such additional funds through public or private equity or debt financings, collaborative licensing and development arrangements and other sources. 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, further 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. This offering and 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 the company s access to capital, cost of capital, and ability to execute its 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 over the past year 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 deteriorated significantly and have adversely affected our access to capital and increased the cost of capital, and there is no certainty that a recovery in the capital and credit markets, enabling us to raise capital, will occur in the 2009 fiscal year or anytime in the foreseeable future. If these economic conditions continue or become worse, the Company s future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, an inability by the Company to access the capital markets on favorable terms due to our low stock price, or upon our 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 current volatile and unpredictable 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 are limited in our ability to raise additional capital and any additional sale of common stock could be significantly dilutive to existing stockholders.

We will need to engage in additional capital raising activities in the near term, even if we sell all shares offered herein. Current economic and market conditions significantly restrict our ability to raise capital through common stock sales and additional indebtedness. Due to these and other conditions, we may not be able to sell shares of our common stock at a price favorable to us or we may need to sell a large block of stock to raise sufficient capital or be able to sell any stock at all. The sale of common stock would cause an immediate equity dilution for existing stockholders which could be substantial. This may depress the market price of our common stock and further impair our ability to raise additional capital by selling our common stock.

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

As of June 30, 2009, we had $8.1 million invested in auction rate securities, which were classified as short-term investments available for sale and carried at their estimated fair value of $6.0 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. Due to recent uncertainties in the credit markets, we may be unable to liquidate some or all of our 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.

Novavax s collaborations with Cadila Pharmaceuticals and ROVI Pharmaceuticals expose the Company to additional risks associated with doing business outside the United States, and any adverse event could have a material negative impact on operations.

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 Limited, a joint venture (the JV), of which 80% is owned by Cadila and 20% is owned by us. The JV will develop and commercialize our seasonal influenza VLP based vaccine candidate and Cadila s therapeutic vaccine candidates against cancer as well as its adjuvants, 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.

On June 30, 2009, we announced our initial agreement to license our VLP vaccine technology to ROVI Pharmaceuticals of Spain (ROVI). ROVI will use the VLP technology to create a comprehensive influenza vaccine solution for the Spanish government under a new 60 million-euro program sponsored and led by the Spanish Ministry of Health and other government groups to develop pandemic and seasonal flu vaccines and establish its only in-border facility.

The Company may enter into other agreements with companies or governments in other countries around 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 U.S. 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;

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.

We have repositioned ourselves from a specialty pharmaceutical company and face all the risks inherent in the implementation of a new business strategy.

In 2005, we changed the focus of the Company from the development and commercialization of specialty pharmaceutical products to the research and development of new products using our proprietary virus-like particle vaccine technology platform. We cannot predict whether we will be successful in implementing our new business strategy.

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 biotechnology 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 market and sell, a product candidate. Product candidates that initially appear promising often fail to yield successful products. In many cases, preclinical 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 preclinical or early clinical trials may not translate into success in large-scale clinical trials. Further, success in clinical trials will likely lead to increased investment, accelerating cumulative losses, to bring such products to market. Even 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.

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;

preclinical testing;

designing and implementing clinical trials;

regulatory processes and approvals;

production and manufacturing; and

sales and marketing of approved products.

Principal competitive factors in our industry include:

the quality and breadth of an organization s technology;

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

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

an organization s intellectual property portfolio;

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

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

Large and established companies such as Merck & Co., Inc., GlaxoSmithKline PLC, Novartis, Inc., Sanofi Pasteur, 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 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 flu vaccines currently approved and marketed. Competition in the sale of these seasonal flu 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 flu 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 flu 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 noncompetitive 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. We may not be able to attract qualified individuals for key management or other personnel positions on terms acceptable to us. We have not purchased key-man life insurance on any of our executive officers or key personnel, and therefore may not have adequate funds to find acceptable replacements for them. 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.

We have experienced significant management turnover.

Our current President and Chief Executive Officer, Rahul Singhvi, assumed this responsibility in August 2005. Most of our executive officers have joined us since that time, including our current Chief Financial Officer, Vice President and Treasurer, Frederick W. Discoll, who was appointed by the Board of Directors in August 2009. This lack of management continuity, and the resulting lack of long-term history with our Company, could result in operational and administrative inefficiencies and added costs. If we were to experience additional turnover at the executive level, these risks would be exacerbated.

We may 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 $10 million for claims arising from the use of our currently marketed products and 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 revenues; and

the inability to commercialize our product candidates.

There are outstanding loans owed by certain of our former directors, which if not repaid, would result in a loss to the Company.

We have two outstanding notes to former directors which are secured by shares of our common stock. The notes were initially due upon the earlier of (a) the date the individual ceased to be a director of Novavax, (b) in whole or in part, to the extent of net proceeds on the date on which the director sold all or a portion of the pledged shares, or (c) March 21, 2007.

In May 2006, one of these directors resigned from the Company s Board of Directors. Following his resignation, we approved an extension of the former director s $448,000 note to December 31, 2007 or earlier to the extent of the net proceeds of the pledged shares. In connection with this extension, the former director executed a general release of all claims against the Company. On May 7, 2008, the Company and the former director entered into an Amended and Restated Promissory Note and an Amended and Restated Pledge Agreement (the Amendment). The Amendment restates the entire amount outstanding as of December 31, 2007, including accrued interest, or $578,848, as the new outstanding principal amount. Furthermore, the Amendment further extended the maturity date of the note to June 30, 2009, permitted the Company to sell the pledged shares if the market price of the common stock exceeds certain targets, increased the interest rate to 8.0% and stipulated quarterly payments beginning on June 30, 2008. The Company received a first payment of $50,000 in July 2008 and a second payment of $5,000 in October 2008, with a balance due by December 31, 2008 of $45,000. In January 2009, the Company received an additional payment of $10,000. The note is currently in default.

In March 2007, the second director resigned from the Board of Directors before the maturity date. In an agreement dated May 7, 2007, the Board agreed to extend the note that was due March 21, 2007 to June 30, 2009 and secured additional collateral in the form of a lien on certain outstanding stock options. Also under the May 7, 2007 agreement, we have the right to exercise the stock options, sell the acquired shares and the other shares held as collateral and use the proceeds to pay the debt, if the share price exceeds a certain target at any time during the period between May 7, 2007 and June 30, 2009. The note continues to accrue interest at 5.07% per annum and continues to be secured by 166,666 shares of common stock owned by the former director. The note is currently in default.

We are uncertain about the collectability of these notes. We do not know if the price of our common stock will reach the target prices allowing us to realize on the pledged collateral. Even if we are able to sell some or all of the pledged shares, we may not recover the full amount outstanding under either

note. We continue to actively work with these two individuals to collect the amounts outstanding and reserve our rights to legal remedies available to us. There are no assurances that the former directors will be able to repay the notes when due under the terms of the current agreements.

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. Such grants 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. Therefore, we may not be able to win grants.

Current economic conditions and capital markets are in a period of disruption and instability which could adversely affect our ability to raise capital and may adversely affect our business and liquidity.

The current economic conditions and related capital markets may have a negative impact on our ability to access the capital markets, and thus have a negative impact on our business and liquidity. The shortage of liquidity and credit combined with recent substantial losses in worldwide equity markets has led to an extended worldwide recession. We may face significant challenges in selling shares of common stock or in obtaining debt financing if conditions in the capital markets do not improve.

If we are not able to enter into a collaborative licensing and development arrangement with a third party or win a government grant, we will need to raise money through additional debt or equity offerings, even if we sell all of the shares offered herein. Our ability to access the capital markets may be severely restricted at a time when we are accessing such markets, which would have a negative impact on our business plans, including our pre-clinical studies and clinical trial schedules and other research and development activities. Even if we are able to raise additional capital, it may not be at a price or on terms that are favorable to us and it may cause a substantial dilution to our existing stockholders. We cannot predict the occurrence of future disruptions or how long the current conditions may continue.

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 even if we sell all shares offered herein. 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 are not 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.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents or short-term investments and our ability to meet our financing objectives.

Our short-term investments consist primarily of auction rate securities and are classified as available for sale. While as of the date of this filing, we have recorded a reduction in the value of these securities due to their illiquidity of approximately $2.1 million, we cannot assure you that further deterioration in conditions of the global credit and financial markets will not occur. Such a deterioration could negatively impact our current portfolio of cash equivalents or short-term investments or our ability to meet our financing objectives. As described above under *A portion of our investments are auction rate securities which present potential liquidity concerns.* , we hold some auction rate securities that could have additional liquidity concerns.

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;

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

we will fail to have our Good Manufacturing Practices pilot plant validated or that the plant will fail to continue to pass regulatory inspections;

proprietary rights of third parties will prevent us or our collaborators from exploiting technologies 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 preclinical 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. We also have product candidates in human clinical trials and preclinical 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 preclinical (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;

submission to the FDA of a BLA or a New Drug Application (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 such 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 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 drugs may not be approved, which could limit our revenues. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our product candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our drug candidates are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

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 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; 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 candidate 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 revenues; 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 current Good Manufacturing Practices. 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.

Because we depend on third parties to conduct some of our laboratory testing and human studies, 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 and human studies. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we request. We may not be able to secure and maintain suitable research organizations to conduct our laboratory testing and human studies. 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. 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 due to the failure to adhere to our clinical 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 for our product candidates.

Our relationship with GE Healthcare may not be profitable.

We have entered into a co-marketing agreement with GE Healthcare to co-market a pandemic influenza vaccine solution to select international countries. The collaboration incorporates GE Healthcare s bioprocess solutions and design expertise with Novavax s VLP manufacturing platform. We cannot predict when, if at all, we will be able to successfully negotiate a definitive agreement with a target country. Even if we do enter into a definitive agreement, it may not result in significant revenues.

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 the Company will continue to receive the same level of funding from the United States government, if at all.

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

Completion of our clinical trials and commercialization of our vaccine product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. 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, 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, then we will need to rely on third parties to manufacture compounds for clinical and commercial purposes. These 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. In addition, 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 would have to enter into a technical transfer agreement and share our know-how with the third party manufacturer.

We rely on a limited number of suppliers for some of our manufacturing materials. Any problems experienced by any of these suppliers could negatively affect our operations.

We rely on third-party suppliers and vendors for some of the materials used in the manufacture of our product candidates. For supply of early clinical trial materials, we rely on a limited number of suppliers. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. We have limited experience with alternative sources of raw materials. Any delay or interruption could negatively affect our operations.

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 revenues will depend upon the

efforts of third parties, over which we may have little or no control. If we are unable to reach and maintain agreements with one or more pharmaceutical companies or collaborators, we may be required to market our products directly. Developing a marketing and sale 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 therapeutic and cost-effective alternative to competing products and treatments. 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;

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.

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 successes may depend, in part, on the extent to which reimbursement for the costs of therapeutic products and related treatments 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.

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 preclinical 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 preclinical 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 preclinical and clinical activities, which are susceptible to varying interpretations and which interpretations could delay, limit or prevent further studies or regulatory approval;
- the availability of skilled and experienced staff to conduct and monitor clinical 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 preclinical studies and clinical trials necessary to obtain regulatory marketing approvals. We may not be permitted to continue or commence additional clinical trials. We also face the risk that the results of our clinical trials may be inconsistent with the results obtained in preclinical studies or clinical trials of similar products, or that the results obtained in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the 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 revenues and harm our financial condition and results of operations.

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 revenues 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 drug by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself, and only if the specific event occurs with some regularity over a period of time does the drug 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 revenues and our financial condition.

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 order to market our products in the European Union, Asia and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. To date, we have not filed for marketing approval for any of our products candidates and may not receive the approvals necessary to commercialize our product candidates in any market. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other foreign countries or by the FDA. 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.

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 Recovery Act. We cannot eliminate the risk of accidental contaminat