

GeoVax Labs, Inc.  
Form 424B1  
May 03, 2016

**Filed pursuant to Rule 424(b)(1)**

**Registration No. 333-208549**

## **PROSPECTUS**

### **GEOVAX LABS, INC.**

Up to 80,456,798 Shares of Common Stock

This prospectus relates to up to 80,456,798 shares of common stock, \$0.001 par value, of GeoVax Labs, Inc., or the “Company,” that may be sold from time to time by the selling stockholders named in this prospectus, which includes up to:

2,327,393 shares of common stock held by the selling stockholders acquired by them upon exercise of Series E Common Stock Purchase Warrants; and

up to 30,460,662 shares of common stock issuable upon conversion of our Series C Convertible Preferred Stock, par value \$0.01 per share, which we refer to as “Series C Preferred Stock; and

up to 47,668,743 shares of common stock issuable to the selling stockholders upon the exercise of Series D, E, and F Warrants and one other warrant (the “Maxim Warrant”), which we refer to collectively as the “2015 Warrants”.

The prices at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. The shares included in this prospectus may be reoffered and sold directly by the selling stockholders in accordance with one or more of the methods described in the plan of distribution, which begins on page 54 of this prospectus.

We will not receive any proceeds from the sales of outstanding shares of common stock by the selling stockholders, but we will receive funds from the exercise of the 2015 Warrants held by the selling stockholders, to the extent they

are exercised for cash.

Our common stock is registered under Section 12(g) of the Securities Exchange Act of 1934 and quoted on the over-the-counter market under the symbol "GOVX." On March 9, 2016, the last reported sale price for our common stock as reported on the over-the-counter market was \$0.07 per share.

This prospectus may only be used where it is legal to offer and sell the shares covered by this prospectus. We have not taken any action to register or obtain permission for this offering or the distribution of this prospectus in any country other than the United States.

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**Investing in the common stock involves a high degree of risk. See "Risk Factors" beginning on page 3 for a discussion of these risks.**

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**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.**

The date of this Prospectus is April 7, 2016

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You should rely only on the information contained in this prospectus and any free-writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with additional or different information. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities. Unless the context otherwise requires, references to “we,” “our,” “us,” or the “Company” mean GeoVax Labs, Inc.

We obtained industry and market data used throughout this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

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## PROSPECTUS SUMMARY

The following is only a summary. We urge you to read the entire prospectus, including the more detailed consolidated financial statements, notes to the consolidated financial statements and other information included. Investing in our securities involves risks. Therefore, please carefully consider the information provided under the heading “Risk Factors” starting on page 3. You should not invest unless you can afford to lose your entire investment.

## COMPANY OVERVIEW

GeoVax Labs, Inc. (“GeoVax” or the “Company”) is a clinical-stage biotechnology company developing human vaccines against infectious diseases using our MVA-VLP vaccine platform. Our platform supports in vivo expression of non-infectious virus-like particles (VLPs) from the cells of the person receiving the vaccine. VLPs work by displaying the virus’ surface glycoproteins which in turn train the person’s immune system to recognize and destroy the actual virus and virus-infected cells to block infection. The production of VLPs in the person being vaccinated mimics a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent and control the target infection should it appear.

Our current development programs are focused on vaccines against Human Immunodeficiency Virus (HIV), Zika virus, and hemorrhagic fever viruses (Ebola, Marburg, Lassa Fever), as well as for use in cancer immunotherapy. We believe our technology and vaccine development expertise are well-suited for a variety of human infectious diseases and we intend to pursue expansion of our product pipeline.

Our most advanced HIV vaccine program is focused on the clade B subtype of HIV prevalent in the Americas and Western Europe. Our preventive clade B HIV vaccine has successfully completed Phase 2a human clinical testing and we expect to enter a follow-on clinical trial in mid-2016 with support from the National Institutes of Health (NIH). We are considered the leading vaccine candidate for protection against the clade B subtype; accordingly, planning has begun for a phase 2b efficacy trial. Our vaccine has shown outstanding safety and excellent and highly reproducible immunogenicity (Journal of Infectious Diseases volume 203, pg 610 and volume 210 pg 99). We have also extended our HIV vaccine effort to the most common virus subtype affecting sub-Saharan Africa (clade C) and are conducting preclinical studies pursuant to a grant from the NIH. Our HIV vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the Centers for Disease Control and Prevention (CDC). The technology developed by the collaboration is exclusively licensed to us from Emory University. We also have nonexclusive licenses to certain patents owned by the NIH.

Our hemorrhagic fever vaccine program was initiated during 2014 with the objective of developing a tetravalent vaccine designed to protect against all major hemorrhagic fever viruses (Ebola, Marburg, Lassa) endemic in African countries. Studies of our first Ebola vaccine candidate have demonstrated 100 percent protection in rodent models. We plan to conduct additional challenge studies in non-human primates in collaboration with the NIH during 2016, with the goal of beginning human clinical trials during 2017. In February 2016 we entered into a Cooperative Research and Development Agreement for material transfer with the United States Army Research Institute of Infectious Disease (USAMRIID). This agreement provides us with access to Ebola, Marburg and Lassa fever monoclonal antibodies for in vitro vaccine characterization, with USAMRIID performing in vitro and in vivo assessment of our vaccine candidates.

In December 2015, we entered into a Collaborative Research Agreement with the University of Pittsburgh to evaluate our MVA-VLP vaccine platform for use in cancer immunotherapy, including the selection and testing of vaccine candidates. We are currently constructing our vaccine candidates and intend to conduct proof-of-concept animal studies during 2016. Cancer immunotherapy (or immuno-oncology), is a technique whereby the patient's immune system is trained to fight solid tumors and is considered to be a very promising area of biotechnology.

In February 2016, we began a program to develop a vaccine for the prevention of Zika virus infections using our MVA-VLP vaccine platform, and we entered into a Collaborative Research Agreement with the University of Georgia (UGA) to speed development of the vaccine. Pursuant to this collaboration, we will develop vaccine antigens that elicit broadly reactive immunity against Zika viruses and UGA will test those vaccines in preclinical models. We are also collaborating with the CDC for reagents and testing of vaccines. We intend to conduct the initial proof-of-concept animal studies during the first half of 2016.

Our HIV vaccine development activities have been, and continue to be, financially supported by the U.S. government. This support has been both in the form of research grants awarded directly to us, as well as indirect support for the conduct of our human clinical trials. Government support is also being sought for our newer vaccine targets. This is discussed further under "Support from the United States Government" below.

We are incorporated under the laws of the State of Delaware. Our principal corporate offices are located at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia 30080 (metropolitan Atlanta). Our telephone number is (678) 384-7220. The address of our web site is [www.geovax.com](http://www.geovax.com). Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the “Investors” section of our web site as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. Information contained on our web site does not form a part of this prospectus.

### The Offering

Common stock offered by selling stockholders Up to 80,456,798 shares including 2,327,393 shares of common stock held by the selling stockholders, 30,460,662 shares of common stock issuable upon conversion of our Series C Preferred Stock owned by selling stockholders and approximately 47,668,743 shares of common stock issuable upon the exercise of 2015 Warrants held by the selling stockholders. This number represents approximately 69.9% of our current outstanding common stock, on a fully diluted basis.. (1)

Common stock outstanding before the offering. 37,015,401 shares (1)

Common stock outstanding after the offering, assuming all the Series A and C Warrants are exercised for cash. 115,144,806 shares (1)

Proceeds to us We will not receive any proceeds from the sale of common stock covered by this prospectus. We will, however, receive approximately \$4,698,000 from the exercise of the 2015 Warrants held by the selling stockholders, if they are exercised in full for cash.

Trading Symbol GOVX

Risk Factors There are significant risks involved in investing in our Company. For a discussion of risk factors you should consider before buying our common stock. See “Risk Factors” beginning on page 3.

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(1) The number of shares of our common stock that will be outstanding immediately after this offering is based on 37,015,401 shares outstanding as of March 4, 2016, and includes 30,460,662 shares of common stock issuable upon conversion of the Series C Preferred Stock and 47,668,743 shares of common stock issuable upon exercise of the 2015 Warrants, but excludes the following:

1,722,529 shares of common stock reserved for future issuance under our equity incentive plans. As of March 4, 2016, there were options to purchase 1,705,500 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$2.41 per share. We plan to seek stockholder approval in 2016 for a new equity incentive plan covering the issuance of up to 3,000,000 shares.

5,108,826 shares of common stock issuable upon exercise of currently outstanding warrants (but not including the 2015 Warrants) as of March 4, 2016, with a weighted average exercise price of \$0.51 per share.

285,714 shares of common stock issuable upon conversion of outstanding Series B Preferred Stock.



## **RISK FACTORS**

*Investing in our securities involves a high degree of risk. You should carefully review and consider the risks, uncertainties and other factors described below before you decide whether to purchase our securities. Any of these factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock, and you may lose some or all of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, may also impair our business operations. You should also refer to the information contained in this prospectus, including our financial statements and the related notes.*

### **Risks Related to Our Business**

*We have a history of operating losses, and we expect losses to continue for the foreseeable future.*

We have had no product revenue to date and there can be no assurance that we will ever generate any product revenue. We have experienced operating losses since we began operations in 2001. As of December 31, 2015, we had an accumulated deficit of approximately \$32.5 million. We expect to incur additional operating losses and expect cumulative losses to increase as our research and development, pre-clinical, clinical, manufacturing and marketing efforts expand. Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of our product candidates, conduct pre-clinical tests and clinical trials, obtain the necessary regulatory approvals, and manufacture and market the resulting products. Unless we are able to successfully meet these challenges, we will not be profitable and may not remain in business.

*Our business will require continued funding. If we do not receive adequate funding, we will not be able to continue our operations.*

To date, we have financed our operations principally through the private placement of our equity securities and through NIH grants. We will require substantial additional financing at various intervals for our operations, including clinical trials, operating expenses, intellectual property protection and enforcement, for pursuit of regulatory approvals, and for establishing or contracting out manufacturing, marketing and sales functions. There is no assurance that such additional funding will be available on terms acceptable to us or at all. If we are not able to secure the significant funding that is required to maintain and continue our operations at current levels, or at levels that may be required in the future, we may be required to delay clinical studies or clinical trials, curtail operations, or obtain funds through collaborative arrangements that may require us to relinquish rights to some of our products or potential markets.

The costs of conducting all of our human clinical trials to date for our preventive HIV vaccine have been borne by the HIV Vaccine Trials Network (HVTN), with funding by the NIH, and we expect NIH support for additional clinical trials. GeoVax incurs costs associated with manufacturing the clinical vaccine supplies and other study support. We cannot predict the level of support we will receive from the HVTN or the NIH for any additional clinical trials of our HIV vaccines.

Our operations are also partially supported by the NIH grants awarded to us to support our HIV/AIDS vaccine program. As of December 31, 2015, there was approximately \$100,500 of unused grant funds remaining and available for use during the first half of 2016. We are pursuing additional grants from the federal government for our HIV, hemorrhagic fever, and Zika virus vaccine programs. However, as we progress to the later stages of our vaccine development activities, government financial support may be more difficult to obtain, or may not be available at all. Furthermore, there is some risk that actual funding for grants could be delayed, cut back, or eliminated due to government budget constraints. Therefore, it will be necessary for us to look to other sources of funding in order to finance our development activities.

We expect that our current working capital, combined with proceeds from the grants awarded to us from the NIH will be sufficient to support our planned level of operations into the third quarter of 2016. We will need to raise additional funds to significantly advance our vaccine development programs and to continue our operations. In order to meet our operating cash flow requirements we plan to seek sources of non-dilutive capital through government grant programs and clinical trial support. We may also plan additional offerings of our equity securities, debt, or convertible debt instruments. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

## **Risks Related to Development and Commercialization of Product Candidates and Dependence on Third Parties**

*Our products are still being developed and are unproven. These products may not be successful*

To become profitable, we must generate revenue through sales of our products. However, our products are in varying stages of development and testing. Our products have not been proven in human clinical trials and have not been approved by any government agency for sale. If we cannot successfully develop and prove our products and processes, or if we do not develop other sources of revenue, we will not become profitable and at some point we would discontinue operations.

*Whether we are successful will be dependent, in part, upon the leadership provided by our management. If we were to lose the services of any of these individuals, our business and operations may be adversely affected. Further, we may not carry key man life insurance on certain of our executive officers or directors.*

Whether our business will be successful will be dependent, in part, upon the leadership provided by our officers, particularly our President and Chief Executive Officer, our Chief Scientific Officer, and our Senior Vice President, Research and Development. The loss of the services of these individuals may have an adverse effect on our operations. Although we carry some key man life insurance on Dr. Harriet L. Robinson, the amount of such coverage may not be sufficient to offset any adverse economic effects on our operations and we do not carry key man insurance on any of our other executive officers or directors. Further, our employees, including our executive officers and directors, are not subject to any covenants not to compete against the Company, and our business could be adversely affected if any of our employees or directors engaged in an enterprise competitive with the Company.

*Regulatory and legal uncertainties could result in significant costs or otherwise harm our business.*

To manufacture and sell our products, we must comply with extensive domestic and international regulation. In order to sell our products in the United States, approval from the FDA is required. Satisfaction of regulatory requirements, including FDA requirements, typically takes many years, and if approval is obtained at all, it is dependent upon the type, complexity and novelty of the product, and requires the expenditure of substantial resources. We cannot predict whether our products will be approved by the FDA. Even if they are approved, we cannot predict the time frame for approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to meet than FDA requirements. As with the FDA, we cannot predict if or when we may obtain these regulatory approvals. If we cannot demonstrate that our products can be used safely and successfully in a broad segment of the patient population on a long-term basis, our products would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

***We face intense competition and rapid technological change that could result in products that are superior to the products we will be commercializing or developing.***

The market for vaccines that protect against or treat human infectious diseases is intensely competitive and is subject to rapid and significant technological change. We have numerous competitors in the United States and abroad, including, among others, large companies with substantially greater resources than us. These competitors may develop technologies and products that are more effective or less costly than any of our future technology or products or that could render our technology or products obsolete or noncompetitive. If our technology or products are not competitive, we may not be able to remain in business.

***Our product candidates are based on new medical technology and, consequently, are inherently risky. Concerns about the safety and efficacy of our products could limit our future success.***

We are subject to the risks of failure inherent in the development of product candidates based on new medical technologies. These risks include the possibility that the products we create will not be effective, that our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals, and that our product candidates will be hard to manufacture on a large scale or will be uneconomical to market.

Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long term follow-up data may reveal additional complications associated with our products. The responses of potential physicians and others to information about complications could materially affect the market acceptance of our products, which in turn would materially harm our business.

***We may experience delays in our clinical trials that could adversely affect our financial results and our commercial prospects.***

We do not know whether planned clinical trials will begin on time or whether we will complete any of our clinical trials on schedule, if at all. Product development costs will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. Significant delays may adversely affect our financial results and the commercial prospects for our products, and delay our ability to become profitable.

We rely heavily on the HVTN, independent clinical investigators, and other third party service providers for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with 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 rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates. There is also a risk of changes in clinical trial strategy and timelines due to the HVTN and the NIH altering their trial strategy.

***Failure to obtain timely regulatory approvals required to exploit the commercial potential of our products could increase our future development costs or impair our future sales.***

None of our vaccines are approved by the FDA for sale in the United States or by other regulatory authorities for sale in foreign countries. To exploit the commercial potential of our technologies, we are conducting and planning to conduct additional pre-clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials could delay or preclude regulatory approval and restrict our ability to commercialize our technology or products. Any such failure may severely harm our business. In addition, any approvals we obtain may not cover all of the clinical indications for which approval is sought, or may contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post-approval study requirements.

***State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.***

Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless we are in full compliance with these laws, we could face enforcement action, fines, and other penalties and could receive adverse publicity, all of which could harm our business.

***We may be subject to new federal and state legislation to submit information on our open and completed clinical trials to public registries and databases.***

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the FDA Modernization Act (FDMA), to promote public awareness of and access to these clinical trials. Under the FDMA, pharmaceutical manufacturers and other trial sponsors are required to post the general purpose of these trials, as well as the eligibility criteria, location and contact information of the trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of trials included in this or other registries, as well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those trials that have been registered with a no-cost, publicly accessible database, such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Federal legislation was introduced in the fall of 2004 to expand [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and to require the inclusion of trial results in this registry. The Pharmaceutical Research and Manufacturers of America also issued voluntary principles for its members to make results from certain clinical trials publicly available and established a website for this purpose. Other groups have adopted or are considering similar proposals for clinical trial registration and the posting of clinical trial results. Failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines and other penalties, all of which could materially harm our business.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the PPACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On March 1, 2013, the President signed an executive order implementing the 2% Medicare payment reductions, and on April 1, 2013, these reductions went into effect. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.



***We may not be successful in establishing collaborations for product candidates we may seek to commercialize, which could adversely affect our ability to discover, develop, and commercialize products.***

We expect to seek collaborations for the development and commercialization of product candidates in the future. The timing and terms of any collaboration will depend on the evaluation by prospective collaborators of the clinical trial results and other aspects of our vaccine's safety and efficacy profile. If we are unable to reach agreements with suitable collaborators for any product candidate, we will be forced to fund the entire development and commercialization of such product candidates, ourselves, and we may not have the resources to do so. If resource constraints require us to enter into a collaboration agreement early in the development of a product candidate, we may be forced to accept a more limited share of any revenues this product may eventually generate. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish collaborations or other alternative arrangements for any product candidate. Even if we are successful in establishing collaborations, we may not be able to ensure fulfillment by collaborators of their obligations or our expectations.

***We do not have manufacturing, sales or marketing experience.***

We do not have experience in manufacturing, selling, or marketing vaccines. To obtain the expertise necessary to successfully manufacture, market, and sell our vaccines, we will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

***Our vaccines under development may not gain market acceptance.***

Our vaccines may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Significant factors in determining whether we will be able to compete successfully include:

- the efficacy and safety of our vaccines;
- the time and scope of regulatory approval;
- reimbursement coverage from insurance companies and others;
  - the price and cost-effectiveness of our products; and
- the ability to maintain patent protection.

***We may be required to defend lawsuits or pay damages for product liability claims.***

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. We carry product liability insurance and we expect to continue such policies. However, product liability claims, regardless of their merits, could exceed policy limits, divert management's attention, and adversely affect our reputation and the demand for our products.

### **Risks Related to Our Intellectual Property**

*We could lose our license rights to our important intellectual property if we do not fulfill our contractual obligations to our licensors.*

Our rights to significant parts of the technology we use in our vaccines are licensed from third parties and are subject to termination if we do not fulfill our contractual obligations to our licensors. Termination of intellectual property rights under any of our license agreements could adversely impact our ability to produce or protect our vaccines. Our obligations under our license agreements include requirements that we make milestone payments to our licensors upon the achievement of clinical development and regulatory approval milestones, royalties as we sell commercial products, and reimbursement of patent filing and maintenance expenses. Should we become bankrupt or otherwise unable to fulfill our contractual obligations, our licensors could terminate our rights to critical technology that we rely upon.

***Other parties may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling products.***

Our success will depend in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use and sale of new products have been subject to substantial patent rights litigation in the pharmaceutical industry. These lawsuits generally relate to the validity and infringement of patents or proprietary rights of third parties. Infringement litigation is prevalent with respect to generic versions of products for which the patent covering the brand name product is expiring, particularly since many companies that market generic products focus their development efforts on products with expiring patents. Pharmaceutical companies, biotechnology companies, universities, research institutions or other third parties may have filed patent applications or may have been granted patents that cover aspects of our products or our licensors' products, product candidates or other technologies.

Future or existing patents issued to third parties may contain patent claims that conflict with our products. We expect to be subject to infringement claims from time to time in the ordinary course of business, and third parties could assert infringement claims against us in the future with respect to our current products or with respect to products that we may develop or license. Litigation or interference proceedings could force us to:

stop or delay selling, manufacturing or using products that incorporate, or are made using the challenged intellectual property;  
pay damages; or  
enter into licensing or royalty agreements that may not be available on acceptable terms, if at all.

Any litigation or interference proceedings, regardless of their outcome, would likely delay the regulatory approval process, be costly and require significant time and attention of our key management and technical personnel.

***Any inability to protect intellectual property rights in the United States and foreign countries could limit our ability to manufacture or sell products.***

We will rely on trade secrets, unpatented proprietary know-how, continuing technological innovation and, in some cases, patent protection to preserve our competitive position. Our patents and licensed patent rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. If patents containing competitive or conflicting claims are issued to third parties, we may be prevented from commercializing the products covered by such patents, or may be required to obtain or develop alternate technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies.

We may not be able to prevent third parties from infringing or using our intellectual property, and the parties from whom we may license intellectual property may not be able to prevent third parties from infringing or using the licensed intellectual property. We generally will attempt to control and limit access to, and the distribution of, our product documentation and other proprietary information. Despite efforts to protect this proprietary information, unauthorized parties may obtain and use information that we may regard as proprietary. Other parties may independently develop similar know-how or may even obtain access to these technologies.

The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

Neither the U.S. Patent and Trademark Office nor the courts have established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

#### **Risks Related To This Offering and Our Securities**

*The market price of our common stock is highly volatile.*

The market price of our common stock has been, and is expected to continue to be, highly volatile. Certain factors, including announcements of new developments by us or other companies, regulatory matters, new or existing medicines or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us, and subsequent sales of common stock by the holders of warrants and options could have an adverse effect on the market price of our shares.

***Our common stock does not have a vigorous trading market and investors may not be able to sell their securities when desired.***

We have a limited active public market for our common shares. A more active public market, allowing investors to buy and sell large quantities of our common stock, may never develop. Consequently, investors may not be able to liquidate their investments in the event of an emergency or for any other reason.

***We have never paid dividends and have no plans to do so.***

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our Board of Directors. To date, we have paid no cash dividends on our shares of common stock and we do not expect to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any potential return investors may have in our common stock will be in the form of appreciation, if any, in the market value of their shares of common stock.

***If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.***

We are subject to reporting obligations under the United States securities laws. The Securities and Exchange Commission (SEC) as required by the Sarbanes-Oxley Act of 2002, adopted rules requiring every public company to include a management report on such company's internal controls over financial reporting in its annual report. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to achieve and maintain effective internal controls over financial reporting could result in the loss of investor confidence in the reliability of our financial statements, which in turn could negatively impact the trading price of our stock.