

GeoVax Labs, Inc.  
Form POS AM  
March 18, 2013

As Filed with the Securities and Exchange Commission on March 18, 2013.

Registration No. 333-180535

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

POST-EFFECTIVE AMENDMENT NO. 1

FORM S-1

REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

GEOVAX LABS, INC.  
(Exact name of registrant as specified in its charter)

Delaware	2834	87-0455038
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1900 Lake Park Drive, Suite 380, Smyrna, Georgia 30080, (678) 384-7220  
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Robert T. McNally, Ph.D.  
President & Chief Executive Officer  
GeoVax Labs, Inc.  
1900 Lake Park Drive, Suite 380  
Smyrna, Georgia 30080  
Tel: (678) 384-7220  
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With a copy to:  
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Amendment No. 1 to registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.  x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

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If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company

The registrant hereby amends this Post-Effective Amendment No. 1 to registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Post-Effective Amendment No. 1 to registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Post-Effective Amendment No. 1 to registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

This Post-Effective Amendment No. 1 to Form S-1 (this “Post-Effective Amendment”) is being filed pursuant to Section 10(a)(3) of the Securities Act to update our registration statement on Form S-1 (Registration No. 333-180535) (the “Registration Statement”), which was previously declared effective by the Securities and Exchange Commission on April 13, 2012, to (i) include the consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K, for the fiscal year ended December 31, 2012, and (ii) update certain other information in the Registration Statement. No additional securities are being registered under this Post-Effective Amendment. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 18, 2013

PROSPECTUS

GEOVAX LABS, INC.

Up to 9,539,562 Shares of Common Stock

This prospectus relates to up to 9,539,562 shares of common stock, \$0.001 par value, of GeoVax Labs, Inc. that may be sold from time to time by the selling stockholders named in this prospectus, which includes up to:

- 1,455,563 shares of common stock held by selling stockholders;
- 1,050,667 shares of common stock underlying Series A convertible preferred stock, par value \$0.01 per share, and
- 7,033,332 shares of common stock issuable to the selling stockholders upon the exercise of Series A, B and C 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 47 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 Series A, B or C Warrants held by the selling stockholders, if 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 15, 2013, the last reported sale price for our common stock as reported on the over-the-counter market was \$0.62 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

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criminal offense.

The date of this Prospectus is March \_\_, 2013

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You should rely only on the information contained in this prospectus and in any accompanying prospectus supplement. We have not authorized anyone to provide you with different information.

We have not authorized the selling stockholders to make an offer of these shares of common stock in any jurisdiction where the offer is not permitted.

You should not assume that the information in this prospectus or prospectus supplement is accurate as of any date other than the date on the front of this prospectus.

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## PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. It does not contain all of the information that you should consider before investing in our securities. Please read the entire prospectus carefully, including the section entitled “Risk Factors” and our consolidated financial statements and the related notes. We have not authorized anyone else to provide you with different information, and if you receive any unauthorized information you should not rely on it. The information appearing in this prospectus is accurate only as of its date. Our business, financial condition, results of operations and prospects may have changed since that date.

You should not invest unless you can afford to lose your entire investment.

### Company Overview

GeoVax Labs, Inc. is a biotechnology company developing vaccines that prevent and fight Human Immunodeficiency Virus (“HIV”) infections. HIV infections result in Acquired Immunodeficiency Syndrome (“AIDS”). We have exclusively licensed from Emory University (“Emory”) vaccine technology which was developed in collaboration with the United States National Institutes of Health (“NIH”) and the United States Centers for Disease Control and Prevention (“CDC”).

Our most advanced vaccines under development address the clade B subtype of the HIV virus that is prevalent in the Americas and western Europe. Our vaccines are being evaluated to determine their potential to (a) prevent HIV infection and (b) to serve as a therapy for individuals who are already infected with HIV. These vaccines are currently being evaluated in humans -- both in those infected with HIV and those who are not.

Our vaccines incorporate two delivery components: a recombinant deoxyribonucleic acid (DNA) vaccine, and a recombinant poxvirus designated modified vaccinia Ankara (MVA) vaccine. Both the DNA and MVA vaccines contain sufficient HIV genes to support the production of non-infectious virus-like particles. These particles display the native trimeric-membrane-bound form of the viral envelope glycoprotein that mediates entry into cells and is the target for protective antibody. When used together, the recombinant DNA component primes immune responses, which are boosted by administration of the recombinant MVA component. We are also testing a new version of our preventive vaccine that co-expresses granulocyte-macrophage colony-stimulating factor (GM-CSF) in the DNA vaccine used to prime the immune response.

Work on our vaccines began during the 1990s at Emory University in Atlanta, Georgia, under the direction of Dr. Harriet L. Robinson, who is now our Chief Scientific Officer. The vaccine technology was developed in collaboration with researchers at the NIH and the CDC. The technology developed by the collaboration is exclusively licensed to us from Emory University.

Our common stock is quoted on the OTCQB market under the symbol “GOVX.” On March 15, 2013, the last reported sale price for our common stock on the OTCQB market was \$0.62 per share.

As used herein, “GeoVax,” the “Company,” “we,” “our,” and similar terms include GeoVax Labs, Inc., and its operating subsidiary, GeoVax, Inc., unless the context indicates otherwise.

We are incorporated under the laws of the State of Delaware. Our principal executive 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 website is [www.geovax.com](http://www.geovax.com). Information on our website is not part of this prospectus.





The Offering

Common stock offered by selling stockholders Up to 9,539,562 shares, consisting of 1,455,563 shares of common stock owned by selling stockholders, 1,050,667 shares of common stock underlying Series A Preferred Stock owned by selling stockholders and 7,033,332 shares of common stock issuable upon the exercise of Series A, B or C Warrants held by the selling stockholders. This number represents approximately 33.4% of our current outstanding common stock, on a fully diluted basis.

Common stock outstanding before the offering 20,499,944 shares (1)

Common stock outstanding after the offering, assuming all the remaining shares of Series A Preferred Stock are converted into common stock and the Series A, B and C Warrants are exercised for cash. 28,583,943 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 \$6.6 million from the exercise of the Series A, B, and C 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, including our history of operating losses and our need for continued funding. For a discussion of these and other 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 to be outstanding after this offering is based on the number of shares outstanding as of March 15, 2013 and excludes:

- 1,197,529 shares of common stock reserved for future issuance under our equity incentive plans. As of March 15, 2013, there were options to purchase 1,069,141 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$4.50 per share;
- 2,425,560 shares of common stock issuable upon exercise of currently outstanding warrants (but not including the Series A, B and C Warrants) as of March 15, 2013, with a weighted average exercise price of \$6.23 per share;



## RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. 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. Also, you should be aware that the risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties, of which we are not yet aware, or that we currently consider to be immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into this prospectus, including our financial statements and the related notes.

### Risks Related to Our Financial Results and Need for Additional Financing

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, 2012, we had an accumulated deficit of approximately \$24.8 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 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 HVTN, funded 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.

Our operations are also partially supported by the NIH grants awarded to us to support our HIV/AIDS vaccine program. As of December 31, 2012, there is approximately \$3.5 million of unused grant funds remaining and available for use through August 31, 2013. We intend to pursue additional grants from the federal government. 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.

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 first quarter of 2014, without giving consideration to the potential proceeds from exercise of the Series A, B or C Warrants. In order to meet our operating cash flow requirements we 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.

The current economic conditions may adversely impact our ability to raise capital.

The recent recession and adverse conditions in the national and global markets may negatively affect both our ability to raise capital and our operations in the future. The volatile equity markets and adverse credit markets may make it difficult for us to raise capital or procure credit in the future to fund the growth of our business, which could have a negative impact on our business and results of operations.

## 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 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 and our Chief Scientific Officer. 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 will 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 HIV/AIDS is intensely competitive and is subject to rapid and significant technological change. We will 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.

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.

In recent years, 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 and 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, or the 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.

We will face uncertainty related to pricing and reimbursement and health care reform.

In both domestic and foreign markets, sales of our products will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations and other health care-related organizations. Reimbursement by such payers is presently undergoing reform and there is significant uncertainty at this time how this will affect sales of certain pharmaceutical products.

Medicare, Medicaid and other governmental healthcare programs govern drug coverage and reimbursement levels in the United States. Federal law requires all pharmaceutical manufacturers to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. Generic drug manufacturers' agreements with federal and state governments provide that the manufacturer will remit to each state Medicaid agency, on a quarterly basis, 11% of the average manufacturer price for generic products marketed and sold under abbreviated new drug applications covered by the state's Medicaid program. For proprietary products, which are marketed and sold under new drug applications, manufacturers are required to rebate the greater of (a) 15.1% of the average manufacturer price or (b) the difference between the average manufacturer price and the lowest manufacturer price for products sold during a specified period.

Both the federal and state governments in the United States, and foreign governments, continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any product developed in the future. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services and litigation has been filed against a number of pharmaceutical companies in relation to these issues. Additionally, some uncertainty may exist as to the reimbursement status of newly approved injectable pharmaceutical products. Our products may not be considered cost-effective or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an adequate return on our investment.

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.

