GeoVax Labs, Inc.
Form POS AM
March 20, 2015
As Filed with the Securities and Exchange Commission on March 20, 2015.

Registration No. 333-193172

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

POST-EFFECTIVE AMENDMENT NO. 2

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.	**With a copy to:**
President & Chief Executive Officer	**T. Clark Fitzgerald III**
	Womble Carlyle Sandridge & Rice, LLP

GeoVax Labs, Inc.

1900 Lake Park Drive, Suite 380
Smyrna, Georgia 30080
Tel: (678) 384-7220

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271 17th Street NW, Suite 2400
Atlanta, Georgia 30363

Tel: (404) 879-2455

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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. 2 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.

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.

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.

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. 2 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. 2 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. 2 to registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Post-Effective Amendment No. 2 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. 333-193172) (the "Registration Statement"), which was previously declared effective by the Securities and Exchange Commission on January 15, 2014, as amended by post-effective Amendment No. 1 which was declared effective on March 26, 2014 as supplemented, 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, 2014, 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.

The information in this prospectus is not complete and may be changed. The selling stockholder 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 20, 2015

PROSPECTUS

GEOVAX LABS, INC.

Up to 285,714 Shares of Common Stock

This prospectus relates to up to 285,714 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 stockholder named in this prospectus, which reflects the up to 285,714 shares of common stock underlying our outstanding Series B convertible preferred stock ("Series B Preferred Stock"), par value $0.01 per share.

The prices at which the selling stockholder 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 stockholder in accordance with one or more of the methods described in the plan of distribution, which begins on page 52 of this prospectus.

We will not receive any proceeds from the sales of outstanding shares of common stock by the selling stockholder.

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 16, 2015, the last reported sale price for our common stock as reported on the over-the-counter market was $0.16 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.

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

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 _____, 2015

TABLE OF CONTENTS

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.

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 novel vaccine platform. Our platform supports production of non-infectious virus-like particles (VLPs) from the cells of the person receiving the vaccine. Producing non-infectious virus-like particles in the person being vaccinated circumvents the need to purify virus-like particles for inoculation. The production of virus-like particles 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 Ebola and Marburg viruses, and a vaccine against Human Immunodeficiency Virus (HIV). We believe our technology and vaccine development expertise is well-suited for a wide variety of human infectious diseases for which there is an unmet medical need, and we intend to pursue expansion of our product pipeline as resources permit.

Our Ebola/Marburg vaccine program was initiated during 2014 with the goal of developing monovalent vaccines capable of controlling existing outbreaks as well as a multivalent vaccine for preventing future outbreaks. We plan to conduct preclinical animal immunogenicity and challenge studies during 2015 for both vaccines with human clinical testing to begin in late 2016.

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 is targeted to enter a follow-on clinical trial in 2015. It has shown outstanding safety and excellent and highly reproducible immunogenicity (*Journal of Infectious Diseases volume 203, pg 610 and volume 210 pg 99*). We also are investigating our HIV vaccines for their potential to contribute to combination therapies for therapeutic treatment leading to a cure for HIV infections. We are also extending our HIV vaccine effort to the most common virus subtype affecting the developing world, clade C. For clade C, we have jointly developed and licensed via Emory University one vaccine from the National Institutes of Health (NIH), completed lead discovery for a second vaccine, and initiated early preclinical research using both approaches. Each of our vaccine development programs is discussed in greater

detail in the sections that follow below.

Our 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. This is discussed further under “Support from the United States Government” below.

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 Ebola/Marburg vaccines have been developed with technology licensed from, and in collaboration with, the NIH.

We are incorporated in Delaware, and our offices and laboratory facilities are located in **S**myrna, Georgia (metropolitan Atlanta).

Recent Development

On February 25, 2015, we entered into a Securities Purchase Agreement with two accredited investors providing for the issuance and sale to the investors of an aggregate of 3,000 shares of our Series C Convertible Preferred Stock (the “Series C Preferred Stock”) and related warrants for gross proceeds to the Company of $3.0 million. Each share of Series C Preferred Stock is initially convertible into approximately 5,555.55 shares of our Common Stock for an aggregate total of 16,666,666 shares of our Common Stock. Pursuant to the Securities Purchase Agreement, each investor was also issued a Series D Warrant, a Series E Warrant and a Series F Warrant (collectively, the “Warrants”), each to purchase up to a number of shares of the Company’s Common Stock equal to 100% of the Conversion Shares underlying the Preferred Shares issued to such Purchaser pursuant to the Securities Purchase Agreement (up to 16,666,666 shares in the aggregate for each of the three series of warrants, or approximately 49,999,997 shares in total). The Company also issued a warrant (the “Maxim Warrant”) to its placement agent to acquire 1,333,333 shares of our common stock at $0.22 per share on substantially the same terms and conditions of the Series D Warrants. See “Description of Securities”.

Company Background

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. 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 stockholder	Up to 285,714 shares, consisting of common stock underlying Series B Preferred Stock owned by the selling stockholder. This number represents approximately 0.9% of our current outstanding common stock, on a fully diluted basis. (1)
Common stock outstanding before the offering.	31,950,813 shares (1)
Common stock outstanding after the offering, assuming all the shares of Series B Preferred Stock are converted into common stock.	32,236,527 shares (1)
Proceeds to us	We will not receive any proceeds from the sale of common stock covered by this prospectus.
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.

(1) The number of shares of our common stock that will be outstanding immediately after this offering is based on 31,950,813 shares outstanding as of March 16, 2015, and includes 285,714 shares of common stock issuable upon conversion of Series B Preferred Stock, but excludes the following:

1,197,529 shares of common stock reserved for future issuance under our equity incentive plans. As of March 16, 2015, there were options to purchase 1,177,500 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of $3.49 per share;

56,442,157 shares of common stock issuable upon exercise of currently outstanding warrants as of March 16, 2015, with a weighted average exercise price of $0.24 per share; and

16,666,666 shares of common stock reserved for issuance upon conversion of our outstanding Series C Convertible Preferred Stock (“Series C 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, 2014, we had an accumulated deficit of approximately $29.8 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 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 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 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, 2014, there is approximately $229,000 of unused grant funds remaining and available for use during 2015. We are pursuing additional grants from the federal government for both our HIV and Ebola/Marburg 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 through the first quarter of 2016. We will need to raise additional funds to significantly advance our vaccine development programs and to continue our operations beyond the first quarter of 2016. 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 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 human infectious diseases 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. 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.

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, 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. Federal legislation was introduced in the fall of 2004 to expand 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 payors. 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