

GeoVax Labs, Inc.

Form S-1

December 15, 2015

As Filed with the Securities and Exchange Commission on December 15, 2015.

Registration No. 333-_____

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

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 (Primary Standard Industrial (I.R.S. Employer

incorporation or organization)Classification Code Number)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.

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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 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

Calculation of Registration Fee

Title of Each Class Of Securities To Be Registered	Amount To Be Registered (1)	Proposed	Proposed	Amount of Registration Fee
		Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	
Common stock, \$0.001 par value per share underlying Series C convertible preferred stock, \$0.001 par value per share	10,733,902 (2)	\$0.102 (3)	\$1,094,858 (3)	\$110.25
TOTAL	10,733,902		\$1,094,858	\$110.25

(1) In accordance with Rule 416(a), the Registrant is also registering hereunder an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(2) Represents shares of the Registrant's common stock underlying shares of Series C convertible preferred stock being registered for resale that have been issued to the selling stockholders named in this registration statement.

(3) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and asked prices reported on the over-the-counter bulletin board on December 11, 2015, which was \$0.102 per share.

The Registrant hereby amends this 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 Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

EXPLANATORY NOTE

The Registrant previously registered 67,999,997 shares of its common stock on a Registration Statement on Form S-1 (File No. 333-202897) filed by the Registrant on March 20, 2015, and declared effective by the Securities and Exchange Commission on April 8, 2015. The Registrant registered an additional 4,460,094 shares of its common stock which became available to the selling stockholders no extra cost to them due to anti-dilution provisions on a Registration Statement on Form S-1 (File No. 333-206617) on August 27, 2015, which was immediately effective pursuant to Rule 462(b).

The shares of common stock being registered pursuant to this Registration Statement have become available to the selling stockholders at no cost to them due to certain anti-dilution provisions in the terms of the Series C Preferred Stock.

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 DECEMBER 15, 2015

PROSPECTUS

GEOVAX LABS, INC.

Up to 10,733,902 Shares of Common Stock

This prospectus relates to up to 10,733,902 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:

10,733,902 shares of common stock underlying Series C Convertible Preferred Stock, par value \$0.01 per share, which we refer to as “Series C Preferred Stock. These shares became available to the selling stockholders at no cost to them due to certain anti-dilution provisions of the Series C Preferred Stock.

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 3 of this prospectus.

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

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 December 11, 2015, the last reported sale price for our common stock as reported on the over-the-counter market was \$0.11 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 December __, 2015

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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.

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 VLPs in the person being vaccinated circumvents the need to purify virus-like particles for inoculation. 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) and hemorrhagic fever viruses (Ebola, Marburg). We believe our technology and vaccine development expertise is well-suited for a variety of human infectious diseases and, potentially, cancer immunotherapy. 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 is targeted to enter a follow-on clinical trial in early 2016. 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 are also extending 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 National Institutes of Health (NIH). Additionally, we are investigating our HIV vaccines for their potential to contribute to combination therapies for therapeutic treatment leading to a cure for HIV infections.

Our hemorrhagic fever vaccine program was initiated during 2014 with the objective of developing both monovalent vaccines and tetravalent vaccines designed to protect not only against current strains for filoviruses such as Ebola and Marburg, but also against other major hemorrhagic fever viruses endemic in African countries. Studies of our first Ebola vaccine candidate have demonstrated 100 percent protection in rodent models. We plan to conduct additional animal challenge studies during 2016 with the goal of beginning human clinical trials during the first half of 2017.

In December 2015, we entered into a Collaborative Research Agreement with the University of Pittsburgh to evaluate our VLP vaccine platform for use in cancer immunotherapy, including the selection and testing of vaccine candidates.

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 hemorrhagic fever virus vaccines have been developed with technology licensed from, and in collaboration with, the NIH.

Each of our vaccine development programs is discussed in greater detail in the sections that follow below.

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 website 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 website does not form a part of this prospectus.

The Offering

Common stock offered by selling stockholders	Up to 10,733,902 shares of common stock underlying Series C Preferred Stock owned by selling stockholders. This number represents approximately 25% of our current outstanding common stock, on a fully diluted basis.
Common stock outstanding before the offering	31,950,813 shares (1)
Common stock outstanding after the offering, assuming all the shares of Series C Preferred Stock being registered hereby are converted into common stock.	42,684,715 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, 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.

(1) The number of shares of our common stock to be outstanding after this offering is based on 31,950,813 shares outstanding as of December 11, 2015 and excludes:

1,722,529 shares of common stock reserved for future issuance under our equity incentive plans. As of December 11, 2015, 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;
 56,442,157 shares of common stock issuable upon exercise of currently outstanding warrants as of December 11, 2015, with a weighted average exercise price of \$0.14 per share;
 21,126,760 shares of common stock issuable upon conversion of our outstanding Series C Convertible Preferred Stock, not covered by this prospectus; and
 285,714 shares of common stock issuable upon conversion of our outstanding Series B Convertible Preferred Stock, which we refer to as our “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 September 30, 2015, we had an accumulated deficit of approximately \$31.8 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 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 September 30, 2015, there was approximately \$261,000 of unused grant funds remaining and available for use during the remainder of 2015 and the first half of 2016. 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 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.

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 (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 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 s