GeoVax Labs, Inc.
Form S-1/A
November 08, 2010

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As filed with the Securities and Exchange Commission on November 8, 2010
Registration No. 333-165828

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

Amendment No. 7 to
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 Dr., 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 Dr., Suite 380
Smyrna Georgia 30080
Telephone: (678) 384-7220
Facsimile: (678) 384-7281
(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.

With Copies To:

T. Clark Fitzgerald III, Esq.
Womble Carlyle Sandridge & Rice, PLLC
271 17th Street, NW, Suite 2400
Atlanta, Georgia 30363
Telephone: (404) 879-2455
Facsimile: (404) 870-4869

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 of 1933, check the following box. þ

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

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. o

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. (Check one):

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o (Do not check if a smaller reporting company)

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 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

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

PROSPECTUS

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION DATED NOVEMBER 8, 2010

GEOVAX LABS, INC.

FROM TO UNITS, EACH CONSISTING OF ONE SHARE OF COMMON STOCK AND A WARRANT TO PURCHASE ONE ADDITIONAL SHARE OF COMMON STOCK

This is a best efforts offering of a minimum of $5,000,000 (units) and a maximum of $10,000,000 (units) at a price of $ per unit. Each unit consists of one share of GeoVax Labs, Inc. common stock ($0.001 par value) and a five-year callable warrant to purchase one additional share of GeoVax Labs, Inc. common stock at an exercise price of $, or 20% above the offering price of the units. The units will separate immediately upon issuance and trade separately. Proceeds will be deposited in an escrow account and returned to investors in full, without interest or deduction, unless at least units offered hereby are sold during the offering period. Investors will have no right to the return of their funds during the term of the escrow.

Our common stock is quoted on the OTC Bulletin Board under the symbol GOVX. On November 5, 2010, the last reported sale price for our common stock on the OTC Bulletin Board was $1.79 per share. We do not intend to apply for listing of the warrants on any securities exchange.

Investing in the common stock involves certain risks. See Risk Factors beginning on page 5 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.

	Per Unit	Total Minimum Offering	Total Maximum Offering
Public offering price	$	$ 5,000,000	$ 10,000,000
Placement agents commissions	$	$ 400,000	$ 800,000
Proceeds to us(1)	$	$ 4,600,000	$ 9,200,000

(1) Before deducting expenses of this offering payable by us estimated to be approximately $550,000.

We have agreed to pay our placement agents an aggregate commission of 8% of the price of each unit sold, and to reimburse certain expenses, up to $174,999. See Plan of Distribution. The placement agents are not required to sell

any specific number of units or dollar amount of units but will use their best efforts to sell the units. Brokers or dealers effecting transactions in these shares should confirm that the units are registered under the applicable state law or that an exemption from registration is available.

This offering will terminate on , 2010, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. All costs associated with the registration will be borne by us.

Global Hunter Securities **Gilford Securities Incorporated**

The date of this Prospectus is November , 2010

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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 anyone 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 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

We are a biotechnology company dedicated to developing vaccines that prevent and fight human immunodeficiency virus (commonly known as HIV) infections that result in acquired immunodeficiency syndrome, also known as AIDS. We have preventative vaccines being evaluated in a Phase 2a human clinical trial in individuals who are not HIV infected and are currently enrolling prospective participants in a Phase 1 human therapeutic clinical trial in individuals who are HIV infected.

Our preventative vaccines are designed to prevent or control infection by HIV, reduce the rate of disease progression to AIDS and reduce the risk of HIV transmission. Our therapeutic vaccines target viral replication to reduce viral load in HIV infected individuals with a goal of reducing or eliminating the need for anti-HIV medications, and thereby reduce both the cost of treatment and the occurrence of detrimental side effects associated with current drug treatments.

Our vaccines are designed to function against the subtype, known as clade B, of the HIV virus that is most prevalent in the developed world. Our vaccines have been shown to induce antibodies and T cells (a type of white blood cell) in Phase 1 human clinical trials. In non-human primate challenge models, the antibodies and T cells elicited by a simian prototype of our vaccine have been shown to protect against mucosal simian immunodeficiency virus infection, the non-human primate version of the HIV virus. Our goals include manufacturing and testing these vaccines consistent with guidelines issued by the United States Food and Drug Administration, or FDA, conducting human trials for vaccine safety and effectiveness, and obtaining regulatory approvals to advance the development and commercialization of our vaccines.

Our preventative vaccine is one of only five vaccine candidates out of more than 80 tested by the HIV Vaccine Trials Network, which we refer to as the HVTN, in Phase 1 human clinical trials to have progressed to Phase 2 testing. Based on current enrollment progress, we expect the Phase 2a clinical trial to be completed during 2011.

The Investigational New Drug, or IND, application to test our therapeutic vaccine in a Phase 1 human clinical trial is based on promising data from three pilot studies we conducted using therapeutic vaccination in simian immunodeficiency virus infected non-human primates. We expect the Phase 1 trial to begin generating vaccine safety and performance data during the first half of 2011, with trial completion in the 2012-2013 timeframe.

Our vaccine candidates incorporate two delivery components: a recombinant deoxyribonucleic acid, or DNA, and a recombinant poxvirus designated modified vaccinia Ankara, or MVA, which both deliver genes that encode inactivated HIV-derived proteins and provide them to the immune system. Both components are designed to support production of non-infectious virus-like particles in vaccinated individuals that prime and boost immune responses.

When properly administered in series, our vaccine candidates induce strong T-cell and antibody responses in non-human primates against multiple HIV proteins.

Both the DNA and MVA vaccines contain sufficient HIV genes to support the production of non-infectious virus-like particles in vaccinated people which display forms of proteins that appear authentic to the immune system. When used together, the recombinant DNA component is used to prime immune responses which are boosted by administration of the recombinant MVA component. In certain settings, the recombinant

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MVA alone may be sufficient for priming and boosting the immune responses. We are also testing use of the recombinant MVA component alone in our ongoing Phase 2a clinical trial.

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 United States National Institutes of Health, or the NIH, National Institute of Allergy and Infectious Disease, or the NIAID, and the United States Centers for Disease Control and Prevention, or the CDC. The technology developed at Emory University is exclusively licensed to us. We also have nonexclusive rights through our license to certain patents owned by the NIH and exclusive license rights to certain manufacturing process patents of MFD, Inc.

In 2005, a Phase 1 human clinical trial to test our preventative vaccine concluded successfully. After receiving Safe to Proceed status for a new IND by the FDA, a Phase 1 clinical trial combining low doses of the DNA vaccine with the MVA vaccine began in May 2006. An additional Phase 1 human clinical trial began in September 2006 to test full doses of the vaccines. In total, this Phase 1 testing included four clinical trial stages. The different clinical trial stages were designed to test various combinations and doses of our DNA and MVA vaccines in human volunteers for their ability to induce HIV-specific immune responses and to document safety. Successful results from all stages of the Phase 1 clinical trial supported the initiation of the first Phase 2 clinical trial which began in January 2009 and will ultimately involve 300 participants at sites in the United States and South America.

We are also conducting pre-clinical research on the impact of adding adjuvants, which are immune system stimulants, to our vaccine components to see if this can improve the effectiveness of our vaccine candidates. This work is being funded by the NIH through an Integrated Pre-clinical/Clinical AIDS Vaccine Development Grant, or an IPCAVD grant, to GeoVax. Pre-clinical animal trials have been conducted with very encouraging results, and we plan to pursue a second clinical program for the development of the next generation of our HIV/AIDS vaccines. We have completed preliminary discussions with the FDA and plan to submit an Investigational New Drug (IND) application for this vaccine in early 2011, and intend to begin a Phase I human clinical trial by the middle of 2011.

All of the human clinical testing completed to date on our vaccines, except for the therapeutic trial, has been conducted by the HVTN using funding from the NIH. Separately, in September 2007, we received a five-year IPCAVD grant from the NIH. The total award of more than $18 million is limited to meritorious HIV/AIDS prevention vaccine programs and subject to annual renewal. The funds we are raising in this offering will be used for general corporate purposes and to expand and accelerate our ability to fund research and clinical trials in hopes of accelerating the date our preventative and therapeutic vaccines receive required regulatory approval for commercial distribution.

Our common stock is quoted on the OTC Bulletin Board under the symbol GOVX. On November 5, 2010, the last reported sale price for our common stock on the OTC Bulletin Board was $1.79 per share. We do not intend to apply for listing of the warrants on any securities exchange.

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. Information on our website is not part of this prospectus.

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SUMMARY FINANCIAL INFORMATION

The following summary financial data are derived from our consolidated financial statements. The historical results presented below are not necessarily indicative of the results to be expected for any future period. You should read the information set forth below in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, and our consolidated financial statements and the related notes, beginning on page F-1 of this prospectus.

	Nine Months Ended September 30,		Years Ended December 31,				
ent of Operations Data	**2010**	**2009**	**2009**	**2008**	**2007**	**2006**	**20**
evenues (grant income)	$ 4,239,017	$ 3,271,506	$ 3,668,195	$ 2,910,170	$ 237,004	$ 852,905	$ 67
s	$ (2,268,544)	$ (2,440,977)	$ (3,284,252)	$ (3,728,187)	$ (4,241,796)	$ (584,166)	$ (1,61
nd diluted net loss per n share(1)	$ (0.14)	$ (0.16)	$ (0.22)	$ (0.25)	$ (0.30)	$ (0.07)	$

	September 30,		December 31,				
Balance Sheet Data:	**2010**	**2009**	**2009**	**2008**	**2007**	**2006**	**2005**
Total assets	$ 2,992,798	$ 4,274,906	$ 4,315,597	$ 3,056,241	$ 3,246,404	$ 2,396,330	$ 1,685,218
Redeemable convertible preferred stock	$	$	$	$	$	$	$ 1,016,555
Total stockholders equity (deficit)	$ 2,145,779	$ 3,926,132	$ 3,744,232	$ 2,709,819	$ 2,647,866	$ 2,203,216	$ (500,583)

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THE OFFERING

Securities Offered	From to units representing an aggregate price of $5,000,000 to $10,000,000. Each unit will consist of one share of our common stock and a warrant to purchase another share of our common stock.
Number of Shares Outstanding Prior to the Offering	15,654,846 shares. (1)
Number of Shares to be Outstanding After the Offering	Minimum: shares(1) Maximum: shares (1)
Description of Unit Warrants:	The five-year callable warrants will have an exercise price of $ per share, or 20% above the offering price of the units. See Description of Capital Stock and Unit Warrants.
Use of Proceeds	To have vaccines manufactured for our clinical trials; to conduct a second human clinical trial for the therapeutic use of our vaccine; toward conducting a Phase 1 human clinical trial of an adjuvanted version of our vaccine, toward conducting our planned Phase 2b human clinical trial for a preventative HIV vaccine in the at risk population; and for working capital and general corporate purposes.
OTC Bulletin Board Symbol for Our Common Stock	**GOVX**
Risk Factors	The securities offered by this prospectus are speculative and involve a high degree of risk and investors purchasing securities should not purchase the securities unless they can afford the loss of their entire investment. See Risk Factors beginning on page 5.

(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 October 31, 2010, and excludes:

1,037,529 shares of common stock reserved for future issuance under our equity incentive plans. As of October 31, 2010, there were options to purchase 1,035,356 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of $5.66 per share;

907,594 shares of common stock issuable upon exercise of currently outstanding warrants as of October 31, 2010, with exercise prices ranging from $7.00 per share to $16.50 per share; and

From to shares of common stock that will be issuable upon exercise of the unit warrants at an exercise price of $ per share (20% above the offering price per unit) sold as part of the units in this offering.

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RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy units. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our securities. 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 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 September 30, 2010, we had an accumulated deficit of approximately $19.8 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 have been borne by the HVTN, funded by the NIH, with GeoVax incurring costs associated with manufacturing the clinical vaccine supplies and other study support. This includes the cost of conducting the ongoing Phase 2a human clinical study of our preventative vaccine. We cannot predict the level of support we will receive from the HVTN or the NIH for any additional clinical trials. We are currently not receiving any governmental support for our Phase 1 therapeutic vaccine human clinical trial.

Our operations are also partially supported by the IPCAVD grant awarded to us to support our HIV/AIDS vaccine program. The project period for the grant, which is renewable annually, covers a five year period which commenced October 2007. The most recent annual award under the grant is for the period from September 1, 2010 through August 31, 2011 in the amount of $3.7 million. 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. Therefore, it will be necessary for us to look to other sources

of funding in order to finance our development activities.

We believe that our current working capital, combined with proceeds from the IPCAVD grant awarded from the NIH, and without consideration given to net proceeds from this offering will be sufficient to support our planned level of operations into the first quarter of 2011, with no changes to our current business plan.

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Assuming the minimum amount of units is sold, we expect to have sufficient funding to support our planned operations through at least the first quarter of 2012. Assuming the maximum amount of units is sold, we expect to have sufficient funding to support our planned and expanded operations at least through the end of 2012. 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 downturn may adversely impact our ability to raise capital.

The 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 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 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.

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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. 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.

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

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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 and our lack of experience may restrict our success in commercializing our product candidates.

We do not have experience in manufacturing, marketing, or selling vaccines. We may be unable to establish satisfactory arrangements for manufacturing, marketing, sales, and distribution capabilities necessary to commercialize and gain market acceptance for our products. 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 make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize our vaccines in the United States or elsewhere.

Furthermore, our products 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.

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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.