Geovax Labs, Inc.
Form S-1/A
June 27, 2008

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As Filed with the Securities and Exchange Commission on June 27, 2008

Registration No. 333-151491

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

PRE-EFFECTIVE AMENDMENT NO. 1
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

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

1256 Briarcliff Road NE, Atlanta, Georgia 30306, (404) 727-0971

(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**
GeoVax Labs, Inc.	**Womble Carlyle Sandridge & Rice, PLLC**
1256 Briarcliff Road NE	**1201 West Peachtree Street, Suite 3500**
Atlanta, Georgia 30306	**Atlanta, Georgia 30309**
(404) 727-0971	**(404) 879-2455**

(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. 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.

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 of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

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EXPLANATORY NOTE

This Pre-Effective Amendment No. 1 to the Registration Statement on Form S-1, Registration No. 333-151491 (the Registration Statement), is being filed pursuant to Rule 414 under the Securities Act of 1933, as amended (the Securities Act) by GeoVax Labs, Inc., a Delaware corporation as the successor to GeoVax Labs, Inc., an Illinois corporation following a merger which was consummated on June 19, 2008. Immediately prior to the merger, the Delaware corporation had no assets or liabilities other than nominal assets or liabilities. Upon consummation of the merger, the Delaware corporation succeeded by operation of law to all of the assets and liabilities of the Illinois corporation. The merger was approved by the stockholders of the Illinois corporation at a meeting held June 17, 2008, and by the sole stockholder of the Delaware corporation. Pursuant to Rule 414(d), the Delaware corporation hereby adopts the Registration Statement as its own registration statement for all purposes of the Securities Act and the Securities Exchange Act of 1934, as amended. This amendment also contains updates and other changes to the initial filing.

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SUBJECT TO COMPLETION, DATED JUNE 27, 2008.

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.

PROSPECTUS

GEOVAX LABS, INC.

40,161,020 Shares of Common Stock

This prospectus relates to the sale of up to 40,161,020 shares of our common stock, $0.001 par value, by Fusion Capital Fund II, LLC. Fusion Capital is sometimes referred to in this prospectus as the selling stockholder. The prices at which Fusion Capital may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of our shares by Fusion Capital.

Our common stock is registered under Section 12(g) of the Securities Exchange Act of 1934 and quoted on the over-the-counter bulletin board under the symbol GOVX. On June 26, 2008, the last reported sale price for our common stock as reported on the over-the-counter bulletin board was $0.145 per share.

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

The selling stockholder is an underwriter within the meaning of the Securities Act of 1933, as amended.

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 July__, 2008

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

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

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

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PROSPECTUS SUMMARY

You should rely only on the information contained in this prospectus and in any prospectus supplement. 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. We have not authorized the selling stockholder to make an offer of these shares in any place where the offer is not permitted. The information appearing in this prospectus or any prospectus supplement is accurate only as of its date. Our business, financial condition, results of operations and prospects may have changed since that date.

Business

GeoVax Labs, Inc. is a clinical stage biotechnology company engaged in research and development activities with a mission to develop, license and commercialize the manufacture and sale of human vaccines for diseases caused by Human Immunodeficiency Virus (HIV) and other infectious agents. We have exclusively licensed from Emory University certain Acquired Immune Deficiency Syndrome (AIDS) vaccine technology that was developed in collaboration with the National Institutes of Health and the Centers for Disease Control and Prevention.

Our vaccines, initially developed by Dr. Harriet L. Robinson at Emory University in collaboration with researchers at the National Institutes of Health (NIH), National Institute of Allergy and Infectious Disease (NIAID), and the United States Centers for Disease Control (CDC), are recombinant DNA (deoxyribonucleic acid) and MVA (Modified Vaccinia Ankara) vaccines. Our focus is on developing AIDS vaccines comprising the major HIV-1 subtypes (A, B and C). These vaccines could be used alone or as combinations depending on a local infection. Subtype B is most common in North America, the EU, Japan and Australia and is our first priority.

When properly administered in series, these AIDS vaccines induce strong cellular and humoral immunity (protection) in non human primates against multiple HIV-1 proteins (AIDS virus components). This suggests that our vaccines could provide protection against the development of AIDS in HIV-1 virus infected people.

The Offering

On May 8, 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, an Illinois limited liability company (Fusion Capital). Under the purchase agreement, Fusion Capital is obligated, under certain conditions, to purchase shares from us in an aggregate amount of up to $10.0 million from time to time over a twenty-five (25) month period. Under the terms of the purchase agreement, Fusion Capital has received a commitment fee consisting of 2,480,510 shares of our common stock. Also, we will issue to Fusion Capital up to an additional 2,480,510 shares as a commitment fee pro rata as we receive the up to $10.0 million of future funding. As of June 26, 2008, 743,414,888 shares of our common stock were outstanding (including shares held by non-affiliates) excluding the up to 37,480,510 of the shares offered by Fusion Capital pursuant to this Prospectus which we have not yet issued to Fusion Capital. If all of such 37,480,510 shares were issued and outstanding as of the date hereof, the 40,161,020 shares offered hereby would represent 4.8% of the total common stock outstanding or 9.2% of the non-affiliate shares outstanding as of the date hereof. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the purchase agreement.

Under the purchase agreement and the related registration rights agreement we are required to register and have included in the offering pursuant to this Prospectus:

2,480,510 shares which were issued as a commitment fee;

200,000 shares which we issued to Fusion Capital as an expense reimbursement;

an additional 2,480,510 shares which we may issue in the future as a commitment fee pro rata as we receive the up to $10.0 million of future funding; and

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35.0 million shares which we may sell to Fusion Capital after this registration statement is declared effective under the Securities Act of 1933, as amended (the Securities Act).

All 40,161,020 shares are being offered pursuant to this Prospectus. Under the Purchase Agreement, we have the right but not the obligation to sell more than the 35.0 million shares to Fusion Capital. As of the date hereof, we do not have any plans or intent to sell to Fusion Capital any shares beyond this 35.0 million shares. However, if we elect to sell more than the 35.0 million shares, we must first register under the Securities Act any additional shares we may elect to sell to Fusion Capital before we can sell such additional shares, which could cause substantial dilution to our shareholders.

We do not have the right to commence any sales of our shares to Fusion Capital until the SEC has declared effective the registration statement of which this Prospectus is a part. After the SEC has declared effective such registration statement, generally we have the right but not the obligation from time to time to sell our shares to Fusion Capital in amounts between $80,000 and $1.0 million depending on certain conditions. We have the right to control the timing and amount of any sales of our shares to Fusion Capital, subject to certain limitations. The purchase price of the shares will be determined pursuant to a formula based upon the market price of our shares without any fixed discount at the time of each sale. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below $0.05. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the purchase agreement or the registration rights agreement. The purchase agreement may be terminated by us at any time at our discretion without any cost to us.

We were an Illinois corporation. On March 11, 2008 our Board of Directors determined that it would be in the best interests of our company and our shareholders to reincorporate in Delaware. In order to accomplish this reincorporation, we formed a corporation in Delaware called GeoVax Labs, Inc.

In conjunction with the reincorporation in Delaware our Board of Directors unanimously adopted and approved an Agreement and Plan of Merger of GeoVax Labs, Inc., an Illinois corporation, and GeoVax Labs, Inc., a Delaware corporation (the Reincorporation Merger Agreement). We submitted the reincorporation proposal to our shareholders by means of our definitive proxy statement dated April 25, 2008. The reincorporation was approved by our shareholders at our annual meeting on June 17, 2008. The reincorporation merger was consummated on June 18, 2008.

As used herein, GeoVax , the Company , we , our and similar terms include GeoVax Labs, Inc., an Illinois corporation, and its subsidiaries, and after the reincorporation includes GeoVax Labs, Inc., a Delaware corporation, unless the context indicates otherwise.

Our principal executive offices are located at 1256 Briarcliff Road NE, Atlanta, Georgia 30306. Our telephone number is (404) 727-0971. The address of our website is *www.geovax.com*. Information on our website is not part of this prospectus.

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RISK FACTORS

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

Risks Related to Our Financial Results and Need for Additional Financing

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

Our ability to generate revenue and achieve profitability depends on our ability to complete successfully the development of our product candidates, conduct preclinical tests and clinical trials, obtain the necessary regulatory approvals and manufacture and market the resulting products. We have had no product revenue to date. We have experienced operating losses since we began operations in 2001. As of March 31, 2008, we had an accumulated deficit of approximately $11.2 million. We expect to incur additional operating losses and expect cumulative losses to increase as our research and development, preclinical, clinical, manufacturing and marketing efforts expand.

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 government grants. We will require substantial additional financing at various intervals for our operations, including for clinical trials, for operating expenses including 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, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to some of our products or potential markets.

We only have the right to receive $80,000 every 4 business days under the agreement with Fusion Capital unless the market price of our stock equals or exceeds $0.11, in which case we can sell greater amounts to Fusion Capital as the market price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than $0.05. Since we are registering 35.0 million of our shares for sale to Fusion Capital, our sale price of these shares to Fusion Capital will have to average at least $0.286 per share for us to receive the maximum proceeds of $10.0 million. Assuming a sale price of $0.145 per share (the closing sale price of the common stock on June 26, 2008) and the purchase by Fusion Capital of the full 35.0 million shares under the common stock purchase agreement, proceeds to us would only be $5,075,000. unless we choose to register and sell more than 35.0 million shares, which we have the right, but not the obligation, to do. Subject to approval by our Board of Directors, we have the right but not the obligation to sell more than 35.0 million shares to Fusion Capital. In the event we elect to sell more than 35.0 million shares, we will be required to file a new registration statement and have it declared effective by the U.S. Securities & Exchange Commission.

The extent we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources, such as through the sale of our products. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business days that the stock sale price of our common stock is less than $0.05. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full $10.0 million under the common stock purchase agreement with Fusion Capital, we may still need additional capital

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to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be 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.

In order 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 research trials and have not been approved by any government agency for sale. If we cannot successfully develop and prove our products, and if we do not develop other sources of revenue, we will not become profitable and at some point we would discontinue operations.

We have sold no products or generated any product revenues and we do not anticipate any significant revenues to be generated in the foreseeable future.

We have conducted pre-clinical trials and are conducting clinical trials and will continue to do so for several more years before we are able to commercialize our technology. Although we have recognized revenues from government grants, there can be no assurance that we will ever generate significant product revenues.

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.

Whether our business will be successful will be dependent, in part, upon the leadership provided by our officers, particularly our Chairman, President and Chief Executive Officer, members of our Board of Directors and our primary scientist. The loss of the services of these individuals may have an adverse effect on our operations.

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

In order to manufacture and sell our products, we must comply with extensive international and domestic regulation. In order to sell our products in the United States, approval from the FDA is required. The FDA approval process is expensive and time-consuming. 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 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 products or that could render our products obsolete or noncompetitive. We expect most of these competitors to have substantially more resources than us. In addition, the pharmaceutical industry continues to experience consolidation, resulting in an increasing number of larger, more diversified companies than us. Among other things, these companies can spread their research and development costs over much broader revenue bases than we can and can influence customer and distributor buying decisions.

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Our products may not gain market acceptance among physicians, patients, healthcare payors 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

patent protection.

Our product candidates are based on new 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 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 or 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.

Because we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates.

We cannot commercialize any of our product candidates until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. The regulatory agencies may not complete their review processes in a timely manner and we may not obtain regulatory approval for any product candidate we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, if approval is obtained at all, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Regulatory approval processes outside the United States may include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

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 or 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 HIV Vaccine Trials Network (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 and 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

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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.

Unsuccessful or delayed 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 products or technologies have been approved by the FDA for sales in the United States or 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 would prevent regulatory approval and restrict our ability to commercialize our technologies. 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, including California, Vermont, Maine, Minnesota, New Mexico and West Virginia, 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 Food and Drug Administration Modernization Act, or the FDMA, in order 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 study results in this registry. The Pharmaceutical Research and Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical studies publicly available and has 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 payors such as government health administration authorities, private health insurers, health maintenance organizations and other health care-related organizations. Reimbursement by such payors is presently undergoing reform and there is significant uncertainty at this time how this will affect sales of certain pharmaceutical products.

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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 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 payors are increasingly challenging the price and cost-effectiveness of medical products and services and litigation has been filed against a number of pharmaceutical companies in relation to these issues. Additionally, some uncertainty may exist as to the reimbursement status of newly approved injectable pharmaceutical products. Our products may not be considered cost effective or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an adequate return on our investment.

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

We expect to seek collaborations for the development and commercialization of product candidates in the future. The timing and terms of any collaboration will depend on the evaluation by prospective collaborators of the 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 would be forced to fund the entire development and commercialization of such product candidates, and we may not have the resources to do so. If resource constraints require us to enter into a collaboration 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 sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates.

We do not have experience in marketing or selling vaccines. We may be unable to establish satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our products. To obtain the expertise necessary to successfully market and sell our vaccines, 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.

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. 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

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 which market generic products focus their development efforts on products with expiring patents. Pharmaceutical companies, biotechnology companies, universities, research institutions or other third parties may have filed patent applications or may have been granted patents that cover aspects of our products or our licensors products, product candidates or other technologies.

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

stop or delay selling, manufacturing or using products that incorporate or are made using the challenged intellectual property;

pay damages; or

enter into licensing or royalty agreements that may not be available on acceptable terms, if at all.

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

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

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

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

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

The U.S. Patent and Trademark Office and the courts have not established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence

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and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

Risks Related to Our Common Stock

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 35.0 million shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital under this prospectus is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All 40,161,020 shares registered in this offering are expected to be freely tradable when sold pursuant to this prospectus. It is anticipated that shares registered in this offering will be sold over a period of up to 25 months from the date of this prospectus. The 2,480,510 shares issued as an initial commitment fee may not be sold by Fusion Capital until the earlier of 500 days from May 8, 2008, or the termination of the common stock purchase agreement, subject to certain exceptions. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately acquire all, some or none of the 37,480,510 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock.

The agreement with Fusion Capital may adversely impact our other fundraising initiatives.

The sale of a substantial number of shares of our common stock under this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

The market price of our common stock is highly volatile.

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

Our common stock is and likely will remain subject to the SEC s Penny Stock rules, which may make our shares more difficult to sell.

Because the price of our common stock is currently and may remain less than $5.00 per share, it is classified as a penny stock. The SEC rules regarding penny stocks may have the effect of reducing trading activity in our shares, making it more difficult for investors to sell. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

make a special written suitability determination for the purchaser;

receive the purchaser s written agreement to a transaction prior to sale;

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provide the purchaser with risk disclosure documents which identify certain risks associated with investing in penny stocks and which describe the market for these penny stocks as well as a purchaser s legal remedies;

obtain a signed and dated acknowledgement from the purchaser demonstrating that the purchaser has received the required risk disclosure document before a transaction in a penny stock can be completed; and

give bid and offer quotations and broker and salesperson compensation information to the customer orally or in writing before or with the confirmation.

These rules make it more difficult for broker-dealers to effectuate customer transactions and trading activity in our securities and may result in a lower trading volume of our common stock and lower trading prices.

The sale of our common stock to Fusion Capital may not be possible when we need it, thus limiting our ability to continue our product development and commercialization.

We cannot begin sales of our common stock to Fusion Capital until the effectiveness of the registration statement of which this prospectus is a part, and the common stock purchase agreement may be terminated in the event of a default under the agreement. In addition, we may not require Fusion Capital to purchase any shares of our common stock if the purchase price is less than $0.05 per share. Thus, we may be unable to sell shares of our common stock to Fusion Capital when we need the funds, and that could severely harm our business and financial condition and our ability to continue to develop and commercialize our products. See The Fusion Transaction.

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FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes forward-looking statements as defined in the Private Securities Reform Act of 1995. These forward-looking statements are often identified by words such as may, will, expect, intend, anticipate, believe, estimate, continue, plan and similar expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including:

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

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

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

We have sold no products or generated any product revenues and we do not anticipate any significant revenues to be generated in the foreseeable future;

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;

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

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;

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

Because we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates;

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

Unsuccessful or delayed regulatory approvals required to exploit the commercial potential of our products could increase our future development costs or impair our future sales;

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;

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

We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates;

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

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;

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The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline; and

Our common stock is and may remain subject to the SEC s Penny Stock rules, which may make our shares more difficult to sell.

You should also consider carefully the statements under Risk Factors and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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BUSINESS

GeoVax is a clinical stage biotechnology company engaged in research and development activities with a mission to develop, license and commercialize the manufacture and sale of human vaccines for diseases caused by Human Immunodeficiency Virus (HIV) and other infectious agents. We have exclusively licensed from Emory University certain Acquired Immune Deficiency Syndrome (AIDS) vaccine technology that was developed in collaboration with the National Institutes of Health and the Centers for Disease Control and Prevention.

GeoVax was originally incorporated under the name of Dauphin Technology, Inc. (Dauphin). Until December 2003, Dauphin marketed mobile hand-held, pen-based computers and broadband set-top boxes and provided private, interactive cable systems to the extended stay hospitality industry. Dauphin was unsuccessful and its operations were terminated in December 2003. On September 28, 2006, Dauphin completed a merger (the Merger) with GeoVax, Inc. Pursuant to the Agreement and Plan of Merger, GeoVax, Inc. merged with and into GeoVax Acquisition Corp., a wholly-owned subsidiary of Dauphin. As a result of the Merger, the shareholders of GeoVax, Inc. exchanged their shares of common stock for Dauphin common stock and GeoVax, Inc. became a wholly-owned subsidiary of Dauphin. In connection with the Merger, Dauphin changed its name to GeoVax Labs, Inc., replaced most of its officers and directors with those of GeoVax, Inc. and moved its offices to Atlanta, Georgia. On June 18, 2008, we consummated a reincorporation merger pursuant to which we became a Delaware corporation. GeoVax, Inc. remains in existence as our wholly-owned subsidiary and conducts most of our business. We currently do not plan to conduct any business other than GeoVax, Inc. s business of developing new products for the treatment or prevention of human diseases.

Overview of HIV/AIDS

What is HIV?

HIV (human immunodeficiency virus) is a retrovirus that carries its genetic code in the form of RNA (ribonucleic acid). Retroviruses use RNA and the reverse transcriptase enzyme to create DNA (deoxyribonucleic acid) from the RNA template. The HIV virus invades a human cell and produces its viral DNA which is subsequently inserted into the genetic material (chromosomes) of the cell. This infection converts helper T-cells (a type of white blood cell) from immunity producing cells into cells that produce and release HIV virus particles into the blood stream destroying the immune defense system of the individual.

There are several AIDS-causing HIV-1 virus subtypes, or clades , that are found in different regions of the world. These subtypes are identified as subtype A, subtype B on through C, D, E, F, etc. The predominant subtype found in Europe, North America, South America, Japan and Australia is B whereas the predominant subtypes in Africa are A and C. In India the predominant subtype is C. Each subtype is at least 20% different in its genetic sequence from other subtypes. These differences may mean that vaccines against one subtype may only be partially effective against other subtypes.

HIV-1, even within subtypes, has a high rate of variation or mutation. In drug treatment programs, virus mutation can result in virus escape, thereby rendering drug therapy ineffective. Hence, multi-drug therapy is very important. If several drugs are active against virus replication, the virus must undergo multiple simultaneous mutations to escape which is very unlikely. The same is true for immune responses. HIV-1 can escape single target immune responses. However, if an immune response is directed against multiple targets (epitopes), virus escape is much less frequent. Vaccination against more than one of the proteins found in HIV-1 maximizes the number of targets for the immune response and increases the chance that HIV will not escape the vaccine-stimulated immune response, thus resulting in protection against clinical AIDS.

What is AIDS?

AIDS is the final, life-threatening stage of infection with the virus known as HIV-1. Infection with HIV-1 severely damages the immune system, the body s defense against disease. HIV-1 infects and gradually destroys T-cells and macrophages, white blood cells that play key roles in protecting humans against infectious disease caused by viruses, bacteria, fungi and other micro-organisms.

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Opportunistic infections by organisms, normally posing no problem for control by a healthy immune system, can ravage persons with immune systems damaged by HIV-1 infections. Destruction of the immune system occurs over years; the average onset of the clinical disease recognized as AIDS occurs after 3-10 years of HIV-1 infection but can be earlier or later.

AIDS in humans was first identified in the US in 1981, but researchers believe that it was present in Central Africa as early as 1959. AIDS is most often transmitted sexually from one person to another but it is also transmitted by blood in shared needles (drug users) and through pregnancy and childbirth. Heterosexual activity is the most frequent route of transmission worldwide.

Viral load is the best indicator of the speed with which an individual will progress to AIDS, as well as the frequency with which an individual will spread infection. An estimated 1% or fewer of those infected have low enough levels of the virus to preclude progression to disease and to not transmit the infection (they are called long-term non-progressors).

AIDS is considered by many in the scientific and medical community to be the most lethal infectious disease in the world. According to the 2007 Report on the Global AIDS Epidemic published by UNAIDS (the Joint United Nations Programme on HIV/AIDS), the total number of people living with HIV is 33.2 million globally with approximately 2.5 million infected in 2007 alone, the most recent year reported. Approximately 25 million people infected with HIV have died since the start of the HIV pandemic in 1981. According to International AIDS Vaccine Research Institute (IAVI) in a model developed with Advanced Marketing Commitment (AMC) dated June 2005, the global market for a safe and effective AIDS vaccine is estimated at approximately $4 billion.

The standard approach to treating HIV infection has been to lower viral loads by using drugs, reverse transcriptase inhibitors (RTIs) and protease inhibitors (PIs), or a combination of these drugs, to inhibit two of the viral enzymes that are necessary for the virus to reproduce. However, HIV is prone to genetic changes that can produce strains of HIV that are resistant to currently approved RTIs and PIs. HIV that is resistant to one drug within a class can become resistant to the entire class, meaning that it may be impossible to re-establish suppression of a genetically altered strain by substituting different RTI and PI combinations. Furthermore, these treatments continue to have significant limitations, such as viral resistance, toxicity and patient non-adherence to the treatment regimens. As a result, over time, many patients develop intolerance to these medications or simply give up taking the medications due to the side effects.

According to the International AIDS Vaccine Initiative, the cost and complexity of new treatment advances for AIDS puts them out of reach for most people in the countries where treatment is needed the most and as noted above, in industrialized nations, where drugs are more readily available, side effects and increased rates of viral resistance have raised concerns about their long term use. AIDS vaccines, therefore, are seen by many as the most promising way to end the HIV/AIDS pandemic. It is expected that vaccines for HIV/AIDS, once developed, will be used internationally by any organization that provides health care services, including hospitals, medical clinics, the military, prisons and schools.

AIDS Vaccines Being Developed by the Company

Our vaccines, initially developed by Dr. Harriet Robinson at Emory University in collaboration with researchers at the United States National Institutes of Health (NIH) National Institute of Allergy and Infectious Disease (NIAID), and the United States Centers for Disease Control (CDC), are recombinant DNA (deoxyribonucleic acid) and MVA (Modified Vaccinia Ankara) vaccines. Our focus is on developing AIDS vaccines comprising the major HIV-1 subtypes (A, B and C). These vaccines could be used alone or as combinations depending on a local infection. Subtype B is most common in North America, the EU, Japan and Australia and is our first priority.

When properly administered in series, these AIDS vaccines induce strong cellular and humoral immunity against the two major HIV-1 proteins, Gag and Env. In non human primate models vaccinations have been done in non-infected macaque monkeys to prevent the development of disease should they become infected (Preventative Vaccination) as well as in already infected macaque monkeys who are on drugs to allow control of virus in the absence of drugs (Therapeutic Vaccination). Both applications have met with success. The preventative

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immunizations have controlled both SHIV (chimeras of SIV and HIV virus) and SIV infections. The therapeutic vaccine, which has only been tested with SIV infections, is most effective when the vaccination regimen is initiated before the destruction of the immune system by the infection.

Because of the difficulty raising antibodies that are capable of totally blocking natural HIV-1 infections, the GeoVax vaccine approach has focused on raising cellular immune responses in addition to antibodies, which together better control HIV-1 infections (prevent AIDS) than either alone. Vaccine induced cellular immune responses are mediated by white blood cells in the body called T-cells that recognize and respond to the presence of foreign proteins presented by an infection such as the HIV-1 virus. CD8 T-cells directly combat these infections by destroying HIV infected cells, while CD4 T-cells provide growth factors that support activation and maintenance of CD8 T-cell responses. Proteins produced in the cells of a person are the best substrates for raising CD8 T-cell responses. GeoVax vaccines are expressed in cells of the vaccinated person by genetically engineered DNA vaccines and live viral vector MVA vaccines.

Our method of stimulating high T-cell frequencies and antibodies in the vaccinated person is to combine DNA vaccine priming with a recombinant live virus MVA vaccine boost. This prime/boost combination elicits protective immune responses in preclinical monkey models and holds high promise for eliciting responses that will protect humans against the development of HIV/AIDS.

DNA as the Priming Vaccine

Proteins that are produced in host cells of the body are the best substrates for raising CD8 T-cell responses. The GeoVax vaccine achieves this cellular stimulation by using DNA vaccines and/or live viral vectors (MVA) as a system to stimulate T-cells to destroy HIV-1 viruses when they appear in the body. An effective method for stimulating high frequencies of T-cells in conjunction with antibodies is to combine DNA priming of the immune response with a recombinant live virus vectored booster (rMVA) of the immune response.

Priming with GeoVax s HIV-1/DNA vaccine focuses the immune response on the HIV-1 components (proteins) expressed by the DNA The proteins expressed by the DNA pose no known risk for infection because they comprise only part of the AIDS virus. The DNA prime is followed by injection of GeoVax s HIV-1/MVA live virus vector booster which enhances the primed response in two ways by expressing larger amounts of antigen than can be achieved with DNA alone, and by the infection stimulating pro-inflammatory response that enhances immunity in the individual.

MVA Booster Vaccine

MVA was chosen as the poxvirus vector to boost immunity induced by GeoVax DNA priming vaccination because of its safety features and because of the excellent protective responses that it has stimulated in preclinical (non-human primate) models.

MVA was originally developed as a safe smallpox vaccine for use in immuno-compromised humans by further attenuating the standard smallpox vaccine. During this attenuation (loss of disease causing ability), MVA also lost essentially all of its ability to replicate in human cells. The attenuation was accomplished by making over 500 passages of the virus in chicken embryos or chick embryo fibroblasts (CEF). During passage, the virus underwent 6 large genomic deletions. These deletions affected the ability of MVA to replicate and cause safety problems in humans, but did not compromise the ability of MVA to grow on avian cells that are required for manufacturing the virus.

The effectiveness of MVA as a vaccine vector is also accounted for by its loss of immune evasion genes during its passages in CEF cells. During the years of the dreaded human smallpox epidemics these immune evasion genes assisted the spread of smallpox infections, even in the presence of human immune responses.

MVA was safely administered to over 120,000 people in the 1970 s to protect them against smallpox. With the advent of bioterrorism, our choice of the MVA vector becomes even more important, because of its potential for immunization for smallpox. GeoVax HIV vaccines may serve as both an HIV and a smallpox vaccine.

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GeoVax s DNA and MVA vaccines express over 66% of the AIDS virus (HIV-1) protein components in order to stimulate a broad anti-HIV immune response. The vaccines cannot cause AIDS because they do not include complete virus. We believe that the vaccines provide multi-target protection against the AIDS virus, thus largely limiting virus escape, large scale viral replication and the onset of clinical signs of AIDS in the vaccinated individual.

Preclinical Studies

Our vaccines underwent efficacy trials in non-human primates for a period of over 42 months. The GeoVax prototype DNA and MVA AIDS vaccines successfully protected rhesus macaque monkeys against AIDS when a highly virulent AIDS inducing virus (SHIV, a hybrid of simian and human immunodeficiency virus) was administered to the monkeys seven months after vaccination. In these pre-clinical trials the vaccines caused no significant side effects and 22 out of 23 monkeys were protected against AIDS while 5 out of 6 non-vaccinated control animals died of clinical AIDS. This level of control is comparable to the intrinsic viral control exhibited by the approximately 1% of the human population that become infected with the HIV virus, but who do not develop clinical signs of AIDS (long-term non-progressors). Over 66% of the AIDS virus proteins are expressed by our DNA and MVA vaccines in vaccinated individuals. This broad coverage of HIV components is anticipated to stimulate broad protective responses in the vaccinated individual thus preventing clinical disease.

Following these animal trials, our vaccines were approved for Phase I trials in humans by the U.S. Food and Drug Administration (FDA). This preclinical work enabling development of the clinical evaluation of our DNA and MVA vaccines was funded and supported by the NIAID. (See Government Regulation below for an explanation of how clinical trials are conducted.)

Phase I Human Clinical Trials

A Phase I clinical study in humans, evaluating our DNA-AIDS vaccine for safety began in January 2003 and was satisfactorily concluded in June 2004. This trial was conducted by the HIV Vaccine Trials Network (HVTN), consortium of trial sites supported by the United States National Institutes of Health.

The start of a series of four additional human trials evaluating our AIDS vaccines at four locations in the United States began in April 2006. These Phase Ia/Ib human trials are designed to determine if our vaccines are safe and will stimulate the level of immune responses (T-cell and antibody) that may protect against the development of clinical signs of AIDS. These trials are intended to provide human data that indicates our vaccine is safe and that it has the potential to protect vaccinated individuals against the development of AIDS.

The first of these four trials evaluated a low dose (1/10th of the vaccine dose) vaccination program. Results from this trial demonstrated excellent vaccine safety and positive anti-HIV-1 immune responses to the vaccine in 7 of 9 participants who received the vaccine. All trial participants were normal, healthy individuals.

The second of four trials, initiated in September 2006, was designed to evaluate results from full dose administration of our HIV/AIDS vaccines. The results indicate excellent safety in this full dose trial with positive immune response data in 88% of the 26 vaccine recipients who completed the trial. This trial protocol included vaccination with two full-doses of GeoVax s DNA vaccine to prime the immune response followed by two full-doses of GeoVax s MVA vaccine to boost the immune response. From data collected from the 26 participants who completed this trial, the following positive conclusions were observed:

- GeoVax HIV/AIDS vaccines, both DNA and MVA, continue to demonstrate that they are quite safe and immunogenic;
- The full-dose regimen of GeoVax vaccines continues to be well tolerated without any type of reaction, mild or systemic, in the majority of participants;
- CD4 T-cell responses are high in both the low and full-dose regimens, 84% and 78% of participants;
- CD8 T-cell responses are present in 42% of the full-dose recipients and 33% of the 1/10th dose recipients;

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Antibody responses to the envelope glycoprotein (Env) increased following the fourth vaccination, and were present in 88% of the full-dose participants; and

Delivery of the fourth vaccination increased the frequency and magnitude of the CD8 T-cell and antibody responses.

In July 2007, we began the third and fourth of this series of Phase I human clinical trials. The third trial is designed to evaluate a single dose DNA prime followed by two MVA boosts, while the fourth trial will utilize only GeoVax s MVA vaccine in a three dose regimen. These trials are continuing with excellent safety results thus far; immunogenicity results are anticipated later in 2008.

All of our Phase I human clinical trials have been conducted by the HIV Vaccine Trials Network (HVTN). The HVTN, funded and supported by the NIH, is the largest worldwide clinical trials program devoted to the development and testing of HIV/AIDS vaccines.

Phase II Human Clinical Trials

Due to the promising positive human vaccine response data from our Phase I trials, the HVTN, together with GeoVax, have accelerated their plans to conduct Phase II human trials on our AIDS vaccines. We expect the Phase II trials to commence during the third quarter of 2008. Plans are for a 225-person trial (150 vaccine recipients and 75 placebo recipients) in low risk individuals at several sites in the United States, evaluating our DNA and MVA vaccines in a four-dose regimen similar to the regimen in our most recent trials.

Support from the NIH

All of our human clinical trials to date have been conducted by, and at the expense of, the HIV Vaccine Trials Network (HVTN), a division of the National Institutes of Health-National Institute of Allergy & Infectious Disease (NIH-NIAID). Our responsibility for these trials has been to provide sufficient supplies of vaccine materials and technical expertise when necessary. The HVTN is also planning to conduct our planned Phase II human clinical trials.

In September 2007, we were the recipient of a $15.0 million Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) Grant to support our HIV/AIDS vaccine program. This large grant was awarded by the NIH-NIAID. The grant funding period is over a five year period commencing October 2007. Only meritorious HIV/AIDS prevention vaccine candidates are considered to receive an IPCAVD award. Candidate companies are highly scrutinized and must supply substantial positive AIDS vaccine data to support their application. IPCAVD grants are awarded on a competitive basis and are designed to support later stage vaccine research, development and human trials. We are utilizing this funding to further our HIV/AIDS vaccine development, optimization, production and human clinical trial testing.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in our ongoing research and development activities and in the manufacture of our products under development. Complying with these regulations involves a considerable amount of time and expense.

In the United States, drugs are subject to rigorous federal and state regulation. The Federal Food, Drug and Cosmetic Act, as amended (the FDC Act), and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of medications and medical devices. Product development and approval within this regulatory framework is difficult to predict, takes a number of years and involves great expense.

The steps required before a pharmaceutical agent may be marketed in the United States include:

pre-clinical laboratory tests, in vivo pre-clinical studies and formulation studies;

the submission to the FDA of an Investigational New Drug Application (IND) for human clinical testing which must become effective before human clinical trials can commence;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;

the submission of a New Drug Application to the FDA; and

FDA approval of the New Drug Application prior to any commercial sale or shipment of the product.

Each of these steps is described further below.

In addition to obtaining FDA approval for each product, each domestic manufacturing establishment must be registered with, and approved by, the FDA. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with the FDA s Good Manufacturing Practices for products, drugs and devices.

Pre-clinical Trials

Pre-clinical testing includes laboratory evaluation of chemistry and formulation, as well as cell culture and animal studies to assess the potential safety and efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices. The results of pre-clinical testing are submitted to the FDA as part of the IND application and are reviewed by the FDA prior to the commencement of human clinical trials. Unless the FDA objects to an IND, the IND becomes effective 30 days following its receipt by the FDA.

Clinical Trials

Clinical trials involve the administration of the AIDS vaccines to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with the FDA s Good Clinical Practices standard under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution where the study will be conducted. The institutional review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the product into healthy human subjects, the vaccine is tested for safety (adverse side effects) and dosage tolerance. Phase II is the proof of principal stage and involves studies in a limited patient population in order to determine the efficacy of the product for specific, targeted indications, determine dosage tolerance and optimal dosage and identify possible adverse side effects and safety risks. When there is evidence that the product may be effective and has an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to test for safety within an expanded patient population at geographically dispersed multi-center clinical study sites. The manufacturer or the FDA may suspend clinical trials at any time if either believes that the individuals participating in the trials are being exposed to unacceptable health risks.

New Drug Application and FDA Approval Process

The results and details of the pre-clinical studies and clinical studies are submitted to the FDA in the form of a New Drug Application. If the New Drug Application is approved, the manufacturer may market the pr