Geovax Labs, Inc.
Form 10-K
March 14, 2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
For fiscal year ended December 31, 2007

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

Commission File No. 000-52091
GEOVAX LABS, INC.
(Exact name of Registrant as specified in its charter)

Illinois	**87-0455038**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification Number)*
1256 Briarcliff Road NE Atlanta, GA	**30306**
(Address of principal executive offices)	*(Zip Code)*

Registrant s telephone number, including area code:
(404) 727-0971

Securities registered pursuant to Section 12(g) of the Act:
Common Stock $.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. (1) Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

The aggregate market value of common stock held by non-affiliates of the Registrant on June 30, 2007, the last business day of the registrant s most recently completed second fiscal quarter, based on the closing price on that date of $0.28, was $94,649,045.

As of March 10, 2008, the number of shares of the registrant s common stock, $.001 par value, is 731,827,926 issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The proxy statement of the registrant with respect to its 2008 Annual Meeting of Shareholders is incorporated by reference in Part III.

GEOVAX LABS, INC.

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SAFE HARBOR STATEMENT

From time to time, we make oral and written statements that may constitute forward-looking statements (rather than historical facts).

All statements in this Annual Report, that are not statements of historical fact are forward-looking statements, including any projections of financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential or could or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein and in documents incorporated by this Annual Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements.

Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth under the heading Risk Factors in this Annual Report, and including risks or uncertainties regarding the clinical testing required by regulatory authorities for products under development; the need for future clinical testing of our products under development; the significant time and expense that will be incurred in developing any of the potential commercial applications for our products; our ability to obtain capital to fund our current and future operations; and risks relating to the enforceability of any patents covering our products and to the possible infringement of third party patents by those products. All forward-looking statements included in this Annual Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements.

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PART I

Item 1. *Description of Business*

GeoVax Labs, Inc. was incorporated in 1988 in the state of Illinois. Our principal corporate offices are located in Atlanta, Georgia. As used herein, GeoVax , the Company , we , our and similar terms include GeoVax Labs, Inc. and subsidiaries, unless the context indicates otherwise.

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 which 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. 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 virus 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.

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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.

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 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. According to UNAIDS, over 40 million people are believed to be HIV-infected globally with infection rates continuing to rise.

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 2006 Report on the Global AIDS Epidemic published by UNAIDS (the Joint United Nations Programme on HIV/AIDS), the number of people living with HIV continues to grow, from 35 million in 2001 to approximately 38 million in 2005, the most recent year reported. Approximately 25 million people have died since the first cases of AIDS were identified in 1981 and, during 2005, approximately four million people became newly infected with HIV. According to an International AIDS Vaccine Research Institute (IAVI) report dated June 13, 2005, the global market for a safe and effective AIDS vaccine has been estimated at approximately $4 billion or greater.

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. Generally, HIV that is resistant to one drug within a class is likely to 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 complicated 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 and the difficult dosing regimens.

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 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

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the major HIV-1 subtypes (A, B and C). These vaccines will be able to 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 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 will provide protection against the development of AIDS in HIV-1 virus infected people.

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 can 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 initially focuses the immune response on the DNA components. This is followed by injection of GeoVax s HIV-1/rMVA live virus vector booster which enhances this immune 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 stimulated in preclinical (monkey) 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 the CEF 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), a division of NIAID-NIH.

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. Preliminary results from this blinded trial demonstrated excellent vaccine safety and positive anti-HIV-1 immune responses to the vaccine in 9 of 11 participants where 9 people received GeoVax HIV/AIDS vaccines and 2 received placebos. 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. Recent data indicates excellent safety in this full dose trial with positive immune response data in the majority of vaccine recipients. Involving 36 participants of which 30 received vaccine and 6 received placebo, 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

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CD8 T-cell responses are present in 42% of the full-dose recipients and 33% of the 1/10th dose recipients.

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

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 in mid-2008. Tentative plans are for a 500 person trial in low risk individuals at several sites in the United States., evaluating our DNA and MVA vaccines in a similar four dose regimen as was successfully implemented 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.

Also, in September 2007, we were the recipient of a $15 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 will utilize 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 regulation and, to a lesser extent, 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.

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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 product in the United States.

International Approval Whether or not the FDA has approved the drug, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval.

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Other Regulations

In addition to FDA regulations, our business activities may also be regulated by the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Violations of regulatory requirements at any stage may result in various adverse consequences, including regulatory delay in approving or refusal to approve a product, enforcement actions, including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions and/or civil or criminal penalties. Any product that we develop must receive all relevant regulatory approvals or clearances before it may be marketed.

Competition

There currently is no FDA licensed and commercialized AIDS vaccine or competitive vaccine available in the world market.

There are several small and large biopharmaceutical companies pursuing AIDS vaccine research and development, including Merck, Chiron, American Home Products, Wyeth, Sanofi-Aventis, Glaxo-Smith Kline and the National Institutes of Health (NIH) Vaccine Research Center [VRC]. Other AIDS vaccines are in varying stages of research, testing and clinical trials including those developed by Oxford University, International AIDS Vaccine Initiative (IAVI), Therion, IDT, FIT Biotech, AlphaVax, University of North Carolina, Yale University Institute for Human Virology, and a few others.

To our knowledge none of our competitors products have, to date, demonstrated the level of protection and duration of protection (in large scale non-human primate trials) elicited by GeoVax s vaccines. Furthermore, some of the AIDS vaccines developed by our competitors require as many as eight or more vaccinations per person, which we believe will lead to patients failing to adhere to their vaccination schedule. Also, many competitor vaccine development programs require very complicated vaccine compositions. For all of these reasons, we believe that it may be possible for our vaccine to compete successfully in the marketplace, if it is approved for sale.

Overall, the biopharmaceutical industry is competitive and subject to rapid and substantial technological change.. Developments by others may render our proposed vaccination technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of the pharmaceutical companies that compete with us have significantly greater research and development capabilities than we have, as well as substantially more marketing, manufacturing, and financial resources. In addition, acquisitions of, or investments in, small pharmaceutical or biotechnology companies by such large corporations could increase their research, financial, marketing, manufacturing and other resources. Competitor technologies may ultimately prove to be safer, more effective or less costly than any vaccine that we develop.

FDA and other regulatory approvals of our vaccines have not yet been obtained and we have not yet generated any revenues from product sales. Our future competitive position depends on our ability to obtain FDA and other regulatory approvals of our vaccines and to license or sell the vaccines to third parties on favorable terms.

Intellectual Property

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are described by valid and enforceable patents or are effectively maintained as trade secrets. Accordingly, we are pursuing and will continue to pursue patent protection for our proprietary technologies developed

through our collaboration between Emory University, the NIH, and the CDC, or developed by us alone. Patent applications have been filed with the United States Patent and Trademark Office and in specific international markets (countries). Patent applications include provisions to cover our DNA and MVA based AIDS vaccines, their genetic inserts expressing multiple HIV protein components, composition, structure, claim of immunization against multiple subtypes of HIV, routes of administration, safety and other

related factors. Patent claims filed for our vaccines include provisions for protection against two diseases: HIV/AIDS and smallpox.

We are the exclusive, worldwide licensee of several patents and other technologies (the Emory Technology) owned or otherwise controlled by Emory University (Emory) pursuant to a License Agreement originally entered into on August 23, 2002 and restated on June 23, 2004 (the License Agreement). The License Agreement expires on the expiration date of the last to expire of the patents licensed thereunder. Currently several of these patents are approved, but not issued by the Patent and Trademark Office (PTO), with several patents pending in other countries, thus until such patents are issued, we will not know the final termination date of the License Agreement.

We may not use the Emory Technology for any purpose other than the purposes permitted by the License Agreement, allow any person to access or use the Emory Technology, or advertise, market, sell or distribute the Emory Technology. Emory also reserved the right to use the Emory Technology for research, educational and non-commercial clinical purposes. Due to the use of federal funds in the development of the Emory Technology, the United States Government has the irrevocable, royalty-free, paid-up right to practice and have practiced certain patents throughout the world, should it choose to exercise such rights.

We are also the exclusive licensee of five patents from MFD, Inc. (the MFD Patents) pursuant to a license agreement dated December 26, 2004 (the MFD License Agreement), related to certain manufacturing processes used in the production of our vaccines. Pursuant to the MFD License Agreement, we obtained a fully paid, worldwide, irrevocable, exclusive license in and to the MFD Patents to use, market, offer for sale, sell, lease and import for any AIDS and smallpox vaccine made with GeoVax technology and non-exclusive rights for other products. The term of the MFD License Agreement ends on the expiration date of the last to expire of the MFD Patents. These patents expire in 2017 through 2019.

We are also a non-exclusive licensee of four patents owned by the NIH related to the ability of our MVA vector vaccine as a vehicle to deliver HIV virus antigens, and also to induce an immune response in humans. These are key licensed patents for the use of MVA as a method for delivering our HIV-1 antigens as an AIDS vaccine. The license agreement with NIH (the NIH License Agreement) was entered into on July 10, 2003 and subsequently amended on April 7, 2004. Pursuant to the NIH License Agreement, we licensed the patent rights and certain materials for the purpose of laboratory experiments conducted to evaluate the suitability for commercial development of the patent rights and materials. The NIH License Agreement is expected to continue on an annual renewable basis.

In addition to patent protection, we also attempt to protect our proprietary products, processes and other information by relying on trade secrets and non-disclosure agreements with our employees, consultants and certain other persons who have access to such products, processes and information. Under the agreements, all inventions conceived by employees are our exclusive property. Nevertheless, there can be no assurance that these agreements will afford significant protection against misappropriation or unauthorized disclosure of our trade secrets and confidential information.

We cannot be certain that any of the current pending patent applications we have licensed, or any new patent applications we may file or license, will ever be issued in the United States or any other country. Even if issued, there can be no assurance that those patents will be sufficiently broad to prevent others from using our products or processes. Furthermore, our patents, as well as those we have licensed or may license in the future, may be held invalid or unenforceable by a court, or third parties could obtain patents that we would need to either license or to design around, which we may be unable to do. Current and future competitors may have licensed or filed patent applications or received patents, and may acquire additional patents and proprietary rights relating to products or processes competitive with ours.

We are not a party to any litigation, opposition, interference, or other potentially adverse proceeding with regard to our patent positions. However, if we become involved in litigation, interference proceedings, oppositions or other intellectual property proceedings, for example as a result of an alleged infringement, or a third-party alleging an earlier date of invention, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we could be subject to liability for damages, invalidation of our

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intellectual property and injunctive relief that could prevent us from using technologies or developing products, any of which could have a significant adverse effect on our business financial condition and results of operation. In addition, any claims relating to the infringement of third-party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, divert management s attention and resources and require us to enter royalty or license agreements which are not advantageous if available at all.

Manufacturing

We do not have the facilities or expertise to manufacture any of the clinical or commercial supplies of any of our products. To be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at an acceptable cost. To date, we have not commercialized any products, nor have we demonstrated that we can manufacture commercial quantities of our product candidates in accordance with regulatory requirements. If we cannot manufacture products in suitable quantities and in accordance with regulatory standards, either on our own or through contracts with third parties, it may delay clinical trials, regulatory approvals and marketing efforts for such products. Such delays could adversely affect our competitive position and our chances of achieving profitability. We cannot be sure that we can manufacture, either on our own or through contracts with third parties, such products at a cost or in quantities which are commercially viable.

We currently rely and intend to continue to rely on third-party contract manufacturers to produce vaccines needed for research and clinical trials. We have entered into arrangements with two third party manufacturers for the supply of our DNA and MVA vaccines for use in our planned clinical trials. These suppliers operate under current Good Manufacturing Practice and guidelines established by the FDA and the European Medicines Agency. We anticipate that these suppliers will be able to provide sufficient vaccine supplies to complete our currently planned clinical trials. Various contractors are generally available in the United States and Europe for manufacture of vaccines for clinical trial evaluation, however, it may be difficult to replace existing contractors for certain manufacturing and testing activities and costs for contracted services may increase substantially if we switch to other contractors.

Research and Development

Our expenditures for research and development activities were approximately $1,757,000, $666,000 and $1,641,000 during the years ended December 31, 2007, 2006 and 2005, respectively. As our vaccines continue to go through the process to obtain regulatory approval, we expect our research and development costs to continue to increase significantly as even larger human trials proceed in the United States and foreign countries.

Employees

As of March 10, 2008, we had ten employees. None our employees are covered by collective bargaining agreements and we believe that our employee relations are good.

Available Information

Our website address is www.geovax.com. We make available on this website under Investors SEC Reports, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the U.S. Securities and Exchange Commission (SEC). We also make available on this website under the heading Investors Corporate Governance our Code of Ethics.

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Item 1A. *Risk Factors*

We face a number of substantial risks. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. The following factors should be considered in connection with the other information contained in this Annual Report on Form 10-K, 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 may not generate revenue or achieve profitability in the future.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, 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 December 31, 2007, we had an accumulated deficit of approximately $10.5 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 may 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.

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 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. There can be no assurance that we will ever generate significant 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

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and our primary scientist, Dr. Harriet Robinson. The loss of the services of these individuals may have an adverse effect 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 obtain than FDA approval. 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.

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.

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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 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 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.

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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 r