

GeoVax Labs, Inc.
Form 10-K
March 18, 2013

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934.
For fiscal year ended December 31, 2012

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)

Delaware 87-0455038
(State or other jurisdiction of (IRS Employer
incorporation or organization) Identification Number)

1900 Lake Park Drive, Suite 380
Smyrna, GA 30080
(Address of principal executive offices) (Zip Code)

(678) 384-7220
Registrant's telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act:
None

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

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

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 No

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. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of

this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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.

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 definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer
 Smaller reporting company

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

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2012, based on the closing price on that date was \$10,176,944.

Number of shares of Common Stock outstanding as of March 15, 2013: 20,499,944.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement with respect to its 2013 Annual Meeting of Stockholders are incorporated by reference in Part III

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“SAFE HARBOR” STATEMENT

From time to time, we make oral and written statements that 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 financial performance, any statements regarding action by the FDA or other regulatory authorities, 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” negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein 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; the possibility that our products may not demonstrate adequate clinical performance or obtain market acceptance, 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 them.

PART I

ITEM 1. BUSINESS

Company Overview

GeoVax, Labs, Inc. was formed in 2001 and is a biotechnology company developing vaccines that prevent and fight human immunodeficiency virus (HIV). HIV infections result in acquired immunodeficiency syndrome (AIDs). We are incorporated in Delaware, and our offices and laboratory facilities are located in Smyrna, Georgia (metropolitan Atlanta).

Our vaccines are being evaluated to determine their potential to (a) prevent HIV infection and (b) to serve as a treatment for individuals who are already infected with HIV. These vaccines are currently being evaluated in human clinical trials.

Our most advanced vaccines under development are designed to function against the clade B subtype of the HIV virus that is prevalent in the Americas and western Europe. An estimated 3.3 million people are infected with clade B HIV virus worldwide, with 130,000 new infections each year (between 55,000 and 58,000 in the United States). The cost of treating HIV-infected individuals in the U.S. is estimated at \$500,000 for each infected individual over their lifetime.

Subject to the availability of funding support from governmental or nongovernmental organizations, we also plan to develop vaccines designed for use to combat the subtypes of HIV that predominate in the developing countries. We have licensed from the U.S. National Institutes of Health (NIH) the modified vaccinia Ankara (MVA) construct for the clade C version of HIV prevalent in South Africa and India, and have begun early development work a vaccine for this subtype of the virus.

Work on our vaccines began during the 1990s at Emory University in Atlanta, Georgia, under the direction of Dr. Harriet L. Robinson, who is now our Chief Scientific Officer. Our vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the U.S. Centers for Disease Control and Prevention (CDC). The technology developed by the collaboration is exclusively licensed to us from Emory University. We also have nonexclusive licenses to certain patents owned by the NIH and exclusive license rights to certain manufacturing process patents of MFD, Inc.

Our Vaccine Pipeline

The following table summarizes key information regarding our vaccine candidates:

Vaccine Candidate	Indication	Stage of Development	Clinical Trial Sponsor
Clade B Vaccines (Americas, Western Europe)			
DNA/MVA	Prevention	Clinical – Phase 2a completed	NIH/HVTN
DNA-G/MVA	Prevention (2nd generation)	Clinical – Phase 1	NIH/HVTN
		Planning – Phase 2 efficacy	NIH/HVTN
DNA/MVA	Therapeutic (treatment interruption)	Clinical – Phase 1/2	GeoVax

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DNA-G/MVA	Therapeutic (drug combo)	Planning – Phase 1	NIH/IMPAACT
Clade C Vaccines (South Africa, India)			
DNA-G/MVA	Prevention	Research/Preclinical	n/a
DNA-G/MVA	Therapeutic	Research/Preclinical	n/a

Our clade B preventive vaccines are being tested in humans by the HIV Vaccine Trials Network (HVTN) and are funded by the NIH. The first generation of our preventive vaccine is one of only 5 vaccine candidates out of more than 90 tested by the HVTN to have successfully progressed to Phase 2 clinical testing. In Phase 1 human trials in uninfected people (150 total participants), our vaccines showed excellent safety and induced both anti-viral antibodies and anti-viral T cells.

A 300 participant Phase 2a clinical trial of our preventive vaccine (HVTN 205) further tested safety and immunogenicity of the two most promising regimens evaluated in Phase 1: (1) Priming with DNA at months 0 and 2 and boosting with MVA at months 4 and 6 (DDMM regimen) and (2) priming and boosting with MVA at months 0, 2 and 6 (MMM regimen). The HVTN 205 trial was completed in 2012 and was the subject of an oral presentation at the AIDS Vaccine 2012 Conference in September 2012. The Phase 2a trial confirmed the Phase 1 results, setting the stage for Phase 2 efficacy trials. We expect formal publication of the full study results by the end of 2013.

The NIH and HVTN are also sponsoring and conducting a Phase 1 clinical trial of a new version of our preventive vaccine. GeoVax's second-generation vaccines include the use of an adjuvant together with our DNA/MVA vaccine. Adjuvants are additives to vaccines that improve vaccine efficacy. One of these, granulocyte-macrophage colony-stimulating factor (GM-CSF), a normal human protein that stimulates the first stages of immune responses, has shown particular promise. When GM-CSF is co-expressed in our DNA priming vaccine, with a subsequent boost with our MVA vaccine, the vaccine achieved 70% prevention of infection with a >90% reduction in the per exposure risk of transmission in a study employing 12 successive weekly exposures to simian immunodeficiency virus (The Journal of Infectious Diseases 204:164 (2011)). The 48-participant Phase 1 trial is fully enrolled and we expect it to be completed in late 2013. Pending successful outcome of this trial, we expect to carry forward this version of our preventive vaccine into Phase 2 efficacy testing. We have begun discussions about protocol development and funding for the Phase 2 trial with potential government sponsors.

Our therapeutic vaccine is currently in a pilot Phase 1/2 clinical trial in HIV-positive individuals who are on standard-of-care drug therapy with well-controlled infections. Through a "treatment interruption" protocol, this 9-participant trial is investigating the concept of removing patients from drug therapy following inoculation with our vaccine to evaluate how well our vaccine may stimulate the patient's own immune system to successfully control their infection. We have completed patient enrollment of this study and expect to begin generating data in late 2013, which might indicate the potential use of our vaccines to treat HIV infection, either as a standalone therapy or in conjunction with an oral drug regimen.

We are also planning a Phase 1 clinical trial to investigate the use of our therapeutic vaccine in combination with standard-of-care drug therapy in young adults. We expect this trial to be conducted by the International Maternal Pediatric Adolescent AIDS Clinical Trial Group (IMPAACT) with financial support from the NIH. The NIH has recently prioritized searching for a cure for those individuals who are HIV positive. Because of the mechanisms by which current oral drugs work, if the virus is in a latent phase these drugs are not effective, thus it is impossible to totally eradicate the virus. Current approaches to a cure include using an effective vaccine and oral medication together to more effectively eradicate the virus. This trial has been assigned a clinical study number (P-1082) and we expect that this study will commence in mid-2013.

Background – Viruses and Vaccines

What are Viruses? Viruses are microscopic organisms consisting of genetic material comprised of deoxyribonucleic acid ("DNA") or ribonucleic acid ("RNA"), surrounded by a protein, lipid (fat), or glycoprotein coat. Viruses invade healthy, living host cells in order to replicate and spread. In many cases, the body's immune system can recognize and effectively combat an infection caused by a virus. However, with certain viral infections, the body's immune system is unable to fully destroy or inhibit the replication of the virus, which results in persistent and ongoing viral replication resulting in disease.

Infections caused by viruses can be chronic or acute. Chronic infections, such as those caused by HIV, do not typically self-resolve with time and can cause chronic disease. Acute infections associated with viruses, such as influenza, generally last for a relatively short period of time, and self-resolve in most immuno-competent individuals.

Viruses can also be characterized as either active or latent. An active virus can cause a persistent infection or disease over an extended period of time. A latent virus will remain in the body for very long periods of time after the initial infection and generally will only cause disease when the body's immune system weakens, fails or is suppressed, allowing the virus to once again replicate. Vaccines have been widely used to prevent active viral infections from occurring.

Viruses that develop resistance to antiviral drugs are increasingly becoming a challenge in the treatment of viral infections, particularly those that are chronic in nature. The ability of viruses to mutate spontaneously during replication allows drug-resistant strains to emerge when patients are using drugs that are not potent enough to quickly and completely inhibit viral replication. Drug resistance occurs because viruses continually replicate making millions of copies of themselves, some of which contain mutations in their genetic material. Mutations that emerge in the presence of a suppressive antiviral drug will give rise to mutant strains that are wholly or partially resistant to that drug. These mutant viruses, while initially low in number, eventually become the predominant strain in an infected patient as those strains that remain susceptible to the drug are inhibited from replicating. Once this occurs, the treatment benefit of that particular antiviral drug often diminishes, resulting in treatment failure and the need for an alternate therapy with different or possibly new drugs, or classes of drugs. In general, viruses that cause chronic infections, such as HIV, are more likely to develop drug resistance due to the long-term and persistent exposure of the virus to the antiviral therapy.

What are Vaccines? Vaccines represent an approach to broaden the ability to prevent serious infectious diseases caused by both viruses and bacteria. A vaccine is a substance introduced into the human body that teaches the immune system to detect and destroy a pathogen (a virus or bacterium that causes disease). All vaccines contain some harmless form or part of the pathogen they target. They exert their effects through the adaptive immune response, an arm of the immune system that learns to recognize and neutralize specific pathogens.

There are several types of vaccines:

- **Whole-killed/Whole-inactivated vaccines:** The active ingredient in these vaccines is an intact virus or bacterium that has been killed or otherwise stripped of its ability to infect humans. Examples include the cholera and injectable polio vaccines. This approach has not been applied to the development of vaccines against HIV due to the small but inevitable risk that the viruses harvested for such preparations may not all have been killed or adequately inactivated.
- **Live attenuated vaccines:** These vaccines use a form of the targeted pathogen that is highly unlikely to be harmful—one capable, say, of multiplying, but not causing disease. Examples include the measles vaccine and the oral vaccine against polio, which has been widely deployed in global eradication efforts. Such vaccines can be very effective because they closely mimic the behavior of the targeted pathogen, giving the immune system a truer picture of what it would be up against. Due to the risk that attenuated HIV might revert to its disease-causing form, this approach has not been applied to the development of human AIDS vaccines.
- **Subunit vaccines:** Vaccines of this variety are composed of purified pieces of the pathogen (known as antigens) that generate a vigorous, protective immune response. Common subunit vaccines include the seasonal flu and hepatitis B vaccines. This approach was employed to devise the first AIDS vaccine candidate tested in humans, which failed to induce protection from HIV infection.
- **DNA vaccines:** These vaccine candidates are also designed to train the immune system to recognize a piece of the targeted bacterium or virus. The difference is that the active ingredients are not the purified antigens themselves but circles of DNA, called plasmids, that carry genes encoding those antigens. Human cells passively take up these plasmids and produce the antigens that, in turn, train the immune system to recognize the targeted pathogen.
- **Recombinant vector vaccines:** These vaccines, like DNA vaccines, introduce genes for targeted antigens into the body. But the genes are inserted into a virus that actively infects human cells. The viruses chosen as vectors are safe to use because they do not ordinarily cause disease in humans and/or have been stripped of their ability to proliferate.

Overview of HIV/AIDS

What is HIV? HIV is a retrovirus that carries its genetic code in the form of ribonucleic acid, or RNA. Retroviruses use RNA and the reverse transcriptase enzyme to create DNA from the RNA template. The HIV-1 virus invades human cells and produces its viral DNA that is subsequently inserted into the chromosomes, which are the genetic material of a cell. HIV preferentially infects and replicates in T-cells, which are a type of white blood cell. Infection of T-cells alters them from immunity mediating cells to cells that produce and release HIV. This process results in the destruction of the immune defense system of infected individuals and ultimately, the development of AIDS.

There are several AIDS-causing HIV virus subtypes, or clades, that are found in different regions of the world. These clades are identified as clade A, clade B and so on. The predominant clade found in Europe, North America, parts of South America, Japan and Australia is clade B whereas the predominant clades in Africa are clades A and C. In India the predominant clade is clade C. Each clade differs by at least 20% with respect to its genetic sequence from other clades. These differences may mean that vaccines or treatments developed against HIV of one clade may only be partially effective or ineffective against HIV of other clades. Thus there is often a geographical focus to designing and developing vaccines suited for the local clade.

HIV, even within clades, has a high rate of mutation that supports a significant level of genetic variation. In drug treatment programs, virus mutation can result in the development of drug resistance, referred to as virus drug escape, thereby rendering drug therapy ineffective. Hence, we believe that 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 less likely. The same is true for immune responses. HIV can escape single targeted immune responses. However, our scientists believe if an immune response is directed against multiple targets, which are referred to as epitopes, virus escape is much less frequent. Vaccination against more than one of the proteins found in HIV increases the number of targets for the immune response as well as the chance that HIV will not escape the vaccine-stimulated immune

response, thus resulting in protection against infection or the development of clinical AIDS once infection occurs.

What is AIDS? AIDS is the final, life-threatening stage of infection with the virus known as HIV. Infection with HIV severely damages the immune system, the body's defense against disease. HIV infects and gradually destroys T-cells and macrophages, which are 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 infections. Destruction of the immune system occurs over years. The average onset of the clinical disease recognized as AIDS occurs after three to ten years of HIV infection if the virus is not treated effectively with drugs, but the time to developing AIDS is highly variable.

AIDS in humans was first identified in the United States 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 and through pregnancy and childbirth. Heterosexual activity is the most frequent route of transmission worldwide.

The level of virus in blood, known as viral load, is the best indicator of the speed with which an individual will progress to AIDS and 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 AIDS and to not transmit the infection. These individuals are commonly called elite controllers or 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 2011 World AIDS Day Report published by UNAIDS, the Joint United Nations Programme on HIV/AIDS, at the end of 2010, an estimated 34 million people were living with HIV worldwide, with approximately 2.7 million newly infected in 2010 alone. Approximately 25 million people infected with HIV have died since the 1981 start of the HIV pandemic. The United States currently suffers about 56,000 infections per year.

At present, the standard approach to treating HIV infection is to inhibit viral replication through the use of combinations of drugs. Available drugs include reverse transcriptase inhibitors, protease inhibitors, integration inhibitors and inhibitors of cell entry to block multiple essential steps in virus replication. However, HIV is prone to genetic changes that can produce strains that are resistant to currently approved drugs. When HIV acquires resistance to one drug within a class, it can often become resistant to the entire class, meaning that it may be impossible to re-establish control of a genetically altered strain by substituting different drugs in the same class. Furthermore, these treatments continue to have significant limitations which include toxicity, patient non-adherence to the treatment regimens and cost. 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 (IAVI), the cost and complexity of new treatment advances for AIDS puts them out of reach for most people in the countries where treatment is most needed, 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 universally and administered worldwide by organizations that provide health care services, including hospitals, medical clinics, the military, prisons and schools.

Our Vaccine Candidates

Our vaccines, initially developed by our Chief Scientific Officer, Dr. Harriet L. Robinson at Emory University in collaboration with scientists at the NIH and the CDC, incorporate two vaccine delivery components: (1) a recombinant DNA (deoxyribonucleic acid) and (2) a recombinant poxvirus, known as MVA (modified vaccinia Ankara), both of which deliver genes that encode inactivated HIV derived proteins to the immune system. Both the DNA and MVA vaccines contain sufficient HIV genes to support the production of non-infectious virus-like particles which display the native trimeric membrane-bound form of the viral envelope glycoprotein that appears authentic to the immune system. When used together, the recombinant DNA component is used to prime the immune response, which is then boosted by administration of the recombinant MVA component. However, in certain settings the recombinant MVA alone may be sufficient for priming and boosting the immune responses.

Our initial work focused on the development of a preventive vaccine for use in uninfected humans to prevent infection should they be exposed to the virus. Later, based on encouraging data in preclinical primate models, we undertook the development of a therapeutic vaccine for use in HIV infected humans to supplement approved drug regimens. For

both preventive and therapeutic applications, our primary focus is on a vaccine for use against clade B, which is common in the United States and the industrially developed world. However, if efficacy is documented against clade B, we plan to develop vaccines designed for use to combat the subtypes of HIV that predominate in developing countries, including clades A, C and an AG recombinant. We have licensed from the NIH the MVA construct for the clade C version of HIV prevalent in South Africa and India, and have begun early development work on a vaccine for this subtype of the virus.

Induction of T-cell and Antibody Immune Responses. In both preclinical and clinical trials, our vaccines induce both anti-viral antibody and T-cell responses. The induction of both antibodies and T-cells is beneficial because these immune responses work through different mechanisms. Antibodies can prevent infection by blocking viruses from infecting cells. In preclinical vaccine studies using repeated rectal challenges with moderate doses of virus, the avidity, or tightness, of antibody binding to the surface envelope glycoprotein of HIV correlates with the prevention of infection (*The Journal of Infectious Diseases*, 204:164 (2011)). In high dose challenges that infect all animals at the first exposure, the avidity of the antibody for envelope glycoprotein correlates with reduced levels of virus replication (*Journal of Virology*, 83:4102 (2009)). These results likely reflect the tightly binding antibody both blocking infection as well as tagging the virus and infected cells for destruction. Our vaccines elicit CD8 T-cells, a type of T-cell that can recognize and kill cells that become infected by virus. CD8 T-cells are important for the control of the virus that has established an infection. In our therapeutic vaccinations, our vaccines elicit high frequencies of CD8 T-cells with the functional characteristics of CD8 T-cells associated with control of viral infections in individuals termed “elite controllers”. Elite controllers, who constitute less than 1% of all HIV-infected individuals, enjoy years of disease-free life without the use of drugs.

DNA and MVA as Vaccine Vectors. Both the DNA and MVA vaccines produce virus-like particles containing the three major proteins of HIV. The virus-like particles cannot cause disease because they were designed with mutated or deleted enzymatic functions that are essential for virus replication. The virus-like particles display trimeric membrane bound forms of the HIV envelope glycoprotein (Env). This is important because the natural form of the envelope glycoprotein elicits antibody capable of recognizing incoming virus and blocking infections. Expression of multiple proteins by the vaccine is important because each protein provides targets for cytotoxic T-cells. Elicitation of a multi-target T-cell response limits immune escape, just as multi-drug therapies limit drug escape.

Figure 1. Electron micrographs showing the virus-like-particles (VLPs) produced by GeoVax recombinant DNA and recombinant MVA vaccines. For the DNA Prime, VLPs are seen budding from a DNA-expressing cell. For the MVA boost, fully formed particles as well as a budding particle are shown. The VLPs display trimeric membrane-bound forms of the viral envelope glycoprotein (Env). This is an important feature of the vaccine because display of the normal Env means that the antibody elicited by the vaccine can recognize the Env on incoming viruses. The VLPs are immature and are rendered non-infectious by deletion of essential genes and introduction of inactivating mutations in essential viral enzymes.

MVA was selected for use as the live viral component of our vaccines because of its well established safety record and because of the ability of this vector to carry sufficient HIV proteins to produce virus-like particles. MVA was originally developed as a safer smallpox vaccine for use in immune compromised humans. It was developed by attenuating the standard smallpox vaccine by making over 500 passages of the virus in chicken embryos or chick embryo fibroblasts which resulted in large genomic deletions. These deletions limited the ability of MVA to replicate in human cells, which can cause safety problems, but did not compromise the ability of MVA to grow on avian cells that are used for manufacturing the virus. The deletions also resulted in the loss of immune evasion genes which assist the spread of wild type smallpox infections, even in the presence of human immune responses. MVA was safely administered to over 120,000 people in the 1970s as a smallpox vaccine.

The availability of DNA and MVA vaccine delivery vectors provides GeoVax with the means to use combination vaccines that induce different patterns of T-cell and antibody responses. Specifically, the use of DNA to prime immune responses and MVA to boost immune responses elicits high levels of T-cells and thus could be particularly well-suited for therapeutic uses. Alternatively, the use of MVA to both prime and boost the immune response elicits higher levels of antibodies and therefore could be well-suited for use in prevention. The DNA prime also facilitates expressing genetic adjuvants, which are co-expressed by the vaccine vector with HIV proteins, at the site of immunization. This has proven to be particularly effective in our work using GM-CSF as an adjuvant in which a single DNA expresses both virus-like particles and GM-CSF. By co-expressing GM-CSF and HIV proteins in the DNA vaccine, GM-CSF is present at the site of the HIV vaccination where it enhances the ability of the vaccine to elicit blocking antibodies for the HIV virus. Blocking antibodies can stop a virus before it infects cells.

Preclinical Studies. During the development of our preventive vaccines, preclinical efficacy trials were conducted by vaccinating non-human primates with simian immunodeficiency virus prototypes of our HIV vaccines and then testing them for resistance to simian immunodeficiency virus. The experimental data produced by these trials documented the ability of the simian prototypes of our vaccines to induce immune responses that can prevent infection as well as reduce the levels of viral replication in those animals that become infected.

GeoVax's second-generation vaccines include the use of adjuvants together with our DNA/MVA vaccine. Adjuvants are additives to vaccines that improve vaccine efficacy. One of these, GM-CSF, a normal human protein that stimulates the first stages of immune responses, has shown particular promise. In normal humans, GM-CSF stimulates the expansion and differentiation of cells in the macrophage and dendritic cell lineages that promote immune responses. The use of GM-CSF in humans is anticipated to have good safety based on its licensure for stimulating production of white blood cells after autologous bone marrow transplantation, as a treatment for fungal infections, and as an adjuvant for the Provenge® prostate cancer vaccine. In preclinical studies in non-human primates, co-expression of GM-CSF in a simian prototype of the DNA vaccine improved the ability of the vaccine to prevent infection. In a study employing 12 successive weekly exposures to simian immunodeficiency virus (SIV), vaccinating in the presence of co-expressed GM-CSF prevented infection in 70% of the animals for a 90% reduction in per exposure risk of transmission, whereas vaccinating in the absence of the co-expressed GM-CSF prevented infection in only 25% of animals and achieved a less effective 60% reduction in the per exposure risk of transmission (The Journal of Infectious Diseases, 204:164 (2011)).

Survivors from this first series of exposures were rested a year, boosted once with the MVA vaccine, and then exposed to a 2nd series of challenges (Figure 2). Greater than 90% reduction in risk of infection per exposure was achieved against the 2nd series of exposures. Survivors of this 2nd series of exposures were again rested for 6 months and then exposed to a 3rd series of challenges. Again, 94% reduction in risk of infection per exposure was achieved. The 1st two series of exposures were to SIVE660, a virus that has neutralization characteristics like viruses undergoing transmission in the current epidemic. The 3rd series of challenges was with SIV251, a virus that is considered the most potent SIV used in nonhuman primate studies and is an outlier in its high resistance to neutralization.

Figure 2. Schematic of serial exposures testing vaccine efficacy. Heavy vertical arrows indicate vaccinations, clusters of thin arrows, serial exposures. Exposures to virus were rectal to mimic mucosal transmissions. Protection against the 3rd series of exposures is shown in Figure 3C below.

To our knowledge, the level of protection achieved by the simian prototype for the GeoVax GM-CSF-adjuvanted HIV vaccine is unprecedented and far better than has been achieved with simian prototypes of other vaccines currently in, or slated for efficacy trials (see Figure 3 below). Figure 3A shows prevention of serial infections by the vaccine currently in efficacy trials that was developed by the NIH Vaccine Research Center. This vaccine consists of priming with a DNA vaccine and boosting with a recombinant Adenovirus 5 vaccine (DNA/Ad5). When challenged with SIV251, vaccinated animals were infected more rapidly than the unvaccinated animals. Figure 3B shows a Johnson and Johnson (Crucell) vaccine developed at Harvard and tested in conjunction with the U.S. military. This vaccine initially provides some protection, however only 13% of the animals remained protected after 6 exposures to SIV251. Figure 3C shows data from serial exposures to the simian prototype for the GeoVax GM-CSF-co-expressing vaccine. This vaccine has provided a 72% per exposure reduction in risk of infection over 12 serial exposures.

Figure 3. Comparison of protection against serial exposures to SIV251 induced by vaccines undergoing or slated for efficacy trials.

A. Vaccine consisting of priming with a recombinant canarypox vaccine and boosting with a bivalent mixture of the gp120 subunit of the Env protein from HIV clades B and C. This vaccine regimen progressed to

Phase 3 human clinical testing in Thailand, yielding 31% protection.

B. Vaccine consisting of priming with an adenovirus 26 vaccine (Ad26) and boosting with an MVA vaccine developed by Harvard and the U.S. Military, owned by Johnson and Johnson (Crucell) and slated for an efficacy trial in South Africa.

C. GeoVax vaccine consisting of priming with a GM-CSF co-expressing DNA and boosting with MVA

Preclinical Studies – Therapeutic Vaccine. In 2007-2008, data were generated in three pilot studies on therapeutic vaccination in simian immunodeficiency virus-infected non-human primates. The vaccine used in these pilot studies was specific for simian immunodeficiency virus but with the design features of our HIV/AIDS vaccine. In these pilot studies, conducted at Yerkes National Primate Research Center of Emory University, non-human primates were infected, drug-treated, vaccinated and then drug-interrupted. Following treatment interruption, median levels of virus in blood, measured as viral RNA, were 10 to 1000-times lower (overall median of 100-times lower) than those measured prior to drug and vaccine treatment. The therapeutic reductions in virus levels were associated with the vaccination regimen eliciting T-cells (a form of white blood cell) with functional characteristics known to successfully control viral infections.

Preventive Vaccine — Phase 1 Human Clinical Trials. All of our preventive vaccination trials in humans have been conducted by the HIV Vaccine Trials Network (HVTN) a network that is funded and supported by the NIH. The HVTN is the largest worldwide clinical trials network focused on the development and testing of HIV/AIDS vaccines. The results of a two group, 30 participant, Phase 1 trial (designated HVTN 045) are published in *AIDS RESEARCH AND HUMAN RETROVIRUSES* 22:678 (2006) and of a four group 120 participant trial (HVTN 065) in *The Journal of Infectious Diseases* 203:610 (2011). Our Phase 1 trials have tested both safety and dosing regimens.

In our first Phase 1 clinical trial, HVTN 045, our DNA vaccine was tested without MVA boosting to document the safety of the DNA. Our second Phase 1 clinical trial, HVTN 065, was designed to test the combined use of DNA and MVA and consisted of a dose escalation as well as regimen studies. The low dose consisted of 0.3 mg of DNA and 1x10⁷ tissue culture infectious doses (TCID₅₀) of MVA. Once safety was demonstrated for the low dose in 10 participants, the full dose (3 mg of DNA and 1x10⁸ TCID₅₀ of MVA) was administered to 30 participants. A single dose of DNA at time 0 followed by MVA at weeks 8 and 24, a DMM regimen, and three doses of MVA administered at weeks 0, 8 and 24, an MMM regimen, were also tested in 30 participants each. Participants were followed for 12 months to assess vaccine safety and to measure vaccine-induced immune responses.

Data from the HVTN 065 trial again documented the safety of the vaccine products but also showed that the DDMM and MMM regimens induced different patterns of immune responses. The full dose DDMM regimen induced higher response rates of CD4+ T-cells (77%) and CD8+ T-cells (42%) compared to the MMM regimen (43% CD4 and 17% CD8 response rates). In contrast, the highest response rates and highest titers of antibodies to the HIV Env protein were induced in the group that received only the MVA using the MMM regimen. Antibody response rates were documented to be higher for the MMM group using three different assays designed to measure total binding antibody levels for an immune dominant portion of the Env protein (27% for DDMM and 75% for MMM), binding of

antibodies to the gp120 subunit of the envelope glycoprotein (81% for DDMM and 86% for MMM) and neutralizing antibodies (7% for DDMM and 30% for MMM). The 1/10th dose DDMM regimen induced overall similar T-cell responses but reduced antibody responses while the response rates were intermediate in the DMM group.

The HVTN is also sponsoring and conducting Phase 1 clinical testing in humans of a new version of our preventive vaccine that has substantially enhanced prevention of infection in non-human primates. This vaccine co-expresses GM-CSF as an adjuvant and achieved a much higher level of prevention of infection than our unadjuvanted vaccine in non-human primate testing. Prevention of infection is seen for serial challenges with tested animals being protected against more than 34 challenges administered over two and one-half years in a >3 year vaccine trial. The co-expressed GM-CSF enhances antibody responses with the enhanced prevention of infection correlating with enhanced tightness of binding of the antibody to the viral envelope glycoprotein that mediates HIV entry into cells. Commencement of a 48 participant Phase 1 clinical testing of the GM-CSF co-expressing vaccine in a trial designated HVTN 094 began in 2012 and is fully enrolled. The study will assess safety and immunogenicity of the adjuvanted vaccine at low-dose and full-dose regimens and is expected to be completed in late 2013. Pending successful outcome of this trial, we expect to carry forward this version of our preventive vaccine into Phase 2 efficacy testing.

Preventive Vaccine — Phase 2 Human Clinical Trials. Based on the safety and the immunogenicity results in the HVTN 045 and HVTN 065 trials, the full dose DNA/MVA and MVA-only regimens were selected for testing by the HVTN in a Phase 2a trial (designated HVTN 205) which was completed in 2012 and the subject of an oral presentation at the AIDS Vaccine 2012 Conference in September 2012. Both vaccine regimens appeared safe and well-tolerated. Similar to Phase 1 testing, the DNA/MVA regimen induced higher rates of T cell responses whereas the MVA-only regimen induced higher rates of antibody responses. Antibody responses to the HIV Envelope protein were seen in more than 90 percent of both groups. The Phase 2a trial confirmed Phase 1 results, setting the stage for Phase 2 efficacy trials. We expect formal publication of the full study results by the end of 2013.

Phase 2 Efficacy Trial Planning. Pending successful outcome of Phase 1 testing of our second generation vaccine (GM-CSF adjuvanted), we expect to carry forward this version of our preventive vaccine into Phase 2 efficacy testing. We are currently in discussions with the HVTN regarding protocol development for Phase 2 efficacy testing. Depending on government funding support and other considerations, the Phase 2 trial may have as many as 4,200 participants equally divided between placebo and vaccine groups, or it may be a multi-stage trial with additional study groups. We anticipate knowing more about the trial design and the government funding consortium in late 2013.

Therapeutic Vaccine — Human Clinical Trials. To help treat those people who are already infected with HIV, we are testing the feasibility of using our vaccine to supplement, or even eliminate, the need for antiretroviral therapeutic drugs in HIV-infected individuals. Antiretroviral therapeutic drugs, which are taken for life by individuals once infected with HIV, have side effects and are expensive, costing \$12,000 - \$15,000 per year (drug cost only, not including physician visits and related costs). And according to a 2010 study by the CDC, of those individuals in the United States who are diagnosed with HIV, only 35% ultimately achieve stable viral load suppression through drug treatment. Thus, even in the United States where the availability of drugs and treatment is good, there is still obvious compelling need for therapies that complement drugs.

Phase 1/2 Trial (Treatment Interruption). Based on encouraging preclinical data, we are conducting a pilot Phase 1/2 clinical trial in HIV-infected individuals who began successful antiretroviral drug treatment within 18 months of a negative HIV-1 antibody test. The primary goals of this clinical trial are to document the safety and immunogenicity of the vaccine in patients with well-controlled infections. Vaccine efficacy will be directly assessed through a brief period of anti-retroviral drug cessation. We have completed patient enrollment of this 9 participant study and expect to begin generating data in late 2013, which might indicate the potential use of our vaccines to treat HIV infection, either as a standalone therapy or in conjunction with an oral drug regimen.

Phase 1 Trial Planning (Drug Combo). We are also planning a Phase 1 clinical trial to investigate the use of our vaccine in combination with standard-of-care drug therapy in young adults. We expect this trial to be conducted by the International Maternal Pediatric Adolescent AIDS Clinical Trial Group (IMPAACT) with financial support from

the NIH. The NIH has recently prioritized searching for a cure for those individuals who are HIV positive. Because of the mechanisms by which current oral drugs work, if the virus is in a latent phase these drugs are not effective, thus it is impossible to totally eradicate the virus. Current approaches to a cure include using an effective vaccine and oral medication together to more effectively eradicate virus. This trial is planned to have two groups of 20 participants, one of which will remain on drugs while being vaccinated and the second of which will remain on drugs but receive placebo. The participants will be monitored for vaccine-associated reductions in viral reservoirs. This trial has been assigned a clinical study number (P-1082) and we expect it to begin in mid-2013.

Support from the United States Government

With the exception of the Phase 1/2 therapeutic trial (treatment interruption protocol), all of our human clinical trials to date have been conducted by the HVTN and funded by NIH. The NIH is also supporting the ongoing Phase 1 trial of our second generation vaccine (GM-CSF adjuvanted), and we anticipate their support for our planned Phase 1 trial with IMPAACT for the therapeutic use of our vaccine. Our responsibility for these clinical trials has been to provide sufficient supplies of vaccine materials and technical expertise when necessary. We are currently in discussions with the HVTN regarding protocol development and government support for Phase 2 efficacy testing of our preventive vaccine. We anticipate knowing more about the trial design and the government funding consortium in late 2013.

In September 2007, the NIH awarded us an Integrated Preclinical-Clinical AIDS Vaccine Development (IPCAVD) grant to support our HIV/AIDS vaccine program, which was subsequently amended such that the total award now totals approximately \$20.4 million. The original project period for the grant covered a five year period ending in August 2012, but was extended for an additional one year period. As of December 31, 2012, there was approximately \$1.6 million of this grant remaining and available for use. 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 and production.

In September 2012, the NIH awarded us an additional grant of \$1.9 million to support development of versions of our HIV/AIDS vaccines to address the clade C subtype of the HIV virus prevalent in the developing world. The project period of this grant covers a one year period ending in August 2013. There is approximately \$1.4 million from this grant remaining and available for use as of December 31, 2012.

Please refer to our Financial Statements at Item 15(a) of this report, and to Management's Discussion and Analysis of Financial Condition and Results of Operations at Item 7 of this report, for additional information regarding revenue.

Regulations

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, or 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 (IND) application 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.

Preclinical Testing. Pre-clinical testing includes laboratory evaluation of chemistry and formulation, as well as cell culture and animal studies to assess the safety and potential efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with the FDA's Good Laboratory Practices, or GLP. 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 HIV vaccines to volunteers or to patients under the supervision of a qualified, medically trained principal investigator. Clinical trials are conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the trial, 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 trial must be conducted under the auspices of an independent institutional review board at the institution where the trial 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 the Phase 1 clinical trial, the initial introduction of the product into healthy human subjects, the vaccine is tested for safety (including adverse side effects) and dosage tolerance. The Phase 2 clinical trial is the proof of principal stage and involves trials in a limited patient population to determine whether the product induces the desired effect (for our vaccines this means immune responses) and to better determine optimal dosage. The continued identification of possible safety risks is also a focus. When there is evidence that the product may be effective and has an acceptable safety profile in Phase 2 clinical trials, Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety within an expanded patient population. Phase 3 trials are completed using multiple clinical study sites which are geographically dispersed. 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 trials 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.

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.

Our Strategy

Our immediate goal is to bring both our preventive and therapeutic HIV/AIDS vaccines into efficacy testing, with the ultimate goal of becoming a leading biopharmaceutical company that develops differentiated products to prevent and treat serious infections, focusing on unmet medical needs. To achieve these strategic goals, we intend to employ the following strategies:

- Leverage the Support of Federal Government Agencies for Trials of our Preventive Vaccine. The NIH and HVTN have been very supportive of our efforts to date in developing our preventive vaccines, and we intend to continue to solicit their assistance and financial support for the efficacy testing of our preventive vaccines.
- Development of Our Therapeutic Vaccine Candidates. We plan to focus our resources on developing our therapeutic vaccines to show initial proof of efficacy in humans. We will leverage governmental support where possible.
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Seek the Support of Nongovernmental Organizations. We also intend to solicit the support of Nongovernmental Organizations (NGOs) toward the development of our vaccine candidates for the versions of the HIV virus prevalent in the developing world.

- Seek Strategic Collaborations to Accelerate the Development of Our Vaccine Candidates to Optimize Economic Returns while Managing Risk. We intend to establish strategic licenses and collaborations, partnerships, alliances or enter into other transactions in the future with pharmaceutical or biopharmaceutical companies with greater clinical development, manufacturing and commercialization capabilities that we believe can accelerate the development and/or commercialization of our vaccine candidates.
- New Business Opportunities. We will be open to new business development opportunities to potentially expand our technology and product pipeline or to otherwise provide additional revenue sources.

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 third party manufacturers for the supply of our DNA and MVA vaccines for use in our planned clinical trials. These suppliers operate under the FDA's Good Manufacturing Practices and similar regulations of 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.

Development of Improved Manufacturing Techniques for MVA – The MVA component of our vaccine is currently manufactured in cells that are cultured from embryonated chicken eggs. This is cumbersome and prone to contamination during the processing of the eggs required to make a large batch of vaccine. GeoVax has explored a number of approaches to growing MVA in continuous cell lines that can be grown in bioreactors. In this process we have identified a duck stem-cell-derived line (termed EB66), that is proprietary to Vivalis, Ltd, Nantes France. We are currently working with Vivalis on the use of EB66 cells for the growth of our MVA vaccines and are pleased with the results the collaboration is obtaining. We anticipate that by the time process development is complete we will be producing vaccine at significantly higher titers, allowing for quality improvements over the current process as well as meaningful cost reductions. The U.S. FDA has reviewed our early-stage plans for transitioning from MVA growth in egg-derived cells to a continuous cell line.

Competition

There currently is no FDA licensed and commercialized HIV/AIDS vaccine or competitive vaccine available in the world market. However, the market for vaccines that protect against or treat HIV/AIDS is intensely competitive and is subject to rapid and significant technological change. We will have numerous competitors in the United States and abroad, including large companies with substantially greater resources than us. These competitors may develop technologies and products that are more effective or less costly than any of our future technology or products or that could render our technology or products obsolete or noncompetitive.

There are several small and large biopharmaceutical companies pursuing HIV/AIDS vaccine research and development, including Novartis, Sanofi-Aventis and GlaxoSmithKline. Other HIV/AIDS vaccines are in varying stages of research, testing and clinical trials including those supported by the NIH Vaccine Research Center, the U.S. Military, IAVI, the European Vaccine Initiative, and the South African AIDS Vaccine Initiative. Following the reported failure of the vaccine developed by Merck & Co., Inc. in September 2007, Merck & Co., Inc.'s vaccine program and the NIH Vaccine Research Center vaccine program, both of which use Ad5 vectors, were placed on hold. Since then, the NIH Vaccine Research Center product has moved into an experimental Phase 2b clinical trial to learn

more about immune responses and AIDS control. This clinical trial has been restricted to individuals who do not have high levels of antibodies to the Ad5 vector used in the vaccine (approximately 50% of U.S. citizens) and to men who are circumcised.

In October 2009, the results from a Phase 3 community-based clinical trial in Thailand using a recombinant canarypox (designated ALVAC and produced by Sanofi Pasteur) as a priming vaccine and a bivalent mixture of the gp120 subunit of Env from HIV clades B and C (produced by VaxGen, Inc. and currently licensed to Global Solutions for Infectious Diseases) as a protein booster vaccine were reported. In this clinical trial, protection against HIV infection at the rate of 31% was reported. The results of this clinical trial are encouraging because they represent the first success of an AIDS vaccine in humans and demonstrate that a vaccine can provide protection against HIV infections.

To our knowledge, none of our competitors' products have been tested in large scale non-human primate trials that have included experimental infection through the rectal site and shown to induce levels of protection or duration of protection comparable to that achieved using experimental prototypes of GeoVax's vaccines. Furthermore, many of our competitors' vaccine development programs require vaccine compositions which are more complicated than ours. For these reasons, we believe that it may be possible for our vaccine to compete successfully in the marketplace if licensed.

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. Competitive 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.

Our 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 collaborations with Emory University, the NIH, and the CDC, or developed by us alone. Patent applications have been filed with the U.S. Patent and Trademark Office and in specific international markets (countries). Patent applications include provisions to cover our DNA and MVA based HIV 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 their therapeutic and prophylactic use against HIV and smallpox.

We are the exclusive, worldwide licensee of a number of patents and patent applications, which we refer to as the Emory Technology, owned, licensed or otherwise controlled by Emory University for HIV or smallpox vaccines pursuant to a License Agreement originally entered into on August 23, 2002 and restated on June 23, 2004, which we refer to as the Emory License. Through the Emory License we are also a non-exclusive licensee of four issued United States patents owned by the NIH related to the ability of our MVA vector vaccine to operate as a vehicle to deliver HIV virus antigens, and also to induce an immune response in humans. The four issued United States patents owned by the NIH expire in 2023. All of our obligations with respect to the NIH-owned MVA patents are covered by the Emory License. In addition to the issued United States patents owned by the NIH, and a recently issued patent owned by Emory University, there are six issued and five pending United States patent applications, 29 issued or pending patents in countries other than the United States. The Emory License expires on the expiration date of the last to expire of the patents licensed thereunder including those that are issued on patents currently pending. We will not know the final termination date of the Emory License until such patents are issued. The Company may terminate the Emory University License upon 90 days' written notice. The Emory License also contains standard provisions allowing Emory University to terminate upon breach of contract by the Company or upon the Company's bankruptcy.

The Emory License, among other contractual obligations, requires payments based on the following:

- **Milestone Payments.** An aggregate of \$3,450,000 is potentially due to Emory University in the future upon the achievement of clinical development and regulatory approval milestones as defined in the Emory License. To date, we have paid a nominal milestone fee upon entering Phase 2 clinical trials for our preventive HIV/AIDS vaccine.
- **Maintenance Fees.** The Company has achieved the specified milestones and met its obligations with regard to the related payments, and no maintenance fees are (or will be) owed to Emory University.
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Royalties. Upon commercialization of products covered by the Emory License, we will owe royalties to Emory University of between 5% and 7.5%, depending on annual sales volume, of net sales made directly by GeoVax. The Emory License also requires minimum annual royalty payments of \$3 million in the third year following product launch, increasing annually to \$12 million in the sixth year.

- Sublicense Royalties. In the event that we sublicense a covered product to a third party, we will owe royalties to Emory University based on all payments, cash or noncash, that we receive from our sublicensees. Those royalties will be 19% of all sublicensing consideration we receive prior to the first commercial sale of a related product. Commencing with the first commercial sale, the royalty owed to Emory University will be 27.5% of all sublicensing consideration we receive.

- **Patent Reimbursements.** During the term of the Emory License we are obligated to reimburse Emory University for ongoing third party costs in connection with the filing, prosecution and maintenance of patent applications subject to the Emory License. The expense associated with these ongoing patent cost reimbursements to Emory University amounted to \$89,885, \$249,907, and \$193,674 for the years ended December 31, 2012, 2011 and 2010, respectively.

We may only use the Emory Technology for therapeutic or prophylactic HIV or smallpox vaccines. Emory University 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 U.S. 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 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 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 conditions or results of operations. 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.

We are also the exclusive licensee of five patents from MFD, Inc., which we refer to as the MFD Patents, pursuant to a license agreement dated December 26, 2004 with MFD, Inc., which we refer to as 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 any AIDS and smallpox vaccine made with GeoVax Technology, as such term is defined in the MFD license agreement, 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, one of which expires in 2017. The license granted also extends to any and all current or future customers of GeoVax the right to commercially practice the GeoVax Technology, as such term is defined in the MFD license agreement, or any portion thereof. The license also extends to any and all current or future GeoVax Users, as such term is defined in the MFD license agreement, the right to use any GeoVax Technology, as such term is defined in the MFD license agreement.

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 these 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 or proprietary rights relating to products or

processes competitive to ours. 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 to us, if available at all.

Research and Development

Our expenditures for research and development activities were \$3,043,522, \$4,276,375, and \$4,793,956 during the years ended December 31, 2012, 2011 and 2010, 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 clinical trials proceed in the United States and foreign countries. We have not yet formulated any plans for marketing and sales of any vaccine candidate we may successfully develop. Compliance with environmental protection laws and regulations has not had a material effect on our capital expenditures, earnings or competitive position to date.

Properties and Employees

We lease approximately 8,400 square feet of office and laboratory space located at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia under a 62 month lease agreement which began November 1, 2009. We believe this space is adequate for our current needs. As of March 15, 2013, we had nine full-time employees. None of our employees are covered by collective bargaining agreements and we believe that our employee relations are good.

Background and Structure

Our primary business is conducted by our subsidiary, GeoVax, Inc., which was incorporated under the laws of Georgia in June 2001. The predecessor of our parent company, GeoVax Labs, Inc. (the reporting entity) was originally incorporated in June 1988 under the laws of Illinois as Dauphin Technology, Inc. (“Dauphin”). In September 2006, Dauphin completed a merger (the “Merger”) with GeoVax, Inc. As a result of the Merger, GeoVax, Inc. became a wholly-owned subsidiary of Dauphin, and Dauphin changed its name to GeoVax Labs, Inc. Unless otherwise indicated, information for periods prior to the September 2006 merger is that of GeoVax, Inc. In June 2008, the Company was reincorporated under the laws of Delaware. We currently do not conduct any business other than GeoVax, Inc.’s business of developing new products for the treatment or prevention of human diseases. Our principal offices are located in Smyrna, Georgia (metropolitan Atlanta).

Available Information

Our website address is www.geovax.com. We make available on this website under “Investors – SEC Reports,” free of charge, our proxy statements, 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 our Code of Ethics on this website under the heading “Investors–Corporate Governance”. Information contained on our website is not incorporated into this Form 10-K.

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 expect losses to continue for the foreseeable future.

We have had no product revenue to date and there can be no assurance that we will ever generate any product revenue. We have experienced operating losses since we began operations in 2001. As of December 31, 2012, we had an accumulated deficit of approximately \$24.8 million. We expect to incur additional operating losses and expect cumulative losses to increase as our research and development, pre-clinical, clinical, manufacturing and marketing efforts expand. Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of our product candidates, conduct pre-clinical tests and clinical trials, obtain the necessary regulatory approvals, and manufacture and market the resulting products. Unless we are able to successfully meet these challenges, we will not be profitable and may not remain in business.

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

To date, we have financed our operations principally through the private placement of equity securities and through NIH grants. We will require substantial additional financing at various intervals for our operations, including clinical trials, operating expenses, intellectual property protection and enforcement, for pursuit of regulatory approvals, and for establishing or contracting out manufacturing, marketing and sales functions. There is no assurance that such additional funding will be available on terms acceptable to us or at all. If we are not able to secure the significant funding that is required to maintain and continue our operations at current levels, or at levels that may be required in the future, we may be required to delay clinical studies or clinical trials, curtail operations, or obtain funds through collaborative arrangements that may require us to relinquish rights to some of our products or potential markets.

The costs of conducting all of our human clinical trials to date for our preventive HIV vaccine have been borne by the HVTN, funded by the NIH, and we expect NIH support for additional clinical trials. GeoVax incurs costs associated with manufacturing the clinical vaccine supplies and other study support. We cannot predict the level of support we will receive from the HVTN or the NIH for any additional clinical trials.

Our operations are also partially supported by the NIH grants awarded to us to support our HIV/AIDS vaccine program. As of December 31, 2012, there is approximately \$3.5 million of unused grant funds remaining and available for use through August 31, 2013. We intend to pursue additional grants from the federal government. However, as we progress to the later stages of our vaccine development activities, government financial support may be more difficult to obtain, or may not be available at all. Furthermore, there is some risk that actual funding for grants could be delayed, cut back, or eliminated due to government budget constraints. Therefore, it will be necessary for us to look to other sources of funding in order to finance our development activities.

Our current working capital, combined with proceeds from grants awarded to us from the NIH will be sufficient to support our planned level of operations into the first quarter of 2014. In order to meet our operating cash flow requirements we plan additional offerings of our equity securities, debt, or convertible debt instruments. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

The current economic conditions may adversely impact our ability to raise capital.

The recent recession and adverse conditions in the national and global markets may negatively affect both our ability to raise capital and our operations in the future. The volatile equity markets and adverse credit markets may make it difficult for us to raise capital or procure credit in the future to fund the growth of our business, which could have a negative impact on our business and results of operations.

Risks Related to Development and Commercialization of Product Candidates and Dependence on Third Parties

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

To become profitable, we must generate revenue through sales of our products. However our products are in varying stages of development and testing. Our products have not been proven in human clinical trials and have not been approved by any government agency for sale. If we cannot successfully develop and prove our products and processes, or if we do not develop other sources of revenue, we will not become profitable and at some point we would discontinue operations.

Whether we are successful will be dependent, in part, upon the leadership provided by our management. If we were to lose the services of any of these individuals, our business and operations may be adversely affected. Further, we may not carry key man life insurance on our executive officers or directors.

Whether our business will be successful will be dependent, in part, upon the leadership provided by our officers, particularly our President and Chief Executive Officer and our Chief Scientific Officer. The loss of the services of these individuals may have an adverse effect on our operations. Although we carry some key man life insurance on Dr. Harriet L. Robinson, the amount of such coverage may not be sufficient to offset any adverse economic effects on our operations and we do not carry key man insurance on any of our other executive officers or directors. Further, our employees, including our executive officers and directors, are not subject to any covenants not to compete against the Company, and our business could be adversely affected if any of our employees or directors engaged in an enterprise competitive with the Company.

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

To manufacture and sell our products, we must comply with extensive domestic and international regulation. In order to sell our products in the United States, approval from the FDA is required. Satisfaction of regulatory requirements, including FDA requirements, typically takes many years, and if approval is obtained at all, it is dependent upon the type, complexity and novelty of the product, and requires the expenditure of substantial resources. We cannot predict whether our products will be approved by the FDA. Even if they are approved, we cannot predict the time frame for approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to meet than FDA requirements. As with the FDA, we cannot predict if or when we may obtain these regulatory approvals. If we cannot demonstrate that our products can be used safely and successfully in a broad segment of the patient population on a long-term basis, our products would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

We will face intense competition and rapid technological change that could result in products that are superior to the products we will be commercializing or developing.

The market for vaccines that protect against or treat HIV/AIDS is intensely competitive and is subject to rapid and significant technological change. We will have numerous competitors in the United States and abroad, including, among others, large companies with substantially greater resources than us. These competitors may develop technologies and products that are more effective or less costly than any of our future technology or products or that could render our technology or products obsolete or noncompetitive. If our technology or products are not competitive, we may not be able to remain in business.

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

We are subject to the risks of failure inherent in the development of product candidates based on new medical technologies. These risks include the possibility that the products we create will not be effective, that our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals, and that our product candidates will be hard to manufacture on a large scale or will be uneconomical to market.

Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long term follow-up data may reveal additional complications associated with our products. The responses of potential physicians and others to information about complications could materially affect the market acceptance of our products, which in turn would materially harm our business.

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

We do not know whether planned clinical trials will begin on time or whether we will complete any of our clinical trials on schedule, if at all. Product development costs will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. Significant delays may adversely affect our financial results and the commercial prospects for our products, and delay our ability to become profitable.

We rely heavily on the HVTN, independent clinical investigators, and other third party service providers for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

Failure to obtain timely regulatory approvals required to exploit the commercial potential of our products could increase our future development costs or impair our future sales.

None of our vaccines are approved by the FDA for sale in the United States or by other regulatory authorities for sale in foreign countries. To exploit the commercial potential of our technologies, we are conducting and planning to

conduct additional pre-clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials could delay or preclude regulatory approval and restrict our ability to commercialize our technology or products. Any such failure may severely harm our business. In addition, any approvals we obtain may not cover all of the clinical indications for which approval is sought, or may contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post-approval study requirements.

State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

In recent years, several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless we are in full compliance with these laws, we could face enforcement action and fines and other penalties and could receive adverse publicity, all of which could harm our business.

We may be subject to new federal and state legislation to submit information on our open and completed clinical trials to public registries and databases.

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the FDA Modernization Act, or the FDMA, to promote public awareness of and access to these clinical trials. Under the FDMA, pharmaceutical manufacturers and other trial sponsors are required to post the general purpose of these trials, as well as the eligibility criteria, location and contact information of the trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of trials included in this or other registries, as well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those trials that have been registered with a no-cost, publicly accessible database, such as www.clinicaltrials.gov. Federal legislation was introduced in the fall of 2004 to expand www.clinicaltrials.gov and to require the inclusion of trial results in this registry. The Pharmaceutical Research and Manufacturers of America also issued voluntary principles for its members to make results from certain clinical trials publicly available and established a website for this purpose. Other groups have adopted or are considering similar proposals for clinical trial registration and the posting of clinical trial results. Failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines and other penalties, all of which could materially harm our business.

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

In both domestic and foreign markets, sales of our products will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations and other health care-related organizations. Reimbursement by such payers is presently undergoing reform and there is significant uncertainty at this time how this will affect sales of certain pharmaceutical products.

Medicare, Medicaid and other governmental healthcare programs govern drug coverage and reimbursement levels in the United States. Federal law requires all pharmaceutical manufacturers to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. Generic drug manufacturers' agreements with federal and state governments provide that the manufacturer will remit to each state Medicaid agency, on a quarterly basis, 11% of the average manufacturer price for generic products marketed and sold under abbreviated new drug applications covered by the state's Medicaid program. For proprietary products, which are marketed and sold under new drug applications, manufacturers are required to rebate the greater of (a) 15.1% of the average manufacturer price or (b) the difference between the average manufacturer price and the lowest manufacturer price for products sold during a specified period.

Both the federal and state governments in the United States, and foreign governments, continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any product developed in the future. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services and litigation has been filed against a number of pharmaceutical companies in relation to these issues. Additionally, some uncertainty may exist as to the reimbursement status of newly approved injectable pharmaceutical products. Our products may not be considered cost-effective or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an adequate return on our investment.

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

We expect to seek collaborations for the development and commercialization of product candidates in the future. The timing and terms of any collaboration will depend on the evaluation by prospective collaborators of the clinical trial results and other aspects of our vaccine's safety and efficacy profile. If we are unable to reach agreements with suitable collaborators for any product candidate, we will be forced to fund the entire development and commercialization of such product candidates, ourselves, and we may not have the resources to do so. If resource constraints require us to enter into a collaboration agreement early in the development of a product candidate, we may be forced to accept a more limited share of any revenues this product may eventually generate. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish collaborations or other alternative arrangements for any product candidate. Even if we are successful in establishing collaborations, we may not be able to ensure fulfillment by collaborators of their obligations or our expectations.

We do not have manufacturing, sales or marketing experience.

We do not have experience in manufacturing, selling, or marketing vaccines. To obtain the expertise necessary to successfully manufacture, market, and sell our vaccines, we will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

Our vaccines under development may not gain market acceptance.

Our vaccines may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Significant factors in determining whether we will be able to compete successfully include:

- the efficacy and safety of our vaccines;
- the time and scope of regulatory approval;
- reimbursement coverage from insurance companies and others;
- the price and cost-effectiveness of our products, and
- the ability to maintain patent protection.

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

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. We carry product liability insurance and we expect to continue such policies. However, product liability claims, regardless of their merits, could exceed policy limits, divert management's attention, and adversely affect our reputation and the demand for our products.

Risks Related to Our Intellectual Property

We could lose our license rights to our important intellectual property if we do not fulfill our contractual obligations to our licensors.

Our rights to significant parts of the technology we use in our vaccines are licensed from third parties and are subject to termination if we do not fulfill our contractual obligations to our licensors. Termination of intellectual property rights under any of our license agreements could adversely impact our ability to produce or protect our vaccines. Our obligations under our license agreements include requirements that we make milestone payments to our licensors upon the achievement of clinical development and regulatory approval milestones, royalties as we sell commercial products, and reimbursement of patent filing and maintenance expenses. Should we become bankrupt or otherwise unable to fulfill our contractual obligations, our licensors could terminate our rights to critical technology that we rely upon.

Other parties may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling products.

Our success will depend in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use and sale of new products have been subject to substantial patent rights litigation in the pharmaceutical industry. These lawsuits generally relate to the validity and infringement of patents or proprietary rights of third parties. Infringement litigation is prevalent with respect to generic versions of products for which the patent covering the brand name product is expiring, particularly since many companies that market generic products focus their development efforts on products with expiring patents. Pharmaceutical companies, biotechnology

companies, universities, research institutions or other third parties may have filed patent applications or may have been granted patents that cover aspects of our products or our licensors' products, product candidates or other technologies.

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

- stop or delay selling, manufacturing or using products that incorporate, or are made using the challenged intellectual property;
- pay damages; or
- 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 our 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, 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.

Neither the U.S. Patent and Trademark Office nor the courts have established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence 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 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. Certain factors, including announcements of new developments by us or other companies, regulatory matters, new or existing medicines 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 us, and subsequent sales 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 does not have a vigorous trading market and investors may not be able to sell their securities when desired.

We have a limited active public market for our common shares. A more active public market, allowing investors to buy and sell large quantities of our common stock, may never develop. Consequently, investors may not be able to

liquidate their investments in the event of an emergency or for any other reason.

We have never paid dividends and have no plans to do so.

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our Board of Directors. To date, we have paid no cash dividends on our shares of common stock and we do not expect to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any potential return investors may have in our common stock will be in the form of appreciation, if any, in the market value of their shares of common stock.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

We are subject to reporting obligations under the United States securities laws. The Securities and Exchange Commission, or the SEC, as required by the Sarbanes-Oxley Act of 2002, adopted rules requiring every public company to include a management report on such company's internal controls over financial reporting in its annual report. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to achieve and maintain effective internal controls over financial reporting could result in the loss of investor confidence in the reliability of our financial statements, which in turn could negatively impact the trading price of our stock.

If we fail to remain current in our reporting requirements, our securities could be removed from the OTC Market, which would limit the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

United States companies trading on the OTC Market must be reporting issuers under Section 12 of the Exchange Act, and must be current in their reports under Section 13. If we fail to remain current on our reporting requirements, we could be removed from the OTC Market. As a result, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

We expect to need additional capital, and the sale of additional shares or other equity securities could result in additional dilution to our stockholders.

We believe that our current cash and cash equivalents, combined with anticipated cash flow from our NIH grants, will be sufficient to meet our anticipated cash needs into the first quarter of 2014. In order to meet our operating cash flow requirements we plan additional offerings of our equity securities, debt, or convertible debt instruments. The sale of additional equity securities could result in additional dilution to our stockholders. Certain equity securities, such as convertible preferred stock, or warrants, may contain anti-dilution provisions which could result in the issuance of additional shares at lower prices if we sell other shares below specified prices. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We cannot assure investors that financing will be available in amounts or on terms acceptable to us, if at all.

Our directors and executive officers beneficially own a significant amount of our common stock and will be able to exercise significant influence on matters requiring stockholder approval.

Our directors and executive officers collectively beneficially own approximately 11.9% of our common stock as of March 15, 2013. Consequently, our directors and executive officers as a group are able to exert significant influence over the election of directors and the outcome of most corporate actions requiring stockholder approval and our business, which may have the effect of delaying or precluding a third party from acquiring control of us. Furthermore, Emory University beneficially owns 22.5% of our common stock as of March 15, 2013. If our directors and executive officers move to act in concert with Emory University, their ability to influence stockholder actions will be even more significant.

The exercise of warrants or options or conversion of our Series A Convertible Preferred Stock may depress our stock price and may result in significant dilution to our common stockholders.

There are a significant number of outstanding warrants and options to purchase our stock and we have issued Series A Convertible Preferred Stock that is convertible into our Common Stock. If the market price of our Common Stock exceeds the exercise price of outstanding warrants and options or the conversion price of the Series A Convertible Preferred Stock, holders of those securities may be likely to exercise their warrants and options or convert their preferred shares and sell the Common Stock acquired upon exercise or conversion of such securities, as applicable, in the open market. Sales of a substantial number of shares of our Common Stock in the public market by holders of warrants, options, or preferred shares may depress the prevailing market price for our Common Stock and could impair our ability to raise capital through the future sale of our equity securities. Additionally, if the holders of outstanding options, warrants, or preferred shares exercise those options or warrants or convert those preferred shares, as applicable, our common stockholders will incur dilution in their relative percentage ownership. The prospect of this possible dilution may also impact the price of our Common Stock.

Our outstanding warrants include warrants to purchase up to 7,033,332 shares of our Common Stock that were issued in March 2012. Of these, warrants to purchase up to 1,166,666 shares have an exercise price of \$0.60 per share, and warrants to purchase up to 5,866,666 shares have an exercise price of \$1.00 per share. These warrants contain anti-dilution provisions, which may, under certain circumstances, reduce the exercise price (but have no effect on the number of shares subject to the warrants) to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the exercise price of the warrants, or if we announce plans to do so. This potential reduction in exercise price could reduce the funds the Company receives upon exercise of the warrants, and increase the likelihood that a dilutive issuance will occur.

Our Common Stock is and likely will remain subject to the SEC's "Penny Stock" rules, which may make its shares more difficult to sell.

Our Common Stock is currently and may remain 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 or accredited investors must:

- make a special written suitability determination for the purchaser;
 - receive the purchaser's written agreement to a transaction prior to sale;
- 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 acknowledgment 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.

Certain provisions of our certificate of incorporation which authorize the issuance of additional shares of preferred stock may make it more difficult for a third party to effect a change in control.

Our certificate of incorporation authorizes our Board of Directors to issue up to 10,000,000 shares of preferred stock. During 2012, we issued 2,200 shares of Series A Convertible Preferred Stock, of which 788 shares remain outstanding as of March 15, 2013. We believe the terms of these preferred shares would not have a substantial impact on the ability of a third party to effect a change in control. The remaining shares of preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by the stockholders. These terms may include voting rights including the right to vote as a series on particular matters, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The issuance of any preferred stock could diminish the rights of holders of our common stock, and therefore could reduce the value of our common stock. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell assets to, a third party. The ability of our Board of Directors to issue preferred stock could make it more difficult, delay, discourage, prevent or make it more costly to acquire or effect a change-in-control, which in turn could prevent the stockholders from recognizing a gain in the event that a favorable offer is extended and could materially and negatively affect the market price of our common stock.

Certain provisions of the warrants we issued in March 2012 may make it more difficult for a third party to effect a change in control.

The warrants we issued in March 2012 contain provisions which permit the holders to require the payment to them of an amount of cash equal to the value (based on a Black-Scholes computation) of the remaining unexercised portion of the warrants on the date of the consummation of a fundamental transaction (as defined, but generally a change in control of the Company) that is (i) an all cash transaction, (ii) a "going private" transaction, or (iii) a transaction involving a person or entity not traded on a national securities exchange. The prospect of making such payments may discourage a potential third party acquirer.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We lease approximately 8,400 square feet of office and laboratory space located at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia under a 62 month lease agreement which began November 1, 2009. We believe this space is adequate for our current needs.

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ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may from time to time become involved in various legal proceedings arising in the ordinary course of business.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently traded on the OTC Market under the symbol "GOVX". The following table sets forth the high and low bid prices for our common stock for the periods indicated. The prices represent quotations between dealers and do not include retail mark-up, markdown, or commission, and do not necessarily represent actual transactions:

	High	Low
2013		
First Quarter (through March 15, 2013)	\$ 0.85	\$ 0.55
2012		
Fourth Quarter	\$ 0.89	\$ 0.52
Third Quarter	\$ 0.96	\$ 0.76
Second Quarter	\$ 1.07	\$ 0.75
First Quarter	\$ 1.24	\$ 0.77
2011		
Fourth Quarter	\$ 1.94	\$ 0.82
Third Quarter	\$ 1.10	\$ 0.80
Second Quarter	\$ 1.40	\$ 0.76
First Quarter	\$ 1.53	\$ 1.10

Holders

On March 15, 2013, there were approximately 900 holders of record of our common stock. The number of record holders does not reflect the number of beneficial owners of our common stock for whom shares are held by brokerage firms and other institutions.

Dividends

We have not paid any dividends since our inception and do not contemplate paying dividends in the foreseeable future.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during the period covered by this report that have not previously been reported on Form 10-Q or Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of 2012.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item will be included in our definitive proxy statement for our 2013 meeting of shareholders to be filed with the SEC under the caption “Securities Authorized for Issuance under Equity Compensation Plans” and is incorporated herein by this reference.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data are derived from our audited consolidated financial statements. The historical results presented below are not necessarily indicative of the results to be expected for any future period. The information set forth below should be read in conjunction with the information contained in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", and our consolidated financial statements and the related notes, beginning on page F-1 of this Report.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
Statement of Operations Data:					
Total revenues (grant income)	\$2,657,327	\$4,899,885	\$5,185,257	\$3,668,195	\$2,910,170
Net loss	(2,135,140)	(2,346,826)	(2,474,328)	(3,284,252)	(3,728,187)
Basic and diluted net loss per common share	(0.12)	(0.15)	(0.18)	(0.22)	(0.25)

	As of December 31,				
	2012	2011	2010	2009	2008
Balance Sheet Data:					
Total assets	1,477,970	1,645,142	2,357,834	4,315,597	3,056,241
Total stockholders' equity	1,150,935	703,607	1,836,226	3,744,232	2,709,819

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with the discussion under "Selected Financial Data" and our consolidated financial statements included in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties because they are based on current expectations and relate to future events and our future financial performance. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report.

Overview

GeoVax is a biotechnology company developing vaccines that prevent and fight HIV/AIDS. We have exclusively licensed from Emory University vaccine technology which was developed in collaboration with the NIH and the CDC.

Our current vaccines under development address the clade B subtype of the HIV virus that is most prevalent in the United States and the developed world. Our vaccines are being evaluated to determine their potential to (a) prevent HIV infection and (b) to serve as a therapy for individuals who are already infected with HIV. These vaccines are currently being evaluated in human clinical trials -- both in those infected with HIV and those who are not.

We have neither received regulatory approval for any of our vaccine candidates, nor do we have any commercialization capabilities; therefore, it is possible that we may never successfully derive significant product revenues from any of our existing or future development programs or product candidates.

We expect for the foreseeable future our operations will result in a net loss on a quarterly and annual basis. As of December 31, 2012, we had an accumulated deficit of \$24.8 million.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and adjusts the estimates as necessary. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are summarized in Note 2 to our consolidated financial statements for the year ended December 31, 2012. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future net cash flows expected to be generated by such assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the discounted expected future net cash flows from the assets.

Revenue Recognition

We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, as amended by Staff Accounting Bulletin No. 104, Revenue Recognition ("SAB 104"). SAB 104 provides guidance in applying U.S. generally accepted accounting principles to revenue recognition issues, and specifically addresses revenue recognition for upfront, non-refundable fees received in connection with research collaboration agreements. Our revenue consists solely of grant funding received from the NIH. Revenue from this arrangement is approximately equal to the costs incurred and is recorded as income as the related costs are incurred.

Stock-Based Compensation

We account for stock-based transactions in which the Company receives services from employees, directors or others in exchange for equity instruments based on the fair value of the award at the grant date. Compensation cost for awards of common stock is estimated based on the price of the underlying common stock on the date of issuance. Compensation cost for stock options or warrants is estimated at the grant date based on each instrument's fair-value as calculated by the Black-Scholes option pricing model. The Company recognizes stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period for the award.

Liquidity and Capital Resources

At December 31, 2012, we had cash and cash equivalents of \$1,035,925 and total assets of \$1,477,970, as compared to \$1,167,980 and \$1,645,142, respectively, at December 31, 2011. Working capital totaled \$1,017,439 at December 31, 2012, compared to \$476,468 at December 31, 2011.

Sources and Uses of Cash

We are a development-stage company as defined by Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 915, "Development Stage Entities" and do not have any products approved for sale. Due to our significant research and development expenditures, we have not been profitable and have generated operating losses since our inception in 2001. Our primary sources of cash are from sales of our equity securities and from government grant funding.

Cash Flows from Operating Activities

Net cash used in operating activities was \$2,441,247, \$303,621, and \$2,437,571 for the years ended December 31, 2012, 2011 and 2010, respectively. Generally, the differences between periods are due to fluctuations in our net losses, offset by non-cash charges such as depreciation and stock-based compensation expense, and by net changes in

our assets and liabilities. Our net losses generally fluctuate based on expenditures for our research activities, offset by government grant revenues. During 2011, net cash used in operating activities was lower (as compared to 2010 and 2012) due mostly to higher than usual offsets for net changes in assets and liabilities (primarily a \$430,402 change in deferred offering costs and a \$419,927 change in accounts payable and accrued expenses).

The NIH has funded the costs of conducting all of our completed and ongoing human clinical trials to date, except for our ongoing pilot Phase 1/2 therapeutic trial, with GeoVax incurring costs associated with manufacturing the clinical vaccine supplies and other study support. We expect the NIH will fund the costs of another Phase 1 therapeutic trial planned to begin in mid-2013. We are also having discussions with the HVTN and NIH with regard to the conduct of a Phase 2 efficacy trial of our preventive vaccine, and we expect the NIH will provide support for this trial as well. We cannot, however, predict the level of support we will receive from the HVTN or the NIH for any additional clinical trials.

In addition to clinical trial support from the NIH, our operations are partially funded by NIH grants. We record the funding we receive pursuant to these grants as revenue at the time the related expenditures are incurred. In September 2007, the NIH awarded us an Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) grant to support our HIV/AIDS vaccine program. We are utilizing this funding to further our HIV/AIDS vaccine development, optimization and production. The original project period for the grant covered a five year period ending in August 2012, but was extended for an additional one year period. The aggregate award totaled \$20.4 million, with approximately \$1.6 million remaining and available for use as of December 31, 2012. In September 2012, the NIH awarded us an additional grant of \$1.9 million to support development of versions of our HIV/AIDS vaccines to address the clade C subtype of the HIV virus prevalent in the developing world. The project period of this grant covers a one year period ending in August 2013. There is approximately \$1.4 million from this grant remaining and available for use as of December 31, 2012.

We are pursuing additional grants from the federal government. However, as we progress to the later stages of our vaccine development activities, government financial support may be more difficult to obtain, or may not be available at all. Therefore, it will be necessary for us to look to other sources of funding in order to finance our clinical trials and other vaccine development activities.

Cash Flows from Investing Activities

Our investing activities have consisted predominantly of capital expenditures. Capital expenditures for the years ended December 31, 2012, 2011 and 2010, were \$-0-, \$11,896, and \$4,706, respectively, and during 2010, we received \$5,580 in proceeds from the sale of equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$2,309,192, \$404,410, and \$-0- for the years ended December 31, 2012, 2011 and 2010, respectively.

In March 2012, we sold 2,200 shares of Series A Convertible Preferred Stock to a group of institutional investors for an aggregate purchase price of \$2.2 million, and five-year Class A warrants to purchase an aggregate of 2,933,333 shares of our common stock at \$1.00 per share. The preferred stock is convertible at any time into shares of our common stock at \$0.75 per share (originally 2,933,333 shares in the aggregate). We also granted to the investors one-year Class B warrants to purchase up to 2,933,333 of our common stock with an exercise price of \$0.75 per share, and five-year Class C warrants to purchase up to 2,933,333 shares of our common stock at \$1.00 per share. The Class B warrants were immediately exercisable upon issuance; the Class C warrants only become exercisable at the time, and to the extent, that the Class B warrants are exercised. During 2012 a total of 1,412 preferred shares were converted into 1,882,667 shares of common stock; as of December 21, 2012, there were 788 shares of preferred stock outstanding, convertible into 1,050,667 shares of common stock.

In January 2013, we reduced the exercise price of our then-outstanding Series B Common Stock Purchase Warrants. The exercise price for all the Series B Warrants was reduced from \$0.75 to \$0.60 per share. The exercise price for the Series A Warrants and Series C Warrants that were issued concurrently with the Series B Warrants did not change. In consideration for the reduction of the exercise price, the holders of the Series B Warrants immediately exercised 1,766,667 of the Series B Warrants for cash, resulting in total proceeds to the Company of \$1,060,000. The expiration date of the remaining Series B Warrants with respect to 1,166,667 shares was extended from March 21, 2013 to May 21, 2013.

The cash generated by our financing activities during 2011 relates to the sale of our common stock to individual accredited investors in a private placement offering initiated during December 2011. During January 2012, we

received an additional \$310,160 from stock sales pursuant to this offering (including \$36,800 received in payment of a stock subscription receivable from December 2011).

Our capital requirements, particularly as they relate to product research and development, have been and will continue to be significant. We anticipate incurring additional losses for several years as we expand our drug development and clinical programs and proceed into higher cost human clinical trials. Conducting clinical trials for our vaccine candidates in development is a lengthy, time-consuming and expensive process. We will not generate revenues from the sale of our technology or products for at least several years, if at all. For the foreseeable future, we will be dependent on obtaining financing from third parties in order to maintain our operations, including our clinical program. Due to the existing uncertainty in the capital and credit markets, and adverse regional and national economic conditions that may persist or worsen, capital may not be available on terms acceptable to the Company or at all. If we fail to obtain additional funding when needed, we would be forced to scale back or terminate our operations, or to seek to merge with or to be acquired by another company.

We expect that our current working capital combined with the remaining available funds from the NIH grants will be sufficient to support our planned level of operations into the first quarter of 2014. We anticipate raising additional capital during 2013, although there can be no assurance that we will be able to do so. While we believe that we will be successful in obtaining the necessary financing to fund our operations through grants, exercise of options and warrants, and/or other sources, there can be no assurances that such additional funding will be available to us on reasonable terms or at all. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

We have no off-balance sheet arrangements that are likely or reasonably likely to have a material effect on our financial condition or results of operations.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payment. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information. Timing of payments and actual amounts paid may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations.

The following table represents our contractual obligations as of December 31, 2012, aggregated by type (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 years
Operating Lease Obligations (1)	\$254	\$125	\$129	\$--	\$--
Firm Purchase Commitments (2)	\$510	\$510	\$--	\$--	\$--
Emory University – License Agreement (3)	--	--	--	--	--
Total	\$764	\$635	\$129	\$--	\$--

- (1) Our operating lease obligations relate to the facility lease for our 8,430 square foot facility in Smyrna, Georgia, which houses our laboratory operations and our administrative offices. The lease, which was effective November 1, 2009, expires on December 31, 2014.
- (2) Firm purchase commitments relate to contracts for production and testing of our vaccine products, conduct of clinical trials, and other research-related activities.
- (3) Pursuant to the Emory License, we have committed to make potential future milestone and royalty payments which are contingent upon the occurrence of future events. Such events include development milestones, regulatory approvals and product sales. Because the achievement of these milestones is currently neither probable nor reasonably estimable, the contingent payments have not been included in the table above or recorded on our Consolidated Balance Sheets. The aggregate total of all potential milestone payments included in the Emory License (excluding royalties on net sales) is approximately \$3.5 million.

As of December 31, 2012, except as disclosed in the table above, we had no other material firm purchase obligations or commitments for capital expenditures and no committed lines of credit or other committed funding or long-term debt. We have employment agreements with our executive officers and a consulting agreement with a member of our Board of Directors, each of which may be terminated with no more than 90 days advance written notice. The table also excludes budgeted expenses under our research agreements with Emory University which are fully

reimbursable to us pursuant to the IPCAVD grant from the NIH and cover a period of less than one year.

Net Operating Loss Carryforwards

At December 31, 2012, we had consolidated net operating loss carryforwards for income tax purposes of \$69.8 million, which will expire in 2013 through 2032 if not utilized. Approximately \$51.9 million of our net operating loss carryforwards relate to the operations of our predecessor, Dauphin Technology, Inc. prior to the 2006 merger between Dauphin Technology, Inc. and GeoVax, Inc. We also have research and development tax credits of approximately \$764,000 available to reduce income taxes, if any, which will expire in 2022 through 2031 if not utilized. The amount of net operating loss carryforwards and research tax credits available to reduce income taxes in any particular year may be limited in certain circumstances. Based on an assessment of all available evidence including, but not limited to, our limited operating history in our core business and lack of profitability, uncertainties of the commercial viability of our technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, we have concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a 100% deferred tax valuation allowance has been recorded against these assets.

Results of Operations

Net Loss

We recorded net losses of \$2,135,140, \$2,346,826, and \$2,747,328 for the years ended December 31, 2012, 2011 and 2010, respectively. Our operating results typically fluctuate due to the timing of activities and related costs associated with our vaccine research and development activities and our general and administrative costs, as described in more detail below.

Grant Revenue

We recorded grant revenues of \$2,657,327, \$4,899,885, and \$5,185,257 for the years ended December 31, 2012, 2011 and 2010, respectively. Grant revenues for all three years relate to grants from the NIH for our vaccine development activities, except that 2010 includes \$244,479 related to our receipt of a Qualified Therapeutic Discover Program (QTDP) grant.

In September 2007, the NIH awarded us an IPCAVD grant to support our HIV/AIDS vaccine development, optimization and production. The original project period for the grant covered a five year period ending in August 2012, but was extended for an additional one year period. The aggregate award totaled \$20.4 million and there is approximately \$1.6 million remaining and available for use as of December 31, 2012.

In September 2012, the NIH awarded us an additional grant of \$1.9 million to support development of versions of our HIV/AIDS vaccines for the clade C subtype of the HIV virus prevalent in the developing world. The project period of this grant covers a one year period ending in August 2013. There is approximately \$1.4 million from this grant remaining and available for use as of December 31, 2012.

Research and Development

Our research and development expenses were \$3,043,522, \$4,276,375, and \$4,793,956 for the years ended December 31, 2012, 2011 and 2010, respectively. Research and development expense for these periods includes stock-based compensation expense of \$78,140, \$179,400, and \$206,501 for 2012, 2011 and 2010, respectively (see discussion under "Stock-Based Compensation Expense" below). Our research and development costs do not include costs incurred by the HVTN in conducting clinical trials of our vaccines; those costs are funded directly by the NIH.

Our research and development expenses can fluctuate considerably on a period-to-period basis, depending on our need for vaccine manufacturing by third parties, the timing of expenditures related to our grants from the NIH, and the timing of costs associated with clinical trials being funded directly by us. The recently completed Phase 2a clinical trial for our preventive vaccine was conducted and funded by the HVTN as is the ongoing Phase 1 clinical trial of our second generation preventive vaccine, but we are responsible for the manufacture of vaccine product to be used in the trials. We are not currently receiving any government support for the ongoing Phase 1 clinical trial of our therapeutic vaccine (treatment interruption protocol). We cannot predict the level of support we may receive from HVTN or other federal agencies (or divisions thereof) for our future clinical trials. We expect that our research and development costs will increase in the future as we progress into the later stage human clinical trials leading up to possible product approval by the FDA.

Since our inception, all of our research and development efforts have been focused on development of our HIV/AIDS vaccines, which we have managed and evaluated to date as a single project. Upon receipt of the IPCAVD grant from the NIH in late 2007, we began incurring additional costs associated with the grant, and reallocated personnel and other internal resources toward activities supported by the grant. The table below summarizes our research and

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development expenses for each of the years in the three year period ended December 31, 2012. The amounts shown related to NIH grants represent all direct costs associated with grant activities, including salaries and personnel-related expenses, supplies, consulting, contract services and travel. The remainder of our research and development expense is allocated to our general HIV/AIDS vaccine program.

R&D Project	2012	2011	2010
NIH Grant Activities	\$ 1,837,085	\$ 3,015,812	\$ 3,385,193
DNA/MVA Vaccines – HIV/AIDS	1,206,437	1,260,563	1,408,763
Total Research and Development Expense	\$ 3,043,522	\$ 4,276,375	\$ 4,793,956

Our vaccine candidates still require significant, time-consuming and costly research and development, testing and regulatory clearances. Completion of clinical development will take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. The NIH has funded the costs of conducting all of our completed and ongoing human clinical trials to date, except for our ongoing pilot Phase 1/2 therapeutic trial, with GeoVax incurring costs associated with manufacturing the clinical vaccine supplies and other study support. We expect the NIH will fund the costs of another Phase 1 therapeutic trial which we anticipate will start in mid-2013. We are also having discussions with the HVTN and NIH with regard to the conduct of a planned Phase 2 efficacy trial of our preventive vaccine, and we expect the NIH will provide support for this trial as well. We intend to seek government and/or third party support for future clinical human trials, but there can be no assurance that we will be successful. The duration and the cost of future clinical trials may vary significantly over the life of the project as a result of differences arising during development of the human clinical trial protocols, including, among others:

- the number of patients that ultimately participate in the clinical trial;
- the duration of patient follow-up that seems appropriate in view of the results;
- the number of clinical sites included in the clinical trials; and
- the length of time required to enroll suitable patient subjects.

Due to the uncertainty regarding the timing and regulatory approval of clinical trials and pre-clinical studies, our future expenditures are likely to be highly volatile in future periods depending on the outcomes of the trials and studies. From time to time, we will make determinations as to how much funding to direct to these programs in response to their scientific, clinical and regulatory success, anticipated market opportunity and the availability of capital to fund our programs.

In developing our product candidates, we are subject to a number of risks that are inherent in the development of products based on innovative technologies. For example, it is possible that our vaccines may be ineffective or toxic, or will otherwise fail to receive the necessary regulatory clearances, causing us to delay, extend or terminate our product development efforts. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase which, in turn, could have a material adverse effect on our results of operations and cash flows. Because of the uncertainties of clinical trials, estimating the completion dates or cost to complete our research and development programs is highly speculative and subjective. As a result of these factors, we are unable to accurately estimate the nature, timing and future costs necessary to complete the development of our product candidates. In addition, we are unable to reasonably estimate the period when material net cash inflows could commence from the sale, licensing or commercialization of such product candidates, if ever.

General and Administrative Expense

Our general and administrative expenses were \$1,752,765, \$2,972,555, and \$3,162,134 for the years ended December 31, 2012, 2011 and 2010, respectively. General and administrative costs include officers' salaries, legal and accounting costs, patent costs, amortization expense associated with intangible assets, and other general corporate expenses. General and administrative expense includes stock-based compensation expense of \$231,936, \$593,597, and \$544,031 for 2012, 2011 and 2010, respectively (see discussion under "Stock-Based Compensation Expense" below). The decline in general and administrative expense from 2011 to 2012 is primarily due to lower legal costs, patent costs and stock-based compensation expense related to investment advisory fees and investor warrant extensions. However, we expect that our general and administrative costs may increase in the future in support of expanded research and development activities and other general corporate activities.

Stock-Based Compensation Expense

We recorded total stock-based compensation expense of \$310,076, \$772,997, and \$750,532 during the years ended December 31, 2012, 2011 and 2010, respectively, which was allocated to research and development expense or general and administrative expense according to the classification of cash compensation paid to the employee, consultant or director to whom the stock compensation was granted. In addition to amounts related to the issuance of stock options to employees, the figures include amounts related to common stock and stock purchase warrants issued to consultants and non-employee directors. The overall decline in stock-based compensation expense during 2012, as compared to 2011 and 2010, can be attributed to expense in the prior years associated with stock issuances for investment advisory fees, warrants granted to investor relations consultants, and extensions to investor warrants. For the three years ended December 31, 2012, stock-based compensation expense was allocated as follows:

	2012	2011	2010
General and administrative expense	\$231,936	\$593,597	\$544,031
Research and development expense	78,140	179,400	206,501
Total stock option expense	\$310,076	\$772,997	\$750,532

Other Income

Interest income was \$3,820, \$2,219, and \$23,505 for the years ended December 31, 2012, 2011 and 2010, respectively. The variances between years are primarily attributable to the cash available for investment and to interest rate fluctuations.

Impact of Inflation

For the three year period ended December 31, 2012, we do not believe that inflation and changing prices had a material impact on our operations or on our financial results.

Off-Balance Sheet Arrangements

We have not entered into off-balance sheet financing arrangements, other than operating leases.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of United States interest rates, particularly because a significant portion of our investments are in institutional money market funds. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income received without significantly increasing risk. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any derivative financial instruments or foreign currency instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and supplemental schedule and notes thereto as of December 31, 2012 and 2011, and for each of the three years ended December 31, 2012, 2011 and 2010, and from inception through December 31, 2012, together with the independent registered public accounting firms' reports thereon, are set forth on pages F-1 to F-18 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There were no disagreements with our accountants on matters of accounting or financial disclosure, or other reportable events requiring disclosure under this Item 9.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that financial information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded,

processed, summarized, and reported within the required time periods, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding disclosure.

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2012. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2012 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2012 based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of this assessment, management concluded that, as of December 31, 2012, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is included in our definitive proxy statement for our 2013 meeting of shareholders to be filed with the SEC under the captions "Directors and Executive Officers" and "Corporate Governance" and is incorporated herein by this reference.

Code of Ethics

We have adopted a Code of Ethics in compliance with the applicable rules of the SEC that applies to our principal executive officer, our principal financial officer and our principal accounting officer or controller, or persons performing similar functions. A copy of this policy is available on our website at www.geovax.com under the heading "Investors – Corporate Governance" and is also available free of charge upon written request to the attention of our Corporate Secretary by regular mail, e-mail to mreynolds@geovax.com, or facsimile at (678) 384-7281. We intend to disclose any amendment to, or a waiver from, a provision of our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that relates to any element of the code of ethics enumerated in applicable rules of the SEC. Such disclosures will be made on our website at www.geovax.com.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is included in our definitive proxy statement for our 2013 meeting of shareholders to be filed with the SEC under the captions “Corporate Governance” and “Compensation Discussion and Analysis” and is incorporated herein by this reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is included in our definitive proxy statement for our 2013 meeting of shareholders to be filed with the SEC under the captions “Security Ownership of Principal Stockholders, Directors and Executive Officers” and “Securities Authorized for Issuance under Equity Compensation Plans” and is incorporated herein by this reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS,
AND DIRECTOR INDEPENDENCE

The information required by this Item is included in our definitive proxy statement for our 2013 meeting of shareholders to be filed with the SEC under the captions “Corporate Governance” and “Certain Relationships and Related Party Transactions” and is incorporated herein by this reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is included in our definitive proxy statement for our 2013 meeting of shareholders to be filed with the SEC under the caption “Ratification of Appointment of the Independent Registered Public Accounting Firm” and is incorporated herein by this reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

(1)	Financial Statements	Page
	Reports of Independent Registered Public Accounting Firms on Financial Reporting	F-2
	Consolidated Balance Sheets as of December 31, 2012 and 2011	F-4
	Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010 and for the Period from Inception (June 27, 2001) to December 31, 2012	F-5
	Consolidated Statements of Stockholders’ Equity (Deficiency) for the Period from Inception (June 27, 2001) to December 31, 2012	F-6
	Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010 and for the Period from Inception (June 27, 2001) to December 31, 2012	F-9
	Notes to Consolidated Financial Statements	F-10
(2)	Financial Statement Schedules	
	The following financial statement schedule is set forth on page F-18 of this Annual Report on Form 10-K: Schedule II—Valuation and Qualifying Accounts for the years ended December 31, 2012, 2011 and 2010	
	All other financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.	
(3)	Exhibits	

See Item 15(b) below. Each management contract or compensatory plan or arrangement required to be filed has been identified.

(b) Exhibits

Exhibit

Number Description

- 2.1 Agreement and Plan of Merger dated January 20, 2006 by and among GeoVax, Inc., GeoVax Acquisition Corp. and Dauphin Technology, Inc. (1)
- 2.2 First Amendment to Agreement and Plan of Merger (2)
- 2.3 Second Amendment to Agreement and Plan of Merger (3)
- 3.1 Certificate of Incorporation (6)
- 3.1.1 Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 13, 2010 (10)
- 3.1.2 Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 27, 2010 (11)
- 3.2 Bylaws (6)
- 4.1 Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed March 20, 2012 (13)
- 4.2 Form of Stock Certificate for the Series A Convertible Preferred Stock (13)

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- 10.1 * Employment Agreement between GeoVax Labs, Inc. and Robert T. McNally effective as of April 1, 2008 (7)
- 10.2 * Employment Agreement between GeoVax, Inc. and Mark W. Reynolds Amended and Restated effective as of January 1, 2010 (9)
- 10.3 * Employment Agreement between GeoVax, Inc. and Harriet Robinson effective as of November 19, 2007 (9)
- 10.4 * GeoVax Labs, Inc. 2006 Equity Incentive Plan (4)
- 10.5 License Agreement (as amended and restated) between GeoVax, Inc. and Emory University, dated August 23, 2002 (3)
- 10.6 Technology Sale and Patent License Agreement between GeoVax, Inc. and MFD, Inc., dated December 26, 2004 (3)
- 10.7 Office and Laboratory Lease between UCB, Inc. and GeoVax, Inc. (8)
- 10.8 * Summary of the GeoVax Labs, Inc. Director Compensation Plan (9)
- 10.9 Form of Warrant dated December 30, 2011 (12)
- 10.10 Form of Securities Purchase Agreement dated March 16, 2012 (13)
- 10.11 Form of Registration Rights Agreement dated March 16, 2012 (13)
- 10.12 Form of Series A Warrant dated March 16, 2012 (13)
- 10.13 Form of Series B Warrant dated March 16, 2012 (13)
- 10.14 Form of Series C Warrant dated March 16, 2012 (13)
- 10.15 Warrant Reset Offer Agreements dated January 17, 2013 (14)
- 14.1 Code of Ethics (5)
- 21.1 Subsidiaries of the Registrant (5)
- 31.1 ** Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
- 31.2 ** Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
- 32.1 ** Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 ** Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
- 101 The following financial information from GeoVax Labs, Inc. Annual Report on Form 10-K for the year ended
,* December 31, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011, (ii) Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010 and for the period from inception (June 27, 2001) to December 31, 2012, (iii) Consolidated Statements of Stockholders' Equity (Deficiency) for the period from inception (June 27, 2001) to December 31, 2012, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010 and for the period from Inception (June 27, 2001) to December 31, 2012, and (v) Notes to Condensed Consolidated Financial Statements.

* Indicates a management contract or compensatory plan or arrangement.

** Filed herewith.

*** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended and otherwise are not subject to liability under those sections.

- (1) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 24, 2006.
- (2) Incorporated by reference from the registrant's Current Report on Form 8-K filed July 13, 2006.
- (3) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 4, 2006.
- (4) Incorporated by reference from the registrant's definitive Information Statement (Schedule 14C) filed August 18, 2006.
- (5) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 28, 2007.

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- (6) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 23, 2008.
- (7) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 24, 2008.
- (8) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 6, 2009.
- (9) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 8, 2010.
- (10) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 14, 2010.
- (11) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 28, 2010.
- (12) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 5, 2012.
- (13) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 22, 2012.
- (14) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 17, 2013.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GEOVAX LABS, INC.

By: /s/ Robert T. McNally
Robert T. McNally
President and Chief Executive Officer