GeoVax Labs, Inc. Form 10-K March 14, 2014

#### 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, 2013

# 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

## 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

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, 2013, based on the closing price on that date was \$7,811,000.
Number of shares of Common Stock outstanding as of March 10, 2014: 24,968,037
DOCUMENTS INCORPORATED BY REFERENCE
Portions of the registrant's definitive Proxy Statement with respect to its 2014 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 U.S. Food and Drug Aministration (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" or the negative thereof or other conterminology. 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

GeoVax, Labs Inc. is a biotechnology company developing vaccines that prevent and control 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 -- both in those infected with HIV and those who are not.

Our most advanced vaccines under development are designed to function against the clade B subtype of the HIV virus that is prevalent in the United States and much of the developed world. An estimated 3.3 million people are infected with clade B HIV virus worldwide, with 187,000 new infections in 2012, of which 51,000 were in the United States. 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 subtype of HIV prevalent in South Africa and India, and have begun early development work on a vaccine for this subtype of the virus.

Our vaccines incorporate two delivery components: a recombinant DNA vaccine, and a recombinant poxvirus designated modified vaccinia Ankara (MVA) vaccine. Both the DNA and MVA vaccines contain sufficient HIV genes to support the production of non-infectious virus-like particles. These particles display the native trimeric-membrane-bound form of the viral envelope glycoprotein that mediates entry into cells and is the target for protective antibody. When used together, the recombinant DNA component primes immune responses, which are boosted by administration of the recombinant MVA component. We have also tested an adjuvanted version of our vaccine that co-expresses granulocyte-macrophage colony-stimulating factor (GM-CSF) in the DNA vaccine used to prime the immune response. An adjuvant is an agent that can improve a vaccine response.

Our vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the 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.

#### **Therapeutic HIV Vaccine Program**

We recently completed a Phase 1 clinical trial (GV-TH-01) investigating the therapeutic use of our GOVX-B11 vaccine in HIV-infected patients. GV-TH-01 is an open label Phase 1 treatment interruption trial investigating the safety and immunogenicity of GOVX-B11 in 9 HIV-infected patients who initiated drug treatment within 18 months of seroconversion and had stably controlled virus for at least 6 months. Patients were vaccinated with two DNA inoculations followed by two MVA inoculations at intervals of two months. Eight weeks following the last inoculation, patients suspended drug therapy for a 12 week period. Vaccinated patients' ability to control the time and temporal height of re-emergent virus in the absence of drugs was then observed. Drug treatment was re-instituted after 12 weeks, and trial participants were observed for an additional 6 months. The primary endpoint of this study is to evaluate the safety of our vaccine in HIV-positive patients with well-controlled infections who are being treated with oral HIV medications. An exploratory objective of the study is to evaluate the ability of the vaccinated patient to control re-emergent virus during the drug treatment interruption period.

Early analysis of GV-TH-01 data indicates that, during the vaccination phase of the trial, enhanced CD8+ T cells were elicited in 8 of 9 participants and enhanced CD4+ T cell in 5 of 9 participants. Antibody responses were boosted in 4 of 9 participants. Analyses during the treatment interruption phase of the trial suggested that individuals with the best immune responses have lower levels of re-emergent virus. Excellent safety was observed throughout the trial, with none of the participants needing to reinstate antiretroviral drugs during the treatment interruption phase of the trial.

Based on the results of GV-TH-01, we are formulating plans for a follow-on Phase 1 clinical trial investigating the treatment of HIV-positive individuals with our GM-CSF adjuvanted DNA/MVA vaccine (GOVX-B21) in combination with standard-of-care antiretroviral drug therapy. The primary and secondary objectives of the study will be to evaluate the safety and immunogenicity of GOVX-B21. An exploratory objective will be to investigate the vaccine's effect on reducing viral reservoirs.

#### **Preventive HIV Vaccine Program**

Clinical trials of our preventive vaccine have been conducted by the HIV Vaccine Trials Network. The HIV Vaccine Trials Network (HVTN) is the largest worldwide clinical trials network dedicated to the development and testing of HIV/AIDS vaccines. Support for the HVTN comes from the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH. The HVTN's HIV Vaccine Trial Units are located at leading research institutions in 27 cities on four continents.

HVTN 065, a 120 person first in humans Phase 1 trial of our GOVX-B11 vaccine (JS7 DNA prime and MVA62B boost) showed good safety and immunogenicity and supported moving to Phase 2 testing. HVTN 205, a 300 person Phase 2a trial for MVA62B with or without a JS7 DNA prime has also been completed. Participants received either 2 doses of JS7 DNA vaccine followed by 2 doses of MVA62B at 0, 2, 4, and 6, months (DDMM regimen), 3 doses of MVA/62B at 0, 2, and 6 months (MMM regimen) or placebo injections. At peak response, 93.2% of the DDMM group and 98.4% of the MMM group had binding antibodies (Ab) for the envelope glycoprotein (Env). These binding Abs were more frequent and of higher magnitude for the transmembrane (gp41) than the receptor binding subunit (gp120) of the HIV envelope glycoprotein (Env). For both regimens, response rates were higher for CD4+ (66.4% DDMM, 43.1% MMM) than CD8+ (21.8% DDMM, 14.9% MMM) T cells. Responding CD4+ and CD8+ T cell were biased towards Gag and >70% produced two, or three, of four tested cytokines. At 6 months post vaccination, the magnitudes of Ab and T cell responses had decreased by <3- fold. These results distinguished our vaccine from other vaccines that have advanced to efficacy testing in the specificity and durability of elicited antibody responses. We believe that the durability of the Ab responses is important, because protection waned with the declining Ab response in the one partially successful HIV vaccine trial (RV144) conducted by the US military and the Thai government in Thailand.

During December 2013, we reviewed preliminary results from an ongoing Phase 1 trial (HVTN 094) of our adjuvanted DNA/MVA vaccine (GOVX-B21) that co-expresses GM-CSF in the priming DNA vaccine. Based on excellent preclinical non-human primate data, this trial was originally initiated with the expectation that GOVX-B21 would be carried forward into Phase 2 testing by the HIV Vaccine Trials Network, with support by the NIH. However, comparison of data between HVTN 094 and HVTN 205 has not shown a significant benefit from adding the adjuvant to the vaccine for preventive use. Following an extensive review of preclinical and clinical data, we have decided to advance GOVX-B11 to the next stage of clinical testing.

We are currently in planning discussions with the HVTN for the next stage of clinical trials, and several scenarios are being considered. Our vaccine is currently the only vaccine being contemplated for efficacy trials for prevention of clade B HIV infection. However, the HVTN believes the best path forward may be to test GOVX-B11 in combination with a protein boost or another approach to preventing HIV infection. Protein boosts may augment antibody responses that can block virus infections (neutralizing antibody) and cause antibody dependent cellular cytotoxicity (ADCC antibody). Protein added to HIV vaccines have shown some success in other trials. The HVTN believes this "dual-action" approach may be a prudent and cost-effective path forward for supporting large clinical trials. We expect our next preventive clinical trial to begin during 2015 and to be fully funded by the NIH, with specific details of the

study determined after further data analysis and input from the HVTN and NIH in mid-2014.

## **Background - Viruses and Vaccines**

What are Viruses? Viruses are microscopic organisms consisting of genetic material comprised of 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 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 report published by UNAIDS/WHO, at the end of 2012, an estimated 36 million people were living with HIV worldwide, with approximately 2.5 million newly infected in 2012 alone. Approximately 25 million people infected with HIV have died since the 1981 start of the HIV pandemic. The United States currently suffers about 51,000 infections per year, of which only an estimated 25% enter into, and maintain, successful drug treatment.

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, by white blood cells such as macrophages, neutrophils and natural killer cells. Our vaccines elicit CD8 T-cells, a type of T-cell that can recognize and kill cells that become infected by virus (without antibody tagging). CD8 T-cells are important for the control of the virus that has established an infection.

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.

*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 infection. 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.

Encouragingly, we found that non-human primates that were protected against a first series of rectal challenges were protected against further series of challenges. Seven survivors from a first series of 12 exposures were rested a year, boosted once with the MVA vaccine, and then exposed to a 2<sup>nd</sup> series of challenges. One of 7 animals was infected by the 10<sup>th</sup> exposure. Survivors of this 2<sup>nd</sup> series of exposures were again rested for 6 months and then exposed to a 3<sup>rd</sup> series of challenges. Again, protection was seen against the challenges with the last animal not becoming infected until the 12<sup>th</sup> challenge. The 1<sup>st</sup> two series of exposures were to SIVE660, a virus that has neutralization characteristics like viruses undergoing transmission in the current epidemic. The 3<sup>rd</sup> 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.

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 than those measured prior to drug and vaccine treatment. The therapeutic reductions in virus levels were best for animals placed on drugs within 12 weeks of infection with lower levels of protection being achieved in animals that were placed on drugs at 3 months or later after infection.

#### Human Clinical Trials -- Preventive Vaccine

Phase 1 Human Clinical Trials. All of our preventive vaccination trials in humans have been conducted by the 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  $1 \times 10^7$  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  $1 \times 10^8$  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 also sponsored and conducted a Phase 1 clinical trial in humans (HVTN 094) of the adjuvanted form of our vaccine that co-expresses GM-CSF in the DNA priming vaccine. We have designated the GM-CSF-adjuvanted version of our DNA/MVA vaccine regimen as GOVX-B21, and the unadjuvanted version as GOVX-B11. During December 2013, we reviewed preliminary results from HVTN 094. Based on excellent preclinical non-human primate data, this trial was originally initiated with the expectation that GOVX-B21 would be carried forward into Phase 2 testing by the HIV Vaccine Trials Network, with support by the NIH. However, comparison of data between HVTN 094 and HVTN 205 has not shown a significant benefit from adding the adjuvant to the vaccine for preventive use. Following an extensive review of preclinical and clinical data, we have decided to advance GOVX-B11 to the next stage of clinical testing.

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 of our first-generation vaccine 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, with further analysis presented at the AIDS Vaccine Meeting in Barcelona, Spain, in October 2013. HVTN 205 was designed to evaluate the safety and immunogenicity of our vaccines in healthy, HIV-uninfected adults. In HVTN 205, 299 participants were randomly assigned to three study arms: 149 participants received two injections of our DNA vaccine followed by two injections of the our MVA vaccine (DDMM arm), 75 participants received three MVA injections followed by one placebo injection (MMM arm), and 75 participants received four injections of placebo. After the final vaccination, antibody responses against the HIV Envelope protein (Env), the target for protective antibody, were detected in 93.2% of the DDMM arm (the vaccination regimen selected for further clinical study). At six months after final vaccination (the latest time point tested), Gp140 IgG antibody response titers in the DDMM arm had declined by less than 3-fold, with response rates only declining from 100% to 84%, indicating significant durability of the antibody response. Additionally, HVTN 205 also showed that the antibody responses after vaccination had high affinity binding, a characteristic which has been associated with prevention of HIV infection in preclinical models.

We are currently in planning discussions with the HVTN for the next stage of clinical trials, and several scenarios are being considered. Our vaccine is currently the only vaccine being contemplated for efficacy trials for prevention of clade B HIV infection. However, the HVTN believes the best path forward may be to test GOVX-B11 in combination with a protein boost or another approach to preventing HIV infection. Protein boosts may augment antibody responses that can block virus infections (neutralizing antibody) and cause antibody dependent cellular cytotoxicity (ADCC antibody). Protein added to HIV vaccines have shown some success in other trials. The HVTN believes this "dual-action" approach may be a prudent and cost-effective path forward for supporting large clinical trials. We expect our next preventive clinical trial to begin during 2015 and to be fully funded by the NIH, with specific details of the study determined after further data analysis and input from the HVTN and NIH in mid-2014.

Human Clinical Trials -- Therapeutic Vaccine. To help treat those people who are already infected with HIV, we are testing the feasibility of using our vaccine to enhance viral control in drug-treated 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 Trial (Treatment Interruption). We recently completed a Phase 1 clinical trial (GV-TH-01) investigating the therapeutic use of our GOVX-B11 vaccine in HIV-infected patients. GV-TH-01 is an open label Phase 1 treatment interruption trial investigating the safety and immunogenicity of GOVX-B11 in 9 HIV-infected patients who initiated drug treatment within 18 months of seroconversion and had stably controlled virus for at least 6 months. Patients were vaccinated with two DNA inoculations followed by two MVA inoculations at intervals of two months. Eight weeks following the last inoculation, patients suspended drug therapy for a 12 week period. Vaccinated patients' ability to control the time and temporal height of re-emergent virus in the absence of drugs was then observed. Drug treatment was re-instituted after 12 weeks, and trial participants were observed for an additional 6 months. The primary endpoint

of this study is to evaluate the safety of our vaccine in HIV-positive patients with well-controlled infections who are being treated with oral HIV medications. An exploratory objective of the study is to evaluate the ability of the vaccinated patient to control re-emergent virus during the drug treatment interruption period.

Early analysis of GV-TH-01 data indicates that, during the vaccination phase of the trial, enhanced CD8+ T cells were elicited in 8 of 9 participants and enhanced CD4+ T cell in 5 of 9 participants. Antibody responses were boosted in 4 of 9 participants. Analyses during the treatment interruption phase of the trial suggested that individuals with the best immune responses have lower levels of re-emergent virus. Excellent safety was observed throughout the trial, with none of the participants needing to reinstate antiretroviral drugs during the treatment interruption phase of the trial.

Phase 1 Trial Planning (Vaccine plus Standard of Care Drug Therapy). 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 the drugs can prevent spread of the virus but cannot kill an infected cell. Immune responses can recognize and kill infected cells if they are expressing viral protein.

Based on the results of GV-TH-01, we are formulating plans for a follow-on Phase 1 clinical trial investigating the treatment of HIV-positive individuals with our GM-CSF adjuvanted DNA/MVA vaccine (GOVX-B21) in combination with standard-of-care antiretroviral drug therapy. The primary and secondary objectives of the study will be to evaluate the safety and immunogenicity of GOVX-B21. An exploratory objective will be to investigate the vaccine's effect on reducing viral reservoirs.

#### **Support from the United States Government**

With the exception of the Phase 1 therapeutic trial (treatment interruption protocol), all of our human clinical trials to date have been conducted by the HVTN and funded by NIH. Our responsibility for these clinical trials has been to provide sufficient supplies of vaccine materials and technical expertise when necessary.

In addition to clinical trial support from the NIH, our operations are partially funded by NIH research grants. 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 aggregate award (including subsequent amendments) totaled \$20.4 million, and there is approximately \$700,000 remaining and available for use as of December 31, 2013. 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. All funding pursuant to this grant has been utilized. In July 2013, the NIH awarded us a Small Business Innovative Research (SBIR) grant for approximately \$277,000 to support preclinical studies evaluating the ability of protein boosts to augment antibody responses. The grant award of approximately \$277,000 is for the first year of a two year project period beginning August 1, 2013, and there is approximately \$122,000 of unused grant funds remaining and available for use as of December 31, 2013.

Please refer to our Financial Statements beginning on page F-1 of this Form 10-K, and to "Management's Discussion and Analysis of Financial Condition and Results of Operations", for additional information regarding revenue and funds availability.

#### **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 short-term goal is to bring both our preventive and therapeutic HIV/AIDS vaccines into efficacy testing, with the ultimate objective 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 indications of efficacy in humans. We will leverage governmental support where possible. 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 embryonic chicken eggs. In an attempt to find a means to reduce costs for large scale manufacturing, we have explored a number of approaches to producing 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 Valneva S.E., France. We are currently working with Valneva on the use of EB66 cells for the growth of our MVA vaccines. We are hopeful that upon completion of process development we will be producing vaccine at significantly higher titers, allowing for quality improvements over the current process as well as meaningful cost reductions.

## 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.

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 seven pending United States patent applications, and thirty-two 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.

*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 \$98,042, \$89,885, and \$249,907 for the years ended December 31, 2013, 2012 and 2011, 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 \$2,914,878, \$3,043,522, and \$4,276,375 during the years ended December 31, 2013, 2012 and 2011, 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 and expires on December 31, 2014. We believe this space is adequate for our current needs and are currently evaluating our needs and facility alternatives beyond the current lease expiration date. As of March 10, 2014, we had six full-time and one part-time employees. None of our employees are covered by collective bargaining agreements and we believe that our employee relations are good.

#### **Corporate Background**

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. 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 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

Investing in our securities involves a high degree of risk. You should carefully review and consider the risks, uncertainties and other factors described below before you decide whether to purchase our securities. Any of these factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock, and you may lose some or all of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, may also impair our business operations. You should also refer to the information contained in this Form 10-K, including our financial statements and the related notes.

#### **Risks Related to Our Business**

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

We have had no product revenue to date and there can be no assurance that we will ever generate any product revenue. We have experienced operating losses since we began operations in 2001. As of December 31, 2013, we had an accumulated deficit of approximately \$27.1 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, 2013, there is approximately \$822,000 of unused grant funds remaining and available for use during 2014. 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.

We expect that our current working capital, combined with proceeds from the grants awarded to us from the NIH will be sufficient to support our planned level of operations into the first quarter of 2015. 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.

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

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

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

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

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

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

To manufacture and sell our products, we must comply with extensive domestic and international regulation. In order to sell our products in the United States, approval from the FDA is required. Satisfaction of regulatory requirements,

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

We 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. There is also a risk of changes in clinical trial strategy and timelines due to the HVTN and the NIH altering their trial strategy. The US government can also affect trial timelines through budget restrictions such as sequestration.

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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the PPACA of importance to our potential drug candidates are:

an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;

extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer's Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; the new requirements under the federal Open Payments program and its implementing regulations; a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On March 1, 2013, the President signed an executive order implementing the 2% Medicare payment reductions, and on April 1, 2013, these reductions went into effect. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

We do not have manufacturing, sales or marketing experience.

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

#### Our vaccines under development may not gain market acceptance.

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

the efficacy and safety of our vaccines; the time and 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, and without consideration given to any potential proceeds from the exercise of the Series A or C Warrants, will be sufficient to meet our anticipated cash needs into the first quarter of 2015. 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 9.6% of our common stock as of March 10, 2014. Consequently, our directors and executive officers as a group may be 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 18.5% of our common stock as of March 10, 2014. 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 B 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 B 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 B 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 Series A and C Warrants to purchase up to 5,866,666 shares of our common stock that were issued in March 2012. These warrants have an exercise price of \$0.35 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. Reduction in the warrant exercise price will 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 make it 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 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, none of which currently remains outstanding. During 2013, we issued 1,650 shares of Series B Convertible Preferred Stock, 1,300 of which remains outstanding as of March 10, 2014. 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 Series A and C Warrants 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 (ii) 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 and expires on December 31, 2014. We believe this space is adequate for our current needs and are currently evaluating our needs and facility alternatives beyond the current lease expiration date.

# ITEM 3. <u>LEGAL PROCEEDINGS</u>

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 OTCQB 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. On March 10, 2014, the last reported sale price for our common stock as reported in the OTCQB Market was \$0.41 per share.

	High	Low
<u>2014</u>		
First Quarter (through March 10, 2014)	\$0.60	\$0.39
<u>2013</u>		
Fourth Quarter	\$0.97	\$0.36
Third Quarter	\$0.51	\$0.36
Second Quarter	\$0.63	\$0.43
First Quarter	\$0.85	\$0.55
<u>2012</u>		
Fourth Quarter	\$0.89	\$0.52
Third Quarter	\$0.96	\$0.76
Second Quarter	\$1.07	\$0.75
First Quarter	\$1.24	\$0.77

# **Holders**

On March 10, 2014, there were approximately 900 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

#### **Dividends**

We have not paid any dividends since our inception and do not contemplate paying dividends in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our Board of Directors and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

# **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 2013.

# **Securities Authorized for Issuance Under Equity Compensation Plans**

The information required by this Item will be included in our definitive proxy statement for our 2014 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.

		Yea	Years Ended December 31,				
		201	3	2012	2011	2010	2009
Statement of Operations D	Pata:						
Total revenues (grant inco	me)	\$2,4	117,550	\$2,657,327	\$4,899,885	\$5,185,257	\$3,668,195
Net loss		(2,	284,943)	(2,135,140)	(2,346,826)	(2,474,328)	(3,284,252)
Basic and diluted net loss	per common	share (0.	.11 )	(0.12)	(0.15)	(0.18)	(0.22)
	As of Dece	mber 31,					
	2013	2012	2011	2010	2009		
Balance Sheet Data:							
Total assets	2,839,576	1,477,970	1,645,1	42 2,357,834	4 4,315,597		
Total stockholders' equity	2,527,227	1,150,935	703,607	1,836,220	5 3,744,232		

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONAND 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 control HIV. Our vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the CDC. The technology developed by the collaboration is exclusively licensed to us from Emory University. We also have nonexclusive licenses to

certain patents owned by the NIH.

Our current vaccines under development address the clade B subtype of the HIV virus that is most prevalent in the United States and much of the developed world. 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 -- 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, 2013, we had an accumulated deficit of \$27.1 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, 2013. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

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. During 2013, 2012 and 2011, our revenue consisted of grant funding received from the NIH. Revenue from these arrangements 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. We recognize 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, 2013, we had cash and cash equivalents of \$2,513,861 and total assets of \$2,839,576, as compared to \$1,035,925 and \$1,477,970, respectively, at December 31, 2012. Working capital totaled \$2,385,990 at December 31, 2013, compared to \$1,017,439 at December 31, 2012.

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 \$1,694,592, \$2,441,247, and \$303,621 for the years ended December 31, 2013, 2012 and 2011, 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 due mostly to higher than usual offsets for net changes in assets and liabilities from the prior year (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 human clinical trials (Phase 1 and Phase 2a) to date for our preventive vaccines, with GeoVax incurring costs associated with manufacturing the clinical vaccine supplies and other study support. We are currently in planning discussions with the HVTN for the next stage of our preventive clinical trials, and several scenarios are being considered. While we expect the next clinical trial to begin during 2015 and to be fully funded by the NIH, with specific details of the study determined after further data analysis and input from the HVTN and NIH in mid-2014. Until the next trial begins, however, we cannot be fully assured of the level of support, if any, we will receive from the HVTN or the NIH for this clinical trial.

We recently completed a Phase 1 clinical trial (GV-TH-01) investigating the therapeutic use of our GOVX-B11 vaccine in HIV-infected patients. GV-TH-01 is an open label Phase 1 treatment interruption trial investigating the safety and immunogenicity of GOVX-B11 in 9 HIV-infected patients who initiated drug treatment within 18 months of seroconversion and had stably controlled virus for at least 6 months. An exploratory objective of the study is to evaluate the ability of the vaccinated patient to control re-emergent virus during the drug treatment interruption period. We received no federal assistance in conducting this study. In a follow-on study, we are formulating plans for a Phase 1 clinical trial investigating the treatment of HIV-positive individuals with GOVX-B21 in combination with standard-of-care antiretroviral drug therapy. The primary and secondary objectives of the study will be to evaluate the safety and immunogenicity of our vaccine. An exploratory objective will be to investigate the vaccine's effect on reducing viral reservoirs. We plan to seek funding from the NIH to conduct this trial which, if we are successful, would allow us to begin in mid-2015. If we are able to secure sufficient capital from issuance of our equity securities or other sources, we may initiate this trial sooner.

In addition to clinical trial support from the NIH, our operations are partially funded by NIH research 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 aggregate award (including subsequent amendments) totaled \$20.4 million, and there is \$700,153 remaining and available for use as of December 31, 2013. 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. All funding pursuant to this grant has been utilized as of December 31, 2013. In July 2013, the NIH awarded us a Small Business Innovative Research (SBIR) grant for approximately \$277,000 to support preclinical studies evaluating the ability of protein boosts to augment antibody responses. The grant award of approximately \$277,000 is for the first year of a two year project period beginning August 1, 2013, and there is \$122,127 remaining and available for use as of December 31, 2013.

We intend to pursue additional grants from the federal government but cannot be assured of success. 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, 2013, 2012 and 2011, were \$86,603, \$-0-, and \$11,896, respectively.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$3,259,131, \$2,309,192, and \$404,410 for the years ended December 31, 2013, 2012 and 2011, respectively.

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).

In March 2012, we sold an aggregate of 2,200 Series A Convertible Preferred Stock ("Series A Preferred Shares"), as well as accompanying warrants to purchase 8,799,999 shares of common stock, to a group of institutional investors for an aggregate purchase price of \$2.2 million. Net proceeds to the Company, after deduction of placement agent fees and other expenses, were approximately \$2.0 million. The Series A Preferred Shares were convertible at any time at the option of the holders into shares of our common stock. The initial conversion price was \$0.75 and during 2012, 1,412 of the Series A Preferred Shares were converted at this price into an aggregate of 1,882,667 shares of our common stock. Effective December 11, 2013, the designation of the Series A Preferred Shares was amended in connection with the issuance of our Series B Convertible Preferred Stock (see discussion below). The amendment had the effect of reducing the conversion price of the then-outstanding Series A Preferred Shares to \$0.35 and during the remainder of 2013, 717 shares of the Series A Preferred Shares were converted at this price into an aggregate of 2,048,570 shares of our common stock. As of December 31, 2013, there were 71 shares of Series A Preferred Shares outstanding, convertible into 202,859 shares of our common stock. All of the remaining Series A Preferred Shares were converted into shares of our common stock during January 2014.

In January 2013, we reduced the exercise price of 2,933,333 of certain stock purchase warrants from \$0.75 to \$0.60 per share. In consideration for the reduction of the exercise price, the holders of the warrants immediately exercised 1,766,667 of the warrants for cash, resulting in total proceeds to the Company of \$1,060,000. We also extended the expiration date of the 1,166,666 unexercised warrants from March 21, 2013 to May 21, 2013. In May 2013, we reduced the exercise price of the 1,166,666 remaining warrants from \$0.60 to \$0.50 per share. In consideration for the reduction of the exercise price, the holders of the warrants immediately exercised all of the remaining warrants for cash, resulting in total proceeds to the Company of \$583,333.

In December 2013, we sold an aggregate of 1,650 Series B Convertible Preferred Stock ("Series B Preferred Shares") for an aggregate purchase price of \$1.65 million. Net proceeds to the Company, after deduction of transaction expenses, were approximately \$1.6 million. No warrants were issued in connection with the transaction. The Series B Preferred Shares may be converted at any time at the option of the holders into shares of our common stock at a conversion price of \$0.35. In conjunction with the sale of the Series B Preferred Shares, we entered into an agreement with the holders of the Series A Preferred Shares to amend the designation of the Series A Preferred Shares. The amendment had the effect of reducing the conversion price of the then-outstanding 788 Series A Preferred Shares from \$0.75 to \$0.35. Upon the consummation of the sale of the Series B Preferred Shares in December 2013, the exercise price of warrants to purchase 5,866,666 shares of our common stock issued in connection with the Series A Preferred Shares was reduced from \$1.00 to \$0.35 pursuant to the anti-dilution provisions contained in the warrant agreements. As of December 31, 2013, there were 1,650 shares of Series B Preferred Shares outstanding, convertible into 4,714,286 shares of our common stock. In January 2014, 350 Series B Preferred Shares were converted into 1,000,000 shares of our common stock.

Our capital requirements, particularly as they relate to our research and development activities, have been and will continue to be significant. We anticipate incurring additional losses for several years as we expand our 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. Such 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 2015. We anticipate raising additional capital during 2014, 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 government grants and clinical trial support, exercise of stock purchase 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, 2013, aggregated by type (in thousands):

	Payments Due by Period					
		Less			More	
		than	1-3	4-5	than	
<b>Contractual Obligations</b>	Total	1	Years	Years	5	
		Year			years	
Operating Lease Obligations (1)	\$129	\$129	\$	\$	\$	
Firm Purchase Commitments (2)	\$78	\$78	\$	\$	\$	
Emory University – License Agreement <sup>(3)</sup>						
Total	\$207	\$207	\$	\$	\$	

Our operating lease obligations relate to the facility lease for our 8,430 square foot facility in Smyrna, Georgia, (1) 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 conduct of clinical trials, and research activities related to NIH grants.
  - 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,
- (3) 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, 2013, 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 research agreements which are fully reimbursable to us pursuant to grants from the NIH and cover a period of less than one year.

# **Net Operating Loss Carryforwards**

At December 31, 2013, we had consolidated net operating loss carryforwards for income tax purposes of \$62.4 million, which will expire in 2014 through 2033 if not utilized. Approximately \$42.6 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 \$799,000 available to reduce income taxes, if any, which will expire in 2022 through 2033 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 \$2,284,943, \$2,135,140, and \$2,346,826 for the years ended December 31, 2013, 2012 and 2011, 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 \$2,417,550, \$2,657,327, and \$4,899,885 for the years ended December 31, 2013, 2012 and 2011, respectively. Grant revenues relate to grants from the NIH in support of our HIV vaccine development activities (see discussion under "Liquidity and Capital Resources" above). We record revenue associated with these grants as the related costs and expenses are incurred. The difference in our grant revenues from period to period is directly related to our expenditures for activities supported by the grants, and can fluctuate significantly based on the timing of the related expenditures. There is an aggregate of approximately \$822,000 in approved grant funds remaining and available for use as of December 31, 2013, which we anticipate recognizing as revenue during 2014.

# Research and Development

Our research and development expenses were \$2,914,878, \$3,043,522, and \$4,276,375 for the years ended December 31, 2013, 2012 and 2011, respectively. Research and development expense for these periods includes stock-based compensation expense of \$41,539, \$78,140, and \$179,400 for 2013, 2012 and 2011, 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 funding directly by us. Our ongoing Phase 1 clinical trial of our second generation preventive vaccine is being conducted by the HVTN with funding from the NIH, 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.

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 development expenses for each of the years in the three year period ended December 31, 2013. 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	2013	2012	2011
NIH Grant Activities	\$1,842,065	\$1,837,085	\$3,015,812
DNA/MVA Vaccines – HIV/AIDS	1,072,813	1,206,437	1,260,563
Total Research and Development Expense	\$2,914,878	\$3,043,522	\$4,276,375

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 for our preventive HIV vaccine, with GeoVax incurring costs associated with manufacturing the clinical vaccine supplies and other study support. We are having discussions with the HVTN and NIH with regard to the conduct of an additional 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 \$1,792,160, \$1,752,765, and \$2,972,555 for the years ended December 31, 2013, 2012 and 2011, 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 \$360,565, \$231,936, and \$593,597 for 2013, 2012 and 2011, respectively (see discussion under "Stock-Based Compensation Expense" below). The decline in general and administrative expense from 2011 to 2012 is primarily due to higher expenses during 2011 for legal costs, patent costs and stock-based compensation expense related to investment advisory fees and investor warrant extensions. 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 \$402,104, \$310,076, and \$772,997 during the years ended December 31, 2013, 2012 and 2011, 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, can be attributed to expense in the prior year 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, 2013, stock-based compensation expense was allocated as follows:

	2013	2012	2011
General and administrative expense	\$360,565	\$231,936	\$593,597
Research and development expense	41,539	78,140	179,400
Total stock option expense	\$402,104	\$310,076	\$772,997

Other Income

Interest income was \$4,545, \$3,820, and \$2,219 for the years ended December 31, 2013, 2012 and 2011, 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, 2013, 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, 2013 and 2012, and for each of the three years ended December 31, 2013, 2012 and 2011, and from inception through December 31, 2013, together with the independent registered public accounting firms' reports thereon, are set forth on pages F-1 to F-20 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, 2013. 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, 2013 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, 2013 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, 2013, 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 2014 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 <a href="www.geovax.com">www.geovax.com</a> 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 <a href="https://www.geovax.com">www.geovax.com</a>.

## **Item 11.** Executive Compensation

The information required by this Item is included in our definitive proxy statement for our 2014 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 2014 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 2014 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 2014 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	<u>Page</u>
	Reports of Independent Registered Public Accounting Firms on Financial	F-2
	Reporting	1'-2
	Consolidated Balance Sheets as of December 31, 2013 and 2012	F-4
	Consolidated Statements of Operations for the years ended December 31,	
	2013, 2012 and 2011 and for the Period from Inception (June 27, 2001) to	F-5
	December 31, 2013	
	Consolidated Statements of Stockholders' Equity (Deficiency) for the	F-6
	Period from Inception (June 27, 2001) to December 31, 2013	Г-0
	Consolidated Statements of Cash Flows for the years ended December 31,	
	2013, 2012 and 2011 and for the Period from Inception (June 27, 2001) to	F-7
	December 31, 2013	
	Notes to Consolidated Financial Statements	F-8

# (2) Financial Statement Schedules

The following financial statement schedule is set forth on page F-19 of this Annual Report on Form 10-K: Schedule II—Valuation and Qualifying Accounts for the years ended December 31, 2013, 2012 and 2011

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 Required by Item 601 of Regulation S-K

The exhibits filed with this report are set forth on the exhibit index following the signature page and are incorporated by reference in their entirety into this item.

# **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
(Principal Executive Officer)

Date: March 14, 2014

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been duly signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature / Name	Title	Date
/s/ Robert T. McNally Robert T. McNally	Director President and Chief Executive Officer (Principal Executive Officer)	March 14, 2014
/s/ Mark W. Reynolds Mark W. Reynolds	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2014
/s/ David A. Dodd David A. Dodd	Director	March 14, 2014
/s/ Dean G. Kollintzas Dean G. Kollintzas	Director	March 14, 2014
/s/ Robert T. McNally Robert T. McNally	Director	March 14, 2014

/s/ Harriet L. Robinson Harriet L. Robinson	Director	March 14, 2014
/s/ John N. Spencer, Jr. John N. Spencer, Jr.	Director	March 14, 2014
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# **EXHIBIT INDEX**

#### **Exhibit**

#### **Description**

### Number

- Agreement and Plan of Merger dated January 20, 2006 by and among GeoVax, Inc., GeoVax Acquisition 2.1 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)
- 3.1.3 Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed August 2, 2013 (17)
- 3.2Bylaws (6)
- 4.1.1 Amendment to Certificate of Designation of Series A Convertible Preferred Stock filed December 13, 2013 (19)
- Form of Stock Certificate for the Series B Convertible Preferred Stock 4.1.2 (19)
- Form of Stock Certificate for the Series A Convertible Preferred Stock 4.2
- 4.3 Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock filed December 13, 2013 (19)
- Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed March 20, 2012 (13)
- 10.1 \*\* Employment Agreement between GeoVax Labs, Inc. and Robert T. McNally effective as of April 1, 2008 (7)
- 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)
- Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Robert T. McNally dated 10.4
- \*\* October 22, 2013 (18)
- Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Harriet Robinson dated 10.5
- October 22, 2013 (18)
- Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Mark W. Reynolds dated 10.6 October 22, 2013 (18)
- 10.7 \*\* GeoVax Labs, Inc. 2006 Equity Incentive Plan (4)
- License Agreement (as amended and restated) between GeoVax, Inc. and Emory University, dated August 23, 2002 (3)
- 10.9 Office and Laboratory Lease between UCB, Inc. and GeoVax, Inc. (8)
- 10.10 Summary of the GeoVax Labs, Inc. Director Compensation Plan (9)
- 10.11 Form of Warrant dated December 30, 2011 (12)
- 10.12 Form of Common Stock Purchase Warrants (13)
- 10.13 Form of Securities Purchase Agreement dated March 16, 2012 (14)
- 10.14 Form of Registration Rights Agreement dated March 16, 2012 (14)
- 10.15 Form of Series A Warrant dated March 16, 2012 (14)
- 10.16Form of Series B Warrant dated March 16, 2012 (14)
- 10.17 Form of Series C Warrant dated March 16, 2012 (14)
- 10.18 Warrant Reset Offer Agreements dated January 17, 2013 (17)

- 10.19 Warrant Reset Offer Agreements dated May 14, 2013 (16)
- 10.20 Securities Purchase Agreement dated December 11, 2013 with Form of Registration Rights Agreement (19)

  10.21 Amendment Agreement and Consent of Holders of Series A Convertible Preferred Stock dated December 11, 2013 (19)
- 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 The following financial information from GeoVax Labs, Inc. Annual Report on Form 10-K for the year ended December 31, 2013, formatted in Extensible Business Reporting Langue (XBRL): (i) Consolidated Balance Sheets as of December 31, 2013 and December 31, 2012, (ii) Consolidated Statements of Operations for the
- years ended December 31, 2013, 2012 and 2011 and for the period from inception (June 27, 2001) to December
- \*,\*\*\* 31, 2013, (iii) Consolidated Statements of Stockholders' Equity (Deficiency) for the period from inception (June 27, 2001) to December 31, 2013, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011 and for the period from Inception (June 27, 2001) to December 31, 2013, and (v) Notes to Condensed Consolidated Financial Statements.

- (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.
- 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.
- (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 February 6, 2012.
- (14) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 22, 2012.
- (15) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 17, 2013.
- (16) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 15, 2013.
- (17) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 2, 2013.
- (18) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 23, 2013.
- (19) Incorporated by reference from the registrant's Current Report on Form 8-K filed December 17, 2013.

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Filed herewith.

<sup>\*\*</sup> Indicates a management contract or compensatory plan or arrangement. 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.

### **GEOVAX LABS, INC.**

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### (A DEVELOPMENT-STAGE ENTERPRISE)

#### INDEX TO 2013 CONSOLIDATED FINANCIAL STATEMENTS

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Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011 and for the Period from Inception (June 27, 2001) to December 31, 2013	F-7
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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

#### ON FINANCIAL STATEMENTS

To the Board of Directors

GeoVax Labs, Inc.

Atlanta, Georgia

We have audited the accompanying consolidated balance sheets of GeoVax Labs, Inc. and subsidiary (a development stage company) (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity (deficiency), and cash flows for each of the three years in the period ended December 31, 2013, and for the period of time considered part of the development stage from June 27, 2001 to December 31, 2013, except we did not audit the Company's financial statements for the period from June 27, 2001 to December 31, 2005 which were audited by other auditors. Our audits also included the financial statement schedule of the Company listed in Item 15(a). These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion of the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of GeoVax Labs, Inc. and subsidiary as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013, and for the period of time considered part of the development stage from June 27, 2001 to December 31, 2013, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in

all material respects the information set forth therein.

/S/ PORTER KEADLE MOORE, LLC

Atlanta, Georgia

March 14, 2014

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

#### ON FINANCIAL STATEMENTS

Board of Directors
GeoVax, Inc.
Atlanta, Georgia
We have audited the statements of operations, stockholders' deficiency and cash flows of GeoVax, Inc. (a Georgia corporation in the development stage) for the period from inception (June 27, 2001) to December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.
We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement

In our opinion, the financial statements of GeoVax, Inc. referred to above present fairly, in all material respects, the results of its operations, changes in stockholders' deficiency and cash flows for the period from inception (June 27, 2001) to December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

presentation. We believe that our audit provides a reasonable basis for our opinion.

/s/ TRIPP, CHAFIN & COMPANY, LLC

Marietta, Georgia

February 8, 2006

## **GEOVAX LABS, INC.**

### (A DEVELOPMENT-STAGE ENTERPRISE)

#### CONSOLIDATED BALANCE SHEETS

ACCETC	December 31, 2013	2012
ASSETS Comment acceptate		
Current assets: Cash and cash equivalents	\$2,513,861	\$1,035,925
Grant funds receivable	140,909	266,248
Prepaid expenses and other current assets	43,569	42,301
rrepaid expenses and other current assets	43,309	42,301
Total current assets	2,698,339	1,344,474
Property and equipment, net	120,227	102,486
Other assets	21,010	31,010
Total assets	\$2,839,576	\$1,477,970
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:		
Accounts payable	\$155,943	\$163,788
Accrued expenses	96,406	33,877
Amounts payable to Emory University (a related party)	60,000	129,370
Total current liabilities	312,349	327,035
Commitments (Note 6)		
Stockholders' equity: Preferred stock, \$.01 par value: Authorized shares – 10,000,000		
Series A convertible preferred stock, \$1,000 stated value; 71 and 788 shares issued and outstanding at December 31, 2013 and 2012, respectively	60,586	312,196
Series B convertible preferred stock, \$1,000 stated value; 1,650 and -0- shares issued and outstanding at December 31, 2013 and 2012, respectively	1,255,569	-
Common stock, \$.001 par value: Authorized shares – 75,000,000 and 40,000,000 at December 31, 2013 and 2012, respectively		
Issued and outstanding shares – 23,765,180 and 18,733,277 at December 31, 2013 and 2012, respectively	23,765	18,733
Additional paid-in capital	28,239,392	25,587,148

Deficit accumulated during the development stage (27,052,085) (24,767,142)

Total stockholders' equity 2,527,227 1,150,935

Total liabilities and stockholders' equity \$2,839,576 \$1,477,970

See accompanying notes to consolidated financial statements.

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#### **GEOVAX LABS. INC.**

### (A DEVELOPMENT-STAGE ENTERPRISE)

#### CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended I	December 31		From Inception
	Tears Effect 1		(June 27, 2001) to	
	2013	2012	2011	December 31, 2013
Grant revenue	\$2,417,550	\$2,657,327	\$4,899,885	\$25,386,569
Operating expenses:				
Research and development	2,914,878	3,043,522	4,276,375	31,589,076
General and administrative	1,792,160	1,752,765	2,972,555	21,192,584
	4,707,038	4,796,287	7,248,930	52,781,660
Loss from operations	(2,289,488)	(2,138,960)	(2,349,045)	(27,395,091)
Other income (expense):				
Interest income	4,545	3,820	2,219	348,675
Interest expense	-	-	-	(5,669)
	4,545	3,820	2,219	343,006
Net loss	\$(2,284,943)	\$(2,135,140)	\$(2,346,826)	\$(27,052,085)
Basic and diluted: Loss per common share Weighted average shares outstanding		\$(0.12) 18,315,669	, ,	\$(2.21 ) 12,241,449

See accompanying notes to consolidated financial statements.

### **GEOVAX LABS, INC.**

### (A DEVELOPMENT-STAGE ENTERPRISE)

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)

	Series A Converti	ble	Ser B Cor		tible Common Sto	Additional Stock		Stock	Deficit  Accumulated		Total Stockholde	
	Preferred	Stock		ferre			Paid-in	,	Subscription	During the		
			Sto	ck						Developmen	t	Equity
	Shares	Amount	Sha	n <b>A</b> em	Silmtres	Amount	Capital	]	Receivable	Stage		(Deficiency
Capital												
contribution at inception		\$-		\$-		\$-	\$10		\$-	\$-		\$10
(June 27,	-	φ-	-	φ-	-	φ-	\$10	•	φ-	Φ-		<b>Φ10</b>
2001)												
Net loss for												
the period												
ended	-	-	-	-	-	-	-		-	(170,592	)	(170,592
December 31,												
2001												
Balance at							10			(170.502	\	(170.502
December 31, 2001	-	-	-	-	-	-	10		-	(170,592	)	(170,582
Sale of												
common stock	_	_	_	_	2,789,954	2,790	(2,320	)	_	_		470
for cash					2,700,00	2,770	(2,320	,				170
Issuance of												
common stock					704,534	705	148,151					148,856
for technology	-	-	-	-	704,334	703	140,131		-	-		140,030
license												
Net loss for												
the year ended	-	-	_	_	-	-	-		-	(618,137	)	(618,137
December 31, 2002												
Balance at												
December 31,	_	_	_	_	3,494,488	3,495	145,841		_	(788,729	)	(639,393
2002					2,121,100	-,	- 10,011			(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(00),000
Sale of												
common stock	-	-	-	-	1,229,278	1,229	2,458,380		-	-		2,459,609
for cash												
Net loss for	-	-	-	-	-	-	-		-	(947,804	)	(947,804
the year ended												

December 31, 2003										
2003	-	-	-	-	4,723,766	4,724	2,604,221	-	(1,736,533 )	872,412
Sale of common stock for cash and stock subscription receivable	-	-	-	-	1,482,605	1,483	2,988,436	(2,750,000)	-	239,919
Cash payments received on stock subscription receivable	-	-	-	-	-	-	-	750,000	-	750,000
Issuance of common stock for technology license	-	-	-	-	49,420	49	99,951	-	-	100,000
Net loss for the year ended December 31, 2004	-	-	-	-	-	-	-	-	(2,351,828 )	(2,351,828
Balance at December 31, 2004	-	-	-	-	6,255,791	6,256	5,692,608	(2,000,000)	(4,088,361)	(389,497
Cash payments received on stock subscription receivable	-	-	-	-	-	-	-	1,500,000	-	1,500,000
Net loss for the year ended December 31, 2005	-	-	-	-	-	-	-	-	(1,611,086 )	(1,611,080
Balance at December 31, 2005	-	-	-	-	6,255,791	6,256	5,692,608	(500,000 )	(5,699,447)	(500,583
Cash payments received on stock subscription receivable	-	-	-	-	-	-	-	500,000	-	500,000
Conversion of preferred stock to common stock	-	-	-	-	3,550,851	3,551	1,071,565	-	-	1,075,116

Common stock issued in connection with merger	-	-	-	-	4,359,891	4,360	1,708,489	-	-	1,712,849
Issuance of common stock for cashless warrant exercise	-	-	-	-	56,825	57	(57 )	-	-	-
Net loss for the year ended December 31, 2006	-	-	-	-	-	-	-	-	(584,166 )	(584,166
Balance at December 31, 2006	-	-	-	-	14,223,358	14,224	8,472,605	-	(6,283,613 )	2,203,216
Sale of common stock for cash	-	-	-	-	406,729	407	3,162,543	-	-	3,162,950
Sale of common stock for cash upon stock option	-	-	-	-	2,471	2	4,998	-	-	5,000
exercise Stock-based compensation expense	-	-	-	-	-	-	1,518,496	-	-	1,518,496
Net loss for the year ended December 31, 2007	-	-	-	-	-	-	-	-	(4,241,796 )	(4,241,796
Balance at December 31, 2007	-	-	-	-	14,632,558	14,633	13,158,642	-	(10,525,409)	2,647,866
Sale of common stock for cash	-	-	-	-	306,419	306	1,770,785	-	-	1,771,091
Issuance of common stock for services	-	-	-	-	10,000	10	73,990	-	-	74,000
Stock-based compensation expense	-	-	-	-	-	-	1,945,049	-	-	1,945,049
Net loss for the year ended December 31, 2008	-	-	-	-	-	-	-	-	(3,728,187)	(3,728,18
Balance at December 31, 2008	-	-	-	-	14,948,977	14,949	16,948,466	-	(14,253,596)	2,709,819
	-	-	-	-	216,261	216	1,519,784	-	-	1,520,000

		-							
-	-	-	-	462,826	463	1,499,537	-	-	1,500,000
-	-	-	-	4,500	5	31,495	-	-	31,500
-	-	-	-	-	-	1,267,165	-	-	1,267,165
_	_	_	_	_	_	_	_	(3.284.252)	(3,284,252
								(5,25 .,25 = )	(3,23 .,
						<b></b>			
-	-	-	-	15,632,564	15,633	21,266,447	-	(17,537,848)	3,744,232
_	_	_	_	12.000	12	89.988	_	-	90,000
				12,000	12	0,,,,,,			,0,000
				10 700	10	72.002			72.012
-	-	-	-	10,500	10	53,803	-	-	53,813
						606 <b>5</b> 10			CO C 710
-	-	-	-	-	-	696,719	-	-	696,719
_	_	-	_	(218)	_	(1,210)	-	_	(1,210
				,		,			,
_	-	-	-	_	-	-	-	(2,747,328)	(2,747,328
				15 654 046	15 (55	22 105 747		(20, 205, 176)	1 026 026
-	-	-	-	15,654,846	15,655	22,105,747	-	(20,285,176)	1,836,226
				(50 500	650	440 551			441 210
-	-	-	-	638,520	639	440,551	-	-	441,210
				100 045	129	149,871			150,000
					1 / 4	149 X / i	_	_	13111111
-	-	-	-	129,245	129	117,071			130,000
-	-	-	-	129,243	129	117,071			130,000
	-	-	-	129,243	129				
-	-	-	-	-	-	622,997	-	-	622,997
					4,500  4,500  15,632,564  12,000  10,500  (218)  15,654,846	4,500 5	4,500 5 31,495  1,267,165  15,632,564 15,633 21,266,447  12,000 12 89,988  10,500 10 53,803  (218 ) - (1,210 )  15,654,846 15,655 22,105,747	4,500 5 31,495 1,267,165 15,632,564 15,633 21,266,447 10,500 10 53,803 (218 ) - (1,210 ) 15,654,846 15,655 22,105,747 -	

Net loss for the year ended December 31, 2011	-	-	-	-	-	-	-	-	(2,346,826 )	(2,346,820
Balance at December 31, 2011	-	-	-	-	16,442,611	16,443	23,319,166	-	(22,632,002)	703,607
Sale of common stock for cash	-	-	-	-	407,999	408	272,952	-	-	273,360
Sale of convertible preferred stock and warrants for cash	2,200	871,614	-	-	-	-	1,127,418	-	-	1,999,032
Conversion of preferred stock to common stock	(1,412)	(559,418)	-	-	1,882,667	1,882	557,536	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	310,076	-	-	310,076
Net loss for the year ended December 31, 2012	-	-	-	-	-	-	-	-	(2,135,140 )	(2,135,140
Balance at December 31, 2012	788	312,196	-	-	18,733,277	18,733				