

GeoVax Labs, Inc.

Form 10-K

March 16, 2016

**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, 2015

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

Commission File No. 000-52091

**GEOVAX LABS, INC.**

*(Exact name of Registrant as specified in its charter)*

**Delaware**

**87-0455038**

*(State or other jurisdiction of*

*(IRS Employer*

*incorporation or organization)*

*Identification Number)*

**1900 Lake Park Drive, Suite 380**

**Smyrna, GA**

**30080**

*(Address of principal executive offices) (Zip Code)*

**(678) 384-7220**

*Registrant's telephone number, including area code:*

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Securities registered pursuant to Section 12(b) of the Act:

**None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock \$.001 par value**

*(Title of class)*

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.  
☐

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

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

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2015, based on the closing price on that date was \$4,389,094.

Number of shares of Common Stock outstanding as of March 15, 2016: 37,015,401

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement with respect to its 2016 Annual Meeting of Stockholders are incorporated by reference in Part III

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**Table of Contents**

**PART I**

Item 1	Business	1
Item 1A	Risk Factors	16
Item 1B	Unresolved Staff Comments	24
Item 2	Properties	24
Item 3	Legal Proceedings	24
Item 4	Mine Safety Disclosures	24

**PART II**

Item 5	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	25
Item 6	Selected Financial Data	26
Item 7	Management’s Discussion and Analysis of Financial Condition and Results of Operations	26
Item 7A	Quantitative and Qualitative Disclosures about Market Risk	34
Item 8	Financial Statements and Supplementary Data	34
Item 9	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	34
Item 9A	Controls and Procedures	34
Item 9B	Other Information	35

**PART III**

Item 10	Directors, Executive Officers and Corporate Governance	35
Item 11	Executive Compensation	35
Item 12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	35
Item 13	Certain Relationships and Related Party Transactions, and Director Independence	35
Item 14	Principal Accountant Fees and Services	35

**PART IV**

Item 15	Exhibits and Financial Statement Schedules	36
Signatures		37
Exhibit		
Index		38

## **PART I**

### **ITEM 1. BUSINESS**

*This Annual Report (including the following section regarding Management’s Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this Annual Report. Additionally, statements concerning future matters, including statements regarding our business, our financial position, the research and development of our products and other statements regarding matters that are not historical are forward-looking statements.*

*Although forward-looking statements in this Annual Report reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include without limitation those discussed under the heading “Risk Factors” below, as well as those discussed elsewhere in this Annual Report. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report. Readers are urged to carefully review and consider the various disclosures made in this Annual Report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.*

#### **Overview**

GeoVax Labs, Inc. (“GeoVax” or the “Company”) is a clinical-stage biotechnology company developing human vaccines against infectious diseases using our MVA-VLP vaccine platform. Our platform supports in vivo expression of non-infectious virus-like particles (VLPs) from the cells of the person receiving the vaccine. VLPs work by displaying the virus’ surface glycoproteins which in turn train the person’s immune system to recognize and destroy the actual virus and virus-infected cells to block infection. The production of VLPs in the person being vaccinated mimics a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent and control the target infection should it appear.

Our current development programs are focused on vaccines against Human Immunodeficiency Virus (HIV), Zika virus, and hemorrhagic fever viruses (Ebola, Marburg, Lassa Fever), as well as for use in cancer immunotherapy. We

believe our technology and vaccine development expertise are well-suited for a variety of human infectious diseases and we intend to pursue expansion of our product pipeline.

Our most advanced HIV vaccine program is focused on the clade B subtype of HIV prevalent in the Americas and Western Europe. Our preventive clade B HIV vaccine has successfully completed Phase 2a human clinical testing and we expect to enter a follow-on clinical trial in mid-2016 with support from the National Institutes of Health (NIH). We are considered the leading vaccine candidate for protection against the clade B subtype; accordingly, planning has begun for a phase 2b efficacy trial. Our vaccine has shown outstanding safety and excellent and highly reproducible immunogenicity (*Journal of Infectious Diseases* volume 203, pg 610 and volume 210 pg 99). We have also extended our HIV vaccine effort to the most common virus subtype affecting sub-Saharan Africa (clade C) and are conducting preclinical studies pursuant to a grant from the NIH. Our HIV vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the Centers for Disease Control and Prevention (CDC). The technology developed by the collaboration is exclusively licensed to us from Emory University. We also have nonexclusive licenses to certain patents owned by the NIH.

Our hemorrhagic fever vaccine program was initiated during 2014 with the objective of developing a tetravalent vaccine designed to protect against all major hemorrhagic fever viruses (Ebola, Marburg, Lassa) endemic in African countries. Studies of our first Ebola vaccine candidate have demonstrated 100 percent protection in rodent models. We plan to conduct additional challenge studies in non-human primates in collaboration with the NIH during 2016, with the goal of beginning human clinical trials during 2017. In February 2016 we entered into a Cooperative Research and Development Agreement for material transfer with the United States Army Research Institute of Infectious Disease (USAMRIID). This agreement provides us with access to Ebola, Marburg and Lassa fever monoclonal antibodies for *in vitro* vaccine characterization, with USAMRIID performing *in vitro* and *in vivo* assessment of our vaccine candidates.

In December 2015, we entered into a Collaborative Research Agreement with the University of Pittsburgh to evaluate our MVA-VLP vaccine platform for use in cancer immunotherapy, including the selection and testing of vaccine candidates. We are currently constructing our vaccine candidates and intend to conduct proof-of-concept animal studies during 2016. Cancer immunotherapy (or immuno-oncology), is a technique whereby the patient's immune system is trained to fight solid tumors and is considered to be a very promising area of biotechnology.

In February 2016, we began a program to develop a vaccine for the prevention of Zika virus infections using our MVA-VLP vaccine platform, and we entered into a Collaborative Research Agreement with the University of Georgia (UGA) to speed development of the vaccine. Pursuant to this collaboration, we will develop vaccine antigens that elicit broadly reactive immunity against Zika viruses and UGA will test those vaccines in preclinical models. We are also collaborating with the CDC for reagents and testing of vaccines. We intend to conduct the initial proof-of-concept animal studies during the first half of 2016.

Our HIV vaccine development activities have been, and continue to be, financially supported by the U.S. government. This support has been both in the form of research grants awarded directly to us, as well as indirect support for the conduct of our human clinical trials. Government support is also being sought for our newer vaccine targets. This is discussed further under "Support from the United States Government" below.

We are incorporated in Delaware, and our offices and laboratory facilities are located in Smyrna, Georgia (metropolitan Atlanta).

## **Our Technology**

Vaccines typically contain agents (antigens) that resemble disease-causing microorganisms. Traditional vaccines are often made from weakened or killed forms of the virus or from its surface proteins. Many newer vaccines use recombinant DNA (deoxyribonucleic acid) technology to generate vaccine antigens in bacteria or cultured cells from specific portions of the DNA sequence of the target pathogen. The generated antigens are then purified and formulated for use in a vaccine. The most successful of these purified antigens have been non-infectious virus-like particles (VLPs) as exemplified by vaccines for hepatitis B (Merck's Recombivax® and GSK's Engerix®) and Papilloma viruses (GSK's Cervarix®, and Merck's Gardasil®). Our approach uses recombinant DNA or recombinant viruses to produce VLPs in the person being vaccinated. In human clinical trials of our HIV vaccines, we have demonstrated that our VLPs, expressed in the cells of the person being vaccinated, are safe, yet elicit both strong and durable humoral and cellular immune response.

All of our vaccines are designed to produce self-assembling non-infectious VLPs in the cells of the person being vaccinated. VLPs train the body's immune system to recognize and kill the authentic virus should a target infection

appear. VLPs also train the immune system to recognize and kill infected cells to control infection and reduce the length and severity of disease. One of the biggest challenges with VLP-based vaccines is to design the vaccines in such a way that the VLPs will be recognized by the immune system in the same way as the authentic virus would be. When VLPs for enveloped viruses like HIV, Ebola, and Marburg are produced *in vivo*, they include not only the protein antigens, but also an envelope consisting of membranes from the vaccinated individual's cells. In this way, they are highly similar to the virus generated in a person's body during a natural infection. VLPs produced externally, by contrast, may have no envelope; or, envelopes from the cultured cells (typically hamster or insect cells) used to produce them. We believe our technology provides distinct advantages by producing VLPs that more closely resemble the authentic virus, which in turn, allows the body's immune system to more readily recognize the authentic virus. By producing VLPs in the individual being vaccinated, we avoid the cost and technical issues associated with *in vitro* production of VLPs in cell culture.

***DNA and MVA as Vaccine Vectors.*** Our HIV vaccines incorporate two delivery components (or vectors): a priming recombinant plasmid DNA vaccine, and a boosting recombinant MVA (modified vaccinia Ankara) vaccine. Our hemorrhagic fever and Zika vaccines use only the MVA vector. Both our DNA and MVA vaccines express sufficient vaccine antigens to support the production of non-infectious VLPs. The VLPs cannot cause disease because they contain mutated or deleted enzymatic functions that are essential for virus replication. VLPs display trimeric membrane bound forms of the viral envelope glycoprotein (Env for HIV, or GP for Ebola/Marburg/Lassa and Zika). This is important because the natural form of the envelope glycoprotein elicits target antibodies with multiple specificities capable of recognizing incoming virus and blocking infections. Expression of multiple proteins by the vaccines is essential for the formation of VLPs. The multiple proteins also provide more targets for immune responses such as cytotoxic T-cells. Elicitation of multi-target humoral and cellular responses limits immune escape, just as multi-drug therapies limit drug escape.



### **Ebola VLPs**

### **HIV VLPs**

**Figure 1. Electron micrographs showing the virus-like particles (VLPs) elicited by GeoVax vaccines from human cells.** Note that the Ebola VLPs on the left self-assemble into the rod-like shape of the actual Ebola virus, while the HIV VLPs shown on the right take on the spherical shape of the actual HIV virus. While below the resolution of these micrographs, both types of VLPs display what we believe to be the native form of their respective viral envelope glycoproteins which we believe is key to generating an effective immune humoral response.

We selected MVA 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 viral 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 chicken embryo fibroblasts, which resulted in a virus with limited ability to replicate in human cells, but did not compromise the ability of MVA to grow on avian cells, which 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.

**Induction of T-cell and Antibody Immune Responses.** In both preclinical and clinical trials, our HIV vaccines have been shown to induce both humoral (antibody) and cellular (T-cell) responses against HIV. The induction of both antibodies and T-cells is beneficial because these immune responses work through different mechanisms. Antibodies prevent infection by blocking viruses from infecting cells. In preclinical simian 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)). Similarly, antibody responses are believed to be critical for vaccine-elicited protection against Ebola and Marburg infection (*Expert Review of Vaccines*, 10:63 (2011)). These results likely reflect the tightly binding antibody both blocking infection as well as tagging 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). For HIV, CD8+ T-cells are important for the control of the virus that has established an infection. For Ebola and Marburg, antibodies can stop or slow the progress of infection, but T cells are important for clearing the infection by killing remaining infected cells.

***Background – What are Vaccines?***

A vaccine is a substance introduced into the human body that teaches the immune system to detect and destroy a pathogen (a virus or other pathogen that causes disease). All vaccines contain some harmless form or part of the pathogen they target or of a highly similar pathogen. They exert their effects through the adaptive immune response, an arm of the immune system that learns to recognize and control 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, influenza, hepatitis A, rabies, injectable polio, tick-borne encephalitis, Japanese encephalitis (both from *Flaviviridae* family that include Zika virus) vaccines. This approach has not been applied to the development of vaccines against HIV due to lack of success in animal experiments and the difficulty of developing an inactivation method capable of ensuring that the product will be entirely free of active virus. Similarly, inactivated Ebola vaccines have not shown great promise in animal models, and any production process starting with live Ebola, Marburg or Lassa fever virus would require such extreme containment measures that it would be difficult to operate at industrial scale.

*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, mumps, rubella (MMR), yellow fever (a flavivirus), Varicella, influenza, smallpox 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 true picture of what it would be up against. Due to the risk that attenuated HIV, Ebola, or Marburg might revert to its disease-causing form, this approach has not been applied to the development of HIV, Ebola, or Marburg 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. To date, subunit vaccines have failed to protect nonhuman primates against Ebola infection (*Human Vaccines*, 6:439 (2010)).

*Purified VLP vaccines:* Purified VLP vaccines consist only of virus-like particles, which are composed of certain viral proteins but do not contain the genetic material of the virus. Unlike subunit vaccines, VLPs typically provide viral antigens in their native form. Due to their structural similarity to actual viruses, VLPs are excellent immunogens capable of raising potent antibody and cellular immune responses. Purified VLPs need to be manufactured and purified in large quantities. They also are difficult to make for relatively fragile viruses with lipid membrane envelopes such as HIV, Ebola, Marburg or Zika vaccines. Examples of successful vaccines using purified VLPs include vaccines for hepatitis B (Merck's Recombivax® and GSK's Engerix®) and Papilloma viruses (GSK's Cervarix®, and Merck's Gardasil®).

*Expressed VLP vaccines:* These vaccines are designed to produce self-assembling non-infectious VLPs in the cells of the person being vaccinated. When VLPs for enveloped viruses like HIV, Ebola, and Marburg are produced *in vivo*, they include not only the protein antigens, but also an envelope consisting of membranes from the vaccinated individual's cells displaying proteins that mediate entry into cells. In this way, they are highly similar to the virus generated in a person's body during a natural infection. Purified VLPs produced externally, by contrast, have no envelope; or, envelopes from the cultured cells (typically hamster or insect cells) used to produce them. By producing VLPs *in vivo*, potential purification issues associated with *in vitro* production of VLPs are avoided. GeoVax employs this approach in our vaccine design.

*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, which carry genes encoding those antigens. Human cells passively take up these plasmids and produce the antigens which, in turn, train the immune system to recognize the targeted pathogen. There currently is no FDA-approved DNA vaccine for humans.

*Recombinant viral vaccines:* These vaccines, like DNA vaccines, introduce genes for targeted antigens into the body. But the genes are inserted into a virus that actively carries the vaccine insert into 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. Examples include two flavivirus vaccines, Japanese encephalitis (IMOJEV®) and dengue (DENGVAxia®) vaccines constructed using the yellow fever 17D vaccine as a vector.

## **Our HIV/AIDS Vaccine Program**

**About HIV/AIDS.** 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 enters human cells and copies its viral RNA to produce complementary DNA (cDNA) 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 defenses 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 HIV vaccines.

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 if infection occurs.

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.

HIV/AIDS is considered by many in the scientific and medical community to be the most lethal infectious disease in the world. An estimated 37 million people are living with HIV worldwide, with approximately 2.5 million newly infected in 2012 alone. Approximately 39 million people infected with HIV have died since the 1981 start of the HIV pandemic. The United States currently has an estimated 1.2 million HIV-infected individuals, with approximately 50,000 new infections per year, a number that has remained virtually the same for 20 years. Alarming the fastest growing demographic for acquiring an HIV infection is the 13 – 24 year old group which is expanding at roughly 10% per year and will soon become the group with the highest total number of infections.

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. 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, viruses acquire drug-resistant mutations, and many patients develop intolerance to the medications or simply give up taking the medications due to cost, inconvenience or 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. 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. Vaccines 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 Preventive HIV Vaccine Program***

Prevention of HIV infection remains a worldwide unmet medical need, even in the United States and other first world countries where effective antiretroviral therapies are available. There is no approved HIV vaccine. Current antiretroviral therapies do not eliminate HIV infection, requiring individuals to remain on antiretroviral drugs for their entire lives. Uptake and successful long term adherence to therapy is also limited. Only 25% of those infected with HIV in the US ultimately remain in HIV care with their viral load sufficiently suppressed to prevent spread of HIV. The annual incidence of new HIV infections has remained virtually unchanged for the past 20 years. Furthermore, the annual financial burden to the U.S. taxpayer for HIV education, prevention, and treatment costs borne through multiple federal agencies is more than \$20 billion annually.

Work on our HIV vaccines began during the 1990s at Emory University in Atlanta, Georgia, under the direction of Dr. Harriet L. Robinson, who is now our Chief Scientific Officer. The vaccine technology was developed in collaboration with researchers at the NIH and the CDC.

Our most clinically advanced vaccine development program is a DNA/MVA vaccine regimen designed to protect against the clade B subtype of the HIV virus. Clade B is prevalent in the Americas and Western Europe. An estimated 3.3 million people are infected with clade B HIV virus worldwide, with 187,000 new infections in 2012.

We have two HIV vaccine components under development: a recombinant DNA vaccine, and a recombinant MVA vaccine. Both the DNA and MVA vaccines contain sufficient HIV genes to support the production of non-infectious virus-like particles. These VLPs display the native trimeric membrane-bound form of the HIV envelope glycoprotein (Env) 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. This prime-boost strategy elicits high avidity antibodies (tightly binding antibodies) and cytotoxic T cells. The antibodies can block infections and initiate the killing of virus and infected cells by bound antibody signaling destruction by virion capture, antibody-dependent cellular cytotoxicity, phagocytosis and complement mediated lysis.

Clinical trials of our preventive HIV vaccine have been conducted by the HIV Vaccine Trials Network (HVTN). The 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.

We have completed multiple Phase 1 trials and a Phase 2a trial (HVTN 205) of various dosing regimens and formulations of our vaccines. These vaccines have been evaluated in nearly 500 humans. All of the clinical trials of our preventive vaccines have been conducted by the HVTN, and fully funded by the NIH.

We expect the NIH to fully fund the cost of another Phase 1 trial (HVTN 114) of our preventive HIV vaccine to begin in mid-2016, which will investigate the effect of adding a "protein boost" component to our vaccine. Protein boosts may augment antibody responses that can block virus infections (neutralizing antibody) and cause antibody dependent cellular cytotoxicity (ADCC). Proteins added to HIV vaccines have shown some success in other trials. The HVTN believes this "dual-action" approach will be a prudent and cost-effective path forward for supporting large clinical trials. Information from this trial would then inform the design of future, larger clinical trials. While efforts are underway to evaluate the protein boost concept, we also intend to seek funding to expedite our vaccine (without the added protein boost) directly into pivotal Phase 2b efficacy trials.

The HVTN is continuing to consider future efficacy studies, and members are working to develop collaborative clinical development plans, as well as initiating regulatory planning. The plans for large-scale clinical trials may change as researchers continue to gather information from our earlier studies and are influenced by results from other vaccine trials. Trial start dates are dependent on many factors and are likely to change.

*Preventive HIV Vaccine Program – Clade C.* We also are developing DNA/MVA vaccines designed for use to combat the subtypes of HIV that predominate in South Africa and India. In June 2015, the NIH awarded us a Small Business Innovative Research (SBIR) grant entitled "Directed Lineage Immunizations for Eliciting Broadly Neutralizing Antibody" toward this effort.

*Preclinical Studies.* We have conducted multiple preclinical efficacy trials of our preventive HIV vaccines by vaccinating non-human primates with simian immunodeficiency virus prototypes of our HIV vaccines and then testing them for resistance to either single high dose, or repeated low dose rectal challenges. The most recent of these studies has shown that the SIV prototype of our HIV vaccine that is advancing in clinical trials provided a 76% reduction in per exposure risk of infection over a series of 12 weekly rectal challenges. This is a very good level of protection to have achieved in the SIV macaque model much better than achieved in preclinical models by simian prototypes of the one partially successful HIV vaccine tested in the RV144 trial in Thailand.

### ***Completed Human Clinical Trials -- Preventive HIV 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). The results of a 300 person Phase 2a trial are published in *The Journal of Infectious Diseases* 210: 99 (2014). These 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 (TCID<sub>50</sub>) of MVA. Once safety was demonstrated for the low dose in 10 participants, the full dose (3 mg of DNA and  $1 \times 10^8$  TCID<sub>50</sub> 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.

*Phase 2 Human Clinical Trials.* Based on the safety and the immunogenicity results in the HVTN 045 and HVTN 065 Phase 1 trials, the full dose DNA/MVA and MVA-only regimens were selected for testing by the HVTN in a Phase 2a trial (designated HVTN 205). HVTN 205 was designed to further 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 our MVA vaccine (DDMM arm), 75 participants received three MVA injections and one placebo injection (MMPM arm), and 75 participants received four injections of placebo. At 2 weeks 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, anti-Env Ab response titers in the DDMM arm had declined by less than 3-fold. The antibody to Env had high affinity binding, a characteristic associated with prevention of infection in preclinical models. The study also showed low response rates for serum IgA, a desirable characteristic because serum IgA can compete for binding with serum IgG and block protective Fc-mediated protection. In the one partially successful HIV vaccine trial, levels of serum IgA were a direct correlate with risk. Encouragingly, response rates for serum IgG3, an isotype associated with Fc-mediated mechanisms of protection such as complement (C')-mediated lysis and antibody-dependent cellular cytotoxicity were excellent (91% response rate). These results reinforce our desire to move to the next level of clinical trial, a Phase 2b efficacy trial using individuals who are at risk of coming into contact with HIV. This type of trial would show whether the vaccine protects against HIV exposure.

### ***HIV Immunotherapy Program***

Current antiretroviral therapies, though highly effective at suppressing HIV viral load, are unable to eliminate latent forms of HIV that are invisible to the immune system and inaccessible to antiretroviral drugs. In response to this problem, the NIH and other leaders in the HIV field have developed a new concept: the “shock and kill” strategy, in which patients remain on standard-of-care anti-retroviral drug therapy while a second drug (“shock agent”) is used to activate latent HIV and a third drug (“kill agent”) is used to recognize and eliminate cells with activated HIV infections. A shock and kill therapy could potentially contribute to a drug-free cure for HIV.

*Preclinical Studies – Therapeutic Vaccine.* In 2007-2008, data were generated in three pilot studies conducted at Yerkes National Primate Research Center of Emory University in which 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.

*Phase 1 Clinical Trial (Treatment Interruption).* In early 2014, we completed a Phase 1 clinical trial (GV-TH-01) investigating the therapeutic use of our GOVX-B11 HIV vaccine in HIV-infected patients. GV-TH-01 was an open label Phase 1 treatment interruption trial investigating the safety and immunogenicity of our DNA/MVA vaccine regimen 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 was 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 was to evaluate the ability of the vaccinated patient to control re-emergent virus during the drug treatment interruption period.

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. Eight participants underwent treatment interruption to test the ability of the vaccine-enhanced responses to control, or prevent, re-emergent virus. Virus re-emerged in all 8 individuals. Interestingly, in 6 of the 8, re-emergent virus appeared to have already escaped the hosts' T cell responses indicating that to be effective, vaccination would need to take place in individuals placed on antiretroviral therapy soon after infection (see preclinical study above, where vaccination was most effective in non-human primates placed on drugs at 12 weeks after infection). In 2 of the 8 participants, escape had not taken place before treatment interruption. In these two participants, the vaccination failed to snuff the infection at the site of re-emergence and escape mutants rapidly appeared. Thus, therapeutic vaccination will need to overcome the challenge of the rapid selection of CD8+ escape viruses in infected individuals (most of whom do not realize that they are infected) and a poor ability of CD8+ T cells to control virus (that has not already escaped the T cell response) at the site of viral re-emergence.

While no reportable medical adverse events were documented during GV-TH-01, it remains clear that in order to achieve a cure for HIV multiple concomitant therapies will be necessary. An approach using the standard of care oral drug therapy, plus a vaccine and a “shock” agent used to expose the virus and make it susceptible to activated antibodies and T-cells is an example of an approach required to achieve such a cure. Observations from GV-TH-01 have led us to postulate that our DNA vaccines may be effective as shock agents to partially reactivate viral reservoirs. Therefore, future therapeutic studies of GeoVax’s vaccine will investigate the vaccine’s ability to act as a shock agent to reactivate latent virus. The timetable and specific clinical plans will depend upon the Company’s ability to secure external funding for the program.

### **Our Hemorrhagic Fever Vaccine Program**

**About Ebola, Marburg and Lassa fever viruses.** Ebola (EBOV, formerly designated as Zaire ebolavirus), Sudan (SUDV), and Marburg viruses (MARV) are the current most virulent species of the Filoviridae family. They can cause up to a 90% fatality rate in humans, and are epizootic in Central and West Africa with multiple outbreaks since 1970. Lassa fever virus (LASV), a member of the Arenaviridae family, causes severe and often fatal hemorrhagic illnesses in an overlapping region with Ebola. In contrast to the unpredictable epidemics of filoviruses, LASV is endemic in West Africa with an annual incidence of >300,000 infections, resulting in 5,000-10,000 deaths. Data from a recent sero-epidemiologic study suggest that the number of annual LASV cases may be much higher, reaching three million infections and 67,000 deaths, putting as many as 200 million persons at risk. Although the timing of the next filovirus outbreak cannot be predicted, it is certain that one will occur due to multiple factors such as: the zoonotic nature of the virus, weak health systems, high population mobility, cultural beliefs and burial practices, and endemic infectious diseases such as malaria and Lassa fever that mimic early Ebola symptoms in those at natural risk; and for those not at natural risk, the risk of intentional release by a bioterrorist.

We believe an ideal vaccine against major filoviruses and LASV viruses must activate both humoral and cellular arms of the immune system. It must include the induction of antibodies to slow the initial rate of infection and a cellular immune response to help clear the infection. Moreover, it must address strain variations by providing broad coverage against potential epizootic filovirus strains, and it must be safe not only in healthy individuals (e.g. travelers or health care workers), but also in immunocompromised persons (e.g., HIV infected) and those with other underlying health concerns.

Despite significant progress being made with some experimental vaccines in clinical trials (e.g. rVSV-ZEBOV), none have been fully tested for both safety and efficacy. The replication competent rVSV-ZEBOV showed safety concerns in Phase 1 trials and by virtue of being replication competent could pose threats to immunocompromised individuals, such as those infected with HIV. The less advanced adeno-vectored vaccine candidates may require relatively cumbersome heterologous prime/boost regimens, for example with MVA, to elicit durable protective immunity. The use of Ad5 vectors also has been associated with concerns over increased susceptibility to HIV infection in areas with high HIV incidence. Even with rVSV-ZEBOV showing promise in the 2013-2015 epidemic, the world would benefit by being prepared with a multivalent, as well as safer vaccine, to prevent or alleviate the effects of the next epidemic.

***Our Vaccines.*** To address the unmet need for a product that can respond to future filovirus epidemics and potentially end LASV infections in West Africa, we are developing an innovative Tetravalent Vaccine (TV) utilizing our proven MVA-VLP platform. We are addressing strain variations, and induction of broad humoral and cellular response through development of 4 monovalent vaccines, which can be blended to provide broad coverage. The MVA vector is highly safe, having been developed for use in immunocompromised individuals. It has had excellent safety in clinical trials in immunocompromised (~1000) as well as normal (>5000) people and is currently licensed by Bavarian Nordic for use as a smallpox vaccine.

Our TV vaccine generates VLPs by expressing both GP and matrix proteins (VP40 for filoviruses, Z for LASV) in single vectors for each of its target viruses. It is designed to elicit protective antibodies against GP as well as protective T cells against GP plus the more conserved VP40, or Z, matrix proteins. It is expected to not only protect at risk individuals against EBOV, SUDV, MARV, and LASV; but also potentially reduce or modify the severity of other re-emerging filovirus pathogens such as Bundibugyo, Ivory Coast, and Reston viruses, based on antigenic cross reactivity and the elicitation of T cells to the more conserved matrix proteins. Thus, the GeoVax MVA-VLP-TV approach offers a unique combination of advantages to achieve breadth and safety of a pan-filo/LASV vaccine. In addition to protecting people in Africa, it is intended to prevent the spread of disease to the US, as with the last outbreak, and for preparedness against terrorist release of any of these four bio-threat pathogens (EBOV, SUDV, MARV, and LASV). The initial markets for the TV vaccine are both NGOs such as the Gavi vaccine alliance and the Bill & Melinda Gates Foundation, as well as US and foreign governments.

***Innovation.*** The innovation in our MVA-VLP-TV vaccine is in the design of the individual vectors, which use unique MVA shuttle vectors combined with appropriate strength promoters and codon optimizations to achieve genetically stable vectors expressing high levels of filovirus and LASV VLPs. We have developed three different generations of shuttle vectors, spanning 15 years of collaboration with NIH in developing MVA/HIV vaccines expressing VLPs. The latest shuttle vectors insert transgenes between essential genes, such that the loss of genes involving adjacent sequences during manufacture (the most frequent genetic mutation associated with loss of gene expression in earlier MVA vectors) results in replication incompetent viruses that do not outgrow the insert containing virus. We use a synthetic early late promoter that provides high, yet not lethal, levels of VLP expression, which is initiated immediately after infection. VLPs, expressed by MVA, in turn, form a basis of a highly effective vaccine, as the VLPs are made in the person being vaccinated and do not have to be purified, reducing manufacturing costs. Moreover, they can express native forms of membrane-displayed viral envelope glycoproteins (the form we use is mutated to not express secreted S). The array of GPs on the VLPs is highly favorable for cross-linking B cell receptors and initiating an Ab response. The expression of VP40 or Z in infected cells stimulates CD8 T cell responses against the relatively conserved matrix proteins broadening protection.

Many consider MVA a boosting, not a priming vaccine. However, our MVA-expressed VLPs are very good priming vaccines. In guinea pigs, a single dose of the GeoVax EBOV vaccine (MVA/Z-VLP) raises the same levels of Abs as raised by a single dose of a recombinant VSV vaccine expressing the EBOV GP.

Our TV-MVA vector affords other unique advantages:

**Safety:** GeoVax/NIAID rMVA HIV vaccines have demonstrated outstanding safety in human clinical trials. Safety for MVA has been shown in more than 120,000 subjects in Europe, including immunocompromised individuals during the initial development of MVA and more recently with the development of MVA as a safer vaccine against smallpox.

**Durability:** GeoVax/NIAID rMVA technology raises highly durable vaccine responses, the most durable in the field of vectored HIV vaccines (G. Tomaras, HVTN Spring Meeting, 2015). We hypothesize that elicitation of durable vaccine responses is conferred on responding B cells by the vaccinia parent of MVA, which raises highly durable responses for smallpox.

**Limited pre-existing immunity to vector:** Following the eradication of smallpox in 1980, smallpox vaccinations subsequently ended, leaving all but those born before 1980 and selected populations (such as vaccinated laboratory workers, first responders) unvaccinated and without pre-existing immunity.

**No need for adjuvants:** MVA stimulates strong innate immune responses and does not require the use of adjuvants.

Thermal stability: MVA is stable in both liquid and lyophilized formats (> 6 years of storage).

Genetic stability and manufacturability: If appropriately engineered, MVA is genetically stable and can reliably be manufactured in either the established Chick Embryo Fibroblast cell substrate, or novel continuous cell lines that support scalability as well as greater process consistency and efficiency.

In February 2016 we entered into a Cooperative Research and Development Agreement for material transfer with the United States Army Research Institute of Infectious Disease (USAMRIID). This agreement provides us with access to Ebola, Marburg and Lassa fever monoclonal antibodies for *in vitro* vaccine characterization, with USAMRIID will performing *in vitro* and *in vivo* assessment of our vaccine candidates.

### **Our Zika Virus Vaccine Program**

**About Zika Virus.** Zika disease is a rapidly spreading emerging infection caused by the Zika virus (ZIKV) and may be linked to an increase in microcephaly in infants and Guillain-Barre syndrome (a neurodegenerative disease) in adults. ZIKV is a member of the *Flaviviridae* family, which includes medically important pathogens such as dengue fever, yellow fever, Japanese encephalitis, tick-borne encephalitis, and West Nile viruses. ZIKV, which was first discovered in 1947 in the Zika forest of Uganda, was considered only a minor public health concern for 60 years. Recently, with its appearance and rapid spread in the Americas, it has emerged as a serious threat with pandemic potential. Symptoms of Zika infection have historically been mild. In the recent epidemic, however, an alarming association between ZIKV infection and fetal brain abnormalities including microcephaly has been suspected. No approved preventive or therapeutic products are currently available to fight the Zika epidemic. Public health officials recommend avoiding exposure to ZIKV, delaying pregnancy, and following basic supportive care (fluids, rest, and acetaminophen) after infection. A vaccine is urgently needed to prevent a Zika pandemic.

**Our Vaccine Development Efforts.** To address the unmet need for a ZIKV vaccine, we are developing novel vaccine candidates constructed in our MVA-VLP live vector platform, which has already shown great promise in our HIV and Ebola vaccines. Unlike other vaccines in development, the GeoVax vaccine combines a highly potent, yet safe, replication deficient viral vector (MVA). Utilizing the MVA vector to express antigens of interest that assemble into VLPs within the vaccinated person, we combine the strengths of the MVA vector with those of VLPs. Advantages of MVA-VLPs include efficient stimulation of highly durable antibody responses with neutralizing and Fc-mediated mechanisms of protection; enhanced cross-protection by the elicitation of antigen specific T cells as well as antibody; and stimulation of the innate immune response without the need for an adjuvant. Also, MVA has an outstanding safety record, which is particularly important given the need to include pregnant women and newborns among those being vaccinated. We expect these features to yield a safe and highly effective vaccine that is well suited to provide potent and durable immunity against ZIKV infection.

Our primary collaboration on the development of a ZIKV vaccine is with the University of Georgia (UGA), which will develop animal models and perform mouse studies. The US Centers for Disease Control (CDC) is developing its own animal models (AG129 mice, developed for dengue vaccine testing, and guinea pigs) and will serve as a backup strategy in case UGA is unsuccessful. Collaborating researchers at the Rocky Mountain Laboratories are developing non-human primate models for ZIKV testing. ZIKV and reagents will be supplied by the University of Texas Medical Branch (UTMB). Working with multiple collaborators and multiple candidate vaccines, we will manage risk by providing multiple paths toward the selection of the best vaccine candidate.

## **Our Cancer Immunotherapy Program**

**About Cancer Immunotherapy.** Cancer is the second most common cause of death in the US, exceeded only by heart disease. Its global burden is expected to rise to 22 million new cases by 2030. Currently, there is only one FDA approved cancer vaccine, PROVENGE® (sipuleucel-T). PROVENGE® is a personalized therapy for prostate cancer patients, which prolongs survival times by about 4 months. However, the field of immune-oncology has received new momentum with the discovery and initial launch of monoclonal antibodies (Mabs) called immune checkpoint inhibitors (ICIs). Tumors hijack the body's natural immune checkpoints by over expressing immune checkpoint ligands (proteins that bind to and activate the inhibitory activity of immune checkpoints), as a mechanism of immune resistance, especially against the T cells that are specific for tumor antigens and can kill cancer cells. ICIs block the interaction of Immune checkpoints with their ligands on tumor cells, allowing poorly functional T cells to resume proliferation, cytokine production and killing of tumor cells.

Unlike conventional therapies (e.g. radiation, chemotherapy, antibody, etc.), cancer vaccines have the potential to induce responses that not only result in the control and even clearance of tumors but also establish immunological memory that can suppress and prevent tumor recurrence. Convenience, safety, and low toxicity of cancer vaccines make them invaluable tools to be included in future immunotherapy approaches for treating tumors. Currently, there are only a few vectored cancer vaccines being tested in combination with ICIs, all of which are in early clinical stages.

***Our Immuno-Oncology Development Efforts.*** GeoVax has established a collaboration with Dr. Olivera Finn, a leading expert in cancer immunotherapy at the University of Pittsburgh. Dr. Finn was the first to show that many tumors express an abnormal form of cell surface-associated Mucin 1 (MUC1) protein that is recognized by the immune system as foreign. Given this, we are developing our MVA-VLP vaccine platform to deliver abnormal forms of MUC1 with the goal of raising protective anti-tumor antibodies and T cell responses in cancer patients.

Our approach to cancer immunotherapy will likely utilize a combination approach, for which each component has already shown some promising results in clinical trials. DNA and MVA-VLP-MUC1 will be used to elicit antibody and T cell responses to MUC1 in the patients' own bodies. Prior to vaccination, patients will undergo their Standard of Care (SOC) treatments, such as chemotherapy or radiation. We expect ICIs will be used to activate suppressed T cells and enable the patients' immune system to respond to VLP-delivered MUC1 antigen, with the goal of causing tumor regression.

We expect to demonstrate proof-of-concept in preclinical engineered murine tumor models for MUC1 at the University of Pittsburgh during 2016 and, subject to adequate funding, we anticipate that within three years GeoVax will be able to file an IND with the FDA and initiate a Phase 1 trial in a limited number of cancer patients.

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

With the exception of the GV-TH-01 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. This financial support has been provided by the NIH directly to the HVTN, so has not been recognized in our financial statements. 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 have been partially funded by NIH research grants. Refer to our Financial Statements beginning on page F-1, and to “Management's Discussion and Analysis of Financial Condition and Results of Operations”, for additional information regarding revenue and funds availability from these grants.

## 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 considerable time and expense.

In the United States, drugs are subject to rigorous federal and state regulation. Our products are regulated under the Federal Food, Drug and Cosmetic Act, as amended (FD&C Act), and the regulations promulgated thereunder, and other federal and state statutes and regulations. These laws 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 human vaccine may be marketed in the United States include:

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

- Manufacturing and testing of the product under strict compliance with current Good Manufacturing Practice (cGMP) regulations;

- 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 Biologics License Application to the FDA, along with the required user fees;

- FDA approval of the Biologics License Application prior to any commercial sale or shipment of the product; and Post-marketing requirements imposed by FDA.

Each of these steps is described further below. Before marketing any drug or biologic for human use, the product sponsor must obtain FDA approval. In addition, each manufacturing establishment must be registered with the FDA and must pass a Pre-Approval Inspection (PAI) before introducing any new drug or biological product into commercial distribution. Because GeoVax does not manufacture vaccines for human use within our own facilities, we must ensure compliance both in our own operations and in the outsourced manufacturing operations. All FDA-regulated manufacturing establishments (both domestic establishments and foreign establishments that export products to the United States) are subject to inspections by the FDA and must comply with the FDA's Good

Manufacturing Practices for products, drugs and devices.

FDA determines compliance with applicable statutes and regulations through documentation review, investigations, and inspections. Several enforcement mechanisms are available to FDA, ranging from a simple demand to correct a minor deficiency to mandatory recalls, closure of facilities, and even criminal charges for the most serious violations.

***Preclinical Testing.*** Preclinical 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. Preclinical safety tests and certain other pivotal preclinical studies 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.

***CGMP-Compliant Manufacturing and Testing.*** FDA has issued, and frequently updates, extensive regulations on current Good Manufacturing Practice (cGMP). Any drug, biologic, or device for human use, whether commercial or investigational, must be manufactured under these regulations. CGMP regulations include a wide variety of requirements covering personnel, documentation, facilities, equipment, testing procedures, and many other aspects of manufacturing and testing.

**Clinical Trials.** Clinical trials involve the administration of investigational drugs to volunteers or to patients under the supervision of a qualified, medically trained clinical 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 and the qualifications of the investigators who plan to carry it out 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.

**Biologics License 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 Biologics License Application (BLA), which is equivalent to the New Drug Application (NDA) submitted by companies seeking to market new drugs. If the BLA is approved, the manufacturer may market the product in the United States. Under the Prescription Drug User Fee Act (PDUFA), FDA charges user fees to applicants to offset the costs of its operations. The PDUFA user fee for a new vaccine is over \$2 million, unless the applicant obtains a waiver or reduction through certain programs designed to encourage development of certain types of products.

**Post-marketing Requirements.** FDA frequently imposes post-marketing requirements as a condition of NDA or BLA approval. Common post-marketing requirements include additional clinical trials (Phase 4 trials) or observational studies. Post-marketing requirements are especially relevant to our Ebola and Marburg vaccines. We intend to pursue approval of these vaccines using the accelerated approval process, in which FDA grants approval based on performance against a criterion other than actual protection against the disease but requires the manufacturer to monitor and submit data on efficacy of the approved product. Unlike pathogens such as human papillomavirus, Ebola and Marburg are not constantly in circulation; instead, they occur in sporadic but extremely deadly outbreaks. For this reason, it would be impractical and potentially unethical to attempt to perform a traditional Phase 3 trial in which vaccinated participants are compared against unvaccinated participants to determine the efficacy of the vaccine in preventing infection with Ebola or Marburg. The accelerated approval process allows FDA to approve a new medicine based on its performance against a surrogate endpoint (in the case of Ebola or Marburg, its performance in raising immune responses). We anticipate that, as a condition of receiving accelerated approval, GeoVax would agree to monitor the real-world performance of our Ebola and Marburg vaccines.

***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.

## **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 that 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 (in the case of European manufacturers) 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.

## **Competition**

The biopharmaceutical industry and the vaccine market 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.

There are currently no FDA licensed and commercialized Zika vaccines, Ebola vaccines, Marburg vaccines, Lassa fever or HIV vaccines available in the world market. We are aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, which are actively engaged in vaccine research and development in these areas. For Ebola, these include NewLink Genetics and Merck, Johnson & Johnson, Novavax, Profectus Biosciences, Protein Sciences, Inovio and GlaxoSmithKline. For HIV, these include Novartis, Sanofi and GlaxoSmithKline. Other HIV 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. For Zika, these include NewLink Genetics, Inovio, Sanofi, Merck and NIH (NIAID). We may also experience competition from companies that have acquired or may acquire technologies from companies, universities and other research institutions. As these companies develop their technologies, they may develop proprietary technologies which may materially and adversely affect our business.

If any of our competitors develop products with efficacy or safety profiles significantly better than our products, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed. Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development

by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive, or result in treatments or cures superior to ours.

Our competitive position will be affected by the disease indications addressed by our product candidates and those of our competitors, the timing of market introduction for these products and the stage of development of other technologies to address these disease indications. For us and our competitors, proprietary technologies, the ability to complete clinical trials on a timely basis and with the desired results, and the ability to obtain timely regulatory approvals to market these product candidates are likely to be significant competitive factors. Other important competitive factors will include the efficacy, safety, ease of use, reliability, availability and price of products and the ability to fund operations during the period between technological conception and commercial sales.

### **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 obtained or developed through our collaborations with Emory University, the NIH, and the CDC, or developed by us alone. Our patent portfolio, described more fully below, includes applications directed to 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 and methods of therapeutic and prophylactic use thereof including administration regimes. Also included are applications directed to preventive vaccines against Ebola, Marburg, Lassa virus, HBV, CMV and Zika virus and use thereof, as well as immuno-oncology vaccine compositions and methods of use thereof. We are the licensee of at least nine issued or allowed U.S. patents and at least fourteen issued or allowed non-U.S. patents. We are actively pursuing five U.S. provisional applications and two international patent applications as the owner of record, in addition to at least four U.S. patent applications and at least fourteen non-U.S. patent applications in five jurisdictions under license.

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 HIV NIH-owned MVA patents are covered by the Emory License. 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. 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.

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 cash or noncash compensation 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 \$113,914, \$179,958, and \$98,042 for the years ended December 31, 2015, 2014 and 2013, respectively.

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.

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 \$1,693,102, \$1,812,969, and \$2,914,878 during the years ended December 31, 2015, 2014 and 2013, respectively. As our vaccines continue to go through the process to obtain regulatory approval, we expect our research and development costs to increase as human clinical trials proceed. 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 lease agreement which expires on December 31, 2016, with a 12-month renewal option. We believe this space is adequate for our current needs. As of March 15, 2016, we had six full-time and three 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 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](http://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 Annual Report.

## **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, 2015, we had an accumulated deficit of approximately \$32.5 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 our 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 HIV Vaccine Trials Network (HVTN), with funding 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 of our HIV vaccines.

Our operations are also partially supported by the NIH grants awarded to us to support our HIV/AIDS vaccine program. As of December 31, 2015, there was approximately \$100,500 of unused grant funds remaining and available for use during the first half of 2016. We are pursuing additional grants from the federal government for our HIV, hemorrhagic fever, and Zika virus vaccine programs. 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 third quarter of 2016. We will need to raise additional funds to significantly advance our vaccine development programs and to continue our operations. In order to meet our operating cash flow requirements we plan to seek sources of non-dilutive capital through government grant programs and clinical trial support. We may also 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, our Chief Scientific Officer, and our Senior Vice President, Research and Development. 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 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 human infectious diseases is intensely competitive and is subject to rapid and significant technological change. We 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.

***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.***

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, 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 (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](http://www.clinicaltrials.gov). Federal legislation was introduced in the fall of 2004 to expand [www.clinicaltrials.gov](http://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 payers. 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 (SEC) as required by the Sarbanes-Oxley Act of 2002, adopted rules requiring every public company to include a management report on such company's internal controls over financial reporting in its annual report. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to achieve and maintain effective internal controls over financial reporting could result in the loss of investor confidence in the reliability of our financial statements, which in turn could negatively impact the trading price of our stock.

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

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

their securities in the secondary market.

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

We believe that our current cash and cash equivalents, combined with anticipated cash flow from our NIH grants will be sufficient to meet our anticipated cash needs into the third quarter of 2016. 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.***

As of March 15, 2016, our directors and executive officers collectively beneficially own approximately 7.6% of our common stock and Emory University beneficially owns 12.5%. If our directors and executive officers move to act in concert with Emory University, they 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.



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

Our outstanding options and warrants include warrants to purchase up to 33,333,332 shares with an exercise price of \$0.11299 per share, warrants to purchase up to 1,207,332 shares with an exercise price of \$0.09416 per share, and warrants to purchase up to 15,818,745 shares with an effective exercise price of \$0.065 per share. These warrants contain anti-dilution provisions, which may, under certain circumstances, reduce the exercise price (but have no effect on the number of shares subject to the warrants) to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the exercise price of the warrants, or if we announce plans to do so. This potential reduction in exercise price could reduce the funds the Company receives upon exercise of the warrants, and increase the likelihood that a dilutive issuance will occur.

***Our common stock is and likely will remain subject to the SEC's "penny stock" rules, which 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. We have issued 100 shares of Series B Convertible Preferred Stock and 2,868 shares of our Series C Convertible Preferred Stock. 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.

*Provisions contained in certain of our outstanding warrants may make it more difficult for a third party to effect a change in control.*

Our outstanding warrants include warrants to purchase up to 50,359,409 shares which contain provisions permitting 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 lease agreement which expires on December 31, 2016. We have an option to renew the lease for an additional 12 month period. We believe this space is adequate for our current needs.

#### **ITEM 3. LEGAL PROCEEDINGS**

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

#### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **PART II**

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

#### **Market Information**

Our common stock is currently traded on the 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 9, 2016, the last reported sale price for our common stock as reported in the OTCQB Market was \$0.07 per share.

	High	Low
<u>2016</u>		
First Quarter (through March 9, 2016)	\$0.14	\$0.05
<u>2015</u>		
Fourth Quarter	\$0.14	\$0.07
Third Quarter	\$0.18	\$0.12
Second Quarter	\$0.20	\$0.15
First Quarter	\$0.24	\$0.14
<u>2014</u>		
Fourth Quarter	\$0.51	\$0.13
Third Quarter	\$0.26	\$0.19
Second Quarter	\$0.37	\$0.21
First Quarter	\$0.60	\$0.34

#### **Holders**

On March 9, 2016, there were approximately 600 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 2015.

## Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information as of December 31, 2015 with respect to compensation plans under which our equity securities are authorized for issuance.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders (1)	720,000	\$ 5.43	-0-
Equity compensation plans not approved by stockholders (2)	985,500	\$ 0.20	19,500

(1) Represents shares to be issued pursuant to the GeoVax Labs, Inc. 2006 Equity Incentive Plan (the “Stock Option Plan”), originally approved by our stockholders effective September 30, 2006. A description of the Stock Option Plan and other information concerning the Stock Option Plan can be found in footnote 9 to our 2015 consolidated financial statements beginning on Page F-1.

(2) Represents increases to the shares available pursuant to the Stock Option Plan approved by our Board of Directors.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data as of and for each of the five years ended December 31, 2015 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 “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.

	Years Ended December 31,				
	2015	2014	2013	2012	2011
<i>Statement of Operations Data:</i>					
Total revenues (grant income)	\$428,081	\$882,956	\$2,417,550	\$2,657,327	\$4,899,885
Net loss	(2,689,287)	(2,733,555)	(2,284,943)	(2,135,140)	(2,346,826)
Basic and diluted net loss per common share	(0.08 )	(0.10 )	(0.11 )	(0.12 )	(0.15 )

	As of December 31,				
	2015	2014	2013	2012	2011
<i>Balance Sheet Data:</i>					
Total assets	1,331,593	1,333,198	2,839,576	1,477,970	1,645,142
Total stockholders' equity	1,204,603	1,146,175	2,527,227	1,150,935	703,607

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

The following discussion and analysis of our financial condition and results of operations should be read together with "Selected Financial Data" and our consolidated financial statements and the related notes beginning on page F-1. 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 clinical-stage biotechnology company developing human vaccines using our novel platform technology. Our current development programs are focused on HIV, hemorrhagic fever viruses, Zika virus, and cancer immunotherapy. Our HIV vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the CDC, and is exclusively licensed to us from Emory University. We also have nonexclusive licenses to certain patents owned by the NIH. Our hemorrhagic fever and Zika vaccines, and our cancer immunotherapy program, are being developed with technology licensed to us from the NIH.

Our most advanced HIV vaccine development efforts are focused on a preventive vaccine to address the clade B subtype of the HIV virus that is most prevalent in the developed world (primarily North America and Western Europe). All of the clinical trials for our preventive HIV vaccine (through Phase 2a) have been conducted by the HIV Vaccine Trials Network (HVTN) with funding from the NIH, and we expect additional clinical trials for this program to be funded by the NIH. We have also begun preclinical studies to develop an HIV vaccine candidate for the clade C subtype of HIV prevalent in the developing world (primarily sub-Saharan Africa and India); this work is currently being supported by NIH grants.

Our hemorrhagic fever vaccine development effort began in 2014 and we are currently conducting preclinical animal studies through a collaboration with the NIH. Our cancer immunotherapy program began in late 2015 and we are currently constructing vaccines to be evaluated and tested through a collaboration with the University of Pittsburgh. Our Zika virus vaccine development effort began in early 2016 and we are currently constructing vaccines to be evaluated and tested through a collaborations with the University of Georgia and with the CDC.

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, 2015, we had an accumulated deficit of \$32.5 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, 2015. 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 ("GAAP") to revenue recognition issues, and specifically addresses revenue recognition for upfront, nonrefundable fees received in connection with research collaboration agreements. During 2015, 2014 and 2013, 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.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which creates a new Topic, Accounting Standards Codification Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective for the Company beginning in 2017 and allows for either full retrospective adoption or modified retrospective adoption. We are currently evaluating the impact of the adoption of ASU 2014-09 on our financial statements.

### *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, 2015, we had cash and cash equivalents of \$1,060,348 and total assets of \$1,331,593, as compared to \$1,101,651 and \$1,333,198, respectively, at December 31, 2014. Working capital totaled \$1,109,985 at December 31, 2015, compared to \$1,038,472 at December 31, 2014.

### *Sources and Uses of Cash*

We have funded our activities to date primarily from government grants and clinical trial assistance, and from sales of our equity securities. Due to our significant research and development expenditures, we have not been profitable and have generated operating losses since our inception in 2001. We will continue to require substantial funds to continue these activities. Our primary sources of cash are from sales of our equity securities and from government grant funding. We believe that our existing cash resources, combined with the proceeds from the NIH grants discussed below will be sufficient to fund our planned operations into the third quarter of 2016. We will require additional funds to continue our planned operations beyond that date. We are currently seeking sources of non-dilutive capital through government grant programs and clinical trial support, and we may also conduct additional offerings of our equity securities. However, additional funding may not be available on favorable terms or at all and if we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs as well as reduce our general and administrative expenses.

### *Cash Flows from Operating Activities*

Net cash used in operating activities was \$2,705,263, \$2,250,107, and \$1,694,592 for the years ended December 31, 2015, 2014 and 2013, 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, partially offset by government grant revenues.

The NIH has funded the costs of conducting all of our human clinical trials (Phase 1 and Phase 2a) to date for our preventive HIV vaccines, with GeoVax incurring certain costs associated with manufacturing the clinical vaccine supplies and other study support. We expect the NIH to fund the cost of another Phase 1 trial (HVTN 114) of our preventive HIV vaccine to begin in mid-2016, which will investigate the effect of adding a “protein boost” component to our vaccine. The HVTN and NIH are continuing to consider future efficacy studies. The plans for large-scale clinical trials may change as researchers continue to gather information from our earlier studies and are influenced by results from other vaccine trials. Trial start dates are dependent on many factors and are likely to change. While efforts are underway to evaluate the protein boost concept, we are also seeking funding to expedite our vaccine (without the additional protein boost) directly into a Phase 2b efficacy trial. There is no assurance we will be successful in securing the funding for advancing directly to a Phase 2b trial.

During 2014, we completed a Phase 1 clinical trial (GV-TH-01) investigating the therapeutic use of our GOVX-B11 vaccine in HIV-infected patients. Future therapeutic studies of our vaccine may investigate the vaccine’s ability to act as a “shock agent” in a shock and kill therapy in combination with standard of care antiretroviral drug therapy to seek a cure for HIV infection. We are currently not contemplating the use of any of our existing cash resources for this program. The timetable and specific plans for additional clinical studies will be dependent upon our ability to secure external funding for the program, and on the nature of any potential collaborations we may establish.

Our hemorrhagic fever vaccine program began in late 2014, and our primary activities during 2015 were focused on constructing the vaccines and conducting preclinical animal studies. During April 2015, we entered into a Research Collaboration Agreement with the National Institute of Allergy and Infectious Disease (NIAID), part of NIH, pursuant to which NIAID is contributing certain materials and carrying out animal protection studies in small animals. We plan to conduct additional challenge studies in non-human primates together with NIH during 2016 with the goal of beginning human clinical trials during 2017. In February 2016 we entered into a Cooperative Research and Development Agreement for material transfer with the United States Army Research Institute of Infectious Disease (USAMRIID). This agreement provides us with access to Ebola, Marburg and Lassa fever monoclonal antibodies for *in vitro* vaccine characterization, with USAMRIID will performing *in vitro* and *in vivo* assessment of our vaccine candidates.

In December 2015, we entered into a Collaborative Research Agreement with the University of Pittsburgh to evaluate our MVA-VLP vaccine platform for use in cancer immunotherapy, including the selection and testing of vaccine candidates. We are currently constructing our vaccine candidates and intend to conduct proof-of-concept animal studies during 2016.

In February 2016, we began a program to develop a vaccine for the prevention of Zika virus infections using our MVA-VLP vaccine platform, and we entered into a Collaborative Research Agreement with the University of Georgia (UGA). Pursuant to this collaboration, we will develop vaccine antigens that elicit broadly reactive immunity against Zika viruses and UGA will test those vaccines in preclinical models. We are also collaborating with the CDC for reagents and testing of vaccines. We intend to conduct the initial proof-of-concept animal studies during the first half of 2016.

In addition to clinical trial support from the NIH for our preventive HIV vaccines and collaborative research support from NIAID for our hemorrhagic fever vaccine program, our operations have been partially funded by NIH research grants for our HIV program. As of December 31, 2015, there was \$100,469 of unused grant funds available for use during the first half of 2016. We are pursuing additional grants from the federal government for our vaccine development programs but cannot be assured of success.

#### *Cash Flows from Investing Activities*

Our investing activities have consisted predominantly of capital expenditures. Capital expenditures for the years ended December 31, 2015, 2014 and 2013, were \$15,850, \$35,503, and \$86,603, respectively.

#### *Cash Flows from Financing Activities*

Net cash provided by financing activities was \$2,679,810, \$873,400, and \$3,259,131 for the years ended December 31, 2015, 2014 and 2013, respectively.

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. 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 1,650 shares of our Series B Convertible Preferred Stock to a group of institutional investors for an aggregate purchase price of \$1.65 million. Net proceeds to the Company, after deduction of transaction expenses, were approximately \$1.6 million.

In October 2014, we entered into an agreement with certain warrant holders to purchase shares of our common stock with respect to the payment to them of a warrant exercise fee of \$0.075 per share for each share purchased upon exercise of warrants held by them. In exchange for the fee, they immediately exercised warrants for an aggregate of 3,176,000 shares of our common stock, resulting in proceeds to us of \$873,400 (net of the exercise fee).

In February 2015, we sold shares of Series C convertible preferred stock for an aggregate purchase price of \$3.0 million. Net proceeds to the Company were approximately \$2.7 million. As part of this transaction, we also issued several series stock purchase warrants. In February 2016, we entered into an agreement with the warrant holders with respect to amending the terms of certain of these warrants. Pursuant to the agreement, we extended the term of the warrants by six months (to August 27, 2016), and we agreed to pay each warrant holder an exercise fee of \$0.02916 per share for each share purchased upon exercise of the warrants. The warrant holders agreed to promptly exercise an aggregate of 3,664,588 the warrants, for which we received \$238,198 in total net proceeds (after deduction of the warrant exercise fee). The remaining warrants that expire on August 27, 2016, if exercised in full, would result in net cash proceeds to us (after deduction of the warrant exercise fee) of approximately \$845,000.

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 third quarter of 2016. We will require additional funds to continue our planned operations beyond that date. We are currently seeking sources of non-dilutive capital through government grant programs and clinical trial support, and we may also conduct additional offerings of our equity securities, 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, 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, 2015, aggregated by type (in thousands):

#### **Payments Due by Period**

		Less than	1-3	4-5	More than
Contractual	Total				
Obligations	1 Year	Years	Years	5 years	
Operating Lease Obligations <sup>(1)</sup>	\$ 149	\$ 149	\$ --	\$ --	\$ --
Firm Purchase Commitments <sup>(2)</sup>	73	73	--	--	--
Emory University – License Agreement <sup>(3)</sup>	--	--	--	--	--
Total	\$ 222	\$ 222	\$ --	\$ --	\$ --

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 (as amended), expires on December 31, 2016, with a 12-month renewal option.

(2) Firm purchase commitments relate to contracts for 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, regulatory approvals and product sales. Because the achievement of these milestones is currently neither probable (3) 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, 2015, 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, each of which may be terminated with no more than 90 days advance written notice.

## **Net Operating Loss Carryforwards**

At December 31, 2015, we had consolidated net operating loss carryforwards for income tax purposes of \$67.2 million, which will expire in 2019 through 2035 if not utilized. We also have research and development tax credits of approximately \$894,000 available to reduce income taxes, if any, which will expire in 2022 through 2035 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 \$2,689,287, \$2,733,555, and \$2,284,943 for the years ended December 31, 2015, 2014 and 2013, 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 \$428,081, \$882,956, and \$2,417,550 for the years ended December 31, 2015, 2014 and 2013, respectively. Grant revenues relate to grants from the NIH in support of our HIV vaccine development activities. 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 \$100,469 in approved grant funds remaining and available for use as of December 31, 2015, which we anticipate recognizing as revenue during 2016. Additional detail concerning our grant revenues is discussed below.

In September 2007, the NIH awarded us an Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) grant entitled “GM-CSF-Adjuvanted Clade C DNA/MVA and MVA/MVA Vaccines”. The aggregate award (including



subsequent amendments) totaled approximately \$20.4 million. We recorded grant revenues of \$75,464, \$624,689, and \$833,390 for the years ended December 31, 2015, 2014 and 2013, respectively, related to this grant, and all funding pursuant to this grant has been utilized as of December 31, 2015.

In September 2012, the NIH awarded us a supplement to the 2007 IPCAVD grant entitled “Immunogens and Manufacturing” to support our HIV/AIDS vaccine development program. The grant award was for approximately \$1.9 million. We recorded grant revenues of \$-0-, \$-0-, and \$1,429,597 for the years ended December 31, 2015, 2014 and 2013, respectively, related to this grant, and all funding pursuant to this grant has been utilized as of December 31, 2015.

In July 2013, the NIH awarded us a Small Business Innovative Research (SBIR) grant entitled “Enhancing Protective Antibody Responses for a GM-CSF Adjuvanted HIV Vaccine.” The initial grant award was \$276,690 for the first year of a two year project period beginning August 1, 2013. In July 2014, the NIH awarded us \$289,641 for the second year of the project period. We recorded grant revenues of \$153,501, \$258,267, and \$154,563 for the years ended December 31, 2015, 2014 and 2013, respectively, related to this grant, and all funding pursuant to this grant has been utilized as of December 31, 2015.

In June 2015, the NIH awarded us an SBIR grant entitled “Directed Lineage Immunizations for Eliciting Broadly Neutralizing Antibody.” The initial grant award was \$299,585 for the first year of a two year project period beginning July 1, 2015. We recorded grant revenues of \$199,116, \$-0-, and \$-0- for the years ended December 31, 2015, 2014 and 2013, respectively, related to this grant, and there is approximately \$100,469 in remaining grant funds available as of December 31, 2015.

### *Research and Development*

Our research and development expenses were \$1,693,102, \$1,812,969, and \$2,914,878 for the years ended December 31, 2015, 2014 and 2013, respectively. Research and development expense for these periods includes stock-based compensation expense of \$22,083, \$32,134, and \$41,539 for 2015, 2014 and 2013, respectively (see discussion under “Stock-Based Compensation Expense” below). Since our inception, all of our research and development efforts have been focused on development of human vaccines – initially with a focus on HIV/AIDS vaccines, and with recent expansion to vaccines for hemorrhagic fever viruses (Ebola, Marburg and Lassa), Zika virus, and for use in cancer immunotherapy. Our research activities conducted pursuant to our NIH grants are also focused solely on the development of human vaccines.

Historically, we have not fully accounted for and disclosed our internal research and development expenses by project, since our employees' time is spread across multiple programs and our internal laboratory facility is used for multiple vaccine candidates. We track the direct cost of government grant revenue and research and development expenses by the percentage of assigned employees' time spent on each grant and other direct costs associated with each grant. Indirect costs associated with grants are not tracked separately, but are applied based on a contracted overhead rate negotiated with the NIH. Therefore, the recorded revenues associated with government grants approximates the costs incurred. We believe that additional project-by-project information would not form a reasonable basis for disclosure to our investors.

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, the timing of costs associated with clinical trials being funded directly by us, and other factors. The overall decrease in research and development expense from 2013 to 2014 can mostly be attributed to lower expenditures related to the activities supported by our grants from the NIH, and lower expenditures associated with a Phase 1 trial of our therapeutic HIV vaccine, which was completed during the first quarter of 2014. We have not received any government support for clinical trials of our therapeutic vaccine. Our research and development costs do not include costs incurred by the HVTN in conducting clinical trials of our preventive HIV vaccines; those costs are funded directly to the HVTN by the NIH.

We cannot predict the level of support we may receive from the HVTN, NIH, 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 for our HIV vaccines and as we expand our vaccine development programs.

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.

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. As we obtain data from pre-clinical studies and clinical trials, we may elect to discontinue or delay vaccine development programs in order to focus our resources on more promising vaccine candidates. Completion of clinical trials may take several years or more, but the length of time can vary substantially depending upon the phase, size of clinical trial, primary and secondary endpoints and the intended use of the vaccine candidate. 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 \$1,429,731, \$1,807,605, and \$1,792,160 for the years ended December 31, 2015, 2014 and 2013, 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 \$45,822, \$446,969, and \$360,565 for 2015, 2014 and 2013, respectively (see discussion under "Stock-Based Compensation Expense" below). 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*

For the three years ended December 31, 2015, the components of stock-based compensation expense were as follows:

	2015	2014	2013
Stock option expense	\$67,905	\$101,191	\$143,435
Stock issued for services	-	100,000	20,500
Warrant modification expense	-	277,912	238,169
Total stock-based compensation expense	\$67,905	\$479,103	\$402,104

In general, stock-based compensation expense is 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. For the three years ended December 31, 2015, stock-based compensation expense was allocated as follows:

	2015	2014	2013
General and administrative expense	\$45,822	\$446,969	\$360,565
Research and development expense	22,083	32,134	41,539
Total stock-based compensation expense	\$67,905	\$479,103	\$402,104

### *Other Income*

Interest income was \$5,465, \$4,063, and \$4,545 for the years ended December 31, 2015, 2014 and 2013, 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, 2015, 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, 2015 and 2014 and for each of the three years ended December 31, 2015, 2014 and 2013 together with the independent registered public accounting firm's report thereon, are set forth on pages F-1 to F-18 of this Annual Report on Form 10-K.

### **Item 9. Changes in and Disagreements with Accountants on Accounting AND Financial Disclosure**

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

### **Item 9A. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures designed to ensure that financial information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized, and reported within the required time periods, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding disclosure.

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2015. 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, 2015 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, 2015 based on criteria established in *Internal Control - Integrated Framework (2013)*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As a result of this assessment, management concluded that, as of December 31, 2015, 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 2016 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 persons performing similar functions. A copy of this policy is available on our website at [www.geovax.com](http://www.geovax.com) under the heading “Investors – Corporate Governance” and is also available free of charge upon written request to the attention of our Corporate Secretary by regular mail, e-mail to [mreynolds@geovax.com](mailto:mreynolds@geovax.com), or facsimile at (678) 384-7281. We intend to disclose any amendment to, or a waiver from, a provision of our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that relates to any element of the code of ethics enumerated in applicable rules of the SEC. Such disclosures will be made on our website at [www.geovax.com](http://www.geovax.com).

## **Item 11. Executive Compensation**

The information required by this Item is included in our definitive proxy statement for our 2016 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**



The information required by this Item is included in our definitive proxy statement for our 2016 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 2016 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 2016 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>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2015 and 2014	F-3
Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013	F-6
Notes to Consolidated Financial Statements	F-7

#### **(2) Financial Statement Schedules**

The following financial statement schedule is set forth on page F-18 of this Annual Report on Form 10-K:

Schedule II—Valuation and Qualifying Accounts for the years ended December 31, 2015, 2014 and 2013

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 on Following Page]***

## 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 15, 2016

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	Director	March 15, 2016
Robert T. McNally	President and Chief Executive Officer (Principal Executive Officer)	
/s/ Mark W. Reynolds	Chief Financial Officer	March 15, 2016
Mark W. Reynolds	(Principal Financial and Accounting Officer)	
/s/ Randal D. Chase	Director	March 15, 2016
Randal D. Chase		
/s/ David A. Dodd	Director	March 15, 2016
David A. Dodd		

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/s/ Dean G. Kollintzas Dean G. Kollintzas	Director	March 15, 2016
/s/ Robert T. McNally Robert T. McNally	Director	March 15, 2016
/s/ Harriet L. Robinson Harriet L. Robinson	Director	March 15, 2015
/s/ John N. Spencer, Jr. John N. Spencer, Jr.	Director	March 15, 2016

## EXHIBIT INDEX

### Exhibit

#### Number Description

- 3.1 Certificate of Incorporation (4)
  - 3.1.1 Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 13, 2010 (8)
  - 3.1.2 Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 27, 2010 (9)
  - 3.1.3 Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed August 2, 2013 (15)
  - 3.1.4 Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed May 13, 2015 (21)
- 3.2 Bylaws (4)
  - 4.1.1 Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed March 20, 2012 (12)
  - 4.1.2 Amendment to Certificate of Designation of Series A Convertible Preferred Stock filed December 13, 2013 (17)
  - 4.1.3 Form of Stock Certificate for the Series A Convertible Preferred Stock (11)
  - 4.2.1 Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock filed December 13, 2013 (17)
  - 4.2.2 Form of Stock Certificate for the Series B Convertible Preferred Stock (17)
  - 4.3.1 Form of Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock filed February 27, 2015 (19)
  - 4.3.2 Form of Stock Certificate for the Series C Convertible Preferred Stock (19)
- 10.1 \*\* Employment Agreement between GeoVax Labs, Inc. and Robert T. McNally effective as of April 1, 2008 (5)
  - 10.1.1 \*\* Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Robert T. McNally dated October 22, 2013 (16)
- 10.2 \*\* Employment Agreement between GeoVax, Inc. and Mark W. Reynolds Amended and Restated effective as of January 1, 2010 (7)
  - 10.2.1 \*\* Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Mark W. Reynolds dated October 22, 2013 (16)
- 10.3 \*\* Employment Agreement between GeoVax, Inc. and Harriet Robinson effective as of November 19, 2007 (7)
  - 10.3.1 \*\* Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Harriet Robinson dated October 22, 2013 (16)
- 10.4 \*\* Employment Agreement between GeoVax, Inc. and Farshad Guirakhoo dated October 19, 2015 (22)
  - 10.4.1 \*, \*\* Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Farshad Guirakhoo dated December 15, 2015
- 10.5 \*\* GeoVax Labs, Inc. 2006 Equity Incentive Plan (2)
- 10.6 License Agreement (as amended and restated) between GeoVax, Inc. and Emory University, dated August 23, 2002 (1)
- 10.7 Office and Laboratory Lease between UCB, Inc. and GeoVax, Inc. (6)
  - 10.7.1 Amendment to Lease Agreement between UCB, Inc. and GeoVax, Inc. (20)
- 10.8 Summary of the GeoVax Labs, Inc. Director Compensation Plan (7)
- 10.9 Form of Warrant dated December 30, 2011 (10)

- 10.10 Form of Common Stock Purchase Warrants (11)
- 10.11 Form of Securities Purchase Agreement dated March 16, 2012 (12)
- 10.12 Form of Registration Rights Agreement dated March 16, 2012 (12)
- 10.13 Form of Series A Warrant dated March 16, 2012 (12)
- 10.14 Form of Series B Warrant dated March 16, 2012 (12)
- 10.15 Form of Series C Warrant dated March 16, 2012 (12)
- 10.16 Warrant Reset Offer Agreements dated January 17, 2013 (15)
- 10.17 Warrant Reset Offer Agreements dated May 14, 2013 (14)
- 10.18 Securities Purchase Agreement dated December 11, 2013 with Form of Registration Rights Agreement (17)
- 10.19 Amendment Agreement and Consent of Holders of Series A Convertible Preferred Stock dated December 11, 2013 (17)
  
- 10.20 Form of Letter Agreement dated October 14, 2014 providing for payment of warrant exercise fee (18)
- 10.21 Form of Securities Purchase Agreement dated February 25, 2015 (19)
- 10.22 Form of Registration Rights Agreement dated February 25, 2015 (19)
- 10.23 Form of Series D Warrant dated February 27, 2015 (19)
- 10.24 Form of Series E Warrant dated February 27, 2015 (19)
- 10.25 Form of Series F Warrant dated February 27, 2015 (19)
- 10.26 Form of Maxim warrant dated February 27, 2015 (19)
- 10.27 Form of Agreement to Amend and Exercise Series E Warrants and Related Matters dated February 15, 2016 (23)
- 14.1 Code of Ethics (3)
- 21.1 Subsidiaries of the Registrant (3)

- 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, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014, (ii) Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013, (iii) Consolidated Statements of Stockholders' Equity for the ended December 31, 2015, 2014 and 2013, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013, and (v) Notes to Condensed Consolidated Financial Statements.

\* Filed herewith.

\*\* 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.

(1) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 4, 2006.

(2) Incorporated by reference from the registrant's definitive Information Statement (Schedule 14C) filed August 18, 2006.

(3) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 28, 2007.

(4) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 23, 2008.

(5) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 24, 2008.

(6) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 6, 2009.

(7) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 8, 2010.

(8) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 14, 2010.

(9) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 28, 2010.

(10) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 5, 2012.

(11) Incorporated by reference from the registrant's Current Report on Form 8-K filed February 6, 2012.

(12) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 22, 2012.

(13) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 17, 2013.

(14) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 15, 2013.

(15) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 2, 2013.

(16) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 23, 2013.

(17) Incorporated by reference from the registrant's Current Report on Form 8-K filed December 17, 2013.

(18) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 15, 2014.

(19) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 2, 2015.

(20) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 20, 2015.

(21) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 14, 2015.

(22) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 12, 2015.

(23) Incorporated by reference from the registrant's Current Report on Form 8-K filed February 16, 2016.





**GEOVAX LABS, INC.**

**INDEX TO 2015 CONSOLIDATED FINANCIAL STATEMENTS**

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2015 and 2014	F-3
Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013	F-6
Notes to Consolidated Financial Statements	F-7
Financial Statement Schedule:	
Schedule II – Valuation and Qualifying Accounts for the years ended December 31, 2015, 2014 and 2013	F-18

F-1

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors

GeoVax Labs, Inc.

Atlanta, Georgia

We have audited the accompanying consolidated balance sheets of GeoVax Labs, Inc. and subsidiary (the “Company”) as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2015. Our audits also included the financial statement schedule of the Company listed in Item 15(a) of the Company’s Form 10-K. 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 and schedule 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, 2015 and 2014, and the results of their

operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. 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.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's recurring losses from operations and continued need for capital raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 2 to the consolidated financial statements. These consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Atlanta, Georgia

March 16, 2016

**GEOVAX LABS, INC.****CONSOLIDATED BALANCE SHEETS**

	December 31, 2015	2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$1,060,348	\$1,101,651
Grant funds receivable	119,978	79,341
Prepaid expenses and other current assets	56,649	44,503
Total current assets	1,236,975	1,225,495
Property and equipment, net	83,608	96,693
Other assets	11,010	11,010
Total assets	\$1,331,593	\$1,333,198
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$100,935	\$55,616
Accrued expenses	4,055	52,490
Amounts due to Emory University (a related party) (Note 12)	22,000	78,917
Total current liabilities	126,990	187,023
Commitments (Note 6)		
Stockholders' equity:		
Preferred stock, \$.01 par value:		
Authorized shares – 10,000,000		
Series B convertible preferred stock, \$1,000 stated value; 100 shares issued and outstanding at December 31, 2015 and 2014, respectively	76,095	76,095
Series C convertible preferred stock, \$1,000 stated value; 3,000 and -0- shares issued and outstanding at December 31, 2015 and 2014, respectively	983,941	-
Common stock, \$.001 par value:		
Authorized shares – 150,000,000 and 75,000,000 at December 31, 2015 and 2014, respectively		
Issued and outstanding shares – 31,950,813 at December 31, 2015 and 2014, respectively	31,951	31,951
Additional paid-in capital	32,587,543	30,823,769
Accumulated deficit	(32,474,927)	(29,785,640)

Total stockholders' equity	1,204,603	1,146,175
Total liabilities and stockholders' equity	\$1,331,593	\$1,333,198

See accompanying notes to consolidated financial statements.

F-3

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**GEOVAX LABS. INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended December 31,		
	2015	2014	2013
Grant revenue	\$428,081	\$882,956	\$2,417,550
Operating expenses:			
Research and development	1,693,102	1,812,969	2,914,878
General and administrative	1,429,731	1,807,605	1,792,160
Total operating expenses	3,122,833	3,620,574	4,707,038
Loss from operations	(2,694,752 )	(2,737,618 )	(2,289,488 )
Other income:			
Interest income	5,465	4,063	4,545
Total other income	5,465	4,063	4,545
Net loss	\$(2,689,287 )	\$(2,733,555 )	\$(2,284,943 )
Basic and diluted:			
Loss per common share	\$(0.08 )	\$(0.10 )	\$(0.11 )
Weighted average shares outstanding	31,950,813	26,645,140	21,212,327

See accompanying notes to consolidated financial statements.

**GEOVAX LABS, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2012	788	\$312,196	-	\$-	-	\$-	18,733,277	\$18,733	25,587,148	\$(24,767,142)	\$1,150,000
Sale of common stock for cash upon warrant exercise	-	-	-	-	-	-	2,933,333	2,933	1,640,400	-	1,643,333
Issuance of common stock for services	-	-	-	-	-	-	50,000	50	20,450	-	20,500
Sale of convertible preferred stock for cash	-	360,229	1,650	1,255,569	-	-	-	-	-	-	1,615,348
Conversion of preferred stock to common stock	(717)	(611,839)	-	-	-	-	2,048,570	2,049	609,790	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	381,604	-	381,604
Net loss for the year ended December 31, 2013	-	-	-	-	-	-	-	-	-	(2,284,943)	(2,284,943)
Balance at December 31, 2013	71	60,586	1,650	1,255,569	-	-	23,765,180	23,765	28,239,392	(27,052,085)	2,527,447
Sale of common stock for cash upon warrant exercise	-	-	-	-	-	-	3,176,000	3,176	870,224	-	873,400

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Issuance of common stock for services	-	-	-	-	-	378,205	378	99,622	-	100,000
Conversion of preferred stock to common stock	(71 )	(60,586 )	(1,550)	(1,179,474)	-	4,631,428	4,632	1,235,428	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	379,103	-	379,103
Net loss for the year ended December 31, 2014	-	-	-	-	-	-	-	-	(2,733,555 )	(2,733,555 )
Balance at December 31, 2014	-	-	100	76,095	-	31,950,813	31,951	30,823,769	(29,785,640)	1,140,228
Sale of convertible preferred stock for cash	-	-	-	-	3,000	983,941	-	1,695,869	-	2,679,890
Stock-based compensation expense	-	-	-	-	-	-	-	67,905	-	67,905
Net loss for the year ended December 31, 2015	-	-	-	-	-	-	-	-	(2,689,287 )	(2,689,287 )
Balance at December 31, 2015	-	\$-	100	\$76,095	3,000	\$983,941	\$31,951	\$32,587,543	\$(32,474,927)	\$1,204,106

See accompanying notes to consolidated financial statements.



**GEOVAX LABS. INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	\$(2,689,287)	\$(2,733,555)	\$(2,284,943)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	28,935	69,037	78,862
Stock-based compensation expense, including common stock issued for services	67,905	479,103	402,104
Changes in assets and liabilities:			
Grant funds receivable	(40,637 )	61,568	125,339
Prepaid expenses and other current assets	(12,146 )	(934 )	(1,268 )
Accounts payable and accrued expenses	(60,033 )	(125,326 )	(14,686 )
Total adjustments	(15,976 )	483,448	590,351
Net cash used in operating activities	(2,705,263)	(2,250,107)	(1,694,592)
Cash flows from investing activities:			
Purchase of property and equipment	(15,850 )	(35,503 )	(86,603 )
Net cash used in investing activities	(15,850 )	(35,503 )	(86,603 )
Cash flows from financing activities:			
Proceeds from sale of common stock	-	873,400	1,643,333
Proceeds from sale of preferred stock	2,679,810	-	1,615,798
Net cash provided in financing activities	2,679,810	873,400	3,259,131
Net increase (decrease) in cash and cash equivalents	(41,303 )	(1,412,210)	1,477,936
Cash and cash equivalents at beginning of period	1,101,651	2,513,861	1,035,925
Cash and cash equivalents at end of period	\$1,060,348	\$1,101,651	\$2,513,861

**Supplemental disclosure of non-cash financing activities:**

As discussed in Note 7, during the year ended December 31, 2014, 71 shares of Series A Convertible Preferred Stock were converted into 202,857 shares of common stock and 1,550 shares of Series B Convertible Preferred Stock were converted into 4,428,571 shares of common stock. During the year ended December 31, 2013, 717 shares of Series A Convertible Preferred Stock were converted into 2,048,570 shares of common stock.

See accompanying notes to consolidated financial statements.

F-6

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**GEOVAX LABS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended December 31, 2015, 2014 and 2013**

**1. Description of Business**

GeoVax Labs, Inc. (“GeoVax” or the “Company”), is a clinical-stage biotechnology company developing human vaccines using our novel vaccine platform. Our vaccine delivery technology generates virus-like particles (VLPs) that are effective at eliciting safe and effective immune responses. Our current development programs are focused on vaccines against Human Immunodeficiency Virus (HIV), hemorrhagic fever viruses (Ebola, Marburg, and Lassa) and Zika virus, and for use in cancer immunotherapy. We believe our technology and vaccine development expertise is well-suited for a variety of human infectious diseases and we intend to pursue further expansion of our product pipeline. Our HIV vaccine technology was developed in collaboration with Emory University, the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) and is exclusively licensed to us. GeoVax is incorporated under the laws of the State of Delaware and our principal offices are located in Smyrna, Georgia (metropolitan Atlanta area).

Our vaccine development activities have been, and continue to be, financially supported by the U.S. government. This support has been both in the form of research grants awarded directly to us, as well as indirect support for preclinical animals studies and for the conduct of our human clinical trials.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration (FDA) in the United States, by the European Medicines Agency (EMA) in the European Union, and by comparable agencies in other countries. Obtaining approval for a new pharmaceutical product is never certain and may take many years and may involve expenditure of substantial resources. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners.

**2. Summary of Significant Accounting Policies**

*Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of GeoVax Labs, Inc. together with those of our wholly-owned subsidiary, GeoVax, Inc. All intercompany transactions have been eliminated in consolidation.

*Basis of Presentation*

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the date of these consolidated financial statements. We are devoting substantially all of our present efforts to research and development. We have funded our activities to date from government grants and clinical trial assistance, and from sales of our equity securities. We will continue to require substantial funds to continue our research and development activities.

We believe that our existing cash resources and grant commitments will be sufficient to fund our planned operations through the second quarter of 2016, but due to our history of operating losses and our continuing need for capital to conduct our research and development activities, there is substantial doubt concerning our ability to operate as a going concern beyond that date. We are currently exploring sources of capital through government grants and clinical trial support and through philanthropic foundation support. We may also secure additional funds through sales of our equity securities or the exercise of currently outstanding stock purchase warrants. Management believes that it will be successful in securing the additional capital required to continue the Company's planned operations, but that its plans do not fully alleviate the substantial doubt about the Company's ability to operate as a going concern. Additional funding may not be available on favorable terms or at all. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs as well as reduce our general and administrative expenses.

### *Use of Estimates*

The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

### *Cash and Cash Equivalents*

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Our cash and cash equivalents consist primarily of bank deposits and money market accounts. The recorded values approximate fair market values due to the short maturities.

### *Fair Value of Financial Instruments and Concentration of Credit Risk*

Financial instruments that subject us to concentration of credit risk consist primarily of cash and cash equivalents, which are maintained by a high credit quality financial institution. The carrying values reported in the balance sheets for cash and cash equivalents approximate fair values.

### *Property and Equipment*

Property and equipment are stated at cost, less accumulated depreciation and amortization. Expenditures for maintenance and repairs are charged to operations as incurred, while additions and improvements are capitalized. We calculate depreciation using the straight-line method over the estimated useful lives of the assets which range from three to five years. We amortize leasehold improvements using the straight-line method over the term of the related lease.

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. It will also require disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases. The guidance is effective for annual

reporting periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted. We are currently evaluating the impact of ASU 2016-02 on our financial statements.

#### *Impairment of Long-Lived Assets*

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

#### *Accrued Liabilities*

As part of the process of preparing our financial statements, we estimate expenses that we believe we have incurred, but have not yet been billed by our third party vendors. This process involves identifying services and activities that have been performed by such vendors on our behalf and estimating the level to which they have been performed and the associated cost incurred for such service as of each balance sheet date.

#### *Net Loss Per Share*

Basic and diluted loss per common share are computed based on the weighted average number of common shares outstanding. Common share equivalents consist of common shares issuable upon conversion of convertible preferred stock, and upon exercise of stock options and stock purchase warrants. All common share equivalents are excluded from the computation of diluted loss per share since the effect would be anti-dilutive. Common share equivalents which could potentially dilute basic earnings per share in the future, and which were excluded from the computation of diluted loss per share, totaled approximately 90.3 million, 6.6 million, and 14.4 million at December 31, 2015, 2014 and 2013, respectively.

#### *Revenue Recognition*

We recognize revenue in accordance with U.S. Securities and Exchange Commission (SEC) 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 GAAP to revenue recognition issues, and specifically addresses revenue recognition for upfront, nonrefundable fees received in connection with research collaboration agreements. During 2015, 2014 and 2013, our revenue consisted of grant funding received from the NIH

(see Note 5). Revenue from these arrangements is approximately equal to the costs incurred and is recorded as income as the related costs are incurred.

F-8

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In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which creates a new Topic, Accounting Standards Codification Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective for the Company beginning in 2017 and allows for either full retrospective adoption or modified retrospective adoption. We are currently evaluating the impact of the adoption of ASU 2014-09 on our financial statements.

#### *Research and Development Expense*

Research and development expense primarily consists of costs incurred in the discovery, development, testing and manufacturing of our product candidates. These expenses consist primarily of (i) fees paid to third-party service providers to perform, monitor and accumulate data related to our preclinical studies and clinical trials, (ii) costs related to sponsored research agreements, (iii) the costs to procure and manufacture materials used in clinical trials, (iv) laboratory supplies and facility-related expenses to conduct development, and (v) salaries, benefits, and stock-based compensation for personnel. These costs are charged to expense as incurred.

#### *Patent Costs*

Our expenditures relating to obtaining and protecting patents are charged to expense when incurred, and are included in general and administrative expense.

#### *Period to Period Comparisons*

Our operating results are expected to fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results for future periods.

#### *Income Taxes*

We account for income taxes using the liability method. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement



carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance unless, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will be realized.

#### *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. See Note 9 for additional stock-based compensation information.

#### *Recent Accounting Pronouncements*

Except as discussed above, there have been no recent accounting pronouncements or changes in accounting pronouncements which we expect to have a material impact on our financial statements, nor do we believe that any recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on our financial statements.

### 3. Property and Equipment

Property and equipment as shown on the accompanying Consolidated Balance Sheets is composed of the following as of December 31, 2015 and 2014:

	2015	2014
Laboratory equipment	\$525,956	\$510,106
Leasehold improvements	115,605	115,605
Other furniture, fixtures & equipment	28,685	28,685
Total property and equipment	670,246	654,396
Accumulated depreciation and amortization	(586,638)	(557,703)
Property and equipment, net	\$83,608	\$96,693

Depreciation and amortization expense was \$28,935, \$59,037, and \$68,862 during the years ended December 31, 2015, 2014 and 2013, respectively.

### 4. Other Assets

Other assets as shown on the accompanying Consolidated Balance Sheets include the following as of December 31, 2015 and 2014:

	2015	2014
Technology licenses	\$248,855	\$248,855
Accumulated amortization – technology licenses	(248,855)	(248,855)
Deposits	11,010	11,010
Total other assets	\$11,010	\$11,010

Amortization expense related to technology licenses was \$0-, \$10,000, and \$10,000 during the years ended December 31, 2015, 2014 and 2013, respectively.

### 5. Government Grants

We record revenue associated with government grants as the related costs and expenses are incurred and such revenue is reported as a separate line item in our statements of operations. Grant revenues relate to grants from the NIH in support of our HIV vaccine development activities. During 2015, 2014, and 2013, we recorded \$428,081, \$882,956

and \$2,417,550, respectively, of aggregate revenue associated with these grants. Additional detail concerning our grant revenues is discussed below.

In September 2007, the NIH awarded us an Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) grant entitled “GM-CSF-Adjuvanted Clade C DNA/MVA and MVA/MVA Vaccines”. The aggregate award (including subsequent amendments) totaled approximately \$20.4 million. We recorded grant revenues of \$75,464, \$624,689, and \$833,390 for the years ended December 31, 2015, 2014 and 2013, respectively, related to this grant, and all funding pursuant to this grant has been utilized as of December 31, 2015.

In September 2012, the NIH awarded us a supplement to the 2007 IPCAVD grant entitled “Immunogens and Manufacturing” to support our HIV/AIDS vaccine development program. The grant award was for approximately \$1.9 million. We recorded grant revenues of \$-0-, \$-0-, and \$1,429,597 for the years ended December 31, 2015, 2014 and 2013, respectively, related to this grant, and all funding pursuant to this grant has been utilized as of December 31, 2015.

In July 2013, the NIH awarded us a Small Business Innovative Research (SBIR) grant entitled “Enhancing Protective Antibody Responses for a GM-CSF Adjuvanted HIV Vaccine.” The initial grant award was \$276,690 for the first year of a two year project period beginning August 1, 2013. In July 2014, the NIH awarded us \$289,641 for the second year of the project period. We recorded grant revenues of \$153,501, \$258,267, and \$154,563 for the years ended December 31, 2015, 2014 and 2013, respectively, related to this grant, and all funding pursuant to this grant has been utilized as of December 31, 2015.

In June 2015, the NIH awarded us an SBIR grant entitled “Directed Lineage Immunizations for Eliciting Broadly Neutralizing Antibody.” The initial grant award was \$299,585 for the first year of a two year project period beginning July 1, 2015. We recorded grant revenue of \$199,116 for the year ended December 31, 2015 related to this grant, and there is approximately \$100,469 in remaining grant funds available as of December 31, 2015.

## 6. Commitments

### *Lease Agreements*

We lease approximately 8,400 square feet of office and laboratory space located in Smyrna, Georgia (metropolitan Atlanta) pursuant to an operating lease which expires on December 31, 2016, with an additional 12-month renewal option. Rent expense for the years ended December 31, 2015, 2014 and 2013 was \$146,092, \$117,084, and \$117,879, respectively. Future minimum lease payments total \$149,042 in 2016.

### *Other Commitments*

In the normal course of business, we may enter into various firm purchase commitments related to production and testing of our vaccine material, conduct of clinical trials, and other research-related activities. As of December 31, 2015, we had approximately \$72,500 of unrecorded outstanding purchase commitments to our vendors and subcontractors, all of which we expect will be due in 2016.

## 7. Preferred Stock

### *Series A Convertible Preferred Stock*

In March 2012, we issued 2,200 shares of our Series A Convertible Preferred Stock, \$1,000 stated value (“Series A Preferred Stock”), and warrants to purchase up to 8,799,999 shares of our common stock for gross proceeds of \$2.2 million. Net proceeds, after deduction of placement agent fees and other expenses, were approximately \$2.0 million.

Each share of Series A Preferred Stock was entitled to a liquidation preference equal to the initial purchase price, had no voting rights, and was not entitled to a dividend. The Series A Preferred Stock was 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, we amended the designation of the Series A Preferred Stock 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 Stock to \$0.35 and during the remainder of 2013, 717 shares of the Series A Preferred Stock were converted at this price into an aggregate of 2,048,570 shares of our common stock. The remaining 71 shares of Series A Preferred Stock were converted into 202,857 shares of our common stock in January 2014, and there are no shares of Series A Preferred Stock outstanding at December 31,

2015.

We assessed the Series A Preferred Stock and the related warrants under ASC Topic 480, “*Distinguishing Liabilities from Equity*” (“ASC 480”), ASC Topic 815, “*Derivatives and Hedging*” (“ASC 815”), and ASC Topic 470, “*Debt*” (“ASC 470”). The preferred stock contains an embedded feature allowing an optional conversion by the holder into common stock which meets the definition of a derivative. However, we determined that the preferred stock is an “equity host” (as described by ASC 815) for purposes of assessing the embedded derivative for potential bifurcation and that the optional conversion feature is clearly and closely associated to the preferred stock host; therefore the embedded derivative does not require bifurcation and separate recognition under ASC 815. We determined there to be a beneficial conversion feature (“BCF”) requiring recognition at its intrinsic value. Since the conversion option of the preferred stock was immediately exercisable, the amount allocated to the BCF was immediately accreted to preferred dividends, resulting in an increase in the carrying value of the preferred stock. We also assessed the warrants issued in connection with the financing under ASC 815 and determined that they did not initially meet the definition of a derivative, but will require evaluation on an on-going basis. As of December 31, 2015, we determined that the warrants still did not meet the definition of a derivative.

F-11

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The following is a summary of the allocation of net proceeds and reconciliation to the carrying value of the Series A Preferred Stock at December 31, 2015:

Net proceeds	\$1,999,032
Fair value of warrants (recorded to Additional Paid-in Capital)	(1,127,418)
Beneficial conversion feature (recorded to Additional Paid-in Capital)	(762,667 )
Net proceeds allocated to preferred stock	108,947
Accretion of beneficial conversion feature (deemed dividend)	762,667
Initial carrying value of preferred stock	871,614
Accretion of beneficial conversion feature (deemed dividend) related to issuance of Series B Convertible Preferred Stock	360,229
Conversions to common stock during 2012, 2013, and 2014	(1,231,843)
Carrying value at December 31, 2015 and 2014	\$-0-

#### *Series B Convertible Preferred Stock*

In December 2013, we issued 1,650 shares of our Series B Convertible Preferred Stock, \$1,000 stated value (“Series B Preferred Stock”), which was originally convertible into 4,714,286 shares of our common stock, for gross proceeds of \$1.65 million. Net proceeds, after deduction of transaction expenses, were approximately \$1.6 million. No warrants were issued in connection with the transaction.

Each share of Series B Preferred Stock has a liquidation preference equal to the initial purchase price, has no voting rights, and is not entitled to a dividend. The Series B Preferred Stock 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. During 2014, 1,550 shares of the Series B Preferred Stock were converted into 4,428,571 shares of our common stock; there were no conversions during 2015. As of December 31, 2015, there were 100 shares of Series B Preferred Stock outstanding, convertible into 285,714 shares of our common stock.

In conjunction with the issuance of the Series B Preferred Stock, we entered into an agreement with the holders of the Series A Preferred Stock to amend the designation of the Series A Preferred Stock. 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.

We assessed the Series B Preferred Stock using the same methodology as for the Series A Preferred Stock (see discussion above), which resulted in the same determinations. The following is a summary of the allocation of net proceeds and reconciliation to the carrying value of the Series B Preferred Stock at December 31, 2015:

Net proceeds	\$1,615,798
Beneficial conversion feature – Series A Preferred Stock (recorded to Additional Paid-in Capital)	(360,229 )
Beneficial conversion feature – Series B Preferred Stock (recorded to Additional Paid-in Capital)	(754,286 )
Net proceeds allocated to preferred stock	501,283
Accretion of beneficial conversion feature (deemed dividend)	754,286
Conversions to common stock during 2014	(1,179,474)
Carrying value at December 31, 2015 and 2014	\$76,095

### *Series C Convertible Preferred Stock*

In February 2015, we issued 3,000 shares of our Series C Convertible Preferred Stock, \$1,000 stated value (“Series C Preferred Stock”), and warrants to purchase up to 51,333,331 shares of our common stock for gross proceeds of \$3.0 million. Net proceeds, after deduction of placement agent fees and other expenses, were approximately \$2.7 million.

Each share of Series C Preferred Stock is entitled to a liquidation preference equal to the initial purchase price, has no voting rights, and is not entitled to a dividend. The Series C Preferred Stock is convertible at any time at the option of the holders into shares of our common stock. The initial conversion price of the Series C Preferred Stock was \$0.18 per share (“Conversion Price”). The Series C Preferred Stock contains price adjustment provisions which reduced the Conversion Price according to a formula based on the then-current market price for our common stock. As discussed below, on April 8, 2015 the Conversion Price was adjusted to \$0.142 per share, and on December 4, 2015 the Conversion Price was further adjusted to \$0.09416 per share, resulting in an aggregate total of 31,860,662 shares of our common stock (“Conversion Shares”) into which the Series C Preferred Stock currently may be converted.

In connection with the Series C Preferred Stock issuance, we also issued to each Purchaser Series D, E and F Warrants (collectively, the “Investor Warrants”), each to purchase up to a number of shares of our common stock equal to 100% of the Conversion Shares underlying the Series C Preferred Stock (up to 16,666,666 shares in the aggregate for each of the three series of warrants, or 49,999,998 shares in total). The Series D Warrants had an initial exercise price of \$0.22 per share, are currently exercisable, and have a term of exercise equal to five years from the date of issuance. The Series E Warrants had an initial exercise price of \$0.18 per share, are currently exercisable, and have a term of exercise equal to one year from the date of issuance. The Series F Warrants had an initial exercise price of \$0.22 per share and have a term of exercise equal to five years from the date of issuance, but only vest and become exercisable upon, and in proportion to, the exercise of the one-year Series E Warrants. We also issued to our placement agent warrants (“Placement Agent Warrants”) to acquire 1,333,333 shares of our Common Stock with terms substantially the same as the Series D Warrants. The Investor Warrants and Placement Agent Warrants contain anti-dilution and price adjustment provisions, which may, under certain circumstances, (i) reduce the exercise price on several future dates according to a formula based on the then-current market price for our common stock and (ii) reduce the exercise price 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. The number of shares subject to warrants will not increase due to such reductions in exercise price. In connection with the price adjustments for the Series C Preferred Stock discussed above, the exercise prices of the Investor Warrants and Placement Agent Warrants were also adjusted. The exercise price of the Series E Warrants has been reduced to \$0.09416, and the exercise price of the Series D Warrants, Series F Warrants and Placement Agent Warrants has been reduced to \$0.11299.

We assessed the Series C Preferred Stock using the same methodology as for the Series A Preferred Stock (see discussion above), which resulted in the same determinations, although we determined there to be no beneficial conversion feature requiring recognition for the Series C Preferred Stock. We also assessed the warrants issued in connection with the financing under ASC 815 and determined that they do not initially meet the definition of a derivative, but will require evaluation on an on-going basis. As of December 31, 2015, we determined that the warrants still did not meet the definition of a derivative.

The following is a summary of the allocation of net proceeds and reconciliation to the carrying value of the Series C Preferred Stock at December 31, 2015

Net proceeds after transaction costs	\$2,679,810
Less: Fair value of warrants (recorded to Additional Paid-in Capital)	(1,695,869)
Recorded value of Series C Preferred Stock at December 31, 2015	\$983,941

## 8. Common Stock

### *Common Stock Transactions*



During January and May 2013, we issued an aggregate of 2,933,333 shares of our common stock pursuant to the exercise of certain stock purchase warrants, resulting in total net proceeds of \$1,643,333 (see “*Stock Purchase Warrants*” below).

During October 2013, we issued 50,000 shares of our common stock to a consultant in exchange for services and recorded stock-based compensation expense of \$20,500 related to the issuance (see Note 9).

During July and November 2014, we issued an aggregate of 378,205 shares of our common stock to a consultant in exchange for services and recorded aggregate stock-based compensation expense of \$100,000 related to the issuances (see see Note 9).

During October 2014, we issued an aggregate of 3,176,000 shares of our common stock pursuant to the exercise of certain stock purchase warrants, resulting in total net proceeds of \$873,400 (see “*Stock Purchase Warrants*” below).

We issued shares of our common stock related to conversions of our Series A and Series B Preferred Stock (see Note 7) as follows:

	2015	2014	2013
Conversion of Series A Preferred Stock	-0-	202,857	2,048,570
Conversion of Series B Preferred Stock	-0-	4,428,571	-0-

*Stock Purchase Warrants*

As of December 31, 2015, we have the following common stock purchase warrants outstanding:

		Weighted Average
Expiration Date	Number of Shares	Exercise Price
February 27, 2016	16,666,666	\$ 0.09
December 31, 2016	1,806,159	1.00
January 16, 2017	45,000	1.00
January 31, 2017	567,001	1.00
March 21, 2017	2,690,666	0.09
February 27, 2020	34,666,665	0.11
Outstanding at December 31, 2015	56,442,157	\$ 0.14
Exercisable at December 31, 2015	39,775,491	\$ 0.16

During January 2013, we reduced the exercise price of warrants to purchase 2,933,333 shares of our common stock 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. We recorded non-cash general and administrative expense of \$218,551 associated with these warrant modifications. During 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. We recorded non-cash general and administrative expense of \$19,617 associated with this warrant modification.

During September 2014, we reduced the exercise price of warrants to purchase 818,376 shares of our common stock from \$16.50 to \$1.00 per share, and extended the expiration dates from December 31, 2014 to December 31, 2016. We recorded non-cash general and administrative expense of \$39,711 associated with these modifications.

During October 2014, we entered into an agreement with certain holders of warrants to purchase shares of our common stock with respect to the payment to them of a warrant exercise fee of \$0.075 per share for each share purchased upon exercise of warrants held by them. In exchange for the fee, they immediately exercised warrants for an aggregate of 3,176,000 shares of our common stock, resulting in proceeds to us of \$873,400 (net of the exercise fee).

*Common Stock Reserved*

A summary of common stock reserved for future issuance as of December 31, 2015 is as follows:

Stock Purchase Warrants	56,442,157
Stock Option Plan	1,722,529
Series B Convertible Preferred Stock	285,714
Series C Convertible Preferred Stock	31,860,662
Total	90,311,062

## 9. Stock-Based Compensation

### *Stock Option Plan*

In 2006, we adopted the GeoVax Labs, Inc. 2006 Equity Incentive Plan (the “Stock Option Plan”) for the granting of qualified incentive stock options (“ISO’s”), nonqualified stock options, restricted stock awards or restricted stock bonuses to employees, officers, directors, consultants and advisors of the Company. The exercise price for any option granted may not be less than fair value (110% of fair value for ISO’s granted to certain employees). Options granted under the Stock Option Plan have a maximum ten-year term and generally vest over three years. We have reserved 1,722,529 shares of our common stock (net of exercises to date) for issuance under the Stock Option Plan.

Certain information concerning the Stock Option Plan as of December 31, 2015, and a summary of activity during the year then ended is presented below:

	Number	Exercise	Weighted- Average Remaining Contractual Term (yrs)	Aggregate Intrinsic Value
Outstanding at December 31, 2014	1,183,100	\$ 3.50		
Granted	590,400	0.11		
Exercised	-	-		
Forfeited or expired	(68,000 )	1.50		
Outstanding at December 31, 2015	1,705,500	\$ 2.41	7.3	\$ -0-
Exercisable at December 31, 2015	906,761	\$ 4.39	5.3	\$ -0-

Additional information concerning our stock options for the years ended December 31, 2015, 2014 and 2013 is as follows:

	2015	2014	2013
Weighted average fair value of options granted	\$0.09	\$0.14	\$0.43
Intrinsic value of options exercised	-0-	-0-	-0-
Total fair value of options vested	66,622	97,707	165,490

We use the Black-Scholes model for determining the grant date fair value of our stock option grants. This model utilizes certain information, such as the interest rate on a risk-free security with a term generally equivalent to the expected life of the option being valued and requires certain other assumptions, such as the expected amount of time an option will be outstanding until it is exercised or expired, to calculate the fair value of stock options granted. The significant assumptions we used in our fair value calculations were as follows:

	2015	2014	2013
Weighted average risk-free interest rates	1.99 %	1.98 %	2.3 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Expected life of option (in years)	7.0	7.0	7.0
Expected volatility	91.43 %	94.88 %	96.60 %

Stock-based compensation expense related to the Stock Option Plan was \$67,905, \$101,191, and \$143,435 during the years ended December 31, 2015, 2014 and 2013, respectively. Stock option expense is allocated to research and development expense or to general and administrative expense based on the nature of the services provided by the related individuals. For the three years ended December 31, 2015, stock option expense was allocated as follows:

	2015	2014	2013
General and administrative expense	\$45,822	\$69,057	\$101,896
Research and development expense	22,083	32,134	41,539
Total stock option expense	\$67,905	\$101,191	\$143,435

As of December 31, 2015, there was \$95,344 of unrecognized compensation expense related to stock-based compensation arrangements pursuant to the Stock Option Plan. The unrecognized compensation expense is expected to be recognized over a weighted average remaining period of 2.2 years.

#### *Other Non-Employee Stock-Based Compensation*

We recorded general and administrative expense of \$-0-, \$100,000, and \$20,500 during the years ended December 31, 2015, 2014 and 2013, respectively, related to the issuance of our common stock in exchange for services rendered by non-employees (See Note 8).

We recorded general and administrative expense of \$-0-, \$39,712, and \$238,168 during the years ended December 31, 2015, 2014 and 2013, respectively, related to modifications made to certain stock purchase warrants. Additionally, during 2014, we recorded general and administrative expense of \$238,200 related to a warrant exercise fee paid to certain holders of our stock purchase warrants as an incentive for the holders to immediately certain warrants (see Note 8).

As of December 31, 2015, there was no unrecognized expense related to non-employee stock-based compensation arrangements.

## 10. Retirement Plan

We participate in a multi-employer defined contribution retirement plan (the “401k Plan”) administered by a third party service provider; and the Company contributes to the 401k Plan on behalf of its employees based upon a matching formula. During the years ended December 31, 2015, 2014 and 2013 our contributions to the 401k Plan were \$40,296, \$35,567, and \$43,132, respectively.

## 11. Income Taxes

At December 31, 2015, we have a consolidated federal net operating loss (“NOL”) carryforward of approximately \$67.2 million, available to offset against future taxable income which expires in varying amounts in 2019 through 2035. Additionally, we have approximately \$894,000 in research and development (“R&D”) tax credits that expire in 2022 through 2035 unless utilized earlier. No income taxes have been paid to date. Section 382 of the Internal Revenue Code contains provisions that may limit our utilization of our NOL and R&D tax credit carryforwards in any given year as a result of significant changes in ownership interests that have occurred in past periods or may occur in future periods.

Deferred income taxes reflect the net effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities included the following at December 31, 2015 and 2014:

	2015	2014
Deferred tax assets:		
Net operating loss carryforward	\$23,822,431	\$22,806,391
Research and development tax credit carryforward	893,797	825,896
Stock-based compensation expense	2,419,892	2,396,805
Total deferred tax assets	27,136,120	26,029,092

Deferred tax liabilities		
Depreciation	(5,086 )	(7,149 )
Total deferred tax liabilities	(5,086 )	(7,149 )
Net deferred tax assets	27,131,034	26,021,943
Valuation allowance	(27,131,034)	(26,021,943)
	\$-0-	\$-0-

We have established a full valuation allowance equal to the amount of our net deferred tax assets due to uncertainties with respect to our ability to generate sufficient taxable income to realize these assets in the future. A reconciliation of the income tax benefit on losses at the U.S. federal statutory rate to the reported income tax expense is as follows:

	2015	2014	2013
U.S. federal statutory rate applied to pretax loss	\$(936,936)	\$(906,830)	\$(776,881)
Permanent differences	2,914	1,734	3,138
Research and development credits	67,901	26,648	14,047
Change in valuation allowance	866,121	878,448	759,696
Reported income tax expense	\$-0-	\$-0-	\$-0-

## 12. Related Party Transactions

We are obligated to reimburse Emory University (a significant stockholder of the Company) for ongoing costs in connection with the filing, prosecution and maintenance of patent applications subject to a license agreement for technology associated with the vaccines we are developing. The expense associated with these ongoing patent cost reimbursements to Emory amounted to \$113,914, \$179,958, and \$98,042 for the years ended December 31, 2015, 2014, and 2013, respectively.

In connection with a grant from the NIH (see Note 5), we entered into subcontracts with Emory University for the purpose of conducting research and development activities related to the grant. During 2015, 2014, and 2013, we recorded \$-0-, \$-0-, and \$252,478, respectively, of expense associated with these subcontracts. All amounts paid to Emory under these subcontracts were reimbursable to us pursuant to the NIH grant.

### 13. Selected Quarterly Financial Data (unaudited)

A summary of selected quarterly financial data for 2015 and 2014 is as follows:

	2015 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue from grants	\$ 103,424	\$ 71,474	\$ 93,130	\$ 160,053
Net loss	(700,454)	(676,203)	(619,899)	(692,731)
Net loss per share	(0.02 )	(0.02 )	(0.02 )	(0.02 )

	2014 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue from grants	\$ 157,340	\$ 180,441	\$ 322,086	\$ 223,089
Net loss	(615,918)	(679,537)	(514,515)	(923,585)
Net loss per share	(0.02 )	(0.03 )	(0.02 )	(0.03 )

### 14. Subsequent Events

During January and February 2016, we issued an aggregate of 1,400,000 shares of our common stock related to conversions of our Series C Preferred Stock.

On February 15, 2016, we entered into an agreement with certain warrant holders (the “Holders”) with respect to amending the terms of our Series E Warrants. Pursuant to the agreement, we agreed to extend the term of the Series E Warrants to August 27, 2016, and we agreed to the payment to each Holder of a warrant exercise fee of \$0.02916 per share for each share purchased upon exercise of the Series E Warrants. The Holders agreed to promptly exercise an aggregate of 3,664,588 Series E Warrants, for which we received \$238,198 in total net proceeds (after deduction of the warrant exercise fee). We recorded non-cash general and administrative expense of \$469,800 associated with the warrant modifications.





**GEOVAX LABS, INC.**

**SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS**

**For the Years Ended December 31, 2015, 2014 and 2013**

Description	Balance at Beginning Of Period	Additions Charged to Costs and Expenses	Charged to		Balance at End Of Period
			Other Accounts	(1) Deductions	
Reserve Deducted in the Balance Sheet From the Asset to Which it Applies:					
Allowance for Deferred Tax Assets					
Year ended December 31, 2015	\$26,021,943	\$1,109,091	\$ -0-	\$	\$27,131,034
Year ended December 31, 2014	25,002,881	1,019,062	-0-	-0-	26,021,943
Year ended December 31, 2013	27,295,741	862,736	-0-	(3,155,596)	25,002,881

(1) Deductions represent the effect of expiring NOL carryforwards from prior year.