GeoVax Labs, Inc.
Form 10-K
March 24, 2017
**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, 2016

**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 incorporation or organization)* | *(IRS Employer Identification Number)* |

**1900 Lake Park Drive, Suite 380**

| **Smyrna, GA** | **30080** |
|---|---|
| *(Address of principal executive offices)* | *(Zip Code)* |

**(678) 384-7220**

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

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

**None**

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

**Common Stock $.001 par value**

*(Title of class)*

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

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

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

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

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

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

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

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

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2016, based on the closing price on that date was $2,582,623.

Number of shares of Common Stock outstanding as of March 21, 2017: 56,218,567

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement with respect to its 2017 Annual Meeting of Stockholders are incorporated by reference in Part III

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**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," "seek "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 and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) vector vaccine platform. In this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses highly effective VLP immunogens in the person being vaccinated. The platform elicits durable immune responses while providing the safety characteristics of a replication-defective vector.

Our current development programs are focused on preventive vaccines against Human Immunodeficiency Virus (HIV), Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines for chronic Hepatitis B infections and cancers. Our most advanced vaccine program is focused on the clade B

subtype of HIV prevalent in the larger commercial markets of the Americas, Western Europe, Japan and Australia; this program is currently undergoing human clinical trials.

Our corporate strategy is to advance and protect our vaccine platform and use its capabilities to design and develop an array of products. We aim to advance products through to human clinical testing, and to seek partnership or licensing arrangements for commercialization. We will also leverage third party resources through collaborations and partnerships for preclinical and clinical testing. Our current collaborators and partners include the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), the HIV Vaccines Trial Network (HVTN), Centers for Disease Control and Prevention (CDC), United States Army Research Institute of Infectious Disease (USAMRIID), Emory University, University of Georgia Research Foundation, University of Pittsburgh, Georgia State University Research Foundation, Peking University, University of Texas Medical Branch, Burnet Institute, American Gene Technologies, Inc., and Viamune, Inc.

We are incorporated in Delaware, and our offices and laboratory facilities are in **S**myrna, 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 MVA to produce VLPs in the person being vaccinated (in vivo). In human clinical trials of our HIV vaccines, we have demonstrated that our VLPs, expressed from the cells of the person being vaccinated, are safe, yet elicit both strong and durable humoral and cellular immune response.

VLPs train the body's immune system to recognize and kill the authentic virus should it appear. VLPs also train the immune system to recognize and kill virus-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, Marburg or Lassa fever 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, 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 virus. By producing VLPs *in vivo*, we also avoid potential purification issues associated with *in vitro* production of VLPs.


**Figure 1. Electron micrographs showing the 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 VLPs. MVA was originally developed as a safer smallpox vaccine for use in immune-compromised people. 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.

Our MVA-VLP vaccine platform affords other unique advantages:

Safety: Our HIV vaccines have demonstrated outstanding safety in human clinical trials. Safety for MVA, generally, 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: Our technology raises highly durable (long-lasting) vaccine responses, the most durable in the field of vectored HIV vaccines. 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.

**Our Product Development Pipeline**

The table below summarizes the status of our product development programs, which are discussed in greater detail in the following pages.

| | Development Status | | | | |
|---|---|---|---|---|---|
| Program | Preclinical | Phase 1 | Phase 2 | Phase 3 | Collaborator / Funding Sponsor |
| HIV-Clade B Preventive Vaccine | X | X | X | | NIAID, HVTN |
| HIV-Clade B Immunotherapy | X | X | | | AGT |
| HIV-Clade C Preventive Vaccine | X | | | | NIAID |
| Hemorrhagic Fever Vaccines | X | | | | NIAID, USAMRIID |
| Zika Vaccine | X | | | | CDC, Univ. of Georgia |
| Malaria Vaccine | X | | | | Burnet Institute |
| Cancer Immunotherapy | X | | | | Univ. of Pittsburgh, Viamune |
| Hepatitis B Immunotherapy | X | | | | Georgia State Univ., Peking Univ. |

**Our HIV/AIDS Vaccine Program**

***About HIV/AIDS.*** 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 annually. 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. Alarmingly the fastest growing demographic for acquiring an HIV infection in the US 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.

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. Genetic differences between the clades 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.

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. Thus, 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.

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 30% of those infected with HIV in the US ultimately remain in HIV care with their viral load sufficiently suppressed to prevent spread of HIV. Furthermore, the financial burden to the US taxpayer for HIV education, prevention, and treatment costs borne through multiple federal agencies is more than $20 billion annually.

According to the International AIDS Vaccine Initiative (IAVI), the cost and complexity of new treatment advances for HIV/AIDS puts them out of reach for most people in the countries where treatment is most needed. 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, once developed, will be used universally and administered worldwide by organizations that provide healthcare services, including hospitals, medical clinics, the military, prisons and schools.

***Our Preventive HIV Vaccine Program***

Our most clinically advanced vaccine is GOVX-B11, designed to protect against the clade B subtype of the HIV virus prevalent in the Americas, Western Europe, Japan and Australia. GOVX-B11 consists of a recombinant DNA vaccine used to prime immune responses and a recombinant MVA vaccine used to boost the primed responses. Both the DNA and MVA vaccines produce non-infectious VLPs in the cells of the vaccinated person.

Phase 1 and phase 2a clinical trials of GOVX-B11 have been conducted by the HIV Vaccine Trials Network (HVTN). In these trials, totaling approximately 500 participants, GOVX-B11 was tested at various doses and regimens and was extremely well tolerated. 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.

Considering prior results from the GeoVax vaccines in non-human primate studies and human trials, we believe that GOVX-B11 vaccine is ready for human efficacy trials. In January 2017 HVTN began the next human clinical trial (HVTN 114) in the path toward human efficacy trials. HVTN 114 will test the ability of late boosts to increase the antibody responses elicited by GOVX-B11. These "late boosts" will consist of the GeoVax MVA vaccine with or without a gp120 protein vaccine. HVTN 114 is being conducted by HVTN with funding from NIAID. Information from this trial will contribute to the design of additional human clinical trials testing our vaccine in the presence and absence of the gp120 proteins. During 2016, NIAID also awarded us a Staged Vaccine Development contract of up to $7.8 million for production of the DNA vaccine component of GOVX-B11 in sufficient quantities for use in future clinical trials.

*Clade C Preventive HIV Vaccine Program.* We also are developing DNA/MVA vaccines designed for use against the clade C subtype of HIV that predominate in South Africa and India. NIAID has awarded us Small Business Innovative Research (SBIR) grants in support of this effort.

***Our HIV Immunotherapy Program***

Finding a cure for HIV/AIDS remains an elusive goal. Current antiretroviral therapies (ART), 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. And the long-term use of ART can lead to loss of drug effectiveness and can come with severe side effects. The lifetime medical costs of treating an HIV-infected patient in the U.S. is estimated to exceed $500,000. Therefore, any new treatment regimen that allows patients to reduce, modify, or discontinue their antiretroviral therapy can offer measurable quality of life benefits to the patient and tremendous value to the

marketplace.

In March 2017, we entered into a collaboration with American Gene Technologies, Inc. (AGT) whereby AGT intends to conduct a Phase 1 human clinical trial with our combined technologies. The GeoVax vaccine will be used to stimulate virus-specific CD4 T cells *in vivo*, which will then be harvested from the patient, genetically modified *ex vivo* using AGT's technology, and reinfused to the patient. The primary objectives of the trial will be to assess the safety and efficacy of the therapy, with secondary objectives to assess the immune responses as a measure of efficacy. The overall goal of the program will be to develop a functional cure for HIV infection.

In a previous phase 1 clinical trial (GV-TH-01), we demonstrated that our vaccine can potently stimulate production of $CD4^+$ T cells in HIV infected patients– the intended use of the MVA-VLP HIV vaccine in the proposed AGT study.

**Our Hemorrhagic Fever Vaccine Program**

***About Ebola, Sudan, 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 28 outbreaks since 1976. The 2013-16 Ebola outbreak caused 28,616 cases and 11,310 deaths (40% fatal). Additional outbreaks are certain due to indigenous reservoirs of the virus (e.g. fruit bats).

Lassa fever virus (LASV), a member of the *Arenaviridae* family, also 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 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 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, 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, potentially with a single dose. The MVA vector is highly safe, having originally been developed for use in immunocompromised individuals as a smallpox vaccine.

Our TV vaccine 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, and for preparedness against terrorist release of any of bio-threat pathogens. 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.

Our initial preclinical studies in rodents and nonhuman primates for our first vaccine candidate (EBOV) have shown 100% protection against a lethal dose of Ebola virus upon a single immunization.

**Our Zika Virus Vaccine Program**

***About Zika Virus***. Zika disease is a rapidly spreading emerging infection caused by the Zika virus (ZIKV) and has been 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 observed. 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***. To address the unmet need for a ZIKV vaccine, we are developing novel vaccine candidates constructed in our MVA live vector platform, which has already shown great promise in our HIV and Ebola vaccines. We believe that, unlike other vaccines in development, the GeoVax vaccine combines a highly potent, yet safe, replication deficient viral vector (MVA) to deliver novel antigens of ZIKV to develop a single-dose vaccine. MVA has an outstanding safety record, which is particularly important given the need to include women of child-bearing age 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.

We are also collaborating with the US Centers for Disease Control (CDC) to develop a lethal challenge model in mice to test our vaccine candidates and with the University of Georgia (UGA) for additional mouse studies. We have demonstrated 100% protection in mice against a lethal challenge after a single dose vaccination. ZIKV and reagents are 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 Malaria Vaccine Program**

***About Malaria***. Malaria is a mosquito-borne disease caused by *Plasmodium* parasites. Symptoms are fever, chills, sweating, vomiting and flu-like illness. If untreated, severe complications (severe anemia, cerebral malaria and organ failure) will lead to death. Over 3 billion people in 106 countries and territories live at risk of malaria infection. According to the latest estimates from the World Health Organization (WHO), 214 million new cases of malaria were recorded worldwide in 2015, resulting in 438,000 deaths. There are 1,500 cases in the US each year (travelers returning home). Children under five years of age are particularly susceptible to malaria illness, infection, and death. In 2015, malaria killed an estimated 306,000 children. Current treatments include bed net distributions, drug treatment and mosquito spraying. Malaria parasite develop resistance to drugs and insecticides. Even though vaccines have shown to be the most cost effective ways to fight and eliminate infectious diseases (Smallpox, polio, etc.), and many decades of research and development, there is no commercial malaria vaccine at the present time. Even a vaccine with efficacy of 30-50% will prevent hundreds of thousands of deaths annually. Current vaccine candidates generally consist of subunit proteins, are poorly immunogenic, based on limited number of antigens (generally 4-5 antigens), do not target multi stages of parasite life cycle, and do not induce strong durable functional antibodies and T cell responses. Therefore, identification of appropriate antigens and vaccine technologies is critical for development of an effective malaria vaccine.

***Our Vaccine Approach***. An ideal malaria vaccine candidate should contain antigens from multiple stages of malaria life cycle, should induce functional antibodies (predominantly IgG1 and IgG3 subtypes shown to be associated with protection) and strong cell mediated immunity (e.g. Th1 biased CD4+ ad CD8+) to reduce parasitemia by clearing infected cells (liver cells or erythrocytes)). We have shown (in animal models and humans) that MVA-VLP vaccines induce a Th1 biased response with both durable functional antibodies (IgG1 and IgG3) and $CD4^+$ and $CD8^+$ T cell responses both of which are hallmarks of an ideal malaria vaccine.

GeoVax has established a collaboration with the Burnet Institute, a leading infectious diseases research institute in Australia, for the development of a vaccine to prevent malaria infection. The project includes the design, construction, and characterization of multiple malaria vaccine candidates using GeoVax's MVA-VLP vaccine platform combined with malaria *Plasmodium falciparum* and *Plasmodium vivax* sequences identified by the Burnet Institute. The vaccine design, construction, and characterization will be performed at GeoVax with further characterization and immunogenicity studies in animal models conducted at Burnet Institute using their unique functional assays that provide key information on vaccine efficacy.

**Our Hepatitis B Vaccine Program**

***About Hepatitis B Disease***. Hepatitis B is a contagious liver disease caused by the Hepatitis B virus (HBV). It is transmitted person-to-person by blood, semen, or other bodily fluids. This can happen through sexual contact, needle sharing, or mother to infant transmission during birth. For some people, Hepatitis B is an acute (or short-term) illness; but for others, it can become a long-term, chronic infection that may lead to serious health issues like cirrhosis or liver cancer. The risk of chronic infection is related to age at infection. Approximately 90% of infected infants will develop chronic infections. As a child gets older, the risk decreases. Approximately 25%–50% of children infected between the ages of 1 and 5 years will develop chronic hepatitis. The risk drops to 6%–10% when a person is infected at over 5 years of age. Worldwide, most people with chronic Hepatitis B were infected at birth or during early childhood.

The CDC estimates that between 700,000 to 1.4 million people in the United States have chronic HBV infections, with an estimated 20,000 new infections every year. Many people are unaware that they are infected or may not show any symptoms. Therefore, they never seek the attention of medical or public health officials. Globally, chronic Hepatitis B affects more than 240 million people and contributes to nearly 686,000 deaths worldwide each year. Even though a preventive HBV vaccine is available, less than 5% of chronic HBV infections are cured.

***Our Hepatitis B Vaccine Approach***. There is a clear medical need to treat chronic HBV infections, which affect hundreds of millions of people around the world, many of whom die due to complications of HBV including cirrhosis and cancer. Multiple vaccines exist to protect against HBV infection, but they cannot help patients already diagnosed with the disease. Although chronic HBV can be treated with drugs, the treatments do not cure 95% of patients; they cannot induce strong neutralizing antibodies and cellular responses needed to break tolerance to HBV antigens and clear infections, but only suppress the replication of the virus. Therefore, most people who start treatments must continue with them for life. Moreover, diagnosis and treatment options are very limited in resource/low income-constrained populations, which leads to many patients succumbing within months of diagnosis.

Our combination therapeutic vaccine strategy is comprised of multivalent vaccine antigens delivered by DNA and MVA-VLP in combination with the standard-of-care treatment to induce functional antibodies and $CD4^+$, $CD8^+$ T cell responses to clear infection and break tolerance needed toward a functional cure. Our goal is to significantly increase the current cure rate of HBV infections while reducing the duration of drug therapy, overall treatment costs, side effects, and potential drug resistance.

We are collaborating with Georgia State University Research Foundation (GSU) to advance the development of a therapeutic vaccine for treatment of chronic HBV infections. The project includes the design, construction, characterization and animal testing of multiple vaccine candidates using our MVA-VLP vaccine platform. Vaccine antigens include both GeoVax and GSU's proprietary designed sequences. The vaccine design, construction, and characterization will be performed at GeoVax with further characterization and immunogenicity studies in mice conducted at GSU in collaboration with the Shenzhen Graduate School of Peking University. Unique functional assays developed by Dr. Ming Luo, Professor in the Department of Chemistry at Georgia State University, and performed at Peking University will provide key information on vaccine efficacy.

**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 per year 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.

We are also collaborating with ViaMune, Inc., which has developed a fully synthetic MUC1 vaccine candidate (MTI). The collaboration will assess each companies' vaccine platform, separately, and in combination, with the goal of developing a tumor MUC1 vaccine that can produce a broad spectrum of anti-tumor antibody and T cell responses. The resulting MUC1 vaccine will be combined with ICIs as a novel vaccination strategy for cancer patients with advanced MUC1+ tumors.

We have produced an MVA-VLP-Muc1 vaccine candidate, demonstrated VLP production by electron microscopy using MUC1 immunogold staining, and showed that the VLPs express hypo-glycosylated form of MUC1 in human cell lines. Preclinical proof of concept is being demonstrated through our collaboration with ViaMune and University of North Carolina at Charlotte, using engineered murine human MUC1 models. Depending on the outcome of the preclinical studies, we anticipate that within 2 years we 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**

***Grants and Contracts.*** We have been the recipient of multiple federal grants and contracts in support of our vaccine development programs. Our most recent awards are as follows:

Staged Vaccine Development Contract. In August 2016, NIAID awarded us a *Staged Vaccine Development* contract to produce our preventive HIV vaccine for use in future clinical trials. The award includes a base contract of $199,442 for the initial twelve-month period beginning August 1, 2016 to support process development, as well as $7.6 million in additional development options that can be exercised by NIAID. Prior to the end of the initial twelve-month base period, we expect that NIAID will exercise the first development option under the contract, which would provide approximately $1.5 million in additional funding for the period August 1, 2017 to January 31, 2018 for the next stage of manufacturing

SBIR Grant No. 2R44AI106422-03. In April 2016, NIAID awarded us a Small Business Innovation Research (SBIR) grant entitled "*Enhancing Protective Antibody Responses for a DNA/MVA HIV Vaccine*." The initial grant award was $740,456 for the first year of a two-year project period beginning April 15, 2016, with a total project budget of $1,398,615. In March 2017, NIAID awarded us $658,159 for the second year of the project period.

SBIR Grant No. 1R43AI120887-01/02. In June 2015, NIAID 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. In June 2016, NIAID awarded us $294,038 for the second year of the project period.

SBIR Grant No. 5R43AI106422-01-02. In July 2013, NIAID awarded us an 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.

***Clinical Trial Support***. All our human clinical trials to date for our preventive HIV vaccines, including the recently initiated HVTN 114 trial, have been conducted by the HVTN and funded by NIAID. This financial support has been provided by NIAID directly to the HVTN, so has not been recognized in our financial statements, and we do not know the cost of these trials.

***Other Federal Support***. We have been the recipient of additional in-kind federal support through collaborative and intramural arrangements with CDC for our Zika vaccine program, the Rocky Mountain Laboratory facility of NIAID for our hemorrhagic fever virus vaccine program, and the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) for our hemorrhagic fever virus vaccine program. This support generally has been for the conduct or support of preclinical animal studies on our behalf.

**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 expertise, 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 several 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 in the US, 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 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 biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be competitive with our products. There are several multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same indications as our product candidates. The number of companies seeking to develop products and therapies for the treatment of unmet needs in these indications is likely to increase. Some of these competitive products and therapies are based on scientific approaches that are the same as, or similar to, our approaches, and others are based on entirely different approaches.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Our competitors' products may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any products that we develop and commercialize to compete based on, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third party payers.

There are currently no FDA licensed and commercialized HIV vaccines, Zika vaccines, or hemorrhagic fever virus 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 hemorrhagic fever viruses, these include NewLink Genetics and Merck, Johnson & Johnson, Novavax, Profectus Biosciences, Protein Sciences, Inovio and GlaxoSmithKline. For HIV, these include Sanofi, GlaxoSmithKline, and Johnson & Johnson. 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, Butantan Institute and NIH (NIAID).

There are numerous FDA-approved treatments for HIV, primarily antiretroviral therapies, marketed by large pharmaceutical companies. Currently, there are no approved therapies for the eradication of HIV. We expect that major pharmaceutical companies that currently market antiretroviral therapy products or other companies that are developing HIV product candidates may seek to develop products for the eradication of HIV.

There are currently no commercialized vaccines to treat chronic HBV infection. Multiple vaccines exist to protect against HBV infection, but they cannot help patients already diagnosed with the disease. Although chronic HBV can be treated with drugs, the treatments do not cure 95% of patients; they cannot induce strong neutralizing antibodies and cellular responses needed to break tolerance to HBV antigens and clear infections, but only suppress the replication of the virus.

There are currently no commercialized vaccines to prevent malaria infection A first generation infection-blocking malaria vaccine, RTS,S, is under regulatory review. It requires 4 doses and has been recommended by the WHO for pilot implementation studies. Since this vaccine is based on a single antigen and has modest efficacy (30-40%, depending on the age of subjects), the WHO has defined a Road Map for developing and licensing of next generation malaria vaccines. These vaccines are expected to contain multiple antigens designed to block both infection and transmission of malaria with at least a 75% efficacy rate.

A number of companies are developing various types of therapeutic vaccines or other immunotherapy approaches to treat cancer including Advaxis, Immune Design, Oncothyreon, Bavarian Nordic, Roche Pharmaceuticals, Merck & Co, Bristol Myers Squibb, AstraZeneca plc, and Medimmune, LLC.

**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 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 hemorrhagic fever viruses (Ebola, Sudan, Marburg and Lassa), Zika virus and malaria, and use thereof; immuno-oncology vaccine compositions and methods of use thereof; and therapeutic vaccines against HBV and 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 several 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 (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 to induce an immune response in humans. The four issued United States patents owned by the NIH expire in 2023. All our obligations with respect to the 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.
*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. If 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 amounted to $50,186, $113,914, and $179,958 for the years ended December 31, 2016, 2015 and 2014, 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 $1,970,859, $1,693,102, and $1,812,969 during the years ended December 31, 2016, 2015 and 2014, respectively. As our vaccines continue to go through the process to obtain regulatory approval, we expect our research and development costs to increase. 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.

**Scientific Advisors**

We seek advice from our Scientific Advisory Board, which consists of a number of leading scientists, on scientific and medical matters. The current members of our Scientific Advisory Board are:

| Name | Position/Institutional Affiliation |
|---|---|
| Thomas P. Monath, MD | Chief Scientific Officer, BioProtection Systems |
| Stanley A. Plotkin, MD | Professor Emeritus, University of Pennsylvania<br>Adjunct Professor, Johns Hopkins University |
| Barney S. Graham, MD, PhD | Senior Investigator, Vaccine Research Center, NIAID |
| Scott C. Weaver, PhD | Director, University of Texas Medical Branch Institute for Human Infections and Immunity<br>Scientific Director, Galveston National Laboratory |
| Olivera J. Finn, PhD | Distinguished Professor of Immunology and Surgery, University of Pittsburgh |

**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, 2017. We believe this space is adequate for our current needs and we expect to renew the lease on a short-term basis. We may experience an adverse impact on our business if we are unable to access suitable facilities for our offices and laboratories. As of March 15, 2017, we had seven full-time and four 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 wholly-owned 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 in Smyrna, Georgia (metropolitan Atlanta).

**Available Information**

Our website address is www.geovax.com. We make available on this website under “Investors – SEC Reports,” free of charge, our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. We also make available our Code of Ethics on this website under the heading “Investors – Corporate Governance”. Information contained on our website is not incorporated into this 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, 2016, we had an accumulated deficit of approximately $35.7 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.

***We have received a going concern opinion from our auditors.***

We have received a "going concern" opinion from our independent registered public accounting firm, reflecting substantial doubt about our ability to continue as a going concern. Our consolidated financial statements contemplate that we will continue as a going concern and do not contain any adjustments that might result if we were unable to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional capital and implement our business plan. If we are unable to achieve or sustain profitability or to secure additional financing on acceptable terms, we may not be able to meet our obligations as they come due, raising substantial doubts as to our ability to continue as a going concern. Any such inability to continue as a going concern may result in our stockholders losing their entire investment. There is no guarantee that we will become profitable or secure additional financing on acceptable terms.

***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 sale of our equity securities and through NIH grants and clinical trial support. 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, 2016, there was approximately $505,000 of unused grant funds remaining and available for use during 2017. We are pursuing additional support from the federal government for our 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 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 second quarter of 2017. 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 needs 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.***

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

***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 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 are not able to provide assurance that the continued healthcare reform debate will not result in legislation, regulation or executive action by the President of the United States that is adverse to our business.

***We may not be successful in establishing collaborations for product candidates we 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.

***Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our vaccines, it is less likely that they will be widely used.***

Market acceptance of vaccines we develop, if approved, will depend on reimbursement policies and may be affected by, among other things, future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for or any vaccines that we may develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for our vaccines. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize vaccines that we develop.

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

In order to meet our operating cash flow needs 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.

***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 30,656,243 shares with an exercise price of $0.05 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 30,656,243 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, 2017. 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 21, 2017, the last reported sale price for our common stock as reported in the OTCQB Market was $0.07 per share.

| | High | Low |
|---|---|---|
| 2017 | | |
| First Quarter (through March 21, 2017) | $0.07 | $0.04 |
| 2016 | | |
| Fourth Quarter | $0.08 | $0.05 |
| Third Quarter | $0.11 | $0.07 |
| Second Quarter | $0.09 | $0.06 |
| First Quarter | $0.14 | $0.05 |
| 2015 | | |
| Fourth Quarter | $0.14 | $0.07 |
| Third Quarter | $0.18 | $0.12 |
| Second Quarter | $0.20 | $0.15 |
| First Quarter | $0.24 | $0.14 |

**Holders**

On March 21, 2017, there were approximately 425 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 2016.

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

The following table sets forth certain information as of December 31, 2016 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 exercise 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 | 2,513,975 | $1.60 | 1,206,025 |
| Equity compensation plans not approved by stockholders | 985,500 | $0.20 | -0- |

A description of our equity compensation plans can be found in footnotes 2 and 9 to our 2016 consolidated financial statements.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data as of and for each of the five years ended December 31, 2016 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, | | | | |
|---|---|---|---|---|---|
| | 2016 | 2015 | 2014 | 2013 | 2012 |
| *Statement of Operations Data:* | | | | | |
| Total revenues (grant income) | $828,918 | $428,081 | $882,956 | $2,417,550 | $2,657,327 |
| Net loss | (3,271,701) | (2,689,287) | (2,733,555) | (2,284,943) | (2,135,140) |
| Basic and diluted net loss per common share | (0.08) | (0.08) | (0.10) | (0.11) | (0.12) |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2016 | 2015 | 2014 | 2013 | 2012 |
| *Balance Sheet Data:* | | | | | |
| Total assets | 610,217 | 1,331,593 | 1,333,198 | 2,839,576 | 1,477,970 |
| Total stockholders’ equity | 240,370 | 1,204,603 | 1,146,175 | 2,527,227 | 1,150,935 |

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

The following discussion and analysis of our financial condition and results of operations should be read together with "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 because 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 against infectious diseases and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) vector vaccine platform. In this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses highly effective VLP immunogens in the person being vaccinated. The platform elicits durable immune responses while providing the safety characteristics of a replication-defective vector.

Our current development programs are focused on vaccines against HIV, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines for chronic Hepatitis B infections and cancers. All of our potential products are in preclinical research and development phases, with the exception of our preventive HIV vaccine, which is currently in human clinical trials.

Our corporate strategy is to advance and protect our vaccine platform and use its capabilities to design and develop an array of products. We aim to advance products through to human clinical testing, and to seek partnership or licensing arrangements for commercialization. We will also leverage third party resources through collaborations and partnerships for preclinical and clinical testing. Our current collaborators include National Institute of Allergy and Infectious Diseases (NIAID), HIV Vaccines Trial Network (HVTN), Centers for Disease Control and Prevention (CDC), United States Army Research Institute of Infectious Disease (USAMRIID), University of Georgia Research Foundation, University of Pittsburgh, Georgia State University Research Foundation, Peking University, Burnet Institute, American Gene Technologies, Inc., and Viamune, Inc.

We have not generated any revenues from the sale of any such products, and we do not expect to generate any such revenues for at least the next several years. Our product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that we advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for

commercialization. We may not be successful in our research and development efforts, and we may never generate sufficient product revenue to be profitable.

**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, 2016. 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 2016, 2015 and 2014, 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, 2016, we had cash and cash equivalents of $454,030 and total assets of $610,217, as compared to $1,060,348 and $1,331,593, respectively, at December 31, 2015. Working capital totaled $174,532 at December 31, 2016, compared to $1,109,985 at December 31, 2015. Historically, our primary uses of cash have been to finance our research and development activities. Since inception, we have funded these activities primarily from government grants and clinical trial assistance, and from sales of our equity securities.

As of December 31, 2016, we had an accumulated deficit of $35.7 million. We expect for the foreseeable future we will continue to operate at a loss. The amount of the accumulated deficit will continue to increase, as it will be expensive to continue research and development efforts. We will continue to require substantial funds to continue our activities and cannot predict the outcome of our efforts. We believe that our existing cash resources, combined with funding from existing NIH grants and clinical trial support will be sufficient to fund our planned operations into the second quarter of 2017. We will require additional funds to continue our planned operations beyond that date. We are currently seeking sources of capital through additional 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.

Net cash used in operating activities was $1,946,119, $2,705,263, and $2,250,107 for the years ended December 31, 2016, 2015 and 2014, respectively. Generally, the variances 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. As of December 31, 2016, there is $505,487 in remaining grant funds available for use during 2017.

Net cash used in investing activities was $ -0-, $15,850, and $35,503 for the years ended December 31, 2016, 2015 and 2014, respectively. Our investing activities have consisted predominantly of capital expenditures.

Net cash provided by financing activities was $1,339,801, $2,679,810, and $873,400 for the years ended December 31, 2016, 2015 and 2014, respectively.

During the year ended December 31, 2014, warrants to purchase 3,176,000 shares of common stock were exercised for total net proceeds to the Company of $873,400.

During the year ended December 31, 2015, we sold 3,000 shares of Series C convertible preferred stock for net proceeds of approximately $2.7 million. As part of this transaction, we also issued several series stock purchase warrants.

During the year ended December 31, 2016, warrants to purchase 21,884,420 shares of common stock were exercised for total net proceeds to the Company of $1,339,801. During March 2017 (through March 21), warrants to purchase 983,334 shares of common stock were exercised for total net proceeds to the Company of $49,167. As of March 21, 2017, warrants to purchase up to 30,656,243 shares of our common stock at $0.05 per share were outstanding.

*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, 2016, aggregated by type (in thousands):

| | **Payments Due by Period** | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **Less than 1 Year** | **1-3 Years** | **4-5 Years** | **More than 5 years** |
| Operating Lease Obligations [1] | $152 | $152 | $ -- | $ -- | $ -- |
| Firm Purchase Commitments [2] | 305 | 305 | -- | -- | -- |
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