

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, 2018

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**

(State or other jurisdiction of incorporation or organization)

**87-0455038**

(IRS Employer Identification Number)

**1900 Lake Park Drive, Suite 380**

**Smyrna, GA**

(Address of principal executive offices)

**30080**

(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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018, based on the closing price on that date was \$6,529,024.

Number of shares of Common Stock outstanding as of March 22, 2019: 278,043,476

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement with respect to its 2019 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,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements but are not the exclusive means of identifying forward-looking statements in this Annual Report. Additionally, statements concerning future matters, including statements regarding our business, our financial position, the research and development of our products and other statements regarding matters that are not historical are forward-looking statements.*

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

#### **Overview**

GeoVax Labs, Inc. (“GeoVax” or the “Company”) is a clinical-stage biotechnology company developing human vaccines and immunotherapies against infectious diseases and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) vaccine platform. In this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens in the person being vaccinated. The MVA-VLP virus replicates to high titers in approved avian cells for manufacturing but cannot productively replicate in mammalian cells. Therefore, the MVA-VLP derived vaccines elicit durable immune responses in the host similar to a live attenuated virus, 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 corporate strategy is to improve the health of patients worldwide by advancing our patented vaccine platform, using its unique capabilities to design and develop an array of products addressing unmet medical needs in the areas of infectious diseases and oncology. In doing this, we seek to provide improved vaccines and therapies, increased value to our stockholders, and career growth opportunities for our employees. We aim to advance products through to human clinical testing, and to seek partnership or licensing arrangements for achieving regulatory approval and commercialization. We also leverage third party resources through collaborations and partnerships for preclinical and clinical testing with multiple government, academic and corporate entities. Our 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), U.S. Department of Defense (DoD), U.S. Army Research Institute of Infectious Disease (USAMRIID), U.S. Naval Research Laboratory (USNRL), Emory University, University of Pittsburgh, Georgia State University Research Foundation (GSURF), University of Texas Medical Branch (UTMB), the Institute of Human Virology (IHV) at the University of Maryland, the Scripps Research Institute (Scripps), Burnet Institute in Australia, the Geneva Foundation, American Gene Technologies International, Inc. (AGT), ViaMune, Inc., Vaxeal Holding SA, Virometix AG, Enesi Pharma, and Leidos, Inc.

Our most advanced vaccine program is focused on prevention of 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 in the United States with support from NIH/NIAID. Additionally, through the efforts of our collaborator, AGT, we expect that our HIV vaccine will enter clinical trials during 2019 in combination with AGT’s gene therapy technology to seek a functional cure for HIV. Our other vaccine and immunotherapy programs are at various stages of preclinical development as described further in the following pages.

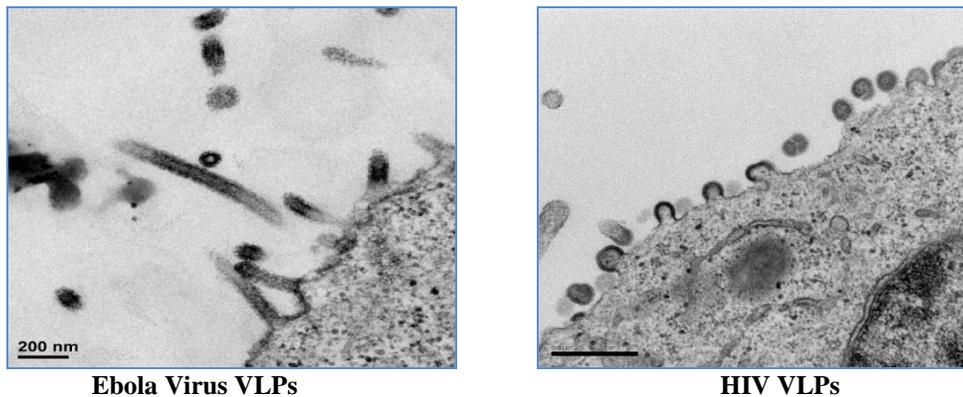
We are incorporated in Delaware, and our offices and laboratory facilities are in Smyrna, Georgia (metropolitan Atlanta).

## Our Differentiated Vaccine and Immunotherapy Platform

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<sup>®</sup> and GSK's Engerix<sup>®</sup>) and Papilloma viruses (GSK's Cervarix<sup>®</sup>, and Merck's Gardasil<sup>®</sup>). Our approach uses recombinant DNA and/or recombinant MVA to produce VLPs in the person being vaccinated (in vivo) reducing complexity and costs of manufacturing. In human clinical trials of our HIV vaccines, we have demonstrated that our VLPs, expressed from within the cells of the person being vaccinated, can be safe, yet elicit both strong and durable humoral and cellular immune response.

VLPs can train the body's immune system to recognize and kill targeted viruses to prevent an infection. VLPs can 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. We design our vaccines such that, when VLPs for enveloped viruses like HIV, Ebola, Marburg or Lassa fever are produced *in vivo* (in the cells of the recipient), 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 *in vitro* (in a pharmaceutical plant), by contrast, have no envelope; or, envelopes from the cultured cells (typically hamster or insect cells) used to produce them. We believe our technology therefore provides distinct advantages by producing VLPs that more closely resemble the authentic viruses. We believe this feature of our immunogens allows the body's immune system to more readily recognize the virus. By producing VLPs *in vivo*, we believe we also avoid potential purification issues associated with *in vitro* production of VLPs.

### Examples of VLPs



**Figure 1. Electron micrographs showing examples of VLPs produced by GeoVax vaccines in human cells.** Note that the Ebola virus 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.

For many viral infectious diseases, natural VLPs are produced by co-assembly of, generally a matrix protein and an envelope protein. These natural VLPs resemble infectious virions but may not contain the virus' full genetic material and are therefore considered "virus byproducts". To develop a vaccine for an infectious disease such as Ebola, Zika, HIV, etc., we use viral proteins that naturally form VLPs. For other diseases such as cancer and malaria where there are no natural VLP counterparts, we use an array of other matrix proteins as scaffolds to deliver such antigens as VLPs. Similar approaches have been used for VLPs produced in vitro including the current malaria vaccine (RTS, S) that uses a matrix S protein from the Hepatitis B virus to deliver the malaria liver-stage protective antigen, CSP. We have successfully used viral matrix proteins as scaffolds for our oncology vaccine (MUC1) and malaria (modified CSP) vaccine candidates.

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 sequences to produce VLPs. MVA was originally developed as a safer smallpox vaccine for use in immune-compromised individuals. It was developed by attenuating the standard smallpox vaccine by passaging it (over 500 passages) in chicken embryos or chicken embryo fibroblasts, resulting in a virus with limited ability to replicate in human cells (thus safe) but with high replication capability in avian cells (thus cost effective for manufacturing). 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 advantages:

- **Safety:** Our HIV vaccines have demonstrated outstanding safety in multiple 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 and first responders) unvaccinated and without pre-existing immunity to MVA-derived vaccines. A potential interference of pre-existing immunity to a vector may be more problematic with those vectors related to parent viruses used in routine vaccinations (e.g. measles) or constitute common viruses that infect people of all ages (e.g. cytomegalovirus).
- **Repeated use of the platform for different vaccines used in sequence.** In mouse experiments, we have shown that two vaccines (e.g. MVA-Zika followed by MVA-Ebola) can be given at  $\leq 4$  weeks intervals without any negative impact on their immunogenicity (lack of vector 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

Our primary focus is to advance, independently and in partnerships, the products developed from our MVA-VLP platform. We are currently developing a number of vaccines and immunotherapies for prevention or treatment of infectious diseases and cancer. The table below summarizes the status of our product development programs, which are discussed in greater detail in the following pages.

<u>Product Area / Indication</u>	<u>Stage of Development</u>	<u>Collaborators / Sponsors</u>
<u>Infectious Diseases</u>		
HIV – Clade B	Phase 2a completed	NIH, HVTN, Emory
HIV – Clade B (immunotherapy)	Phase 1	AGT
HIV – Clade C	Preclinical	NIH
Zika	Preclinical	NIH, CDC
Malaria	Preclinical	Leidos, Burnet Institute
Ebola	Preclinical	NIH, USAMRIID
Lassa Fever	Preclinical	NIH, DoD, Scripps, IHV, UTMB, USNRL, Geneva Foundation
Sudan / Marburg	Preclinical	UTMB
Hepatitis B (immunotherapy)	Preclinical	GSURF, CaroGen
Novel delivery (multiple targets)	Preclinical	Enesi
<u>Cancer</u>		
HPV-related cancers	Preclinical	Emory, Virometix
MUC1-expressing tumors	Preclinical	Univ of Pittsburgh, ViaMune
Cyclin B1-expressing tumors	Preclinical	Vaxeal
Checkpoint inhibitors	Preclinical	Leidos

## **Our HIV/AIDS Vaccine Programs**

**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 1.8 million newly infected annually. Since the beginning of the epidemic, more than 70 million people have been infected with the HIV virus and about 35 million have died of HIV. The United States currently has an estimated 1.1 million HIV-infected individuals, with approximately 40,000 new infections per year. Gay and bisexual men bear the greatest burden by risk group, representing nearly 70% of new infections in the U.S. African-Americans also bear a disproportionate burden, representing 43% of people living with HIV, yet representing just 12% of the total population.

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.

There is no approved vaccine to prevent HIV infection. 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. Current antiretroviral therapies (ART) do not eliminate HIV infection, requiring individuals to remain on such 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 U.S. taxpayer for HIV education, prevention, and treatment costs is borne through multiple federal agencies, totaling over \$25 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. We expect 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***

***Clade B 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 induce the production of non-infectious VLPs by the cells of the vaccinated person.

Phase 1 and phase 2a human clinical trials of GOVX-B11 have been conducted by the 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 NIAID, part of the NIH. The HVTN's HIV Vaccine Trial Units are located at leading research institutions in 27 cities on four continents.

In January 2017 HVTN began the next human clinical trial (HVTN 114) in the path toward pivotal efficacy trials. HVTN 114 enrolled individuals who previously participated in the HVTN 205 Phase 2a trial of the GOVX-B11 vaccine, which concluded in 2012. HVTN 114 tested the ability of late boosts (additional vaccinations) to increase the antibody responses elicited by the

GeoVax vaccine regimen. These “late boosts” consist of the GeoVax MVA62B vaccine with or without a gp120 protein vaccine. The gp120 protein, AIDS<sup>®</sup>VAX B/E, is the same protein used to boost immune responses in the partially protective RV144 trial in Thailand and is being used in HVTN 114 to assess the effect of adding a protein vaccine to GOVX-B11. Participants in HVTN 114 receive either (a) another MVA62B boost, (b) a combined boost of MVA62B and AIDS<sup>®</sup>VAX B/E, or (c) AIDS<sup>®</sup>VAX B/E alone. HVTN 114 was completed during 2018 and results were presented during the HIV Research for Prevention (HIVR4P) conference in Madrid, Spain in October. The study demonstrated the most effective boost to be the combination of MVA62B live vector and AIDS<sup>®</sup>VAX B/E proteins, which increased titers of antibodies to the HIV envelope glycoproteins by more than 600-fold.

Following completion of HVTN 114, the HVTN is moving forward with plans for an additional phase 1 trial, designated HVTN 132, which will be a multi-center, randomized, double-blind trial, enrolling up to 70 healthy adults. The primary objectives of HVTN 132 will be to further assess the safety, tolerability and immunogenicity (elicited antibody responses) of a prime-boost regimen of GOVX-B11, in combination with protein boost vaccines. The protein boosts are being tested for their ability to enhance the antibody response elicited by GOVX-B11 to gp120. The protein boosts to be evaluated in the trial were developed by Duke University and by the Institute of Human Virology of the University of Maryland School of Medicine. HVTN 132 will be conducted by the HVTN with support from NIAID and is expected to commence patient enrollment in mid-2019.

*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 GeoVax Small Business Innovative Research (SBIR) grants in support of this effort.

### ***Our HIV Immunotherapy Program – Seeking a Cure***

Finding a cure for HIV/AIDS remains an elusive goal. Current 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. Long-term use of ART can lead to loss of drug effectiveness and can come with severe side effects. The lifetime medical costs saved by preventing (or curing) a single HIV infection in the U.S. are estimated to approach \$400,000. 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. Recently scientists have reportedly cured a second patient (London patient), duplicating the procedure that led to the first long-term remission in a patient (Berlin patient) 12 years ago. That procedure involved a bone marrow transplant from a patient with the CCR5 mutation in his cells that make them resistant to HIV infections, into a cancer patient with HIV. The transplanted cells resistant to HIV seem to have fully replaced the patient’s vulnerable cells. Although this procedure is risky, has harsh side effects that can last for years, is only for cancer patients with HIV, and does not guarantee that the patient will remain HIV-free throughout his life, it opens the possibility to develop gene therapy approaches to knock out CCR5 on immune cells, making them resistant to HIV infections.

*Collaboration with AGT* – In March 2017, we entered into collaboration with American Gene Technologies International, Inc. (AGT) whereby AGT intends to conduct a Phase 1 human clinical trial with our combined technologies, with the ultimate goal of developing a functional cure for HIV infection. In the AGT trial, the GeoVax vaccine will be used to stimulate virus-specific CD4<sup>+</sup> 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. In a previous phase 1 clinical trial (GV-TH-01), we demonstrated that our vaccine can stimulate production of CD4<sup>+</sup> T cells in HIV infected patients—the intended use of the MVA-VLP HIV vaccine in the proposed AGT study. AGT has recently stated their intention to begin the phase 1 trial during the second half of 2019.

Additionally, we are currently in discussions with two other consortiums for the use of our vaccine in similar efforts toward developing a cure for HIV infection. We expect one or both of these studies to begin in late 2019 or early 2020.

### **Our Ebola Vaccine Program**

Ebola (EBOV, formerly designated as Zaire ebolavirus), Sudan (SUDV), and Marburg viruses (MARV) are the 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 29 outbreaks since 1976. The 2013-16 Ebola outbreak caused 28,616 cases and 11,310 deaths (40% fatal). In August 2018, the Ministry of Health of the Democratic Republic of the Congo declared a new outbreak of Ebola virus disease in North Kivu Province. Despite responses from the Ministry of Health, WHO, and its partners to contain this outbreak, there have been 897 cases (832 confirmed and 65 probable) resulting in 563 death (498 confirmed, and 65 probable, ~63% fatal) as of March 3, 2019. Even after the current outbreak is contained, additional outbreaks are certain in future due to indigenous

reservoirs of the virus (e.g. fruit bats), the zoonotic nature of the virus, weak health systems, high population mobility, political unrest, cultural beliefs and burial practices, and for those not at natural risk, the risk of intentional release by a bioterrorist.

We believe an ideal vaccine against major filoviruses must activate both humoral and cellular arms of the immune system. It should include the induction of antibodies to slow the initial rate of infection and a cellular immune response to help clear the infection. Moreover, it should address strain variations by providing broad coverage against potential epizootic filovirus strains, and it should 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 living in West Africa where recent Ebola epidemics started. 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 safer and effective vaccine, to prevent or alleviate the effects of the next epidemic.

To address the unmet need for a product that can respond to future filovirus epidemics we are developing innovative vaccines utilizing our MVA-VLP platform. We are addressing strain variations, and induction of broad humoral and cellular response through development of monovalent vaccines, which we may also investigate blending together as a single vaccine to provide broad coverage, potentially with a single dose. The MVA vector itself is considered safe, having originally been developed for use in immunocompromised individuals as a smallpox vaccine. Our vaccines are expected to not only protect at-risk individuals against EBOV, SUDV and MARV, 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 (e.g. VP40 or Z) in addition to standard GP proteins used by us and other manufacturers. Thus, the GeoVax MVA-VLP approach could offer a unique combination of advantages to achieve breadth and safety of a pan-filo 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.

Our initial preclinical studies in rodents and nonhuman primates for our EBOV vaccine candidate have shown 100% protection against a lethal dose of EBOV upon a single immunization. These studies were conducted with support from NIAID and USAMRIID. We have also designed and constructed vaccine candidates for SUDV and MARV. In a recent independent, peer-reviewed paper published by Lazaro Frias et al ([J Virol](#). 2018 Jun 1; 92(11): e00363-18), the authors concluded that the MVA-VLP-Ebola and MVA-VLP-Sudan vaccines are the best-in class vaccine in development. Further development of our filovirus vaccines will be dependent upon additional funding support.

### **Our Lassa Fever Vaccine Program**

Lassa fever virus (LASV), a member of the *Arenaviridae* family, causes severe and often fatal hemorrhagic illnesses in an overlapping region with Ebola. Lassa Fever is an acute viral hemorrhagic illness caused by LASV. 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 independent study suggest that the number of annual Lassa Fever cases may be much higher, reaching three million infections and 67,000 deaths, putting as many as 200 million persons at risk.

Our initial preclinical studies in rodents for our LASV vaccine candidate have shown 100% single-dose protection against a lethal dose of LASV challenge composed of multiple strains delivered directly into the brain. The study was conducted at the Institute of Human Virology at the University of Maryland School of Medicine in Baltimore. Multiple repeats of the study confirmed the findings.

*SBIR Grant* – Subsequent to these initial findings, in April 2018 NIAID awarded us a Fast Track Phase I/II Small Business Innovative Research (SBIR) grant in support of further advancing our development program. The \$300,000 grant is for Phase I of the project, with an anticipated total project budget of up to \$1.9 million following the expected Phase II award. The grant will support preclinical testing of vaccine candidates in preparation for human clinical trials. The work will be performed in collaboration with the Institute of Human Virology at the University of Maryland, The Scripps Research Institute, and the University of Texas Medical Branch. Through the work supported by this grant, we are building upon our initial success to implement a novel immunogen design for eliciting broadly cross-reactive neutralizing antibodies. Capitalizing on recent breakthroughs in the structural characterization of LASV glycoprotein by Scripps Research, we plan to develop and test novel immunogen designs in the context of its proprietary vaccine platform.

*Defense Department Grant* – In September 2018, the U.S. Department of Defense (DoD) awarded us a \$2,442,307 cooperative agreement in support of our LASV vaccine development program. The grant was awarded by the U.S. Army Medical Research Acquisition Activity pursuant to the Peer Reviewed Medical Research Program (PRMRP), part of the Congressionally Directed Medical Research Programs (CDMRP). In addition to the grant funds provided directly to GeoVax, DoD will also fund testing of the GeoVax vaccine by U.S. Army scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), under a separate subaward. The project award is supporting generation of immunogenicity and efficacy data for our vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparation for human clinical trials. The work will be performed in collaboration with USAMRIID, the Geneva Foundation, and Advanced Bioscience Laboratories (ABL).

The studies funded by the DoD grant are complementary to those being funded by the SBIR grant from NIAID which is supporting development of a potentially “universal” vaccine by eliciting broadly neutralizing antibodies to the LASV glycoprotein designed by Scripps Research. Both avenues are building upon previous work that demonstrates the full protective efficacy of our MVA recombinant vaccines after a single inoculation.

*Collaboration with USNRL* – In December 2017, we began a collaboration with the U.S. Naval Research Laboratory (USNRL) to develop high-quality antibodies useful for detection of LASV, and potentially as a treatment for Lassa Fever. The USNRL and the DoD has an interest in the early detection of the presence of LASV to better protect and treat troops that may be in areas where exposure may occur. Development of high-quality antibodies useful for detection applications requires a high-quality vaccine. Our LASV vaccine represents the state of the art and is the best starting point for USNRL’s efforts to develop single domain antibodies that recognize LASV with high affinity and specificity. USNRL is utilizing the GeoVax vaccine to immunize llamas, whose immune systems are uniquely suited for rapid and cost-effective production of single domain antibodies suitable for use in biosensor applications.

### **Our Zika Vaccine Program**

Zika disease is an emerging infectious disease 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 needed to prevent a Zika pandemic.

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 promise in our HIV, Ebola and Lassa 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. Our Zika vaccine does not appear to induce Antibody Dependent Enhancement (ADE) of infection. ADE is a serious side effect induced when a vaccinated individual is bitten a second time by a mosquito carrying a second *flavivirus* such as dengue, resulting in a more virulent reaction. We expect these features to yield a safe and highly effective vaccine that is well suited to provide potent and durable immunity against ZIKV infection.

Our initial preclinical studies in rodents for our ZIKV vaccine candidate have shown 100% single-dose protection against a lethal dose of ZIKV delivered directly into the brain. The study was conducted and funded by the US Centers for Disease Control and Prevention (CDC), which also provided technical assistance.

*SBIR Grant* – Subsequent to these initial findings, in June 2017 NIAID awarded us a Small Business Innovative Research (SBIR) grant in support of further advancing our development program. The \$600,000 two-year grant is supporting preclinical testing of our ZIKV vaccine in nonhuman primates in preparation for human clinical trials.

Further development of our ZIKV vaccine will be dependent upon additional funding and/or partnering support.

## **Our Malaria Vaccine Programs**

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 parasites 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 after 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 multiple 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.

An ideal malaria vaccine candidate should contain antigens from multiple stages of the malaria parasite's life cycle, and should induce both functional antibodies (predominantly IgG1 and IgG3 subtypes shown to be associated with protection) and strong cell mediated immunity (e.g. Th1 biased CD4+ and CD8+) to reduce parasitemia by clearing infected cells (liver cells or erythrocytes). We have shown (in animal models and humans) that MVA-VLP vaccines for non-malarial disease targets can induce a Th1 biased response with both durable functional antibodies (IgG1 and IgG3) and CD4<sup>+</sup> and CD8<sup>+</sup> T cell responses, both of which are hallmarks of an ideal malaria vaccine.

*Collaboration with Burnet Institute* – We have 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.

*Collaboration with Leidos* – In February 2019, we began a collaboration with Leidos, Inc. to develop malaria vaccine candidates. The work will be supported under a contract to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). Leidos has been tasked by USAID to advance promising vaccine candidates against *P. falciparum* malaria and selected the GeoVax MVA-VLP platform as part of this development effort. The new collaboration with Leidos complements our ongoing malaria vaccine development project with Burnet Institute and offers a separate opportunity for success. The collaboration also expands upon our existing relationship with Leidos for our cancer immunotherapy program (see below).

## **Our Hepatitis B Vaccine Program**

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 through currently available therapies.

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<sup>+</sup>, CD8<sup>+</sup> 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.

*Collaboration with GSURF* – Given the challenges and difficulties of developing an effective therapy for chronic HBV infections, our strategy is to engage with multiple collaborators for combination therapies to increase our chances of success. We are collaborating with Georgia State University Research Foundation (GSURF) on a project that 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. This project is ongoing.

*Collaboration with CaroGen* – In February 2018, we began collaborating with CaroGen Corporation to evaluate our MVA-VLP-HBV vaccine candidates in combination with CaroGen’s HBV virus-like vesicles (VSV) vaccine candidate. This project is ongoing.

### **Novel Vaccine Delivery Evaluations**

Given that several of our programs involve infectious disease targets (e.g. EBOV, LASV, etc.) prevalent in third world countries, we are exploring novel vaccine delivery platforms that may simplify vaccine administration and/or reduce storage and distribution costs.

*Collaboration with Enesi* – In January 2019, we announced a collaboration with Enesi Pharma, an innovative pharmaceutical company developing unique injectable solid-dose drug-device vaccine products, to develop solid-dose needle-free vaccine formulations utilizing our MVA-VLP vaccine platform in combination with Enesi’s Implavax® device and formulation technology. The collaboration is expected to include development of thermostable solid-dose needle-free vaccines for a variety of infectious diseases and evaluation of the potential to generate improved vaccine responses with simplified administration and reduced storage and distribution costs. Enesi’s proprietary Implavax® solid-dose formulation and needle-free device technology comprises three main components: a single precision-engineered solid-dose Universal Vaccine Implant (UVI) containing the vaccine construct, a separate single-use disposable unit dose cassette pre-loaded with a single solid UVI and a reusable handheld spring-powered actuator. The benefits could include assured consistency with dosing, better product stability and ease of use as well as the potential to minimize vaccination pain and stress, and to eliminate needle disposal and needle stick injuries.

### **Our Cancer Immunotherapy Programs**

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 immuno-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 otherwise poorly functional T cells to resume proliferation, cytokine production and killing of tumor cells.

Unlike conventional therapies (e.g. radiation, chemotherapy, antibody, etc.), therapeutic 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 could 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.

*Collaborations with University of Pittsburgh and ViaMune* – We have 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 would 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 a hypo-glycosylated form of MUC1 in human cell lines. Preclinical studies of the combined MTI and MVA-VLP-MUC1 vaccines conducted at the University of North Carolina at Charlotte have shown the combination of our vaccine with MTI and ICI have significantly reduced the tumor burden in a mouse model for colorectal cancer.

*Collaboration with Vaxéal* -- In January 2018, we began a collaboration with Vaxéal Holding SA, in Switzerland to investigate a combination approach with another tumor-associated antigen (Cyclin B1). The collaboration between GeoVax and Vaxéal includes the design, construction, characterization and animal testing of vaccine candidates using our MVA-VLP vaccine platform in combination with Vaxéal's proprietary designed antigen sequences. We have completed construction of one of the two vaccine candidates planned for testing at Vaxéal in the upcoming months.

*Collaboration with Emory Vaccine Center* – In July 2018, we began collaborating with Emory University on the development of a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). This is an important research area as there are currently no medical treatments for chronic HPV infections, which can lead to the formation of cancerous tumors. The GeoVax/Emory collaboration will include testing GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV in the laboratory of Dr. Rafi Ahmed, Director of the Emory Vaccine Center. Dr. Ahmed, a member of the National Academy of Sciences, is a world-renowned immunologist whose work during the past decade has been highly influential in shaping understanding of memory T cell differentiation and T and B cell-mediated antiviral immunity. We believe our collaboration with Emory on the HPV project is extremely valuable as it was Dr. Ahmed who first discovered in 2006 that the PD-1 pathway could also be exploited by many pathogens to repress normal T cell function during chronic viral infection. This led to development of numerous blockbuster anti-PD1 antibodies currently being used for treatment of various cancers and which hold promise as adjunctive therapy for several chronic infectious diseases. In HIV, Ebola, Zika, and Lassa Fever, our MVA-VLP vaccine candidates have demonstrated eliciting strong antigen-specific T cell responses in the host, a response that is critical to fight against HPV infections in HNC patients. To increase the therapeutic efficacy of our HPV vaccine, we intend to apply a combination strategy which could include co-administration of anti-PD1 antibodies and/or other newly discovered immunotherapy drugs to improve a patient's own anti-cancer immune response.

*Collaboration with Virometix* – In November 2018, we announced a collaboration with Virometix AG, a company developing next-generation Synthetic Virus-Like Particle (SVLP) based vaccines, to develop a therapeutic vaccine for HPV infection. The collaboration will include preclinical animal testing of GeoVax's MVA-vectored HPV vaccine candidates in combination with Virometix' synthetic HPV vaccine candidate. This collaboration complements our collaboration with Emory University for HPV-related head and neck cancers in patients who express oncogene products of HPV16, E6 and E7 proteins. Similar to the strategy we are utilizing in our clinical trials for HIV and preclinical testing of our cancer vaccines (e.g. vector and protein combination), we believe the combination of our MVA-vectored HPV vaccines and Virometix' SVLP-based HPV vaccine will bring a synergy that significantly increases the therapeutic potential over each platform used separately.

*Collaboration with Leidos* – In November 2018, we began collaborating with Leidos, Inc. on a research program evaluating the combination of the companies' respective technologies in the field of cancer immunotherapy. Currently, there are major limitations on cancer immunotherapies which include high costs (limiting patient access, straining both the healthcare system and the patient's own finances), the need for multiple injections, and significant side effects. Moreover, monotherapy with one checkpoint inhibitor drug can induce drug resistance in some patients making it necessary to combine with other drugs and treatments, which in turn may further increase toxicity. We have shown that our MVA platform is safe in humans without any major side effects and hope that delivery of the immune checkpoint inhibitors with or without the tumor-associated antigens may overcome some of the challenges associated with the use of immune checkpoint inhibitors in cancers or other chronic infectious diseases. The GeoVax/Leidos collaboration will include the design, construction, and characterization of multiple immunotherapeutic vaccine candidates using our MVA-VLP vaccine platform combined with certain novel peptide PD-1 checkpoint inhibitors developed by Leidos. The vaccine design, construction, and characterization will be performed at

GeoVax with further analysis conducted by Leidos. We believe this effort may lead to expanded efforts in cancer immunotherapy, treatments for chronic Hepatitis B infections, or other diseases where an immunological-based therapeutic approach would be beneficial.

## **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:

**Lassa DoD Grant.** In September 2018, the U.S. Department of Defense (DoD) awarded us a \$2,442,307 cooperative agreement in support of our LASV vaccine development program. The grant was awarded by the U.S. Army Medical Research Acquisition Activity pursuant to the Peer Reviewed Medical Research Program (PRMRP), part of the Congressionally Directed Medical Research Programs (CDMRP). In addition to the grant funds provided directly to GeoVax, DoD will also fund testing of our vaccine by U.S. Army scientists under a separate subaward. The award, entitled “*Advanced Preclinical Development and Production of Master Seed Virus of GEO-LM01, a Novel MVA-VLP Vaccine Against Lassa Fever*”, will support generation of immunogenicity and efficacy data for our vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparation for human clinical trials.

**Lassa SBIR Grant.** In April 2018, NIAID awarded us a Fast Track Phase I/II SBIR grant entitled “*Construction and efficacy testing of novel recombinant vaccine designs for eliciting both broadly neutralizing antibodies and T cells against Lassa virus.*” The \$300,000 grant is for Phase I of the project; with a total project budget of up to \$1.9 million following the anticipated Phase II award.

**Zika SBIR Grant.** In June 2017, NIAID awarded us a SBIR grant entitled “*Advanced Preclinical Testing of a Novel Recombinant Vaccine Against Zika Virus.*” The initial grant award was \$300,000 for the first year of a two-year project period beginning June 24, 2017, with a total project budget of \$600,000. In May 2018, the second-year grant of \$300,000 was awarded to us.

**HIV 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 included a base contract of \$199,442 for the initial period from August 1, 2016 to December 31, 2017 (the “base period”) 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 base period NIAID notified us that it did not plan to exercise the additional development option under the contract due to funds availability and NIAID’s programmatic needs. We do not expect this to have an impact on the human clinical trials of our preventive HIV vaccine currently being conducted by the HVTN, or future trials being planned.

**HIV SBIR Grant.** In April 2016, NIAID awarded us a 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 to test the effects of adding two proteins to our vaccine regimen, and we subsequently received a one-year no-cost extension of the project period, which is nearing completion. Results from the studies supported by this grant are being used to inform the design of human clinical trials.

**HIV SBIR Grant.** In June 2015, NIAID awarded us a 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 to develop a clade C HIV vaccine. Clade C is the most prevalent subtype of HIV in eastern South American, sub-Saharan Africa and India. This grant has concluded, and we are evaluating our options for further development of the clade C version of our HIV vaccine.

**Clinical Trial Support.** All our human clinical trials to date for our preventive HIV vaccines, including the recently completed HVTN 114 trial and the HVTN 132 trial currently planned, 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. See “Our Preventive HIV Vaccine Program” above for the current status of our human clinical 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.

## **Government Regulation**

Regulation by governmental authorities in the United States and other countries is a significant factor in our ongoing research and development activities and in the manufacture of our products. Complying with these regulations involves considerable expertise, time and expense.

In the United States, drugs and biologics are subject to rigorous federal and state regulation. Our products are regulated under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and the regulations promulgated under these statutes, 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:

- Preclinical laboratory tests, in vivo preclinical 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 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; and
- FDA approval of the BLA prior to any commercial sale or shipment of the product

Before marketing any drug or biologic for human use in the United States, 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 before introducing any new drug or biologic 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 cGMP regulations 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.

Even if FDA regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

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.

We also are subject to various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted.

## **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.

The MVA component of our vaccine is currently manufactured in cells that are cultured from embryonated eggs. We have explored a number of approaches to growing MVA in continuous cell lines that can be grown in bioreactors more suitable for commercial-scale manufacturing. During this process we identified a duck stem-cell-derived line (termed EB66), that is proprietary to Valneva SE, and under a prior collaboration with Valneva we have developed the manufacturing process for growing our MVA vaccines using the EB66 cell line. Under a research license from Valneva we are currently using the EB66 cell line to produce and evaluate our Lassa Fever vaccine pursuant to work supported by our grant from the U.S. Department of Defense (see "Our Lassa Fever Vaccine Program" above). Should we determine to use the EB66 cell line to produce any of our vaccines for human clinical trials or commercial use, we will pursue the appropriate licenses from Valneva.

## **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. As we develop and seek to ultimately commercialize our product candidates, we face and will continue to encounter competition with an array of existing or development-stage drug and immunotherapy approaches targeting diseases we are pursuing. We are aware of various established enterprises, including major pharmaceutical companies, broadly engaged in vaccine/immunotherapy research and development. These include Janssen Pharmaceuticals, Sanofi-Aventis, GlaxoSmithKline, Merck, Pfizer, and MedImmune. There are also various development-stage biotechnology companies involved in different vaccine and immunotherapy technologies including Aduro Biotech, Advaxis, BioNTech, Curevac, Dynavax, Juno, Moderna, and Novavax. If these companies are successful in developing their technologies, it could materially and adversely affect our business and our future growth prospects. 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 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, 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 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 twenty-three issued or allowed non-U.S. patents. We are actively pursuing two U.S. provisional applications, two non-U.S. and two international patent applications as the owner of record, in addition to at least two non-U.S. patent applications 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.

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 \$1,878,652, \$2,017,350, and \$1,970,859 during the years ended December 31, 2018, 2017 and 2016, 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:

<u>Name</u>	<u>Position/Institutional Affiliation</u>
Thomas P. Monath, MD	Managing Partner and Chief Scientific Officer at Crozet Biopharma
Stanley A. Plotkin, MD	Professor Emeritus, University of Pennsylvania, 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 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, 2019, with annual extension options through December 31, 2022. 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. We currently have eight full-time and one part-time employees. None of our employees are covered by collective bargaining agreements and we believe that our employee relations are good.

## Corporate Background

Our primary business is conducted by our wholly-owned subsidiary, GeoVax, Inc., which was incorporated under the laws of Georgia in June 2001. Our address is 1900 Lake Park Drive, Smyrna, Georgia 30080, and our telephone number at that address is 678-384-7220. 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](http://www.geovax.com). We make available on this website under "Investors – SEC Reports," free of charge, our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. We also make available our Code of Ethics on this website under the heading "Investors – Corporate Governance". Information contained on our website is not incorporated into this Annual Report.

## **ITEM 1A. RISK FACTORS**

*Ownership of 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 own 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 other 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, 2018, we had an accumulated deficit of approximately \$40.5 million. We expect to incur additional operating losses and expect cumulative losses to increase as our research and development, preclinical, clinical, manufacturing and marketing efforts expand. Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of our product candidates, conduct preclinical tests and clinical trials, obtain the necessary regulatory approvals, and manufacture and market the resulting products, or otherwise commercialize our 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 government 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 NIAID, and we expect NIAID 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 NIAID for any additional clinical trials of our HIV vaccines.

Our operations are also partially supported by U.S. government grants awarded to us to support our HIV, Zika and Lassa Fever vaccine programs. As of December 31, 2018, there was \$2,589,247 of unused grant funds remaining and available for use during 2019 and 2020. 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 current government grants and committed sources of equity capital will be sufficient to support our planned level of operations into the third quarter of 2019. 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, vaccine manufacturers, 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 NIAID 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.

***Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, includes a number of provisions that are intended to lower healthcare costs, including prescription drug prices and government spending on medical products.

Since its enactment, there have also been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the statute. We continue to evaluate the effect that the Affordable Care Act and subsequent changes to the statute has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

There has also been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products. There have been several Congressional inquiries and proposed bills, as well as state efforts, designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In June 2017, FDA issued a Drug Competition Action plan intended to lower prescription drug prices by encouraging competition from generic versions of existing products. The Agency announced that it will issue a similar plan intended to promote competition to prescription biologics from biosimilars later this year.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, in September 2017, the California State Assembly approved SB17, which requires pharmaceutical companies to notify health insurers and government health plans at least 60 days before any scheduled increases in the prices of their products if they exceed 16% over a two-year period, and further requiring pharmaceutical companies to explain the reasons for such increase. Effective in 2016, Vermont passed a law requiring certain manufacturers identified by the state to justify their price increases.

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

***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, especially as compared to any competitive 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 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 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 those of 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 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.

***Our common stock is currently subject to the SEC's "penny stock" rules, which make it more difficult to sell.***

Our common stock is currently 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.

***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 impact of a proposed reverse stock split on the price of our common stock is uncertain.***

On April 15, 2019, we intend to hold a Special Meeting of Stockholders for the purpose of granting our Board of Directors discretionary authority to amend our Certificate of Incorporation to effect a reverse stock split of our issued and outstanding common stock at a ratio of between 1-for-100 to 1-for-500, as determined by the Board. The Board believes that, among other things, the proposed reverse stock split may help the Company to attract additional financing, facilitate higher levels of institutional stock ownership, and potentially meet the requirements for listing our Common Stock on The Nasdaq Capital Market. There is, however, no assurance that our stockholders will approve the proposal.

Should our stockholders approve the reverse stock split proposal, and should our Board then take action to effect a reverse stock split for the purpose of increasing the price per share of our common stock, the price may subsequently decline due to many factors including: (i) the negative perception of reverse stock splits held by some stock market participants; (ii) the adverse effect on liquidity that might be caused by a reduced number of shares outstanding; and (iii) the costs associated with implementing a reverse stock split. The effect of the reverse stock split upon the market price of our common stock cannot be predicted with any certainty, and the history of similar stock splits for companies in similar circumstances to ours is varied. It is also possible that a reverse stock split may not increase the per share price of our common stock in proportion to the reduction in the number of shares of our common stock outstanding or result in a permanent increase in the per share price, which depends on many factors.

Furthermore, there is no guarantee that our common stock will be listed on Nasdaq. In addition to the stock price requirements, which may or may not be satisfied through effectuating a reverse stock split, there are other listing requirements which we may not meet. If we are unsuccessful in listing on Nasdaq, our common stock will continue to be quoted on the OTC Market.

***The exercise of options or warrants or conversion of our preferred stock may depress our stock price and may result in significant dilution to our common stockholders.***

There are a significant number of outstanding options and warrants to purchase our common stock and we have issued Series B, Series F, and Series G Convertible Preferred Stock that is currently outstanding and convertible into our common stock. If the market price of our common stock exceeds the conversion prices of the preferred shares, holders of those securities may be likely to convert their preferred shares and sell the common stock acquired upon conversion of such securities in the open market. Sales of a substantial number of shares of our common stock in the public market by holders of 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 preferred shares convert those preferred shares, 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.

***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, and there are outstanding, 100 shares of Series B Convertible Preferred Stock, 2,763 shares of our Series F Convertible Preferred Stock, and 500 shares of our Series G 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 costlier 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.

***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.

#### **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, 2019, with annual extension options through December 31, 2022. We believe this space is adequate for our current needs and we expect to exercise our option to extend the lease before the end of the current lease period.

**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". Quotations for our common stock reflect inter-dealer prices and do not include retail mark-up, markdown, or commission, and may not necessarily represent actual transactions.

**Holders**

On March 22, 2019, there were approximately 530 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. The certificates of designation for our outstanding preferred stock would prohibit the payment of dividends on our common stock if there were any dividends due but unpaid on our preferred stock. 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 2018.

## Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information as of December 31, 2018 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	3,720,000	\$0.31	-0-
Equity compensation plans not approved by stockholders	10,999,275	\$0.04	5,000,725

A description of our equity compensation plans can be found in footnote 8 to our 2018 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, 2018 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,				
	2018	2017	2016	2015	2014
<i>Statement of Operations Data:</i>					
Total revenues	\$ 963,203	\$ 1,075,270	\$ 828,918	\$ 428,081	\$ 882,956
Net loss	(2,560,094)	(2,170,162)	(3,271,701)	(2,689,287)	(2,733,555)
Basic and diluted net loss per common share	(0.02)	(0.03)	(0.08)	(0.08)	(0.10)
	As of December 31,				
	2018	2017	2016	2015	2014
<i>Balance Sheet Data:</i>					
Total assets	642,064	490,235	610,217	1,331,593	1,333,198
Total stockholders’ equity (deficiency)	(1,022,347)	(321,057)	240,370	1,204,603	1,146,175

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

The following discussion and analysis of our financial condition and results of operations should be read together with “Selected Financial Data” and our consolidated financial statements and the related notes beginning on page F-1. This discussion contains forward-looking statements that involve risks and uncertainties because they are based on current expectations and relate to future events and our future financial performance. Our actual results may differ materially from those anticipated in these forward-looking statements 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) vaccine platform. In this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens in the person being vaccinated. The MVA-VLP derived vaccines elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

Our current development programs are focused on preventive 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. 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 improve the health of patients worldwide by advancing our patented vaccine platform, using its unique capabilities to design and develop an array of products addressing unmet medical needs in the areas of infectious diseases and oncology. We aim to advance products through to human clinical testing, and to seek partnership or licensing arrangements for commercialization. We also leverage third party resources through government, academic and corporate research collaborations and partnerships for preclinical and clinical testing.

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, 2018. 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*

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which created 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. We adopted ASU 2014-09 effective January 1, 2018 using the modified retrospective transition method. Under this method, our prior results will remain as reported and starting in 2018 are recognized under the new method. The adoption of ASU 2014-09 had no material impact on the measurement, timing, or recognition of our grant and collaboration revenues, nor on the related research and development expenses.

**Grant revenue** – We receive payments from government entities under non-refundable grants in support of our vaccine development programs. We record revenue associated with these grants when the reimbursable costs are incurred and we have complied with all conditions necessary to receive the grant funds.

**Research collaborations** – We are pursuing a strategy of co-developing or licensing our technology for specific vaccine development approaches and/or disease indications. Accordingly, we have entered into multiple collaborative research and development agreements and have received third-party funding for preclinical research under certain of these arrangements. Each agreement is evaluated in accordance with the process defined by ASU 2014-09 and revenue is recognized accordingly.

#### *Stock-Based Compensation*

We account for stock-based transactions in which the Company receives services from employees, directors or others in exchange for equity instruments based on the fair value of the award at the grant date. Compensation cost for awards of common stock is estimated based on the price of the underlying common stock on the date of issuance. Compensation cost for stock options or warrants is estimated at the grant date based on each instrument's fair value as calculated by the Black-Scholes

option pricing model. We recognize stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period for the award. See Note 9 to our financial statements for additional stock-based compensation information.

In May 2017, the FASB issued Accounting Standards Update 2017-09, *Scope of Modification Accounting* (“ASU 2017-09”), which amends Accounting Standards Codification Topic 718, Compensation – Stock Compensation. ASU 2017-09 is an attempt to provide clarity and reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718 Compensation – Stock Compensation, to a change to the terms or conditions of a share-based payment award. We adopted ASU 2017-09 effective January 1, 2018; such adoption had no material impact on our financial statements.

In June 2018, the FASB issued Accounting Standards Update 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. We do not expect the adoption of ASU 2018-07 to have a material impact on our financial statements.

## **Liquidity and Capital Resources**

Our principal uses of cash are 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. At December 31, 2018, we had cash and cash equivalents of \$259,701 and total assets of \$642,064, as compared to \$312,727 and \$490,235, respectively, at December 31, 2017. At December 31, 2018, we had a working capital deficit of \$1,005,127, compared to \$363,218 at December 31, 2017. Our current liabilities at December 31, 2018 and 2017 include \$1,220,179 and \$715,235, respectively, of accrued management salaries and director fees, payment of which is continuing to be deferred as discussed further below.

Net cash used in operating activities was \$1,543,026, \$1,688,464, and \$1,946,119 for the years ended December 31, 2018, 2017 and 2016, 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 and deferred 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, 2018, there is \$2,589,247 in approved grant funds available for use during 2019 and 2020. Of this amount, we expect that approximately \$1,385,000 will be used by us to reimburse third parties who will provide services covered by these grants. See “Results of Operations – Grant and Collaboration Revenues” below for additional details concerning our government grants.

Members of our executive management team and our board of directors have deferred receipt of portions of their salaries and fees in order to help conserve the Company’s cash resources. As of December 31, 2018, the accumulated deferrals totaled \$1,220,179. We expect the ongoing deferrals of approximately \$36,200 per month for the management salaries to continue until such time as a significant financing event (as determined by the board of directors) is consummated.

NIAID has funded the costs of conducting all of our human clinical trials (Phase 1 and Phase 2a) to date for our preventive HIV vaccines, with GeoVax incurring certain costs associated with manufacturing the clinical vaccine supplies and other study support. NIAID will also fund the cost of a planned Phase 1 trial (HVTN 132) to further evaluate the safety and immunogenicity of adding “protein boost” components to our vaccine, GOVX-B11. We expect HVTN 132 to commence patient enrollment in mid-2019. Additionally, we are party to a collaboration with American Gene Technologies International, Inc. (AGT) whereby AGT intends to conduct a Phase 1 human clinical trial with our combined technologies, with the ultimate goal of developing a functional cure for HIV infection; we expect that AGT will begin the phase 1 trial during the second half of 2019. We are also currently in discussions with two other consortiums for the use of our vaccine in similar efforts toward developing a cure for HIV infection; we expect one or both of these studies to begin in late 2019 or early 2020.

Net cash used in investing activities was \$-0-, \$4,350, and \$ -0- for the years ended December 31, 2018, 2017 and 2016, respectively. Our investing activities have consisted predominantly of capital expenditures for laboratory equipment.

Net cash provided by financing activities was \$1,490,000, \$1,551,511, and \$1,339,801 for the years ended December 31, 2018, 2017 and 2016, respectively. During December 2018, we issued non-interest-bearing Term Promissory Notes (the “Term Notes”) to two current investors in exchange for an aggregate of \$250,000. In February 2019, the Term Notes were cancelled in exchange for shares of our convertible preferred stock. During March and September 2018, we sold shares of our Series E convertible preferred stock for total net proceeds of \$1,190,000. During February 2018, we entered into a Senior Note Purchase Agreement with Georgia Research Alliance, Inc. pursuant to which we issued a five-year Senior Promissory Note (the “GRA Note”) for \$50,000. The GRA Note bears an annual interest rate of 5%, payable monthly, with principal repayments

beginning in the second year. In May 2017, we sold shares of our Series D convertible preferred stock for net proceeds of \$980,000. During 2017, warrants to purchase an aggregate of 31,639,577 shares of common stock were exercised for total net proceeds of \$571,511. During 2016, warrants to purchase 21,884,420 shares of common stock were exercised for total net proceeds to the Company of \$1,339,801.

On February 25, 2019, we entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) with the purchasers identified therein (the “Purchasers”) providing for the issuance and sale to the Purchasers of an aggregate of up to 1,000 shares of our Series G Convertible Preferred Stock (“Series G Preferred Stock”) and related warrants for gross proceeds of up to \$1.0 million, to be funded at up to three different closings. At the first closing, which occurred on February 26, 2019, we issued 500 shares of Series G Preferred Stock and related warrants in exchange for the payment by the Purchasers of \$250,000 in the aggregate, plus the cancellation by them of the Term Notes in the aggregate amount of \$250,000. Within 50 to 60 days after the first closing, we may exercise the right to sell the Purchasers an aggregate of up to \$250,000 of Series G Preferred Stock and related warrants at the second closing. Within 110 to 120 days after the first closing, we may exercise the right to sell the Purchasers an aggregate of up to \$250,000 of Series G Preferred Stock and related warrants at the third closing. At the first closing we issued the Purchasers Series I Warrants to purchase an aggregate of 16,666,666 shares of our common stock. The warrants have an exercise price of \$0.015 per share, are exercisable six months from the issuance date, and have a term of exercise equal to five years from the date they first become exercisable. The warrants contain anti-dilution and price adjustment provisions, which may, under certain circumstances reduce the exercise price to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the then exercise price of the warrants. The number of shares subject to the warrants will also increase so that the aggregate exercise price remains the same for each warrant. At the second and third closings, assuming the sale of all of the Series G Preferred Stock that may be sold at those times, the Purchasers will receive aggregate additional Series I Warrants to purchase up to 33,333,332 shares of our common stock.

As of December 31, 2018, we had an accumulated deficit of \$40.5 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 our research and development efforts. We will continue to require substantial funds to continue our activities and cannot predict the outcome of our efforts. We have received a “going concern” opinion from our independent registered public accountants reflecting substantial doubt about our ability to continue as a going concern. We believe that our existing cash resources, combined with funding from existing government grants and clinical trial support, and committed sources of equity capital will be sufficient to fund our planned operations into the third quarter of 2019. 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 plan to conduct at least one additional offering of our equity securities. 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.

### *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 summarizes our contractual obligations as of December 31, 2018, aggregated by type (in thousands):

<b>Contractual Obligations</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>More than 5 years</b>
Operating Lease Obligations <sup>(1)</sup>	\$ 161	\$ 161	\$ --	\$ --	\$ --
Purchase Obligations <sup>(2)</sup>	625	625	--	--	--
<b>Total</b>	<b>\$ 786</b>	<b>\$ 786</b>	<b>\$ --</b>	<b>\$ --</b>	<b>\$ --</b>

- (1) Our operating lease obligations relate to the facility lease for our 8,430 square foot facility in Smyrna, Georgia, which houses our laboratory operations and our administrative offices. The current term of our lease expires on December 31, 2019. We have annual extension options through December 31, 2022 which have not yet been exercised by us.
- (2) Purchase obligations relate to contracts for research activities, payment of which will be reimbursable to us pursuant to our government grants.

As of December 31, 2018, except as disclosed in the table above, we had no other material firm purchase obligations or commitments for capital expenditures and no committed lines of credit or other committed funding or long-term debt. We have employment agreements with our executive officers, each of which may be terminated with no more than 90 days' advance written notice. Pursuant to the Emory License, we have committed to make potential future milestone and royalty payments which are contingent upon the occurrence of future events. Such events include development milestones, regulatory approvals and product sales. Because the achievement of these milestones is currently neither probable nor reasonably estimable, the contingent payments have not been included in the table above or recorded on our Consolidated Balance Sheets. The aggregate total of all potential milestone payments included in the Emory License (excluding royalties on net sales) is approximately \$3.5 million.

#### *Net Operating Loss Carryforwards*

At December 31, 2018, we had consolidated net operating loss carryforwards for income tax purposes of \$72.5 million, which will expire in 2019 through 2038 if not utilized. We also have research and development tax credits of approximately \$1.1 million available to reduce income taxes, if any, which will expire in 2022 through 2038 if not utilized. The amount of net operating loss carryforwards and research tax credits available to reduce income taxes in any year may be limited in certain circumstances.

#### *Off-Balance Sheet Arrangements*

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

#### **Results of Operations**

We recorded net losses of \$2,560,094, \$2,170,162, and \$3,271,701 for the years ended December 31, 2018, 2017, and 2016, respectively. Our operating results typically fluctuate due to the timing of activities and related costs associated with our research and development activities and our general and administrative costs, as described below.

#### *Grant and Collaboration Revenues*

We recorded grant and collaboration revenues of \$963,203, \$1,075,270, and \$828,918 for the years ended December 31, 2018, 2017 and 2016, respectively.

Grant Revenues – Our grant revenues relate to grants and contracts from agencies of the U.S. government in support of our vaccine development activities. We record revenue associated with these grants as the related costs and expenses are incurred. The difference in our grant revenues from period to period is dependent upon our expenditures for activities supported by the grants and fluctuates based on the timing of the expenditures. Additional detail concerning our grant revenues and the remaining funds available for use as of December 31, 2018 is presented in the table below.

Grant/Contract No.	Grant Revenue Recorded During			Unused Funds Available at December 31, 2018
	Year Ended December 31,			
	2018	2017	2016	
Lassa Fever – U.S. Army Grant	\$ 162,563	\$ -	\$ -	\$ 2,279,744
Lassa Fever – SBIR Grant	152,778	-	-	147,042
Zika – NIH SBIR Grant	363,184	74,355	-	162,461
HIV – NIH SBIR Grant	256,050	604,703	537,862	-
HIV – NIH SBIR Grant	-	158,972	235,535	-
HIV – NIH Vaccine Development Contract	-	142,240	55,521	-
Total	\$ 934,575	\$ 980,270	\$ 828,918	\$ 2,589,247

Collaboration Revenues – In addition to the grant revenues above, during the year ended December 31, 2018, we recorded \$28,628 of revenue associated with several research collaborations with third parties. These amounts primarily represent amounts paid to us by the other parties for materials and other costs associated with joint studies. In March 2017, we entered into a collaboration with American Gene Technologies International, Inc. (AGT) whereby AGT intends to conduct a Phase 1 human clinical trial with our combined technologies, with the goal of developing a functional cure for HIV infection. The cost of the clinical trial will be borne by AGT. In exchange for use of our vaccine product in the clinical trial, AGT paid us a fee of \$95,000 which we recorded as revenue during 2017. No commercial rights or licenses have yet been granted to AGT.

### *Research and Development Expenses*

Our research and development expenses were \$1,878,652, \$2,017,350, and \$1,970,859 for the years ended December 31, 2018, 2017 and 2016, respectively. Research and development expense for these periods includes stock-based compensation expense of \$41,998, \$25,953, and \$23,614 for 2018, 2017 and 2016, respectively (see discussion under “Stock-Based Compensation Expense” below).

Our research and development expenses can fluctuate considerably on a period-to-period basis, depending on our need for vaccine manufacturing by third parties, the timing of expenditures related to our government grants, the timing of costs associated with any clinical trials being funded directly by us, and other factors. Research and development expenses increased by \$46,491, or 2.4%, from 2016 to 2017, and decreased by \$138,698, or 6.9%, from 2017 to 2018. These fluctuations are primarily due to the timing of expenditures related to our government grants. Our research and development costs do not include costs incurred by the HVTN in conducting clinical trials of our preventive HIV vaccines; those costs are funded directly to the HVTN by NIAID.

We do not disclose our research and development expenses by project, since our employees’ time is spread across multiple programs and our laboratory facility is used for multiple vaccine candidates. We track the direct cost of research and development expenses related to government grant revenue by the percentage of assigned employees’ time spent on each grant and other direct costs associated with each grant. Indirect costs associated with grants are not tracked separately but are applied based on a contracted overhead rate negotiated with the NIH. Therefore, the recorded revenues associated with government grants approximates the costs incurred.

We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine development. Due to these uncertainties, our future expenditures are likely to be highly volatile in future periods depending on the outcomes of the trials and studies. As we obtain data from pre-clinical studies and clinical trials, we may elect to discontinue or delay vaccine development programs to focus our resources on more promising vaccine candidates. Completion of preclinical studies and human clinical trials may take several years or more, but the length of time can vary substantially depending upon several factors. The duration and the cost of future clinical trials may vary significantly over the life of the project because of differences arising during development of the human clinical trial protocols, including the number of patients that ultimately participate in the clinical trial; the duration of patient follow-up that seems appropriate in view of the results; the number of clinical sites included in the clinical trials; and the length of time required to enroll suitable patient subjects.

### *General and Administrative Expenses*

Our general and administrative expenses were \$1,647,268, \$1,232,368, and \$2,131,426 for the years ended December 31, 2018, 2017 and 2016, respectively. General and administrative costs include officers’ salaries, legal and accounting costs, patent costs, and other general corporate expenses. General and administrative expense includes stock-based compensation expense of \$427,725, \$31,271, and \$944,053 for 2018, 2017 and 2016, respectively (see discussion under “Stock-Based Compensation Expense” below). Excluding stock-based compensation expense, general and administrative expenses were \$1,219,541, \$1,201,097, and \$1,187,373 for 2018, 2017 and 2016, respectively. We expect that our general and administrative costs may increase in the future in support of expanded research and development activities and other general corporate activities.

### *Stock-Based Compensation Expense*

For the three years ended December 31, 2018, the components of stock-based compensation expense were as follows:

	2018	2017	2016
Stock option expense	\$ 155,304	\$ 57,224	\$ 54,805
Stock issued for non-employee services	314,419	-	-
Warrant modification expense	-	-	912,862
Total stock-based compensation expense	<u>\$ 469,723</u>	<u>\$ 57,224</u>	<u>\$ 967,667</u>

In general, stock-based compensation expense is allocated to research and development expense or general and administrative expense according to the classification of cash compensation paid to the employee, consultant or director to whom the stock compensation was granted. For the three years ended December 31, 2018, stock-based compensation expense was allocated as follows:

	2018	2017	2016
General and administrative expense	\$ 427,725	\$ 31,271	\$ 944,053
Research and development expense	41,998	25,953	23,614
Total stock-based compensation expense	<u>\$ 469,723</u>	<u>\$ 57,224</u>	<u>\$ 967,667</u>

*Other Income (Expense)*

Interest income was \$5,213, \$4,286, and \$1,666 for the years ended December 31, 2018, 2017 and 2016, respectively. The variances between years are primarily attributable to the cash available for investment and to interest rate fluctuations.

Interest expense for the year ended December 31, 2018 was \$2,590, related to the note payable issued to the GRA in February 2018 and financing costs associated with insurance premiums. There was no interest expense during the comparable periods in 2017 or 2016.

*Impact of Inflation*

For the three-year period ended December 31, 2018, we do not believe that inflation and changing prices had a material impact on our operations or on our financial results.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our consolidated financial statements and supplemental schedule and notes thereto as of December 31, 2018 and 2017 and for each of the three years ended December 31, 2018, 2017 and 2016 together with the independent registered public accounting firm's report thereon, are set forth on pages F-1 to F-17 of this Annual Report on Form 10-K.

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

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

### **ITEM 9A. CONTROLS AND PROCEDURES**

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

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

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2018. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2018 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

#### **Management's Report on Internal Control Over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on criteria established in *Internal Control - Integrated Framework (2013)*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As a result of this assessment, management concluded that, as of December 31, 2018, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

#### **Changes in Internal Control Over Financial Reporting**

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

#### **Limitations on Controls**

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

### **ITEM 9B. OTHER INFORMATION**

None.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information required by this Item is included in our definitive proxy statement for our 2019 annual meeting of stockholders to be filed with the SEC under the captions “Directors and Executive Officers” and “Corporate Governance” and is incorporated herein by this reference.

##### **Code of Ethics**

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

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is included in our definitive proxy statement for our 2019 annual meeting of stockholders to be filed with the SEC under the captions “Corporate Governance” and “Executive Compensation” and is incorporated herein by this reference.

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

The information required by this Item is included in our definitive proxy statement for our 2019 annual meeting of stockholders to be filed with the SEC under the captions “Security Ownership of Principal Stockholders, Directors and Executive Officers” and “Securities Authorized for Issuance under Equity Compensation Plans” and is incorporated herein by this reference.

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

The information required by this Item is included in our definitive proxy statement for our 2019 annual meeting of stockholders to be filed with the SEC under the captions “Corporate Governance” and “Certain Relationships and Related Party Transactions” and is incorporated herein by this reference.

#### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this Item is included in our definitive proxy statement for our 2019 annual meeting of stockholders to be filed with the SEC under the caption “Ratification of Appointment of the Independent Registered Public Accounting Firm” and is incorporated herein by this reference.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (a) Documents filed as part of this report:

	<u>Page</u>
(1) Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2018 and 2017	F-3
Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016	F-6
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#### (2) Financial Statement Schedules

The following financial statement schedule is set forth on page F-17 of this Annual Report on Form 10-K: Schedule II—Valuation and Qualifying Accounts for the years ended December 31, 2018, 2017 and 2016

All other financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

#### (3) Exhibits Required by Item 601 of Regulation S-K

<u>Exhibit Number</u>	<u>Description</u>
3.1	<a href="#">Certificate of Incorporation (4)</a>
3.1.1	<a href="#">Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 13, 2010 (8)</a>
3.1.2	<a href="#">Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 27, 2010 (9)</a>
3.1.3	<a href="#">Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed August 2, 2013 (10)</a>
3.1.4	<a href="#">Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed May 13, 2015 (15)</a>
3.1.5	<a href="#">Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed June 14, 2016 (17)</a>
3.1.6	<a href="#">Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed August 4, 2017 (22)</a>
3.2	<a href="#">Bylaws (4)</a>
4.1.1	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (12)</a>
4.1.2	<a href="#">Form of Stock Certificate for the Series B Convertible Preferred Stock (12)</a>
4.2.1	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (13)</a>
4.2.2	<a href="#">Form of Stock Certificate for the Series C Convertible Preferred Stock (13)</a>
4.3.1	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (21)</a>
4.3.2	<a href="#">Form of Stock Certificate for the Series D Convertible Preferred Stock (21)</a>
4.4.1	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock (23)</a>
4.4.2	<a href="#">Form of Stock Certificate for the Series E Convertible Preferred Stock (23)</a>
4.5.1	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock (28)</a>
4.5.2	<a href="#">Form of Stock Certificate for the Series F Convertible Preferred Stock (28)</a>
4.6.1	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock (29)</a>
4.6.2	<a href="#">Form of Stock Certificate for the Series G Convertible Preferred Stock (29)</a>
10.1 **	<a href="#">Employment Agreement between GeoVax Labs, Inc. and David A. Dodd (25)</a>
10.2 **	<a href="#">Employment Agreement between GeoVax Labs, Inc. and Robert T. McNally (5)</a>
10.2.1 **	<a href="#">Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Robert T. McNally (11)</a>
10.2.2 **	<a href="#">Salary Deferral Agreement between GeoVax, Inc. and Robert T. McNally (24)</a>
10.2.3 **	<a href="#">Amendment to Salary Deferral Agreement between GeoVax, Inc. and Robert T. McNally (24)</a>
10.3 **	<a href="#">Employment Agreement between GeoVax, Inc. and Mark W. Reynolds (7)</a>
10.3.1 **	<a href="#">Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Mark W. Reynolds (11)</a>
10.3.2 **	<a href="#">Salary Deferral Agreement between GeoVax, Inc. and Mark W. Reynolds (24)</a>
10.3.3 **	<a href="#">Amendment to Salary Deferral Agreement between GeoVax, Inc. and Mark W. Reynolds (24)</a>
10.4 **	<a href="#">Employment Agreement between GeoVax, Inc. and Harriet Robinson (7)</a>
10.4.1 **	<a href="#">Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Harriet Robinson (11)</a>
10.4.2 **	<a href="#">Salary Deferral Agreement between GeoVax, Inc. and Harriet Robinson (24)</a>

10.4.3 **	<a href="#">Amendment to Salary Deferral Agreement between GeoVax, Inc. and Harriet Robinson (24)</a>
10.5 **	<a href="#">Employment Agreement between GeoVax, Inc. and Farshad Guirakhoo (16)</a>
10.5.1 **	<a href="#">Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Farshad Guirakhoo (18)</a>
10.5.2 **	<a href="#">Salary Deferral Agreement between GeoVax, Inc. and Farshad Guirakhoo (24)</a>
10.6 **	<a href="#">GeoVax Labs, Inc. 2006 Equity Incentive Plan (2)</a>
10.6.1 **	<a href="#">GeoVax Labs, Inc. 2016 Stock Incentive Plan, as amended (26)</a>
10.6.2 **	<a href="#">Form of Employee Stock Option Agreement (20)</a>
10.6.3 **	<a href="#">Form of Non-Qualified Stock Option Agreement (20)</a>
10.7	<a href="#">License Agreement (as amended and restated) between GeoVax, Inc. and Emory University (1)</a>
10.8	<a href="#">Office and Laboratory Lease between UCB, Inc. and GeoVax, Inc. (6)</a>
10.8.1	<a href="#">Amendment to Lease Agreement between UCB, Inc. and GeoVax, Inc. (14)</a>
10.8.2	<a href="#">Second Amendment to Lease Agreement between UCB, Inc. and GeoVax, Inc. (24)</a>
10.9	<a href="#">Summary of the GeoVax Labs, Inc. Director Compensation Plan (7)</a>
10.10	<a href="#">Form of Securities Purchase Agreement dated December 11, 2013 (12)</a>
10.11	<a href="#">Form of Registration Rights Agreement dated December 11, 2013 (12)</a>
10.12	<a href="#">Form of Securities Purchase Agreement dated February 25, 2015 (13)</a>
10.13	<a href="#">Form of Registration Rights Agreement dated February 25, 2015 (13)</a>
10.14	<a href="#">Form of Securities Purchase Agreement dated May 8, 2017 (21)</a>
10.15	<a href="#">Form of Registration Rights Agreement dated May 8, 2017 (21)</a>
10.16	<a href="#">Form of Securities Purchase Agreement dated March 5, 2018 (23)</a>
10.17	<a href="#">Form of Additional Securities Purchase Agreement, dated September 5, 2018 (26)</a>
10.18	<a href="#">Senior Note Purchase Agreement between Georgia Research Alliance, Inc. and GeoVax Labs, Inc. (24)</a>
10.19	<a href="#">Common Stock Purchase Warrant dated February 28, 2018 (24)</a>
10.20	<a href="#">Agreement with Maxim Group LLC dated February 14, 2018 (24)</a>
10.20.1	<a href="#">Amendment to Agreement with Maxim Group LLC, dated October 19, 2018 (26)</a>
10.21	<a href="#">Consulting Agreement with Bespoke Growth Partners, Inc., dated October 12, 2018 (26)</a>
10.22	<a href="#">Form of Series G Common Stock Purchase Warrant (26)</a>
10.23	<a href="#">Form of Term Promissory Note, dated December 27, 2018 (27)</a>
10.24	<a href="#">Additional Issuance Agreement, dated December 27, 2018 (27)</a>
10.25	<a href="#">Form of Series H Common Stock Purchase Warrant (27)</a>
10.26	<a href="#">Form of Exchange Agreement, dated February 18, 2019 (28)</a>
10.27	<a href="#">Form of Securities Purchase Agreement dated February 25, 2019 (29)</a>
10.28	<a href="#">Form of Series I Common Stock Purchase Warrant (29)</a>
14.1 *	Code of Ethics
21.1	<a href="#">Subsidiaries of the Registrant (3)</a>
31.1 *	Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
31.2 *	Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
32.1 *	Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
32.2 *	Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
101 *,***	The following financial information from GeoVax Labs, Inc. Annual Report on Form 10-K for the year ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2018 and 2017, (ii) Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016, and (v) Notes to Condensed Consolidated Financial Statements.

\* Filed herewith.

\*\* Indicates a management contract or compensatory plan or arrangement.

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

- (1) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 4, 2006.
- (2) Incorporated by reference from the registrant's definitive Information Statement filed August 18, 2006.
- (3) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 28, 2007.
- (4) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 23, 2008.
- (5) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 24, 2008.
- (6) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 6, 2009.

- (7) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 8, 2010.
- (8) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 14, 2010.
- (9) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 28, 2010.
- (10) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 2, 2013.
- (11) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 23, 2013.
- (12) Incorporated by reference from the registrant's Current Report on Form 8-K filed December 17, 2013.
- (13) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 2, 2015.
- (14) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 20, 2015.
- (15) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 14, 2015.
- (16) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 12, 2015.
- (17) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 16, 2016.
- (18) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 16, 2016.
- (19) Incorporated by reference from the registrant's definitive Proxy Statement filed April 29, 2016.
- (20) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed August 5, 2016.
- (21) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 9, 2017.
- (22) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 4, 2017.
- (23) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 6, 2018.
- (24) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 23, 2018.
- (25) Incorporated by reference from the registrant's Current Report on Form 8-K filed September 7, 2018.
- (26) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 8, 2018.
- (27) Incorporated by reference from the registrant's Current Report on Form 8-K filed December 28, 2018.
- (28) Incorporated by reference from the registrant's Current Report on Form 8-K filed February 19, 2019.
- (29) Incorporated by reference from the registrant's Current Report on Form 8-K filed February 26, 2019

**ITEM 16. FORM 10-K SUMMARY**

None.

## SIGNATURES

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

### GEOVAX LABS, INC.

BY: /s/ David A. Dodd  
David A. Dodd  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: March 26, 2019

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

Signature / Name	Title	Date
<u>/s/ David A. Dodd</u> David A. Dodd	Director President and Chief Executive Officer (Principal Executive Officer)	March 26, 2019
<u>/s/ Mark W. Reynolds</u> Mark W. Reynolds	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2019
<u>/s/ Randal D. Chase</u> Randal D. Chase	Director	March 26, 2019
<u>/s/ David A. Dodd</u> David A. Dodd	Director	March 26, 2019
<u>/s/ Dean G. Kollintzas</u> Dean G. Kollintzas	Director	March 26, 2019
<u>/s/ Robert T. McNally</u> Robert T. McNally	Director	March 26, 2019
<u>/s/ Harriet L. Robinson</u> Harriet L. Robinson	Director	March 26, 2019
<u>/s/ John N. Spencer, Jr.</u> John N. Spencer, Jr.	Director	March 26, 2019

**GEOVAX LABS, INC.**  
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of GeoVax Labs, Inc.

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of GeoVax Labs, Inc. and subsidiary (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes to the consolidated financial statements and schedule (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

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

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness on the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

*PORTER KEADLE MOORE, LLC*

We have served as the Company's auditor since 2005.

Atlanta, Georgia  
March 26, 2019

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

	December 31,	
	2018	2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 259,701	\$ 312,727
Grant funds and other receivables	121,814	59,758
Prepaid expenses and other current assets	238,189	75,589
Total current assets	619,704	448,074
Property and equipment, net (Note 3)	11,350	31,151
Deposits	11,010	11,010
Total assets	\$ 642,064	\$ 490,235
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$ 125,859	\$ 77,581
Accrued expenses (Note 4)	1,238,552	733,711
Current portion of notes payable (Note 5)	260,420	-
Total current liabilities	1,624,831	811,292
Note payable, net of current portion (Note 5)	39,580	-
Total liabilities	1,664,411	811,292
 Commitments (Note 6)		
Stockholders' equity (deficiency):		
Preferred stock, \$.01 par value:		
Authorized shares – 10,000,000		
Series B convertible preferred stock, \$1,000 stated value; 100 shares issued and outstanding at December 31, 2018 and 2017	76,095	76,095
Series C convertible preferred stock, \$1,000 stated value; 2,150 and 2,570 shares issued and outstanding at December 31, 2018 and 2017, respectively	705,238	842,990
Series D convertible preferred stock, \$1,000 stated value; -0- and 1,000 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	980,000
Series E convertible preferred stock, \$1,000 stated value; 1,200 and -0- shares issued and outstanding at December 31, 2018 and 2017, respectively	1,190,000	-
Common stock, \$.001 par value:		
Authorized shares – 600,000,000		
Issued and outstanding shares – 218,903,476 and 106,736,810 at December 31, 2018 and 2017, respectively	218,903	106,737
Additional paid-in capital	37,264,301	35,589,911
Accumulated deficit	(40,476,884)	(37,916,790)
Total stockholders' equity (deficiency)	(1,022,347)	(321,057)
Total liabilities and stockholders' equity (deficiency)	\$ 642,064	\$ 490,235

See accompanying notes to consolidated financial statements.

**GEOVAX LABS. INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended December 31,		
	2018	2017	2016
Grant and collaboration revenue	\$ 963,203	\$ 1,075,270	\$ 828,918
Operating expenses:			
Research and development	1,878,652	2,017,350	1,970,859
General and administrative	1,647,268	1,232,368	2,131,426
Total operating expenses	<u>3,525,920</u>	<u>3,249,718</u>	<u>4,102,285</u>
Loss from operations	(2,562,717)	(2,174,448)	(3,273,367)
Other income (expense):			
Interest income	5,213	4,286	1,666
Interest expense	(2,590)	-	-
Total other income (expense)	<u>2,623</u>	<u>4,286</u>	<u>1,666</u>
Net loss	<u>\$ (2,560,094)</u>	<u>\$ (2,170,162)</u>	<u>\$ (3,271,701)</u>
Basic and diluted:			
Loss per common share	\$ (0.02)	\$ (0.03)	\$ (0.08)
Weighted average shares outstanding	163,584,755	68,605,817	41,516,514

See accompanying notes to consolidated financial statements.

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

	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series E Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance at December 31, 2015	100	\$ 76,095	3,000	\$ 983,941	-	\$ -	-	\$ -
Conversion of preferred stock to common stock	-	-	(132)	(43,236)	-	-	-	-
Balance at December 31, 2016	100	76,095	2,868	940,705	-	-	-	-
Sale of convertible preferred stock for cash	-	-	-	-	1,000	980,000	-	-
Conversion of preferred stock to common stock	-	-	(298)	(97,715)	-	-	-	-
Balance at December 31, 2017	100	76,095	2,570	842,990	1,000	980,000	-	-
Sale of convertible preferred stock for cash	-	-	-	-	-	-	1,200	1,190,000
Conversion of preferred stock to common stock	-	-	(420)	(137,752)	(1,000)	(980,000)	-	-
Balance at December 31, 2018	100	\$ 76,095	2,150	\$ 705,238	-	\$ -	1,200	\$ 1,190,000

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount			
Balance at December 31, 2015	31,950,813	\$ 31,951	\$ 32,587,543	\$ (32,474,927)	\$ 1,204,603
Conversion of preferred stock to common stock	1,400,000	1,400	41,836	-	-
Sale of common stock for cash upon warrant exercise	21,884,420	21,884	1,317,917	-	1,339,801
Stock-based compensation expense	-	-	967,667	-	967,667
Net loss for the year ended December 31, 2016	-	-	-	(3,271,701)	(3,271,701)
Balance at December 31, 2016	55,235,233	55,235	34,914,963	(35,746,628)	240,370
Sale of convertible preferred stock for cash	-	-	-	-	980,000
Conversion of preferred stock to common stock	19,862,000	19,862	77,853	-	-
Sale of common stock for cash upon warrant exercise	31,639,577	31,640	539,871	-	571,511
Stock-based compensation expense	-	-	57,224	-	57,224
Net loss for the year ended December 31, 2017	-	-	-	(2,170,162)	(2,170,162)
Balance at December 31, 2017	106,736,810	106,737	35,589,911	(37,916,790)	(321,057)
Sale of convertible preferred stock for cash	-	-	-	-	1,190,000
Issuance of common stock for services	17,500,000	17,500	496,000	-	513,500
Conversion of preferred stock to common stock	94,666,666	94,666	1,023,086	-	-
Stock-based compensation expense	-	-	155,304	-	155,304
Net loss for the year ended December 31, 2018	-	-	-	(2,560,094)	(2,560,094)
Balance at December 31, 2018	218,903,476	\$ 218,903	\$ 37,264,301	\$ (40,476,884)	\$ (1,022,347)

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	\$(2,560,094)	\$(2,170,162)	\$(3,271,701)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	19,801	28,027	28,780
Stock-based compensation expense	469,724	57,224	967,667
Changes in assets and liabilities:			
Grant funds and other receivables	(62,056)	(31,684)	91,904
Prepaid expenses and other current assets	36,480	(13,314)	(5,626)
Accounts payable and accrued expenses	553,119	441,445	242,857
Total adjustments	<u>1,017,068</u>	<u>481,698</u>	<u>1,325,582</u>
Net cash used in operating activities	<u>(1,543,026)</u>	<u>(1,688,464)</u>	<u>(1,946,119)</u>
Cash flows from investing activities:			
Purchase of property and equipment	-	(4,350)	-
Net cash used in investing activities	<u>-</u>	<u>(4,350)</u>	<u>-</u>
Cash flows from financing activities:			
Net proceeds from sale of preferred stock	1,190,000	980,000	-
Net proceeds from sale of common stock	-	571,511	1,339,801
Proceeds from issuance of notes payable	300,000	-	-
Net cash provided by financing activities	<u>1,490,000</u>	<u>1,551,511</u>	<u>1,339,801</u>
Net decrease in cash and cash equivalents	(53,026)	(141,303)	(606,318)
Cash and cash equivalents at beginning of period	<u>312,727</u>	<u>454,030</u>	<u>1,060,348</u>
Cash and cash equivalents at end of period	<u>\$ 259,701</u>	<u>\$ 312,727</u>	<u>\$ 454,030</u>

Supplemental disclosure of non-cash financing activities:

As discussed in Note 7, during the year ended December 31, 2018, 420 shares of Series C Convertible Preferred Stock were converted into 28,000,000 shares of common stock and 1,000 shares of Series D Convertible Preferred Stock were converted into 66,666,666 shares of common stock; during the year ended December 31, 2017, 298 shares of Series C Convertible Preferred Stock were converted into 19,862,000 shares of common stock; and during the year ended December 31, 2016, 132 shares of Series C Convertible Preferred Stock were converted into 1,400,000 shares of common stock.

See accompanying notes to consolidated financial statements.

**GEOVAX LABS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended December 31, 2018, 2017 and 2016**

**1. Description of Business**

GeoVax Labs, Inc. (“GeoVax” or the “Company”), is a clinical-stage biotechnology company developing human vaccines and immunotherapies against infectious diseases and cancers using a novel patented Modified Vaccinia Ankara Virus-Like Particle (MVA-VLP) vaccine platform. In this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into highly effective VLP immunogens in the person being vaccinated. The MVA-VLP virus replicates to high titers in approved avian cells for manufacturing but cannot productively replicate in mammalian cells. Therefore, the MVA-VLP derived vaccines elicit durable immune responses in the host similar to a live attenuated virus, 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, Lassa), and malaria, as well as therapeutic vaccines for chronic Hepatitis B infections and cancers. We believe our technology and vaccine development expertise are well-suited for a variety of human infectious diseases and we intend to pursue further expansion of our product pipeline.

Our corporate strategy is to improve health to patients worldwide by advancing our vaccine platform, using its unique capabilities to design and develop an array of products addressing unmet medical needs in the areas of infectious diseases and oncology. We aim to advance products through to human clinical testing, and to seek partnership or licensing arrangements for achieving regulatory approval and commercialization. We also leverage third party resources through collaborations and partnerships for preclinical and clinical testing with multiple government, academic and corporate entities.

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

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

GeoVax is incorporated under the laws of the State of Delaware and our principal offices are located in the metropolitan Atlanta, Georgia area.

**2. Summary of Significant Accounting Policies**

*Principles of Consolidation*

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

*Basis of Presentation*

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

We believe that our existing cash resources, government funding commitments, and equity funding commitments discussed in Note 13 will be sufficient to continue our planned operations into the third quarter of 2019. Due to our history of operating losses and our continuing need for capital to conduct our research and development activities, there is substantial doubt concerning our ability to operate as a going concern beyond that date. We are currently exploring sources of capital through additional government grants and corporate collaborations. We also intend to secure additional funds through sales of our equity securities or by other means. Management believes that we will be successful in securing the additional capital required to continue the Company's planned operations, but that our plans do not fully alleviate the substantial doubt about the Company's ability to operate as a going concern. Additional funding may not be available on favorable terms or at all. If we fail to obtain additional capital when needed, we will be required to delay, scale back, or eliminate some or all of our research and development programs as well as reduce our general and administrative expenses.

#### *Use of Estimates*

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

#### *Cash and Cash Equivalents*

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

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

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

#### *Property and Equipment*

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

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. It will also require disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases. The guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted. We are currently evaluating the impact of the adoption of ASU 2016-02 on our financial statements.

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

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

#### *Accrued Expenses*

As part of the process of preparing our financial statements, we estimate expenses that we believe we have incurred, but have not yet been billed by our third-party vendors. This process involves identifying services and activities that have been

performed by such vendors on our behalf and estimating the level to which they have been performed and the associated cost incurred for such service as of each balance sheet date.

#### *Net Loss Per Share*

Basic and diluted loss per common share are computed based on the weighted average number of common shares outstanding. Common share equivalents consist of common shares issuable upon conversion of convertible preferred stock, and upon exercise of stock options and stock purchase warrants. All common share equivalents are excluded from the computation of diluted loss per share since the effect would be anti-dilutive. Common share equivalents which could potentially dilute basic earnings per share in the future, and which were excluded from the computation of diluted loss per share, totaled approximately 262.9 million, 245.3 million, and 93.9 million at December 31, 2018, 2017 and 2016, respectively.

#### *Revenue Recognition*

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which created 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. We adopted ASU 2014-09 effective January 1, 2018 using the modified retrospective transition method. Under this method, our prior results will remain as reported and starting in 2018 are recognized under the new method. The adoption of ASU 2014-09 had no material impact on the measurement, timing, or recognition of our grant and collaboration revenues, nor on the related research and development expenses.

Grant revenue – We receive payments from government entities under non-refundable grants in support of our vaccine development programs. We record revenue associated with these grants when the reimbursable costs are incurred and we have complied with all conditions necessary to receive the grant funds.

Research collaborations – We are pursuing a strategy of co-developing or licensing our technology for specific vaccine development approaches and/or disease indications. Accordingly, we have entered into multiple collaborative research and development agreements and have received third-party funding for preclinical research under certain of these arrangements. Each agreement is evaluated in accordance with the process defined by ASU 2014-09 and revenue is recognized accordingly.

#### *Research and Development Expense*

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

#### *Patent Costs*

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

#### *Period-to-Period Comparisons*

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

#### *Income Taxes*

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

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

#### *Stock-Based Compensation*

We account for stock-based transactions in which the Company receives services from employees, directors or others in exchange for equity instruments based on the fair value of the award at the grant date. Compensation cost for awards of common stock is estimated based on the price of the underlying common stock on the date of issuance. Compensation cost for stock options or warrants is estimated at the grant date based on each instrument's fair value as calculated by the Black-Scholes option pricing model. We recognize stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period for the award. See Note 9 for additional stock-based compensation information.

In May 2017, the FASB issued Accounting Standards Update 2017-09, *Scope of Modification Accounting* ("ASU 2017-09"), which amends Accounting Standards Codification Topic 718, Compensation – Stock Compensation. ASU 2017-09 is an attempt to provide clarity and reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718 Compensation – Stock Compensation, to a change to the terms or conditions of a share-based payment award. We adopted ASU 2017-09 effective January 1, 2018; such adoption had no material impact on our financial statements.

In June 2018, the FASB issued Accounting Standards Update 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. We do not expect the adoption of ASU 2018-07 to have a material impact on our financial statements.

#### *Other Recent Accounting Pronouncements*

In July 2017, the FASB issued Accounting Standards Update 2017-11, *(Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"), which amends Accounting Standards Codification Topic 260, Earnings Per Share, Topic 480, Distinguishing Liabilities from Equity, and Topic 815, Derivatives and Hedging. ASU 2017-11 changes the classification of certain equity-linked financial instruments (or embedded features) with down round features and clarifies existing disclosure requirements for equity-classified instruments. ASU 2017-11 is effective for the Company beginning January 1, 2019. We are currently evaluating the impact of the adoption of ASU 2017-11 on our financial statements.

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

### **3. Property and Equipment**

Property and equipment as shown on the accompanying Consolidated Balance Sheets is composed of the following as of December 31, 2018 and 2017:

	2018	2017
Laboratory equipment	\$ 530,306	\$ 530,306
Leasehold improvements	115,605	115,605
Other furniture, fixtures & equipment	28,685	28,685
Total property and equipment	674,596	674,596
Accumulated depreciation and amortization	(663,246)	(643,445)
Property and equipment, net	\$ 11,350	\$ 31,151

Depreciation and leasehold amortization expense was \$19,801, \$28,027, and \$28,780 during the years ended December 31, 2018, 2017 and 2016, respectively.

#### 4. Accrued Expenses

Accrued expenses as shown on the accompanying Consolidated Balance Sheets is composed of the following as of December 31, 2018 and 2017:

	2018	2017
Accrued management salaries	\$ 924,509	\$ 532,615
Accrued directors' fees	295,670	182,620
Other accrued expenses	18,373	18,476
Total accrued expenses	<u>\$ 1,238,552</u>	<u>\$ 733,711</u>

#### 5. Notes Payable

On February 28, 2018, we entered into a Senior Note Purchase Agreement with Georgia Research Alliance, Inc. (GRA) pursuant to which we issued a five-year Senior Promissory Note (the "GRA Note") to GRA in exchange for \$50,000. The GRA Note bears an annual interest rate of 5%, payable monthly, with principal repayments beginning in the second year. Principal repayments are expected to be \$10,420 in 2019, \$12,500 in 2020, 2021 and 2022, and \$2,080 in 2023. In connection with the GRA Note, we also issued to GRA a five-year warrant to purchase 178,571 shares of our common stock. Interest expense related to the GRA Note for 2018 was \$2,083.

On December 27, 2018, we issued short-term non-interest-bearing Term Promissory Notes (the "Term Notes") to two current investors in exchange for an aggregate of \$250,000. These notes are presented as current liabilities on the consolidated balance sheet. In connection with the Term Notes, we also issued to the investors three-year warrants to purchase an aggregate of 10,000,000 shares of our common stock. In February 2019, the Term Notes were cancelled in exchange for shares of our convertible preferred stock (see Note 12).

#### 6. Commitments

##### *Lease Agreement*

We lease approximately 8,400 square feet of office and laboratory space pursuant to an operating lease which expires on December 31, 2019, with annual extension options through December 31, 2022. Rent expense for the years ended December 31, 2018, 2017 and 2016 was \$156,939, \$151,748, and \$149,288, respectively. Future minimum lease payments total \$161,266 in 2019, although our current intention is to exercise our option to extend the lease at least for the subsequent one-year renewal period.

##### *Other Commitments*

In the normal course of business, we enter into various firm purchase commitments related to production and testing of our vaccine, conduct of research studies, and other activities. As of December 31, 2018, we had approximately \$625,000 of unrecorded outstanding purchase commitments to our vendors and subcontractors, all of which we expect will be due in 2019. We expect this entire amount to be reimbursable to us pursuant to currently outstanding government grants.

#### 7. Preferred Stock

##### *Series B Convertible Preferred Stock*

Our Series B Convertible Preferred Stock, \$1,000 stated value ("Series B Preferred Stock"), has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series B Preferred Stock has no voting rights and is not entitled to a dividend. As of December 31, 2018, there were 100 shares of Series B Preferred Stock outstanding, convertible at any time at the option of the holder into 285,714 shares of common stock, with a recorded carrying value of \$76,095.

##### *Series C Convertible Preferred Stock*

In February 2015, we issued 3,000 shares of our Series C Convertible Preferred Stock, \$1,000 stated value ("Series C Preferred Stock") and warrants to purchase up to an aggregate of 51,333,331 shares of our common stock for total net proceeds of \$2,679,810. We allocated \$1,695,869 of the purchase price to the fair value of the warrants issued in the

transaction (recorded to Additional Paid-in Capital) and recorded the net amount of \$983,941 as the initial carrying value of the Series C Preferred Stock.

The Series C Preferred Stock has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series C Preferred Stock has no voting rights and is not entitled to a dividend. The Series C Preferred Stock is convertible at any time at the option of the holders into shares of our common stock, and contains price adjustment provisions which may, under certain circumstances, reduce the conversion price if we sell, or grant options to purchase, our common stock at a price lower than the then conversion price of the Series C Preferred Stock. During 2016, 132 shares of Series C Preferred Stock were converted into 1,400,000 shares of common stock. During 2017, 298 shares of Series C Preferred Stock were converted into 19,862,000 shares of common stock. In May 2017, in connection with the issuance of our Series D Convertible Preferred Stock discussed below, the conversion price of our Series C Preferred Stock was automatically reduced from \$0.05 per share to \$0.015 per share. During 2018, 420 shares of Series C Preferred Stock were converted into 28,000,000 shares of common stock. As of December 31, 2018, there were 2,150 shares of Series C Preferred Stock outstanding, convertible into 143,349,733 shares of common stock, with a recorded carrying value of \$705,238.

#### *Series D Convertible Preferred Stock*

In May 2017, we issued 1,000 shares of our Series D Convertible Preferred Stock, \$1,000 stated value (“Series D Preferred Stock”), for net proceeds, after deduction of certain expenses, of \$980,000. Our Series D Preferred Stock has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series D Preferred Stock has no voting rights and is not entitled to a dividend. During 2018, all of the shares of Series D Preferred Stock were converted into 66,666,666 shares of common stock, and as of December 31, 2018, there were no shares of Series D Preferred Stock outstanding.

#### *Series E Convertible Preferred Stock*

In March 2018, we issued 600 shares of our Series E Convertible Preferred Stock, \$1,000 stated value (“Series E Preferred Stock”), for net proceeds, after deduction of certain expenses, of \$590,000. In September 2018, we issued an additional 600 shares of Series E Preferred Stock for net proceeds of \$600,000. Each share of Series E Preferred Stock is entitled to a liquidation preference equal to the initial purchase price, has no voting rights, and is not entitled to a dividend. The Series E Preferred Stock is convertible at any time at the option of the holders into shares of our common stock, at a conversion price of \$0.02544 per share. The Series E Preferred Shares contains price adjustment provisions, which may, under certain circumstances reduce the conversion price to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the then conversion price of the Series E Preferred Stock, or if we announce plans to do so. As of December 31, 2018, there were 1,200 shares of Series E Preferred Stock outstanding, convertible into 47,169,812 shares of common stock, with a recorded carrying value of \$1,190,000.

In connection with the Series E Preferred Stock issuance in September 2018, we also issued the purchasers Series G Warrants to purchase an aggregate of up to 47,169,812 shares of our common stock. The warrants have an exercise price of \$0.02544 per share, are exercisable once they have been outstanding for six months and have a term equal to 3 years from the date of issuance. The warrants contain anti-dilution and price adjustment provisions, which may, under certain circumstances reduce the exercise price to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the then exercise price of the warrants.

## **8. Common Stock**

#### *Common Stock Transactions*

During 2018, 2017, and 2016 we issued an aggregate of 94,666,666, 19,862,000 and 1,400,000 shares of our common stock, respectively, pursuant to the conversion of our Series C and Series D Preferred Stock (see Note 7).

During 2017 and 2016 we issued 31,639,577 and 21,884,420 shares, respectively, of our common stock related to the exercise of stock purchase warrants, resulting in net proceeds to us of \$571,511, and \$1,339,801, respectively.

During 2018, we issued 17,500,000 shares of our common stock in connection with our entering into consulting and investment banking agreements (see Note 9).

### Stock Option Plans

In 2006 we adopted the GeoVax Labs, Inc. 2006 Equity Incentive Plan (the “2006 Plan”) and during 2016, our stockholders approved the GeoVax Labs, Inc. 2016 Stock Incentive Plan (the “2016 Plan”) which provides our Board of Directors broad discretion in creating equity incentives for employees, officers, directors and consultants. We have reserved 1,412,300 shares of our common stock for currently outstanding stock options under the 2006 Plan, and 16,000,000 shares for outstanding stock options and future issuances under the 2016 Plan. The 2016 Plan replaces the 2006 Plan, which expired September 28, 2016, and no further grants may be made under the 2006 Plan. As such, the 2016 Plan serves as the sole equity incentive compensation plan for the Company. The exercise price for any option granted may not be less than fair value (110% of fair value for ISO’s granted to certain employees). Options have a maximum ten-year term and generally vest over three years.

Certain information concerning our stock option plans as of December 31, 2018, and a summary of activity during the year then ended is presented below:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (yrs)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	7,024,275	\$ 0.29		
Granted	7,930,000	0.03		
Exercised	-	-		
Forfeited or expired	(235,000)	2.96		
Outstanding at December 31, 2018	14,719,275	\$ 0.11	9.0	\$ -0-
Exercisable at December 31, 2018	6,795,277	\$ 0.19	8.3	\$ -0-

### Stock Purchase Warrants

The following table presents a summary of stock purchase warrant activity during the year ended December 31, 2018:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2017	-	\$ -
Issued	57,348,383	0.03
Exercised	-	-
Forfeited or expired	-	-
Outstanding and exercisable at December 31, 2018	57,348,383	\$ 0.03

### Common Stock Reserved

A summary of common stock reserved for future issuance as of December 31, 2018 is as follows:

Stock Option Plans	17,412,300
Stock Purchase Warrants	57,348,383
Series B Convertible Preferred Stock	285,714
Series C Convertible Preferred Stock	143,349,733
Series E Convertible Preferred Stock	47,169,812
Total	<u>265,565,942</u>

## 9. Stock-Based Compensation

### Stock Option Plans

We use the Black-Scholes model for determining the grant date fair value of our stock option grants. This model utilizes certain information, such as the interest rate on a risk-free security with a term generally equivalent to the expected life of the option being valued and requires certain other assumptions, such as the expected amount of time an option will be

outstanding until it is exercised or expired, to calculate the fair value of stock options granted. The significant assumptions we used in our fair value calculations were as follows:

	2018	2017	2016
Weighted average risk-free interest rates	2.79%	2.40%	2.26%
Expected dividend yield	0.0%	0.0%	0.0%
Expected life of option	7.0 yrs	7.0 yrs	7.0 yrs
Expected volatility	71.34%	89.73%	88.72%

Stock-based compensation expense related to our stock option plans was \$155,304, \$57,224, and \$54,805 during the years ended December 31, 2018, 2017 and 2016, respectively. Stock option expense is allocated to research and development expense or to general and administrative expense based on the nature of the services provided by the related individuals. For the three years ended December 31, 2018, stock option expense was allocated as follows:

	2018	2017	2016
General and administrative expense	\$ 113,306	\$ 31,271	\$ 31,191
Research and development expense	41,998	25,953	23,614
Total stock option expense	<u>\$ 155,304</u>	<u>\$ 57,224</u>	<u>\$ 54,805</u>

As of December 31, 2018, there was \$211,234 of unrecognized compensation expense related to stock-based compensation arrangements pursuant to our stock option plans. The unrecognized compensation expense is expected to be recognized over a weighted average remaining period of 2.2 years.

Additional information concerning our stock options for the years ended December 31, 2018, 2017 and 2016 is as follows:

	2018	2017	2016
Weighted average fair value of options granted	\$ 0.02	\$ 0.04	\$ 0.05
Intrinsic value of options exercised	-	-	-
Total fair value of options vested	153,838	58,337	54,757

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

During 2018, we issued an aggregate of 17,500,000 shares of our common stock pursuant to certain consulting and investment banking agreements. We assigned an aggregate value to these shares of \$513,500, \$314,419 of which was expensed during 2018. The remaining \$199,081 is recorded as a prepaid expense as of December 31, 2018 and will be recognized during 2019 over the terms of the related agreements. During 2016, we recorded general and administrative expense of \$912,862 related to modifications made to certain stock purchase warrants.

## **10. Retirement Plan**

We participate in a multi-employer defined contribution retirement plan (the “401k Plan”) administered by a third-party service provider, and the Company contributes to the 401k Plan on behalf of its employees based upon a matching formula. During the years ended December 31, 2018, 2017 and 2016 our contributions to the 401k Plan were \$23,354, \$29,265, and \$33,871, respectively.

## **11. Income Taxes**

At December 31, 2018, we have a consolidated federal net operating loss (“NOL”) carryforward of approximately \$72.5 million, available to offset against future taxable income which expires in varying amounts in 2019 through 2038. Additionally, we have approximately \$1,064,000 in research and development (“R&D”) tax credits that expire in 2022 through 2038 unless utilized earlier. No income taxes have been paid to date. Section 382 of the Internal Revenue Code contains provisions that may limit our utilization of our NOL and R&D tax credit carryforwards in any given year as a result of significant changes in ownership interests that have occurred in past periods or may occur in future periods.

On December 22, 2017, the Tax Cuts and Jobs Act (the “Tax Act”) was enacted into law in the United States. The Tax Act made broad changes to the U.S. tax code, including, but not limited to, reducing the U.S. federal corporate tax rate from 35% to 21%. With regard to the Tax Act impact to the Company for the year ended December 31, 2017, we have recognized the impact of tax reform related to the revaluation of deferred tax assets and liabilities based on the rates we

expect them to reverse in the future, which is generally 21%. The amount recorded as tax expense related to the remeasurement of the deferred tax balance was approximately \$10.1 million, which was fully offset by a reduction in the valuation allowance.

Deferred income taxes reflect the net effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities included the following at December 31, 2018 and 2017:

	2018	2017
Deferred tax assets:		
Net operating loss carryforward	\$ 16,681,908	\$ 16,273,259
Research and development tax credit carryforward	1,063,877	949,340
Stock-based compensation expense	1,808,509	1,709,867
Accrued salaries and directors' fees	317,246	185,961
Depreciation	8,414	5,532
Total deferred tax assets	<u>19,879,954</u>	<u>19,123,959</u>
Deferred tax liabilities	-	-
Net deferred tax assets	<u>19,879,954</u>	<u>19,123,959</u>
Valuation allowance	<u>(19,879,954)</u>	<u>(19,123,959)</u>
Net deferred tax asset after reduction for valuation allowance	<u>\$ -0-</u>	<u>\$ -0-</u>

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

	2018	2017	2016
U.S. federal statutory rate applied to pretax loss	\$ (537,620)	\$ (737,855)	\$ (1,112,378)
Permanent differences	549	436	2,012
Research and development credits	(53,884)	(57,109)	(59,087)
Impact of Tax Act	-	10,086,795	-
Change in valuation allowance	590,955	(9,292,267)	1,169,453
Reported income tax expense	<u>\$ -0-</u>	<u>\$ -0-</u>	<u>\$ -0-</u>

## 12. Grants and Collaboration Revenue

We receive payments from government entities under our grants from the National Institute of Allergy and Infectious Diseases (NIAID) and from the U.S. Department of Defense in support of our vaccine research and development efforts. We record revenue associated with government grants as the reimbursable costs are incurred. During 2018, 2017, and 2016, we recorded \$934,575, \$980,270, and \$828,918, respectively, of revenue associated with these grants. As of December 31, 2018, there is an aggregate of \$2,589,247 in remaining grant funds available for use during 2019 and 2020.

During 2018, 2017, and 2016, we recorded \$28,628, \$95,000, and \$-0-, respectively, of revenues associated with research collaboration agreements with several third parties.

## 13. Subsequent Events

### *Conversions of Preferred Stock to Common Stock*

During January and February 2019, 587 shares of Series C Preferred Stock were converted into 39,140,000 shares of our common stock. During March 2019, 180 shares of Series F Preferred Stock (see below) were converted into 20,000,000 shares of our common stock.

### *Exchange of Series C and Series E Preferred Stock for Series F Preferred Stock*

On February 18, 2019, we entered into Exchange Agreements (the "Exchange Agreements") with holders of our Series C and Series E Preferred Stock, pursuant to which the holders exchanged all shares of Series C and Series E Preferred Stock held by them for an aggregate of 2,763 shares of Series F Convertible Preferred Stock, \$1,000 stated value ("Series F Preferred Stock"). Each share of Series F Preferred Stock is entitled to a liquidation preference equal to its stated value, has

no voting rights, and is not entitled to a dividend. The Series F Preferred Stock is convertible at any time at the option of the holders into shares of our common stock, at a conversion price equal to the lesser of (i) \$0.015 per share and (ii) 90% of the volume weighted average price of the Common Stock immediately preceding the delivery of a notice of conversion. The Series F Preferred Shares contains price adjustment provisions, which may, under certain circumstances reduce the conversion price to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the then conversion price of the Series F Preferred Stock. Subsequent to this transaction we have no outstanding shares of Series C or Series E Preferred Stock.

#### *Issuance of Series G Preferred Stock*

On February 25, 2019, we entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) with the purchasers identified therein (the “Purchasers”) providing for the issuance and sale to the Purchasers of an aggregate of up to 1,000 shares of our Series G Convertible Preferred Stock (“Series G Preferred Stock”) and related warrants for gross proceeds of up to \$1.0 million, to be funded at up to three different closings. At the first closing, which occurred on February 26, 2019, we issued 500 shares of Series G Preferred Stock and related warrants in exchange for the payment by the Purchasers of \$250,000 in the aggregate, plus the cancellation by them of the Term Notes (see Note 5) in the aggregate amount of \$250,000. Within 50 to 60 days after the first closing, we may exercise the right to sell the Purchasers an aggregate of up to \$250,000 of Series G Preferred Stock and related warrants at the second closing. Within 110 to 120 days after the first closing, we may exercise the right to sell the Purchasers an aggregate of up to \$250,000 of Series G Preferred Stock and related warrants at the third closing.

Each share of Series G Preferred Stock is entitled to a liquidation preference equal to its stated value, has no voting rights, and is not entitled to a dividend. The Series G Preferred Stock is convertible at any time at the option of the holders into shares of our common stock, at a conversion price equal to the lesser of (i) \$0.015 per share and (ii) 90% of the volume weighted average price of the common stock immediately preceding the delivery of a notice of conversion. The Series G Preferred Stock contains price adjustment provisions, which may, under certain circumstances reduce the conversion price to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the then conversion price of the Series G Preferred Stock.

At the first closing we issued the Purchasers Series I Warrants to purchase an aggregate of 16,666,666 shares of our common stock. The warrants have an exercise price of \$0.015 per share, are exercisable six months from the issuance date, and have a term of exercise equal to five years from the date they first become exercisable. The warrants contain anti-dilution and price adjustment provisions, which may, under certain circumstances reduce the exercise price to match if we sell or grant options to purchase, including rights to reprice, our common stock or common stock equivalents at a price lower than the then exercise price of the warrants. The number of shares subject to the warrants will also increase so that the aggregate exercise price remains the same for each warrant. At the second and third closings, assuming the sale of all of the Series G Preferred Stock that may be sold at those times, the Purchasers will receive aggregate additional Series I Warrants to purchase up to 33,333,332 shares of our common stock.

**GEOVAX LABS, INC.**  
**SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS**

**For the Years Ended December 31, 2018, 2017 and 2016**

Description	Balance at Beginning Of Period	Additions (Reductions)		Deductions	Balance at End Of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
Reserve Deducted in the Balance Sheet From the Asset to Which it Applies:					
Allowance for Deferred Tax Assets					
Year ended December 31, 2018	\$ 19,123,959	\$ 755,995	\$ -0-	\$ -0-	\$ 19,879,954
Year ended December 31, 2017	28,331,759	(9,207,800)	-0-	-0-	19,123,959
Year ended December 31, 2016	27,131,034	1,200,725	-0-	-0-	28,331,759