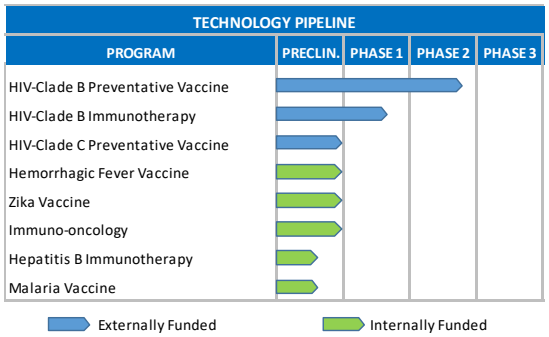
GeoVax Labs, Inc.
1900 Lake Park Drive, Suite 380
Smyrna, GA 30080
Phone (678) 384-7220
Fax (678) 384-7281
www.geovax.com

Ticker (Exchange)	GOVX (OTC.BB)
Recent Price (06/15/2017)	$0.04
52-week Range	$0.03 – $0.11
Shares Outstanding*	61.9 million
Market Capitalization	$2.4 million
Average 3-month Volume	260,000
Insider Ownership +>5%	4.2%
Institutional Ownership	17.5%
EPS (Year ended 12/31/2016)	($0.08)
Employees	11

**As of June 14, 2017*

GeoVax Labs, Inc. (GOVX-OTC.BB)



Company Description

GeoVax Labs, Inc. ("GeoVax" or "the Company") is a clinical-stage biotechnology company developing preventative and therapeutic human vaccines against infectious diseases and cancer. The Company's unique and patented **Modified Vaccinia Ankara Virus-Like Particle (MVA-VLP)** technology is the foundation for producing non-infectious virus-like particles (VLPs) from the cells of the individual receiving the vaccine. Producing VLPs in a vaccinated person mimics a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection should it appear, while maintaining the safety characteristics of a replication-defective vector. GeoVax is currently focused on developing vaccines against **human immunodeficiency virus (HIV)**, **Zika virus (ZIKV)**, **hemorrhagic fever (HF) viruses (Ebola**, **Sudan**, **Marburg**, and **Lassa)**, and **malaria**. The Company also has programs to develop a vaccine to treat chronic **Hepatitis B** virus **(HBV)** infection and to apply its MVA-VLP technology to cancer immunotherapy **(immuno-oncology)**. GeoVax believes its technology and development expertise is complementary to a range of other human diseases for which there is an unmet medical need, and accordingly, has plans to expand its pipeline.

Key Points

- GeoVax's most advanced vaccine in the clinic, GOVX-B11, is designed to protect against the **clade** B subtype of the HIV virus (prevalent in the Americas, Western Europe, Japan, and Australia). This vaccine has demonstrated safety and highly reproducible **immunogenicity**; has successfully completed Phase 2a human clinical testing; and has entered a follow-on clinical trial.
- GeoVax's novel Zika vaccine is designed to avoid a safety concern associated with all other Zika vaccines under development. The vaccine also has the potential to block transmission of Zika from humans to its mosquito vectors, thereby limiting further spread of the disease. Preclinical studies in a lethal challenge model have demonstrated 100% protection.
- Responding to the Ebola epidemic in western Africa, GeoVax is developing second-generation **monovalent** and **multivalent** vaccines capable of preventing or containing future hemorrhagic fever (HF) outbreaks. Initial preclinical studies have shown 100% protection against death with only a single dose.
- GeoVax's HIV vaccine technology was developed in collaboration with researchers at Emory University, the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC). The technology is exclusively licensed to GeoVax from Emory. GeoVax also has nonexclusive licenses to certain patents owned by the NIH used to develop the Company's other vaccines.
- The Company's vaccine development activities are financially supported by the U.S. Government in the form of research grants, in-kind support in terms of animal experiments, and indirect support for human clinical trials. GeoVax's HIV program receives substantial federal support (>$50 million to date from the NIH).
- By working with multiple collaborators on a variety of vaccine candidates, GeoVax manages its risk by providing many paths on the road to selecting the best vaccine candidate.

Table of Contents

Investment Highlights

- GeoVax Labs, Inc. ("GeoVax" or the "Company") is a clinical-stage biotechnology company creating human vaccines against infectious diseases and cancer using an innovative and patented Modified Vaccinia Ankara Virus Like Particle (MVA-VLP) platform technology. This technology supports production of non-infectious virus-like particles (VLPs) from the cells of the individual receiving the vaccine.

- The Company is currently focused on developing vaccines against human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), and malaria. The Company also has programs to develop a vaccine to treat chronic Hepatitis B virus (HBV) infection and to apply its MVA-VLP technology to cancer immunotherapy (immuno-oncology).

- GeoVax employs Modified Vaccinia Ankara (MVA) as a vector to express foreign **antigens** on VLPs generated *in vivo* within vaccinated patients. Its MVA-VLP is the fourth generation MVA vector, licensed from the National Institutes of Health (NIH), which is modified for insertion sites for high expression and transgene stability during manufacture. This platform has shown to be suitable for vaccination against a range of disease agents.

- The Company has multiple license and research collaboration agreements to advance its product candidates, including: (1) a Cooperative Research and Development Agreement (CRADA) with the NIH for MVAs used in the development of HF, Zika, HBV, malaria, and immuno-oncology vaccines; (2) a collaboration with the U.S. Centers for Disease Control and Prevention (CDC) for the development of a Zika vaccine; (3) a collaboration agreement with Georgia State University (GSU) for the advancement of the Company's HBV therapeutic program; (4) a collaboration agreement with the Burnet Institute in Australia (www.burnet.edu.au) for the development of a malaria vaccine; (5) a research collaboration agreement with the University of Pittsburgh for the development of the Company's immuno-oncology program; and (6) exclusive license from Emory University for HIV vaccines. ***Importantly, by working with collaborators on multiple vaccine candidates, GeoVax is able to manage risk by providing multiple paths on the road to selecting the best vaccine candidate.***

HIV/AIDS Vaccine Program

- The Company's most advanced program is a preventive vaccine (GOVX-B11) for the clade B subtype of HIV, the most common form of HIV in the Americas, Western and Central Europe, Australia, and Japan. The preventive clade B HIV vaccine has successfully completed Phase 2a human clinical testing and in January 2017, GeoVax began the next human clinical trial (HVTN 114) on the path toward human efficacy trials. HVTN 114 is testing the ability of "late boosts" to increase the antibody responses elicited by GOVX-B11. These "late boosts" consist of the GeoVax MVA62B vaccine with or without a gp120 protein vaccine.

    - HVTN 114 is being conducted by the **HIV Vaccine Trials Network (HVTN)**—the world's largest publicly-funded international collaboration focused on developing vaccines to prevent HIV/AIDS (www.hvtn.org). with funding from the National Institute of Allergy and Infectious Diseases (NIAID). Information from this trial is expected to contribute to the design of future human clinical trials testing GOVX-B11 in the presence and absence of newer gp120 proteins, which are currently being **cGMP (Current Good Manufacturing Practice)** manufactured.

    - During 2016, NIAID awarded GeoVax a Staged Vaccine Development contract of up to $7.8 million for production of the DNA vaccine component of GOVX-B11 in sufficient quantities for use in advanced clinical trials.

    - Within the HIV category (in existence for roughly 35 years), there are no approved vaccines. GeoVax continues to move down the clinical pathway. The next goal is to reach an efficacy trial, which would be a Phase 2b trial (involving thousands of individuals). Current **antiretroviral therapies (ARTs)** do not eliminate HIV infection, where infected individuals must remain on ARTs for life.

- In March 2017, GeoVax began a collaboration with American Gene Technologies International Inc., (AGT) in which AGT plans to commence a Phase 1 human clinical trial testing the companies' combined technologies to develop a functional cure for HIV infection.

    - In an earlier Phase 1 clinical trial of the Company's MVA-VLP HIV vaccine, GeoVax observed the ability of its vaccine to stimulate production of **CD4+ T cells** in HIV-positive individuals. The GeoVax vaccine will be used to stimulate virus-specific CD4+ T cells *in vivo*, which will then be harvested from the patient, genetically modified using AGT's proprietary technology, and reinfused into the patient. The primary objectives of the trial (targeted to begin in 2017) are to assess the safety and efficacy of the combined therapy, with secondary objectives to assess the immune responses and levels of virus reservoirs as measures of efficacy.

Hemorrhagic Fever (HF) Vaccine Program

- Initiated during 2014 in response to the Ebola epidemic in western Africa, GeoVax's HF vaccine program is focused on developing a **tetravalent vaccine (TV)** designed to protect against all major HF viruses (Ebola, Sudan, Marburg, and Lassa) endemic in African countries. Each vaccine is also being developed as a monovalent vaccine.

    - The Company's initial preclinical studies in rodents and nonhuman primates for its first Ebola (EBOV) vaccine candidate (GEO-EM01) have shown 100% protection against a lethal dose of Ebola virus upon a single immunization. GeoVax is currently conducting challenge studies for its Lassa fever vaccine (GEO-LM01).

Zika Virus (ZIKV) Vaccine Program

- GeoVax is also collaborating with the CDC to develop a preventive vaccine against the Zika virus (ZIKV). Zika disease is an emerging, rapidly-spreading mosquito-borne infectious disease that has been linked to an increase in **microcephaly** in infants (a condition in which a baby's head is significantly smaller than expected, often due to abnormal brain development) and **Guillain-Barré syndrome** in adults (a condition in which the immune system attacks the nerves).

    - A highly rigorous preclinical challenge model has been developed and has demonstrated impressive results for the Company's Zika vaccine, protecting 100% of outbred immunocompetent mice infected with a lethal dose of ZIKV delivered directly to the brain. The vaccine also generated strong humoral and T cell responses against ZIKV.

    - The Company's Zika vaccine (GEO-ZM02) is based on the **NS1 (non-structural-1)** protein of Zika, which is not associated with **Antibody Dependent Enhancement (ADE)** of infection—a safety concern for all other Zika vaccines under development. An NS1-based vaccine, GeoVax's candidate also has the potential to block transmission of ZIKV from humans to its mosquito vectors, as was shown with antibodies generated against NS1 proteins of DEN2 and ZIKV. Based on these results, GeoVax is advancing into non-human primates (NHP), GMP manufacture, and Phase 1 human trials.

Cancer Immunotherapy Vaccine Program

- GeoVax is employing its MVA-VLP platform to express abnormal **hypoglycosylated** forms of the cell surface-associated Mucin 1 (MUC1) protein, linked to a range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung. The Company's approach is to use standard-of-care (SOC) treatments, vaccinations, and **immune checkpoint inhibitors (ICIs)** to harness patient's immune system to fight their cancer.

    - GeoVax has a research collaboration with a leading expert in cancer immunotherapy at the University of Pittsburgh to help select vaccine candidates. The Company is also collaborating with ViaMune, Inc. of Athens, Georgia, with preliminary testing demonstrating that the MVA-VLP-MUC1 vaccine in combination with ViaMune's synthetic MUC1 vaccine has meaningfully reduced tumor burden in a transgenic (Tg) human MUC1 therapeutic mouse model.

Hepatitis B Virus (HBV) Vaccine Program

- Approximately 240 million people are chronically infected with HBV, of which 780,000 die each year despite the availability of an effective prophylactic vaccine since 1982. Currently, a variety of therapeutic vaccine candidates are being evaluated in clinical trials though none have induced the strong IgG1, IgG3, and CD4+ and CD8+ T cell responses necessary for complete viral clearance.

    - Clinical data from GeoVax's HIV vaccine trials have demonstrated that its MVA-VLP HIV vaccine elicited strong IgG1, IgG3, and CD4+/CD8+T cell responses. The Company has constructed vaccine candidates containing multiple protective antigens from the HBV genotype D (causing more severe disease), which are currently being tested in mice in its collaborator's laboratories at Georgia State University (GSU) and Shenzen Graduate School of Peking University.

Malaria Vaccine Program

- Malaria causes 214 million infections and 438,000 deaths every year worldwide. Despite decades of research, tested vaccine candidates have yet to be successful at inducing substantial protection (e.g. >50%). The majority of these vaccines have been based on truncated proteins or VLP proteins targeting a limited number of antigens derived from only one stage of the malaria life cycle.

    - GeoVax's MVA-VLP multi-antigen malaria vaccine candidates are designed to induce a Th1-biased immune response with durable functional **antibodies** (IgG1 and IgG3) and CD4+ and CD8+ T cell responses—all attributes of an ideal malaria vaccine. The Company is developing this vaccine with the Burnet Institute to prevent both malaria infection as well as its transmission by targeting antigens derived from multiple stages of the parasites' life cycle. GeoVax has completed construction of multiple vaccine candidates, which are expected to be tested at Burnet Institute in July 2017.

Intellectual Property

- GeoVax is the licensee of 10 issued and two patent applications in the U.S. and 12 issued and 4 patent applications in non-U.S. jurisdictions. GeoVax's 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, including administration. GeoVax has patents pending for HF, Zika, HBV, malaria, and immuno-oncology vaccines.

Leadership

- GeoVax recently appointed Farshad Guirakhoo, Ph.D., as its new chief scientific officer (CSO) to succeed Harriet Robinson, Ph.D., who remains as CSO Emeritus and director of the Company's HIV vaccine program and who is very well known in the HIV community. Dr. Guirakhoo was named one of the '50 Most Influential People in Vaccines' in Vaccine Nation's 2014 list.

- In January 2017, GeoVax announced the formation of a Scientific Advisory Board composed of world-class scientists, including Thomas Monath, MD; Stanley Plotkin, MD; Barney Graham, MD, Ph.D.; Scott Weaver, Ph.D.; and Olivera Finn, Ph.D. This group of experts is focused on helping the Company advance its various development programs.

Government Support

- The Company's vaccine development activities are financially supported by the U.S. Government in the form of research grants, in-kind support in terms of animal experiments, and indirect support for human clinical trials. GeoVax's HIV program receives substantial federal support (>$50 million to date from the NIH).

Executive Overview

GeoVax Labs, Inc. ("GeoVax") is a clinical-stage biotechnology company focused on developing human vaccines—both preventative and therapeutic—against infectious diseases as well as cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) vector vaccine platform. The Company's proprietary MVA platform, a large virus capable of carrying several vaccine antigens, expresses highly effective virus like particle (VLP) immunogens in the vaccinated individual, prompting durable immune responses while providing the safety features of a replication defective vector.

The Company's development efforts are focused on preventive vaccines within the following important areas: human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), and malaria. GeoVax is also developing therapeutic vaccines for chronic HBV infections and immuno-oncology, and is collaborating on a combination approach to developing a functional cure for HIV infection. The Company's vaccine development activities have been, and continue to be financially supported by the U.S. Government in the form of research grants awarded directly to the Company, in-kind support in terms of animal experiments, as well as indirect support for conducting human clinical trials. In particular, GeoVax's HIV program receives substantial federal support (with over $50 million received to date from the NIH). Importantly, large pharmaceutical or biotechnology companies typically do not have a significant interest in sponsoring early-stage activity in HIV until the development at least reaches an efficacy trial. All of GeoVax's preventative vaccine trials have been sponsored by the NIH, with the NIH (through the HIV Vaccine Trials Network [HVTN]), in fact, running the Company's trials—something that is unusual within the biotechnology space.

MVA-VLP Technology Platform

GeoVax's MVA-VLP vector vaccine technology platform combines the safety of a replication-defective live vector (MVA) with the immunogenicity of VLPs and the durability of immune responses elicited by vaccinia vectors. An overview of the Company's MVA-VLP-based technology pipeline is provided in Figure 1, followed by brief descriptions of each program. Greater details are provided within the Core Story (pages 21-52).

Figure 1

TECHNOLOGY PIPELINE

PROGRAM	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	COLLABORATOR/ FUNDING	STATUS
HIV-Clade B / Preventive Vaccine					NIH / HVTN	Phase 2a completed – vaccine alone Protein boost trial ongoing
HIV-Clade B / Immunotherapy					AGT	Phase 1 "Functional Cure" trial beginning in 2017
HIV-Clade C / Preventive Vaccine					NIH	Grant-supported preclinical
Hemorrhagic Fever Vaccines					NIH, USAMRIID	100% protection with a single dose in a non-human primate model
Zika Vaccine					CDC	100% protection with a single dose in mice against a lethal Zika challenge
Immuno-oncology					Univ. of Pittsburgh, ViaMune	Significant tumor reduction in therapeutic Tg. human-MUC1 mouse model
Hepatitis B Immunotherapy					Georgia State Univ. – Peking Univ.	Vaccine constructs being tested in mice
Malaria					Burnet Institute	Vaccine constructs under development

Externally Funded Internally Funded

Source: GeoVax, Inc.

Vaccines are most often made of agents (**antigens**) that resemble disease-causing microorganisms and are traditionally created from weakened or killed forms of the virus or from its surface proteins. Newer vaccines largely use recombinant **deoxyribonucleic acid (DNA)** technology to produce vaccine antigens in bacteria or cultured cells from specific portions of the DNA sequence of the target pathogen, where the generated antigens are then purified and formulated for use in a vaccine. The most successful of these purified antigens have been non-infectious VLPs, such as the hepatitis B vaccines (Merck's Recombivax® and GlaxoSmithKline's [GSK's] Engerix®) and human papillomavirus vaccine (GSKs Cervarix® and Merck's Gardasil®).

VLPs train the body's immune system to identify and kill the authentic virus should it appear. Furthermore, VLPs train the immune system to recognize and kill infected cells to control infection and decrease the length and severity of disease. Among the most challenging aspects of VLP-based vaccines is to design the vaccines in such a way that the VLPs are recognized by the immune system in the same way as would be the authentic virus. GeoVax employs the use of recombinant DNA or recombinant viruses to produce VLPs in the person being vaccinated.

When VLPs for enveloped viruses such as HIV, Ebola, Sudan, Marburg, or Lassa fever are produced *in vivo*, they include not only the protein antigens, but also an envelope consisting of membranes from the vaccinated individual's cells, where they are then highly similar to the virus generated in a person's body during a natural infection. In contrast, VLPs produced externally have no envelope or envelopes from the cultured cells used to produce them. Based on its efforts to date, GeoVax believes its technology provides unique advantages by producing VLPs that more closely resemble the authentic virus, thus enabling the body's immune system to more readily recognize the authentic virus. By producing VLPs *in vivo*, GeoVax's vaccines avoid potential purification issues related to *in vitro* VLP production.

Noteworthy is that MVA was initially developed as a safer smallpox vaccine for use in immune-compromised individuals, where it was developed by attenuating the standard smallpox vaccine by making over 500 passages of the virus in chicken embryos or chicken embryo fibroblasts. This lead to a virus with limited ability to replicate in human cells though did not compromise the ability of MVA to grow on avian cells (used for manufacturing the virus). The deletions also lead to the loss of immune evasion genes, which help the spread of wild-type smallpox infections (even in the presence of human immune responses).

Advantages

GeoVax's MVA-VLP platform has unique advantages, summarized below and further described within the report in context.

- *Safety.* GeoVax's HIV vaccines have demonstrated a remarkable safety profile in human clinical trials. In general, safety for MVA has been shown in more than 120,000 subjects in Europe, including immunocompromised individuals during the initial development of MVA. As well, this safety profile has been shown lately in developing MVA as a safer vaccine against smallpox.

- *Durability.* The Company's technology promotes highly durable vaccine responses that are long lasting. GeoVax theorizes that elicitation of durable vaccine responses is conferred on responding B cells by the vaccinia parent of MVA, raising highly durable responses for smallpox.

- *Limited pre-existing immunity to vector.* Following the eradication of smallpox in 1980, smallpox vaccinations ended, which left everyone except for those individuals born before 1980 and selected populations (such as vaccinated laboratory workers, first responders, etc.) unvaccinated and without pre-existing immunity.

- *No need for **adjuvants***. MVA stimulates strong innate immune responses without the use of adjuvants.

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

- *Genetic stability and manufacturability*. MVA is genetically stable when properly engineered and can be reliably manufactured in either the established **chick embryo fibroblast (CEF)** cell substrate or in continuous cell lines that support scalability along with consistency and efficiency.

HIV/AIDS Vaccine Program

HIV (Preventive Vaccine)

GeoVax's most advanced program is a preventive vaccine (GOVX-B11) for the clade B subtype of HIV, the most common form of HIV in the Americas, Western and Central Europe, Australia, and Japan. As the Company's most advanced program, the HIV clade B vaccine has successfully completed Phase 1 and Phase 2a human clinical trials, in which GeoVax demonstrated that its VLPs, expressed in the cells of the person being vaccinated, are safe, yet elicit both strong and durable humoral and cellular immune response. These trials are supported by the NIH and conducted by the HIV Vaccine Trials Network (HVTN)—the world's largest publicly-funded international collaboration focused on developing vaccines to prevent HIV/AIDS (www.hvtn.org). Support for the HVTN comes from the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, with the HVTN located at leading research institutions in 27 cities on four continents.

In January 2017, GeoVax announced that it had begun the next human clinical trial (HVTN 114) on the path toward human efficacy trials. HVTN 114 is testing the ability of "late boosts" to increase the antibody responses elicited by GOVX-B11. These "late boosts" consist of GeoVax's MVA62B vaccine with or without a gp120 protein vaccine. HVTN 114 is being conducted by HVTN with funding from the NIAID. Information from this trial is expected to contribute to the design of future human clinical trial testing for GOVX-B11 in the presence and absence of newer gp120 proteins, which are currently being cGMP manufactured. During 2016, NIAID also awarded GeoVax a Staged Vaccine Development contract of up to $7.8 million for the production of the DNA vaccine component of GOVX-B11 in sufficient quantities for use in advanced clinical trials.

HIV (Therapeutic Vaccine)

In March 2017, GeoVax announced a collaboration with American Gene Technologies International Inc. (AGT www.americangene.com) in which AGT plans to commence a Phase 1 human clinical trial testing the Company's combined technologies to develop a functional cure for HIV infection. In an earlier Phase 1 clinical trial of GeoVax's MVA-VLP HIV vaccine, the vaccine was shown to stimulate production of CD4+ T cells in HIV-positive individuals, which is the intended use of the vaccine in the AGT study. The GeoVax vaccine will be used to stimulate virus-specific CD4+ T cells *in vivo*, which will then be harvested from the patient, genetically modified using AGT's proprietary lentiviral vector technology, and reinfused into the patient. The primary objectives of the trial, slated to begin in 2017, are to assess the safety and efficacy of the combined therapy, with secondary objectives to assess the immune responses and levels of virus reservoirs as measures of efficacy.

Program's History

The Company was formed out of an agreement with Emory University (Atlanta, Georgia). One of its founders, Harriet Robinson, GeoVax's chief scientific officer, emeritus (biography on page 18), who is very well known in the HIV community, was recruited to Emory University concentrating her efforts to develop a vaccine against HIV. Using a license from Emory, there was a collaboration of two vaccines that were licensed from the Company's Government laboratory: the CDC licensed GeoVax a priming vaccine and the NIH licensed to GeoVax a boosting vaccine.

Within the HIV category (which has been in existence for roughly 35 years), there are no approved vaccines. GeoVax continues to move down the clinical pathway, where the Company had its vaccine tested in approximately 500 individuals, progressing through a Phase 2a clinical trial. The next goal is to reach an efficacy trial, which would be a Phase 2b trial (involving many thousands of individuals). For HIV, it is typically the NIH who would be the trial's sponsor (rather than the larger pharmaceutical companies). GeoVax's efforts are directed at the clade B subtype of the HIV virus, which is prevalent in the Americas, Western Europe, Japan, and Australia. Within this subtype, the Company believes that it may be the most advanced HIV vaccine, as demonstrated by the continued NIH support, with the NIH currently running GeoVax's trials.

Under this trial, the NIH is attempting to add a protein to GeoVax's vaccine to determine whether they can make it even better using individuals who had received treatment several years back. Each of GeoVax's preventative vaccine trials have been sponsored by the NIH, garnering GeoVax roughly $50 million in either research support or in-kinds funds—presenting a very unique circumstance for GeoVax.

Hemorrhagic Fever (HF) Vaccine Program

Ebola (EBOV, formerly designated as Zaire ebolavirus), Sudan virus (SUDV), and Marburg viruses (MARV) are currently the most virulent species of the **Filoviridae** family, causing up to a 90% fatality rate in humans, and are **epizootic** in Central and West Africa (28 outbreaks since 1976). In the most recent outbreak of 2013-2016, Ebola caused 28,616 cases and 11,310 deaths (a 40% fatality rate). Lassa fever virus (LASV) also causes severe and often fatal hemorrhagic illnesses in an overlapping region to that of Ebola. Compared to the random epidemics of filoviruses, LASV is endemic in West Africa, with an annual rate of >300,000 infections, and leading to 5,000-10,000 deaths. Data from a recent sero-epidemiologic study suggest that the number of annual LASV cases may be much higher, reaching three million infections and 67,000 deaths, and leaving up to 200 million people at risk. While the timing of the next filovirus outbreak is uncertain, it is almost certain that one will occur resulting from the following factors: the zoonotic nature of the virus, weak healthcare systems, high population mobility, cultural beliefs and burial practices, and endemic infectious diseases, such as malaria and LASV, that mimic early Ebola symptoms.

GeoVax operates under the premise that an ideal vaccine against major filoviruses and LASV must activate both humoral and cellular arms of the immune system and include the induction of antibodies to slow the initial rate of infection and a cellular immune response to help clear the infection. Further, it must target strain variations by providing broad coverage against potential epizootic filovirus strains, and prove safe not only in healthy individuals (such as travelers or healthcare workers), but also those who are immunocompromised (HIV infected) and those with other underlying health issues. While there has been progress with some experimental vaccines in clinical trials, there has not yet been fully tested for both safety and efficacy.

GeoVax is developing an innovative tetravalent vaccine (TV) utilizing its MVA-VLP platform to address the unmet need for a product that can respond to future filovirus epidemics and potentially end LASV infections in West Africa. The Company is addressing strain variations as well as induction of broad humoral and cellular responses through development of four monovalent vaccines, which can either be used individually against a specific disease or be blended to provide broad coverage. The MVA vector has demonstrated to be highly safe, as it has been developed for use in immunocompromised individuals. As well, it has demonstrated excellent safety in clinical trials of immunocompromised (~1,000) as well as healthy (>120,000) individuals. This vaccine is currently licensed by Bavarian Nordic of Denmark (a biotechnology company specializing in research, development, and manufacture of active cancer immunotherapies and vaccines for infectious diseases) for use as a smallpox vaccine.

Beyond protecting people in Africa, GeoVax's TV vaccine is intended to prevent the spread of disease in the U.S. as well as for preparedness against bioterrorist release of any of these four bio-threat pathogens (EBOV, SUDV, MARV, and LASV). The initial markets for the TV vaccine are both non-governmental organizations (NGOs) such as GAVI, the Vaccine Alliance (a public–private global health partnership committed to increasing access to immunization in poor countries), and the Bill & Melinda Gates Foundation, as well as U.S. and foreign governments.

The Company's initial preclinical studies in rodents and nonhuman primates for its first vaccine candidate (EBOV) have shown 100% protection against a lethal dose of Ebola virus upon a single immunization. The Company is currently conducting challenge studies for its LASV vaccine.

ZIKA Virus (ZIKV) Vaccine Program

Following the Zika epidemic in 2016, GeoVax is focused on developing an MVA-Zika vaccine (GEO-ZM02). For preclinical testing support, the Company has collaborations with the CDC to develop a lethal challenge model in mice to test the vaccine candidates. ZIKV and reagents will be supplied by the University of Texas Medical Branch (UTMB). To date, GeoVax has demonstrated 100% protection of mice vaccinated with a single-dose of the Zika vaccine and exposed to a lethal dose of ZIKV.

The Company's Zika vaccine is based on the NS1 (non-structural) protein of Zika, which is not associated with Antibody Dependent Enhancement (ADE) of infection—a safety concern for all other Zika vaccines under development. An NS1-based vaccine, GeoVax's candidate has the potential to block transmission of ZIKV from humans to its mosquito vectors, as was shown for ZIKV and other flaviviruses. Furthermore, GEO-ZM02 not only has the potential to be a single-dose vaccine, which is practical to combat epidemics in resource strained countries, but also does not bear the risk of enhancing other flavivirus infections, such as dengue virus, in vaccinated subjects. Based on these results, GeoVax is advancing into non-human primates (NHP), GMP manufacture, and Phase 1 human trials.

Cancer Immunotherapy Vaccine Program

The field of immune-oncology has been given greater attention due to the discovery and initial launch of **monoclonal antibodies (Mabs)**, called immune checkpoint inhibitors (ICIs). Tumors take over 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, permitting poorly functional T cells the ability to resume proliferation, cytokine production, and killing of tumor cells.

Differing from conventional therapies (e.g. radiation, chemotherapy, antibody, etc.), cancer vaccines may be able to induce responses that not only result in the control and clearance of tumors but can create immunological memory that is able to suppress and prevent the reappearance of tumors. Convenience, safety, and low toxicity of cancer vaccines make them invaluable tools to be included in future immunotherapy approaches for treating tumors. There are currently only a few vectored cancer vaccines being tested in combination with ICIs—all of which are in early clinical stages.

GeoVax is employing its MVA-VLP vaccine platform to express abnormal hypoglycosylated forms of the cell surface-associated Mucin 1 (MUC1) protein, which is linked to a range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung. The Company's clinical approach is to use standard-of-care (SOC) treatments, vaccinations, and ICIs to harness a patient's immune systems to fight their cancer. GeoVax has a research collaboration with a leading expert in cancer immunotherapy at the University of Pittsburgh to help select vaccine candidates. The Company is further collaborating with ViaMune, Inc. of Athens, Georgia, with preliminary testing demonstrating that the MVA-VLP-MUC1 vaccine, in combination with ViaMune's synthetic MUC1 vaccine, may meaningfully reduce tumor burden in a transgenic (Tg) human MUC1 therapeutic mouse model. GeoVax believes that this program has the potential to generate several vaccines against different types of cancers.

Hepatitis B Virus (HBV) Vaccine Program

Despite the availability an effective *prophylactic vaccine* since 1982, there are roughly 240 million people chronically infected with HBV, of which about 780,000 die each year due to complications, including cirrhosis and cancer. Multiple vaccines exist to protect against HBV infection, though they are not able to help patients already diagnosed with the disease. While chronic HBV can be treated with drugs, these treatments do not cure 95% of patients—they are not able to induce strong neutralizing antibodies and cellular responses needed to break tolerance to HBV antigens and clear infections as they only suppress the replication of the virus. As a result, people who start treatments must continue for life. Additionally, diagnosis and treatment options are limited in resource/low income-constrained populations, leading to many patients dying within months of diagnosis.

In patients with undetectable HBV-DNA have shown to respond primarily with IgG1 and/or IgG3, while in the HBV-DNA-positive group, a high contribution of IgG4 was found. The correlation of protection is mainly induction of CD4+ response to core and IgG3 response to S antigens. GeoVax's HIV data shows that the DNA and MVA-VLP produced strong CD4+ response and high ratio of IgG3. The Company's combination therapeutic vaccine strategy comprises multivalent vaccine antigens delivered by DNA and MVA-VLP in combination with the SOC treatment to induce functional antibodies and CD4+, CD8+ T cell responses to clear infection and break tolerance needed toward a functional cure. GeoVax seeks to increase the current cure rate of HBV infections while reducing the duration of drug therapy, overall treatment costs, side effects, and potential drug resistance.

GeoVax has entered a Research Collaboration Agreement with Georgia State University Research Foundation (GSU) to advance the Company's development efforts of a therapeutic vaccine to treat chronic HBV infections. The project is to include the design, construction, characterization, and animal testing of multiple vaccine candidates using GeoVax's MVA-VLP vaccine platform. Vaccine antigens include both GeoVax and GSU's proprietary designed sequences. Vaccine design, construction, and characterization are performed at GeoVax with further characterization and immunogenicity studies in mice currently being conducted at GSU in collaboration with the Shenzhen Graduate School of Peking University.

Malaria Vaccine Program

Worldwide, malaria causes 214 million infections and 438,000 deaths every year. The perfect malaria vaccine candidate should contain antigens from multiple stages of the malaria life cycle, should induce functional antibodies (predominantly IgG1 and IgG3 subtypes, which have been associated with protection), and strong cell mediated immunity (Th1 biased CD4+ ad CD8+) to reduce **parasitemia** by clearing infected cells (liver cells or erythrocytes). GeoVax has demonstrated in both animal models and humans that its MVA-VLP vaccines induce a Th1-biased response with both durable functional antibodies (IgG1 and IgG3) and CD4+ and CD8+ T cell responses—both marks of an ideal malaria vaccine.

Despite decades of research, tested vaccine candidates have been unsuccessful to date at inducing substantial protection (e.g. >50%). The majority of these vaccines have been based on truncated proteins or VLP proteins targeting a limited number of antigens derived from only one stage of the malaria life cycle.

GeoVax has established a collaboration agreement with the Burnet Institute, a leading infectious diseases research institute in Australia, to develop a vaccine to prevent malaria. This project is to include 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 were performed at GeoVax with further characterization and immunogenicity studies in mice and rabbits currently being conducted at Burnet Institute using their unique functional assays, which provide key information on vaccine efficacy.

Collaborations and Government Support

GeoVax's HIV vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the CDC. The technology is exclusively licensed to GeoVax from Emory University. The Company also has nonexclusive licenses to certain patents owned by the NIH used in developing its other vaccines. Its immuno-oncology program is being developed pursuant to a research collaboration with the University of Pittsburgh. Its ZIKV vaccine program is in collaboration with the CDC. Its HBV therapeutic program is in collaboration with Georgia State University. As well, the Company's malaria vaccine is being developed in collaboration with the Burnet Institute in Australia. A summary of the Company's vaccine development collaborations is provided in Figure 2 (page 12).

Figure 2
VACCINE DEVELOPMENT COLLABORATIONS

— Clade C & HIV protein boost
- Duke University

— Zika
- CDC – Ft. Collins
- UTMB

— Lassa fever
- University of Maryland

— Oncology, MUC1
- University of NC – Charlotte
- ViaMune, Inc.

— HBV Therapeutic
- Georgia State University
- Peking University

— Malaria
- Burnet Institute, Australia

Source: GeoVax, Inc.

GeoVax seeks to advance and protect its vaccine platform, while using its core competences to design and develop a broad range of products. The Company seeks to move its products through to human clinical testing, and pursue partnership(s) and/or licensing arrangement(s) at the pre-commercialization stage. Furthermore, for preclinical and clinical testing, GeoVax leverages third party resources via collaborations and partnerships, some of which currently include: the NIAID, the HVTN, CDC, United States Army Research Institute of Infectious Disease (USAMRIID), Emory University, University of Georgia Research Foundation, University of Pittsburgh, Georgia State University Research Foundation, Peking University, University of Texas Medical Branch, the Burnet Institute, American Gene Technologies International Inc. (AGT), and ViaMune, Inc.

Corporate Background, Properties, and Employees

GeoVax leases roughly 8,400 sq. ft. of office and laboratory space at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia under a lease agreement that expires on December 31, 2017. The Company feels this space is suitable for its current needs and expects to renew the lease. GeoVax currently employs seven full-time and four part-time individuals. The Company's primary business is conducted by its wholly-owned subsidiary, GeoVax, Inc., which was incorporated under the laws of Georgia in June 2001. The predecessor to its parent company, GeoVax Labs, Inc. was originally incorporated in June 1988 under the laws of Illinois as Dauphin Technology, Inc. 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.

Milestones

Recent Milestones

GeoVax's MVA-VLP vaccine platform continues to advance through the Company's expanding product portfolio, with a growing list of high-quality corporate and academic collaborators, and promising preclinical and clinical testing results. Recent highlights include:

- Positive preclinical results (100% protection) for the Company's Zika vaccine from a highly rigorous lethal challenge model conducted by the CDC. GeoVax's approach to a Zika vaccine is unique as it is based on the NS1 (non-structural-1) protein of the ZIKV, avoiding the Antibody Dependent Enhancement (ADE) of infection safety issue, which is a concern for other Zika vaccines candidates.

- GeoVax initiated a new clinical trial (HVTN 114) for its preventive clade B HIV vaccine (GOVX B11) for the developed world. This trial is being fully funded by NIAID. The Company continues its work under a $7.8 million NIAID contract for production of the DNA component of its vaccine intended for later stage clinical trials.

- The Company was awarded a $658,000 grant from NIAID to continue its work toward a clade C HIV vaccine for the developing world.

- GeoVax began a collaboration with American Gene Technologies International Inc. (AGT), with the goal of developing a functional cure for HIV infection. The Company expects AGT to begin human clinical trials using its combined technologies later this year.

- The Company began a new program to develop a malaria vaccine through a collaboration with The Burnet Institute. The work to develop the vaccine constructs is complete and GeoVax expects the initial preclinical proof-of-concept studies to commence during the second quarter 2017.

- GeoVax added Georgia State University (GSU) and Peking University as collaborators to develop a therapeutic vaccine for chronic HBV and has begun the initial preclinical proof-of-concept studies.

- The Company continued its collaboration with ViaMune, Inc. for co-development of its cancer immunotherapy programs. The proof-of-concept preclinical studies are ongoing, with data readouts expected in June/July 2017.

- GeoVax formed a Scientific Advisory Board composed of world-class scientists, including Thomas Monath, MD; Stanley Plotkin, MD; Barney Graham, MD, Ph.D.; Scott Weaver, Ph.D.; and Olivera Finn, Ph.D., as profiled in Figure 6 (page 20). This group of experts is focused on helping the Company advance in its various development programs.

Potential Milestones (2017 and Beyond)

Zika

- NIH Grant for Zika program (June 2017)
- Determine immunogenicity and efficacy in non-human primates
- Determine correlation of protection by passive protection studies in mice
- Produce GMP vaccine
- File IND with the FDA
- Initiate Phase 1 studies

HIV

- Data released - elicitation of HIV neutralizing antibody (June 2017)
- Initiate Phase 1 HIV clinical trial by AGT (gene therapy cure trial in combination with GeoVax's vaccine), (Q4 2017)
- Initiate Phase 1 HIV protein boost clinical trial by HVTN (continued pathway to efficacy trial at no cost to GeoVax), (Q1 2018)

Hemorrhagic Fever (HF)

- Preclinical protection (rodent) data for Lassa vaccine (June 2017)

Cancer Immunotherapy

- Initial preclinical Proof of Concept (PoC) cancer data in combination with ViaMune technology (June/July 2017)

Malaria

- Preclinical data on efficacy of malaria vaccine (Q3 2017)

Intellectual Property

GeoVax has a patent portfolio that consists of issued and pending patents covering the Company's vaccine technology, manufacturing methods, and applications. The Company has acquired its global patent position through its research operations, collaborations, and license agreements. GeoVax is the licensee of 10 issued and two patent applications in the U.S. and 12 issued and 4 patent applications in non-U.S. jurisdictions. The Company is also owner of record of an additional nine pending applications in the U.S. and one international patent application. Figure 3 (page 16) provides highlights of the Company's key intellectual property (IP) portfolio.

GeoVax's IP portfolio includes patent and patent applications related to DNA- and MVA-based HIV vaccines, including 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 of its HIV vaccine platform. In addition, the Company is pursuing patent applications related to preventive vaccines against HF viruses (Ebola, Sudan, Marburg, and Lassa), ZIKV, and malaria; therapeutic vaccines against HBV; and immuno-oncology vaccine compositions.

Emory License Agreement

GeoVax's vaccine technology was developed in collaboration with researchers at Emory University, the U.S. National Institutes of Health (NIH), and the U.S. Centers for Disease Control and Prevention (CDC). The technology is based on patents exclusively licensed to GeoVax from Emory University, in addition to non-exclusive licenses to certain patents owned by the NIH, pursuant to a license agreement originally entered into on August 23, 2002 and restated on June 23, 2004. The agreement grants GeoVax with the exclusive, worldwide license for several patents and patent applications owned, licensed, or otherwise controlled by Emory University for HIV or smallpox vaccines. The agreement also grants the Company with the non-exclusive license to four issued U.S. patents owned by the NIH related to the ability of the Company's MVA vector vaccine to operate as a vehicle to deliver HIV virus antigens, as well as to induce an immune response in humans.

Due to the use of federal funds in the development of the Emory Technology, the U.S. Government has the royalty-free-, paid-up right to practice and have practiced certain patents throughout the world, should it choose to exercise such rights. The Emory license contains standard milestone and royalty payment obligations.

Furthermore, the Company has the following license and research collaboration agreements to advance its product candidates: (1) a cooperative research and development agreement (CRADA) with the NIH for the development of HF, Zika, HBV, malaria, and immuno-oncology vaccines; (2) a collaboration with the CDC for the development of a Zika vaccine; (3) a collaboration agreement with GSU for the advancements of the Company's HBV therapeutic program; (4) a collaboration agreement with the Burnet Institute in Australia to develop a malaria vaccine; and (5) a research collaboration agreement with the University of Pittsburgh to develop the Company's immuno-oncology program.

In addition to patent protection, GeoVax also plans to protect its proprietary products, processes, and other information by relying on manufacturing technical know, trade secrets, and non-disclosure agreements with its employees, consultants, and other persons who have access to such information. Under these agreements, all inventions conceived by the Company's employees are the exclusive property of GeoVax.

Figure 3
INTELLECTUAL PROPERTY HIGHLIGHTS

Patent Family	Jurisdiction	Patent	Filed	Status
Parent DNA Family (Emory University, NIH, CDC) DNA Expression Vectors and Methods of Use	USSN 11/009,063	7,795,017	9-Dec-04	Issued
	CA	2,401,974	2-Mar-01	Granted
	IN	245,816	2-Mar-01	Granted
Emory 2nd CIP Family (Emory University, NIH, CDC)	USSN 14/137,095	9,254,319	20-Dec-13	Issued
	USSN 10/336,566	8,623,379	3-Jan-03	Issued
	AU	2,003,220,111	10-Mar-03	Granted
	CA	2,478,371	10-Mar-03	Granted
	IN	248,360	10-Mar-03	Granted
	EP	3,716,404	10-Mar-03	Pending
	EP	10,184,785	10-Mar-03	Pending
NIH Filed 1st MVA Family (Emory, NIH) MVA Expressing Modified HIV Envelope, GAG and POL genes	USSN 12/018,150	7,867,982	22-Jan-08	Issued
	USSN 12/987,791	8,916,172	10-Jan-11	Issued
	AU	2,002,252,199	1-Mar-02	Granted
	IN	234,835	1-Mar-02	Granted
	JP	4,554,887	1-Mar-02	Granted
	EP	1,372,710	1-Mar-02	Granted
	CA 2,454,959		1-Mar-02	Pending
NIH Filed 2nd MVA Family (Emory, NIH) Recombinant MVA Viruses Expressing Clade A/G, Clade B, and Clade C Modified HIV ENV, GAG and POL genes	USSN 11/574,285	9,453,239	27-Aug-05	Granted
	EP 05807378.4	1,789,438	27-Aug-05	Granted
	CA	2,578,403	27-Aug-05	Granted
	AU	2,012,202,786	27-Aug-05	Granted
	IN	1814/DELNP/2007	27-Aug-05	Granted
	JP	5,178,196	27-Aug-05	Granted
NIH Background MVA (NIH) Recombinant Vaccinia Virus Containing a Chimeric Gene Having Foreign DNA Flanked by Vaccinia Regulatory DNA - non-exclusive license	USSN 07/987,546	7,045,313	7-Dec-92	Issued
	USSN 08/470,360	6,998,252	6-Jun-95	Issued
	USSN 08/470,359	7,045,136	6-Jun-95	Issued
	USSN 08/470,357	7,015,024	6-Jun-95	Issued
Ebola/Marburg/Lassa Virus Compositions	PCT/US2016/013021		12-Jan-16	Pending
	USSN 62/102,425		12-Jan-15	Filed
	USSN 62/213,819		3-Sep-15	Filed
	USSN 62/215,536		8-Sep-15	Filed
Multivalent HIV Vaccine Boost (SBIR Ph2)	PCT/US2017/018103		16-Feb-17	Pending
	USSN 62/295,779		16-Feb-16	Filed
MUC-1 Vaccine	PCT/US2017/012704		9-Jan-17	Pending
	USSN 62/301,885		1-Mar-16	Filed
	USSN 62/276,479		8-Jan-16	Filed
Zika Virus Vaccine Compositions	PCT/US2017/012704		9-Jan-17	Pending
	USSN 62/290,744		3-Feb-16	Filed
Malaria Vaccine	USSN 62/397,213		20-Sep-16	Pending
Malaria Vaccine	USSN 62/397,461		21-Sep-16	Pending
HBV Vaccine Compositions	USSN 62/343,074		30-May-16	Pending
HBV Vaccine Compositions	PCT/US2017/034983		30-May-17	Pending

Sources: GeoVax Labs, Inc. and Crystal Research Associates.

Company Leadership

Executive Management

Key members of GeoVax's management team are highlighted in Figure 4 and profiled below.

Figure 4
MANAGEMENT

Name	Position
Robert T. McNally, Ph.D.	President, Chief Executive Officer, and Director
Mark W. Reynolds	Chief Financial Officer and Corporate Secretary
Farshad Guirakhoo, Ph.D.	Chief Scientific Officer
Harriet L. Robinson, Ph.D.	Chief Scientific Officer Emeritus, Director

Source: GeoVax, Inc.

Robert T. McNally, Ph.D., President, Chief Executive Officer, and Director

Dr. McNally joined the Board of Directors in December 2006 and was appointed as president and chief executive officer (CEO) effective April 1, 2008. From 2000 to March 2008, Dr. McNally served as CEO of Cell Dynamics LLC, a cGMP laboratory services company. Previously, Dr. McNally was a co-founder and senior vice president of clinical research for CryoLife, Inc., a pioneering company in transplantable human tissues. He has over 35 years of experience in academic and corporate clinical investigations, management, research, business, quality, and regulatory affairs. Dr. McNally is a Fellow of the American Institute for Medical and Biological Engineering, serves on the advisory boards of the Petit Institute for Bioengineering and Dupree College of Management at the Georgia Institute of Technology, and is a former chairman of Georgia Bio, a trade association. Dr. McNally graduated with a Ph.D. in biomedical engineering from the University of Pennsylvania.

Mark W. Reynolds, Chief Financial Officer and Corporate Secretary

Mr. Reynolds joined GeoVax on a part-time basis in October 2006 as chief financial officer (CFO) and corporate secretary, becoming a full-time employee in January 2010. From 2003 to 2006, before being named CFO of GeoVax, Mr. Reynolds provided financial and accounting services to the Company as an independent contractor. From 2004 to 2008, he served as CFO for HealthWatchSystems, Inc., a privately-held company in the consumer healthcare industry. From 2004 to 2006, he served as CFO for Duska Therapeutics, Inc., a publicly-held biotechnology company. From 1988 to 2002, Mr. Reynolds was first controller and later CFO of CytRx Corporation, a publicly-held biopharmaceutical company. Mr. Reynolds began his career as an auditor with Arthur Andersen & Co. from 1985 to 1988. He is a certified public accountant (CPA) and earned a master's of accountancy degree from the University of Georgia.

Farshad Guirakhoo, Ph.D., Chief Scientific Officer

Dr. Guirakhoo joined GeoVax as senior vice president of research and development in October 2015 and was promoted to chief scientific officer (CSO) in January 2017. Dr. Guirakhoo was named one of the '50 Most Influential People in Vaccines' in Vaccine Nation's 2014 list. His previous assignment was chief technology officer at Vaxess Technologies, a Cambridge, MA-based biotechnology company researching thermostabilization of vaccines and biologics using silk fibroin protein. Prior to this, he served as CSO at Hookipa Biotech in Vienna, Austria, developing vaccines against Cytomegalovirus and cancers based on a novel replication-deficient viral vector platform. Prior to that, Dr. Guirakhoo held the position of executive director of external R&D at Sanofi Pasteur from 2007-2012. Before joining Sanofi Pasteur in 2007, Dr. Guirakhoo was head of virology research at Acambis for 15 years. During this time, he co-invented the ChimeriVax™ technology platform in association with St. Louis University. This platform utilizes the YF 17D vaccine virus as a vector to develop chimeric live viruses. The ChimeriVax™ vector platform was successfully used in the development of innovative vaccines such as: (a) a single dose vaccine against Japanese encephalitis (IMOJEV™), marketed in Asian countries by Sanofi, (b) a single dose veterinary vaccine for

the prevention of West Nile encephalitis (PREVNILE™), marketed by Merck Animal Health, and (c) DENGVAXIA®, the world's first dengue vaccine approved in Mexico and Brazil in December 2015 and marketed by Sanofi. This tetravalent vaccine represents a historic milestone for half of the world's population who lives at risk of dengue. Dr. Guirakhoo has over 30 years of experience in developing vaccines against infectious diseases. Dr. Guirakhoo holds a BSc in Biology, a MSc in genetics, and a Ph.D. in Virology from the Medical University of Vienna, Austria, and was awarded a National Research Council post-doctoral fellowship at the CDC in Fort Collins, CO, from 1990-1992.

Harriet L. Robinson, Ph.D., Chief Scientific Officer Emeritus and Director

Dr. Robinson joined the Company as senior vice president, research and development on a part-time basis in November 2007 and on a full-time basis in February 2008, and was promoted to CSO in 2010. She was elected to the Board of Directors in June 2008. Dr. Robinson is the developer of GeoVax's HIV/AIDS vaccine technology and is one of the world's leaders in HIV/AIDS vaccine research. She co-founded GeoVax in 2001 to facilitate taking the AIDS vaccine developed in her laboratory at the Emory Vaccine Center in collaboration with scientists at the National Institutes of Health into the clinic. From 1999 to February 2008, Dr. Robinson served as the Asa Griggs Candler Professor of Microbiology and Immunology at Emory University in Atlanta, Georgia, and from 1998 to February 2008 as Chief, Division of Microbiology and Immunology, Yerkes National Primate Research Center. She was a Professor in the Department of Pathology at the University of Massachusetts Medical Center from 1988 to 1997 and Staff, then Senior, then Principal Scientist at the Worcester Foundation for Experimental Biology from 1977 to 1987. Dr. Robinson received a bachelor of arts degree from Swarthmore College and M.S. and Ph.D. degrees from the Massachusetts Institute of Technology.

Board of Directors

The Board of Directors oversees the conduct of and supervises the Company's management. Figure 5 provides a summary of Board members, followed by detailed biographies.

Figure 5
BOARD OF DIRECTORS

Name	Position
David A. Dodd	Chairman of the Board
Randal D. Chase, Ph.D.	Member
Dean G. Kollintzas	Member
Robert T. McNally, Ph.D.	Member
Harriet L. Robinson, Ph.D.	Member
John "Jack" N. Spencer, Jr.	Member

Source: GeoVax, Inc.

David A. Dodd, Chairman of the Board

Mr. Dodd joined the Board of Directors in March 2010 and became Chairman of the Board on January 1, 2011. He has more than 35 years of executive experience in the healthcare industry. Since April 2013, he has served as president and CEO, and as a member of the Board of Directors of Aeterna Zentaris Inc., an oncology and endocrinology drug development company. He is also the CEO of RiversEdge BioVentures, an investment and advisory firm focused on the life sciences and pharmaceuticals industries, which he founded in 2009. From December 2007 to June 2009, Mr. Dodd was president, CEO, and chairman of BioReliance Corporation, an organization that provided biological safety testing, viral clearance testing, genetic and mammalian technology testing and laboratory animal diagnostic services testing. From October 2006 to April 2009, he served as non-executive chairman of Stem Cell Sciences Plc. Before that, Mr. Dodd served as president, CEO, and director of Serologicals Corporation before it was sold to Millipore Corporation in July 2006 for $1.5 billion. For five years prior to his employment by Serologicals Corporation, Mr. Dodd served as president and CEO of Solvay Pharmaceuticals, Inc. and chairman of its subsidiary Unimed Pharmaceuticals, Inc.

Randal D. Chase, Ph.D.

Dr. Chase joined the Board of Directors in March 2015. Since 2011, he has served as a business advisor and consultant to companies in the life science sector. From 2006 to 2011, he served as president and CEO of Immunovaccine, Inc., a clinical-stage biotechnology company developing vaccines against cancer and infectious diseases. Dr. Chase is also a former president of Shire Biologics, North American Vaccine, Pasteur Merieux Connaught, and Quadra Logic Technologies, Inc. His early career was at Bristol Myers and Glaxo Pharmaceuticals. Dr. Chase has also served as a member of the Board of Directors for numerous companies, and recently served as Chairman of the Board for Medicago, Inc. until its sale to Mitsubishi Tanabe Pharma Corporation in 2013. He currently serves as Chairman of the Board for Medimabs, Inc., a privately-held antibody company. Dr. Chase attended the Senior Executive Program of the London Business School in the United Kingdom, holds a bachelor of sciences degree in biochemistry from Bishop's University, and a Ph.D. in biochemistry from the University of British Columbia. Dr. Chase completed a post-doctoral fellowship at the McArdle Cancer Institute of the University of Wisconsin.

Dean G. Kollintzas

Mr. Kollintzas joined the Board of Directors upon consummation of the merger with GeoVax, Inc. in September 2006. Since 2001, Mr. Kollintzas has been an intellectual property attorney specializing in biotechnology and pharmaceutical licensing, FDA regulation, and corporate/international transactions. Mr. Kollintzas received a microbiology degree from the University of Illinois and a J.D. from Franklin Pierce Law Center. He is a member of the Wisconsin and American Bar Associations. In 2014, he founded Procare Clinical, LLC, a clinical trial management company headquartered in Naperville, IL.

Robert T. McNally, Ph.D.

Biography on page 17.

Harriet L. Robinson, Ph.D.

Biography on page 18.

John "Jack" N. Spencer, Jr.

Mr. Spencer joined the Board of Directors in September 2006. Mr. Spencer is a CPA and was a partner of Ernst & Young LLP, where he spent more than 38 years until he retired in 2000. While at Ernst & Young, Mr. Spencer was the partner in charge of that firm's life sciences practice for the southeastern U.S., and his clients included a large number of publicly-owned and privately-held medical technology companies. Mr. Spencer also serves as a director of MRI Interventions, Inc., a medical device company, where he also chairs the audit committee and serves on the compensation committee. He served as the temporary CFO of Applied Genetic Technologies Corporation from November 2013 until February 2014, while that company prepared its initial public offering (IPO). He also serves as a consultant to various companies primarily relating to financial accounting and reporting matters. Mr. Spencer received a bachelor of science degree from Syracuse University, and earned an M.B.A. from Babson College. He also attended the Harvard Business School Advanced Management Program.

Scientific Advisory Board

GeoVax seeks advice from its Scientific Advisory Board and HIV Scientific Advisors, which consist of leading scientists and medical professionals. The current members of these Boards are listed in Figures 6 and 7.

Figure 6

SCIENTIFIC ADVISORS

Name	Position/Institutional Affiliation
Thomas P. Monath, MD	Chief Scientific Officer, BioProtection Systems
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

Source: GeoVax, Inc.

Figure 7

HIV SCIENTIFIC ADVISORS

Name	Position/Institutional Affiliation
Henry Hebel, MBA	Aeglea BioTherapeutics
Jeff Ulmer, PhD	GSK
Margaret Liu, MD	ProTherImmune
Rafi Ahmed, PhD	Emory Vaccine Center
Stanley Plotkin, MD	Vaxconsult, LLC

Source: GeoVax, Inc.

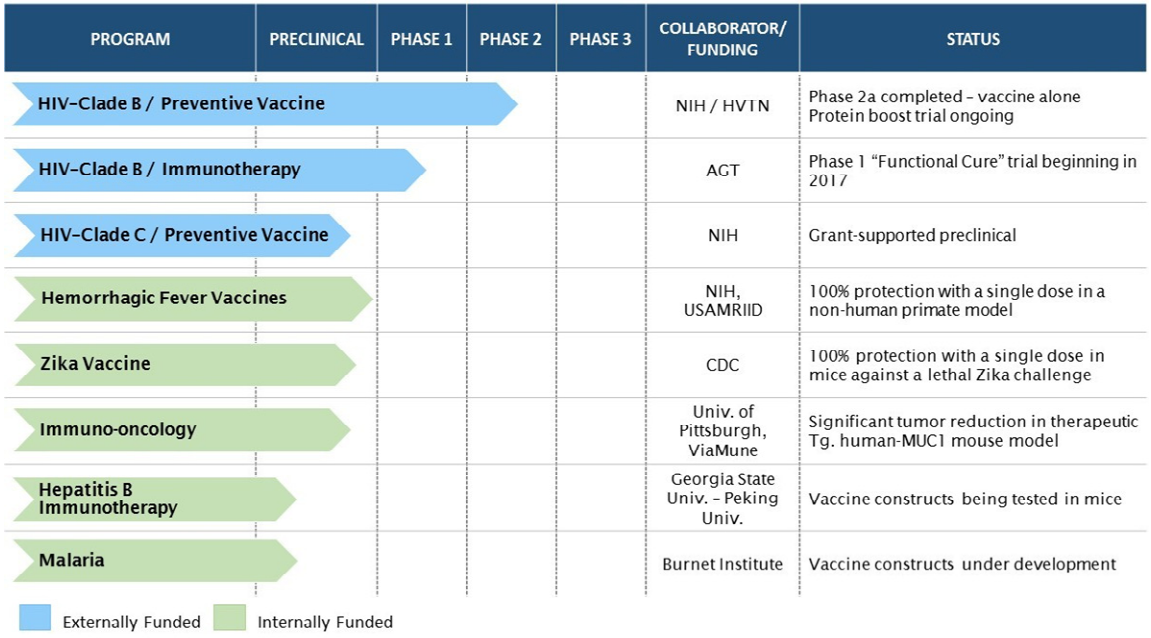
Core Story

GeoVax Labs, Inc. ("GeoVax" or the "Company") is a clinical-stage biotechnology company creating human vaccines against infectious diseases and cancer using an innovative and patented Modified Vaccinia Ankara Virus-Like Particle (MVA-VLP) platform technology. The Company's platform technology supports production of non-infectious virus-like particles (VLPs) from the cells of the individual receiving the vaccine. Producing VLPs in the person being vaccinated mimics a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection should it appear, while maintaining the safety characteristics of a replication-defective vector.

The Company's development programs are focused on vaccines against human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), and malaria. The Company also has programs to develop a vaccine to treat chronic Hepatitis B (HBV) infection and to apply its MVA-VLP technology to cancer immunotherapy (immuno-oncology). GeoVax believes that its technology and vaccine development expertise is well-suited for a variety of human diseases for which there is an unmet medical need. A summary of the Company's pipeline is provided in Figure 8, followed by greater details of each development effort.

Figure 8

TECHNOLOGY PIPELINE



Source: GeoVax, Inc.

As described in the accompany section (pages 22-26), MVA-VLP has distinct advantages, including the ability to use single inoculations to achieve protection for HF and ZIKV, the ability to generate both antibody and T-cell responses, and the production of durable immune responses. Recent preclinical studies have demonstrated complete protection against lethal challenge with Ebola and ZIKV via a single dose vaccination without the need for a boost. The Company's vaccines for HIV, HF viruses, and ZIKV have proven safe, immunogenic, and protective in preclinical trials, with the HIV vaccine demonstrating outstanding safety and immunogenicity in clinical trials, and now being prepared for efficacy testing in the presence and absence of a protein boost.

MVA-VLP AND MVA Platform Technology

Vaccines largely contain agents (antigens) that resemble disease-causing microorganisms, with traditional vaccines typically made of weakened or killed forms of the virus or from its surface proteins. More modern vaccines employ recombinant deoxyribonucleic acid (DNA) technology to generate vaccine antigens in bacteria or cultured cells from specific portions of the DNA sequence of the target pathogen. The antigens that are created are then purified and formulated for use within a vaccine. The most effective of these purified antigens have been non-infectious virus-like particles (VLPs), as established by vaccines for hepatitis B (Merck's Recombivax® and GlaxoSmithKline's [GSK's] Engerix®) and Papilloma viruses (GSK's Cervarix® and Merck's Gardasil®).

GeoVax employs Modified Vaccinia Ankara (MVA) as a vector to express foreign antigens on VLPs generated *in vivo* within vaccinated patients. Its MVA-VLP is the fourth generation MVA vector, licensed from the NIH, which is modified for insertion sites for high expression and transgene stability during manufacture. This platform has shown to be suitable for vaccination against a range of disease agents.

Origination of MVA

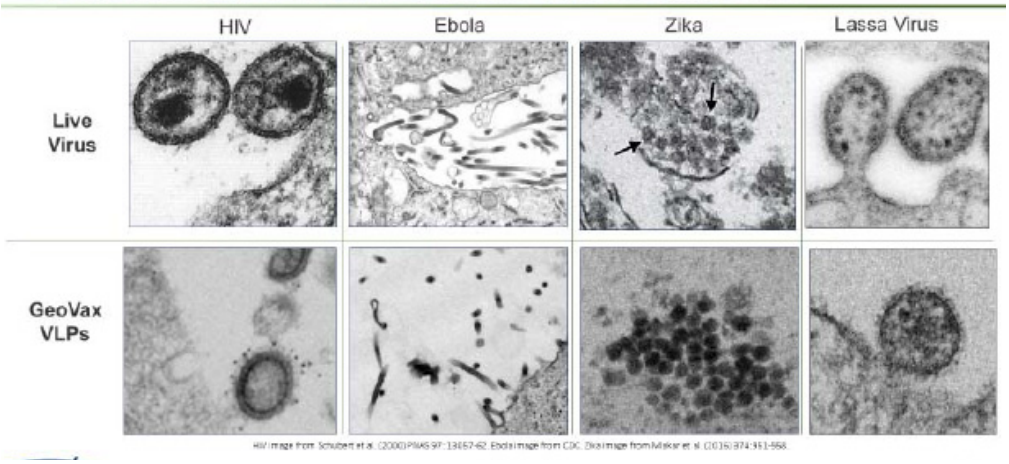
MVA is an attenuated form of the smallpox vaccine developed for use in individuals considered to be at risk for the standard smallpox inoculation. MVA originated from the dermovaccinia strain of vaccinia virus (smallpox vaccine) that was retained for many years at the Ankara Vaccination Station in Turkey via donkey-calf-donkey passages. In 1958, attenuation experiments were conducted by terminal dilutions in chick embryo fibroblasts (CEF). In the process of 570 serial passages in CEF, about 15% of the approximately 200,000 base pair vaccinia virus genome was lost, resulting in the inability to replicate in mammalian cells. After 516 passages, the virus was called "modified vaccinia virus Ankara" and was given to the German State Institution, Bayerische Landesimpfanstalt, where human clinical trials for prevention of smallpox were conducted in about 120,000 people, including those who were immunocompromised. In the prevailing years, roughly 10,000 patients have been exposed to various MVA vaccinations without significant adverse reactions. In addition, GeoVax has conducted four human trials of the MVA-HIV-VLP platform with no serious adverse reactions.

With the advent of recombinant DNA technology and the ability to construct live viral vectors carrying foreign genes, MVA was among the first viral vectors developed due to safety and large carrying capacity for foreign genes that theoretically could occupy the >20,000 base pairs lost during attenuation. The ability to express several foreign viral proteins affords the opportunity to express sufficient foreign proteins to assemble into VLPs. The envelopes of VLPs display the viral glycoproteins and host-specific patterns of glycosylation that mediate critical functions, including the attachment for entry into cells and membrane fusion for release of their genome into the host—making them prime targets for protective antibody responses.

VLPs impersonate the viral presentation of these antigens and thus generate strong and specific immune responses to a wide variety of viruses. Most VLPs exit cells using the pathways of their parent virus. Figure 9 (page 23) illustrates examples of thin section electron micrographs of actual viruses and VLPs for these viruses expressed by GeoVax MVA-VLP vaccines. The MVA vectors can also be used to express proteins that do not form VLPs.

Figure 9

GEOVAX'S VLPs MIMIC NATIVE VIRUS STRUCTURE



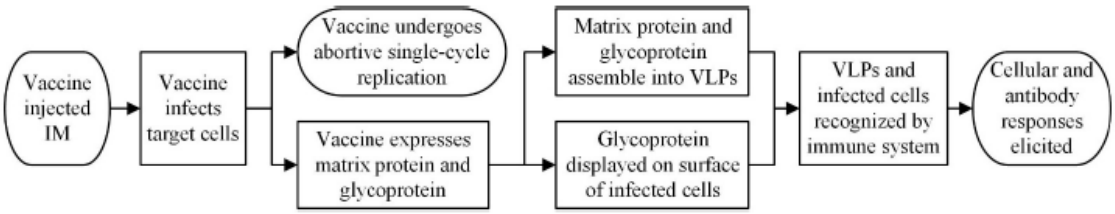
Source: GeoVax, Inc.

GeoVax has worked with Dr. Bernard Moss at NIAID/NIH (https://irp.nih.gov/pi/bernard-moss) for over 15 years on four different generations of MVA vectors to effectively express vaccine proteins that assemble into VLPs. These constructs use different shuttle vectors to introduce foreign genes into MVA and different transcriptional control elements to express the foreign genes in MVA-infected cells. The latest shuttle vectors insert foreign sequences between essential genes for MVA replication, such that the loss of inserts involving adjacent sequences during manufacture (the most frequent genetic mutation associated with loss of vaccine inserts in earlier MVA vectors) results in replication incompetent viruses that do not outgrow the insert-containing viruses.

Each MVA-VLP vaccine has up to two expression cassettes, each expressing one or more antigens selected from pathogens of interest. At a minimum, each vaccine expresses two antigens required for VLP formation; in the case of HIV and HF vaccines, a viral matrix protein and an envelope glycoprotein. GeoVax use a synthetic early/late promoter that provides high (non-lethal) levels of insert expression, which is initiated immediately after infection. The process by which MVA-VLP vaccines elicit cellular and humoral immune responses is shown in Figure 10, assuming intramuscular injection (noting that vaccines administered by other routes function by the same mechanism).

Figure 10

ELICITATION OF IMMUNE RESPONSES BY MVA-VLP VACCINE



Source: GeoVax, Inc.

Assembled spontaneously by vaccine proteins expressed by MVA, VLPs are highly effective vaccine immunogens for enveloped viruses as they elicit antibodies (Abs) to native forms of viral envelope glycoproteins. As well, the array of glycoproteins on dedicated single target VLPs is highly favorable for cross linking B cell receptors and eliciting antibody responses. The expression of matrix proteins in infected cells stimulates $CD8^+$ T cell responses against the relatively conserved matrix proteins broadening protection. The matrix protein and glycoprotein assemble into VLPs within the vaccinated person, providing strong and balanced immune responses and eliminating the need to purify VLPs.

GeoVax's Approach

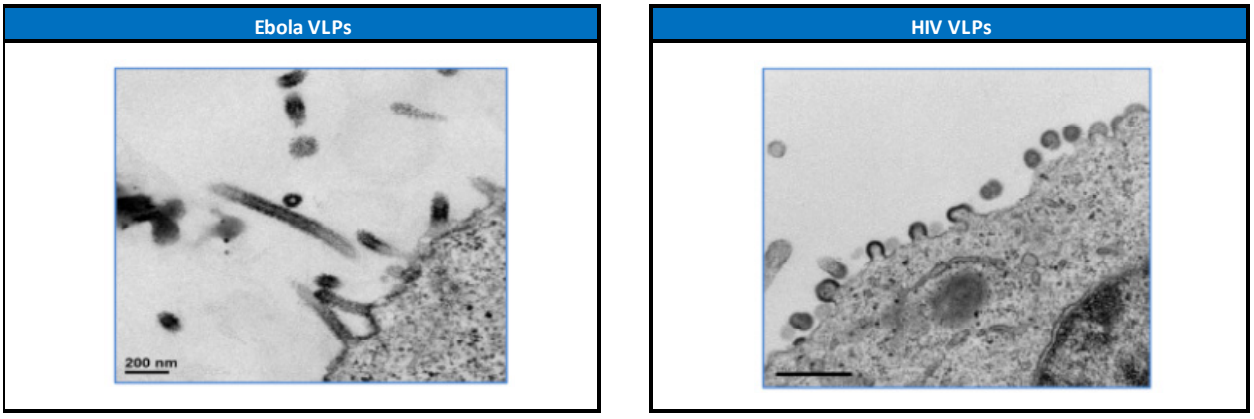
The approach employed by GeoVax uses recombinant DNA or recombinant MVA to produce VLPs within the individual being vaccinated *(in vivo*). Human clinical trials of the Company's HIV vaccines have demonstrated that its VLPs, expressed from the cells of the vaccinated individual, are safe and produce both strong and durable humoral and cellular immune response. With VLPs, the body's immune system is trained to identify and kill the authentic virus if it appears. VLPs further teach the immune system to recognize and kill virus-infected cells to control infection and reduce the length and severity of disease. A significant challenge with VLP-based vaccines is to create them in such a way that the VLPs are recognized by the immune system in the same way as the authentic virus.

When VLPs are produced *in vivo* for enveloped viruses such as HIV, Ebola, Marburg, or Lassa fever, they include the protein antigens along with an envelope consisting of membranes from the vaccinated person's cells. In this manner, they are extremely similar to the virus created within an individual's body during a natural infection. In contrast, VLPs created externally have no envelope or envelopes from the cultured cells (typically hamster or insect cells) used to create them. GeoVax believes its technology is unique and carries specific advantages by producing VLPs that more closely resemble the authentic virus—allowing the body's immune system to more readily identify the virus. By producing VLPs *in vivo*, the Company further circumvents possible purification issues that may be associated with VLP *in vitro* production.

As shown in Figure 11, the Ebola VLPs (left) self-assemble into the rod-like shape of the actual Ebola virus, while the HIV VLPs (right) assume the spherical shape of the actual HIV virus. Thus, both types of VLPs display what GeoVax believes to be the native form of the respective viral envelope glycoproteins—something which the Company feels is critical to producing an effective immune humoral response. MVA was selected by GeoVax for the live viral component of its vaccines due to its well-known safety record along with the vector's ability to carry adequate viral proteins in order to produce VLPs.

Figure 11

ELECTRON MICROGRAPHS SHOWING THE VLPs ELICITED BY GEOVAX VACCINES FROM HUMAN CELLS



Source: GeoVax, Inc.

Proven Delivery Platform

GeoVax has developed an MVA-based VLP platform and successfully tested it in preclinical models for HIV and Ebola vaccines as well as in Phase 1 and Phase 2 clinical trials for an HIV vaccine. The advantages of MVA-VLP versus other MVAs and vaccinia viruses, as summarized in both Figures 12 and 13 (page 26), include: VLP formation, expression of hypo-glycosylated forms of MUC1 in vaccinated individuals, immunogenicity, safety and transgene stability (MUC1 gene is inserted between MVA essential genes so that empty vectors cannot outcompete the vaccine vectors during manufacturing).

Figure 12

COMPETITIVE ADVANTAGE OF MVA-VLP VERSUS OTHER MVAS AND VACCINIA VIRUS

Vector	VLP Formation	Potential for Single-Dose	Non-Replicating	Immunogenicity	No Preexisting Immunity	Transgene Stability	Thermal Stability	Self Adjuvanted
MVA-VLP	++	++	++	++	++	++	++	++
MVA	-	-	++	+	++	?	++	++
Vaccinia	-	++	-	++	+	?	++	++

++ High + Medium - Low

Source: GeoVax, Inc.

Potential Competition

Since the 1980s, MVA vaccines have been under development in academic as well as commercial settings. GeoVax is focused on developing MVA vaccines expressing VLPs, which is unique. Two companies also use MVA as a vaccine vector; Bavarian Nordic and Transgene. The Jenner Institute of Oxford University has an active MVA program in which MVA vaccines are being used primarily as heterologous boosts.

Use of the proposed GeoVax MVA platform affords the follow unique advantages, as summarized in Figure 13.

Figure 13
ADVANTAGES OF THE GEOVAX MVA PLATFORM

Feature	Advantage
Safety in all targeted populations, including immunocompromised individuals	MVA vaccines are expected to be safe in all targeted populations, including the immunocompromised, based on the safety of GeoVax's HIV vaccines in clinical trials. Safety for the MVA vector 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.
Rapid elicitation of protective immunity after a single dose	GeoVax MVA vaccines are expected to elicit protective immunity after a single dose based on GeoVax results against Ebola challenge in macaques. In the Ebola study, antibody responses reached levels generally considered to be protective in under two weeks.
Durability of immune response	GeoVax/NIAID rMVA technology raises highly durable Ab responses, the most durable in the field of vectored HIV vaccines. The Company hypothesizes 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.
Elicitation of both humoral and cellular immune responses	Extensive experience with MVA vectors has demonstrated their ability to raise humoral and cellular immune responses, and has provided strong precedent for safe and effective use against multiple indications.
Rapid production of prototype vaccines	MVA is well established as a vaccine vector, and vaccines can be constructed quickly and easily using standard molecular biology techniques.
High "carrying capacity" to express multiple viral antigens	GeoVax has had success expressing multiple HIV-1 proteins with a single MVA vector. Immunogenicity and safety have been demonstrated for other MVA vaccines expressing up to four antigens from a single construct.
Thermostable formulation	MVA is stable in both liquid and lyophilized dosage forms. Precedent for lyophilization of MVA-vectored vaccines suggest that a lyophilized MVA vaccine would be highly thermostable and suitable for long term storage at refrigerator temperature.
No need for adjuvants	MVA stimulates strong innate immune responses and does not require the use of adjuvants.
Limited pre-existing immunity to vector, suitability for repeated use	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 works, first responders) unvaccinated and without pre-existing immunity. Repeated immunizations with rMVA have been shown to boost responses, including neutralizing antibody
Robust, flexible, and scalable manufacturing processes	A scalable, cell culture-based process, which uses single-use bioreactor technology for robust flexible and scalable upstream manufacturing process combined with downstream process, which uses industry standard product and impurity binding membranes, which also leverages the Company's disposables-based approach for flexible manufacturing. The manufacturing process developed for other MVA-based vaccines has been demonstrated to support most constructs produced to date.
Genetic stability in manufacturing	If appropriately engineered, MVA can reliably be manufactured in Chicken Embryo Fibroblasts (CEFs) or novel continuous cell lines that support scalability as well as greater process consistency and efficiency.

Source: GeoVax, Inc.

Research and Development Programs

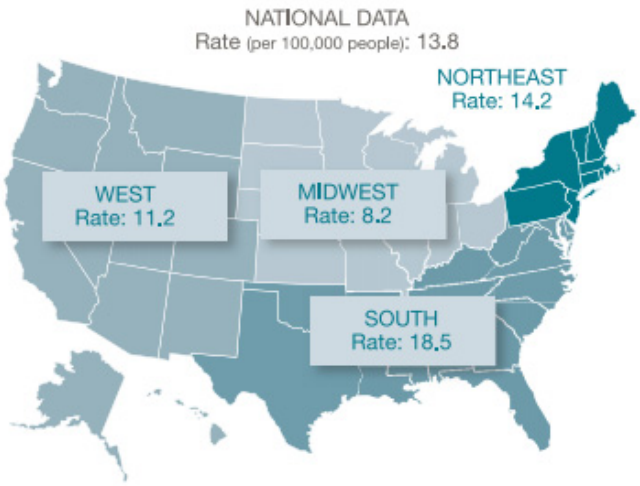
GeoVax's HIV/AIDS Vaccine Program

With an estimated 37 million people living with HIV worldwide and roughly 2.5 million newly infected annually, HIV/AIDS is considered by most in the scientific and medical community to be the most lethal infectious disease in the world and is the 5th leading cause of death globally. Since the start of the HIV pandemic in 1981, about 39 million people infected with virus have died. The U.S. has an estimated 1.2 million individuals infected with HIV, with roughly 50,000 new infections per year—a number that has remained about the same for the past two decades. Worldwide, there are roughly 1.6 million deaths per year, with 15,000 of these in the U.S. The fastest-growing age group in the U.S. to acquire HIV is 13-24-year-olds (growing by roughly 10% per year) with this group expected to have the largest total number of infected individuals in the very near term.

In the U.S., a person has a 1 in 99 chance of being diagnosed with HIV at some point in his or her life. HIV affects every corner of the U.S., though the rate (number of diagnoses per 100,000 people) is highest in the South (18.5 per 100,000 people), followed by the Northeast (14.2), West (11.2) and the Midwest (8.2), as depicted in Figure 14. The majority of new HIV infections happen in men who have sex with men (MSM) of all races and ethnicities, followed by African American heterosexual women. By race/ethnicity overall, African Americans are the most heavily affected population (with 44% of new infections occurring in African-Americans), followed by Latinos.

Figure 14

HIV DIAGNOSES, 2014



Source: U.S. Department of Health and Human ServicesCenters for Disease Control and Prevention

HIV remains a significant health problem in the U.S., particularly among gay and bisexual men, who bear the greatest burden by risk group, and were the only group that did not experience an overall decline in annual HIV infections from 2008 to 2014 (annual infections remained stable at about 26,000 per year). Furthermore, Infections were stable among black gay and bisexual men (about 10,000 per year). This stabilization is a hopeful symbol after more than a decade of increases in these populations; however, progress must be fast-tracked.

Several AIDS-causing HIV virus subtypes, or clades, are found throughout 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 could mean that vaccines or treatments developed against HIV of one clade may be only somewhat effective or in fact, ineffective against HIV of other clades. Therefore, a geographical focus to designing and developing HIV vaccines is important. Figure 15 (page 28) illustrates the global distribution of HIV.

Figure 15
GLOBAL DISTRIBUTION OF HIV

Source: 2012 Report on the Global AIDS Epidemic. UNAIDS/WHO.

HIV Treatment Landscape

Today's treatment approaches for HIV are largely to inhibit viral replication through the use of a combination of drugs, including reverse transcriptase inhibitors, protease inhibitors, integration inhibitors, and inhibitors of cell entry. HIV is prone to genetic changes that can produce strains that are resistant to these approved drugs. After HIV acquires resistance to one drug within a class, it can and often times does become resistant to the entire class—making it impossible to re-establish control of a genetically altered strain by substituting different drugs in the same class. As well, these treatments have substantial limitations, including toxicity, patient non-adherence to the treatment regimens, and cost. Because of this, viruses acquire drug-resistant mutations over time and many patients develop intolerance to the medications or stop taking the medications due to cost, inconvenience, or side effects. Preventing HIV infection is a significant unmet global medical need, even in the U.S. and other first world countries, where there are obtainable antiretroviral therapies.

Importantly, there is no approved HIV vaccine. Current antiretroviral therapies (ARTs) do not eliminate HIV infection and infected individuals must remain on these drugs for their entire lives. Successful long term adherence to therapy is also limited, where only about 30% of infected individuals remain on HIV care with their viral load sufficiently suppressed to prevent spread of HIV. As well, the financial load to U.S. taxpayers for HIV education, prevention, and treatment costs could reach over $20 billion every year.

The International AIDS Vaccine Initiative (IAVI) has stated that the cost and complexity of new treatment advances for HIV/AIDS makes them impracticable for most people, especially in countries where treatment is most necessary. In industrialized countries, where drugs are more readily available, side effects and increased rates of viral resistance have created concerns with regard to their long-term use. That being said, vaccines largely remain the most promising way to eradicate the HIV/AIDS pandemic. Once developed, it is expected that they will be used universally and administered worldwide by healthcare services organizations, including hospitals, medical clinics, the military, prisons, and schools, among others.

History of HIV Vaccines and the RV144 Trial

Since HIV was recognized as the cause of AIDS in 1983, six efficacy trials have been conducted for candidate AIDS vaccines; of these, only one has shown protection. This trial, termed RV144 and conducted in Thailand, achieved 60% efficacy in the initial six months post vaccination. By 12 months, efficacy was declining, and the vaccine was only 31% efficacious through 36 months post vaccination. RV144 was a community-based trial, involving 16,000 individuals from Thailand. An in-depth analysis of this trial led to the hypotheses that:

(i) Antibody to the V1V2 region of the Envelope protein (Env) could directly block infection (Env mediates HIV entry into cells); and

(ii) Antibody to several regions in Env could tag infected cells or virus for destruction by natural killer cells, macrophages, neutrophils, and complement (C').

a. This killing was particularly effective for Ab of the IgG3 subgroup.

b. This killing activity could be blocked by Ab of the IgA isotype in serum.

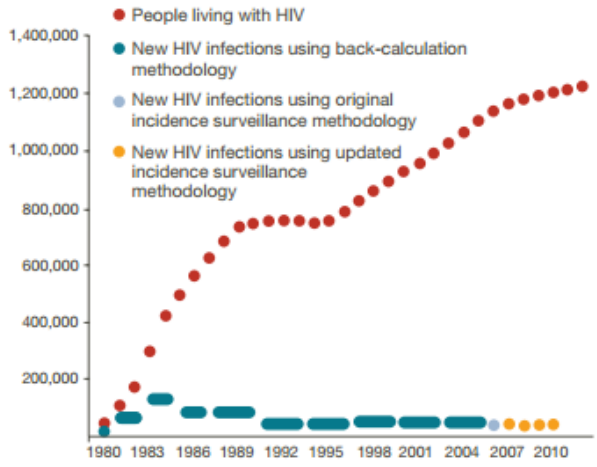
The Need for an HIV/AIDS Vaccine

The CDC estimates that there are approximately 1.2 million people in the U.S. living with HIV, with about one in eight of these individuals unaware that they are infected. Efforts to prevent HIV have led to hopeful declines in new diagnoses among certain populations, including African American women, people who inject drugs, and heterosexuals, along with a steadying in new diagnoses among gay and bisexual men, including African American men. With this steadying, however, up to 50,000 people still become newly infected every year. Beyond the known risk behaviors, there are other social and economic factors that create a higher risk for HIV infection among certain individuals.

According to the CDC, and as illustrated in Figure 16, since the peak of the epidemic in the mid-1980s, the number of new HIV infections every year in the U.S. has been reduced by roughly two-thirds—from roughly 130,000 in 1985 to approximately 50,000 in 2010. Due to treatment advances since the late 1990s, the number of people living with HIV (HIV prevalence) has increased dramatically. However, despite increasing HIV prevalence and more opportunities for HIV transmission, the number of new infections was relatively stable from the mid-1990s through 2010 (Figure 17, page 30).

Figure 16

HIV PREVALENCE AND NEW INFECTIONS, 1980-2012

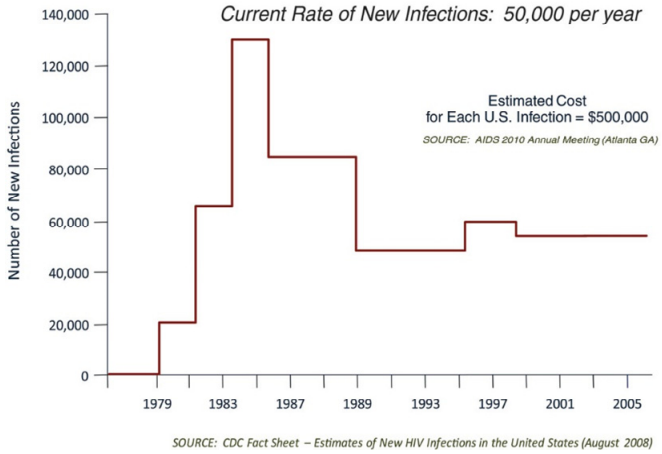


Source: U.S. Department of Health and Human ServicesCenters for Disease Control and Prevention

Figure 17

ESTIMATES FOR NEW HIV INFECTIONS

New HIV Infections in the U.S. Have Remained Virtually Unchanged for the Past 20 Years



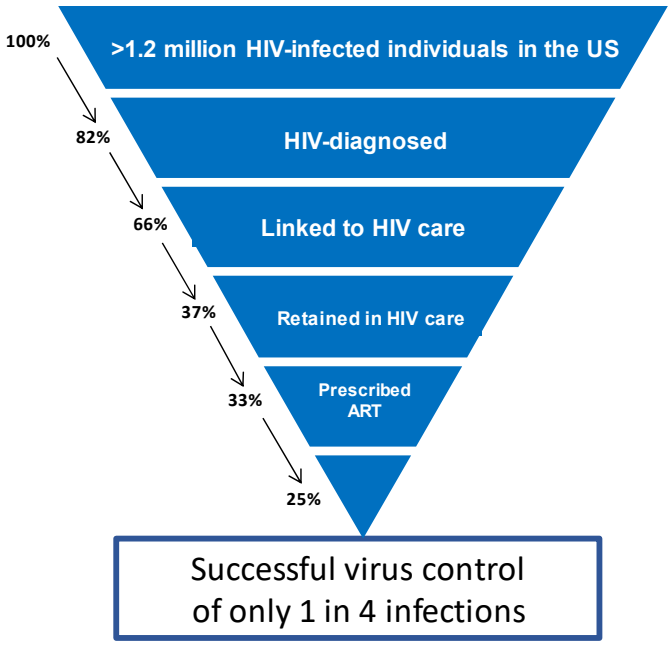
Source: CDC Fact Sheet - Estimates of New HIV Infections in the U.S. (August 2008)

As shown in Figure 18, of the 1.2 million individuals who are known or suspected of being infected with HIV, only 25% ultimately remain in viral control (1 in 4).

Figure 18

HIV IN THE U.S. REMAINS AN UNMET MEDICAL NEED

In the U.S., out of the 1.2 million individuals who are known or suspected of being infected with HIV, only 25% ultimately remain in viral control.



Source: HI Hall et al. JAMA Intern Med 173:1337, 2013

Financial Impacts of HIV

According to the NIH, there is tremendous economic value for HIV prevention in the U.S. given the high cost of treatment. The estimated discounted lifetime cost for individuals who become HIV infected at age 35 is $326,500 (60% for ART medications, 15% for other medications, 25% non-drug costs), compared to $96,700 for individuals who remain uninfected but at high risk for infection. Thus, the medical cost saved by avoiding one HIV infection is $229,800. This number would reach $338,400 if all HIV-infected individuals presented early and remained in care due to the cost savings of avoiding secondary infections (Source: *Medical Care*, Vol. 53(4): 293–301, April 2015)

Other estimates are higher. According to the CDC, for every HIV infection that is prevented, an estimated $379,668 is saved in lifetime medical care—a significant cost-savings for the U.S. federal government that spent an $27.5 billion on domestic HIV research, care, and treatment in 2016, through numerous federal programs and departments, including the **Ryan White Act** (the largest federally funded program in the U.S. for people living with HIV/AIDS), Medicare, Medicaid, the NIH, the CDC, and the U.S. Department of Veterans Affairs (VA), among others (Sources: CDC and the U.S. Department of Health & Human Services' HIV.gov). Additionally, it has been estimated that the U.S. annual loss of productivity due to new HIV infections could be as high as $29.7 billion (Source: *Journal of Acquired Immune Deficiency Syndromes*, Vol. 43(4):451-7, 2006).

GeoVax's Preventive HIV Vaccine Program

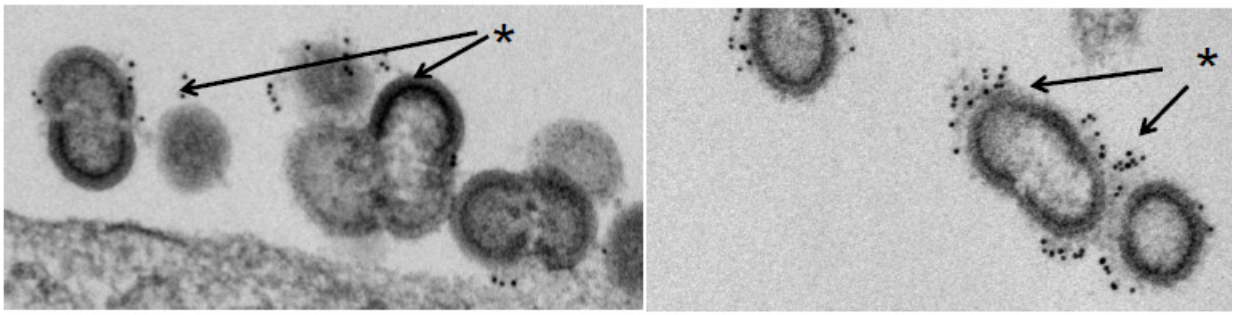
GOVX-B11: A Clade B HIV Vaccine for the Developed World

GeoVax's most advanced vaccine, GOVX-B11, is designed to protect against the clade B subtype of the HIV virus, which is prevalent in the Americas, Western Europe, Japan, and Australia. The vaccine consists of a recombinant DNA vaccine (used to prime immune responses) and a recombinant MVA vaccine (used to boost the primed responses), where both the DNA and MVA vaccines produce non-infectious VLPs in the cells of the vaccinated person (Figure 19). This vaccine was developed by scientists at Emory University, the NIH, and the CDC, and has been licensed by GeoVax for commercialization.

Figure 19

GOVX-B11: A CLADE B HIV VACCINE

VLPs expressed by DNA vaccine	VLPs expressed by MVA vaccine



- DNA prime - MVA boost vaccine
- Vaccine produces VLPs displaying native Env
- Completed Phase 1 and 2a clinical trials

Source: GeoVax, Inc.

In preclinical challenge studies, the vaccine delayed infection of monkeys during repeated rectal challenges. In comparison with the RV144 vaccine (described on page 29), which elicited antibody responses that correlated with a reduced risk for infection in the one partially successful AIDS vaccine trial, GOVX-B11 elicits a more favorable profile of antibody classes (isotypes), a broader specificity of antibody for the viral envelope protein (Env), and a more durable antibody response.

Based on previous trial results from GeoVax's vaccines in non-human primate studies and human trials, the Company believes that its GOVX-B11 vaccine is prepared for pivotal human efficacy trials. The proposed regimen for the Phase 2b efficacy trial consists of DNA delivered into the muscle with a needle and syringe at 0 and 2 months and MVA delivered into the muscle with a needle and syringe at 4, 6, and 10 months (DDMM_M regimen).

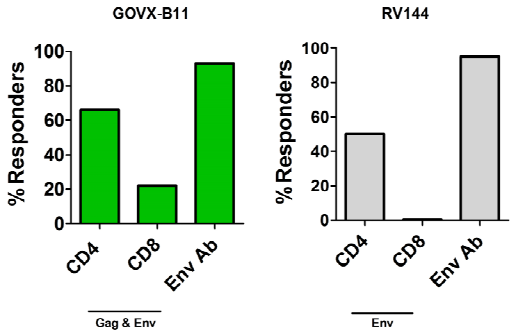
Phase 1 And 2a Clinical Trials

GeoVax's GOVX-B11 vaccine has been tested at various doses and regimens by the HVTN in trials involving approximately 500 participants. In these trials, the vaccine has been extremely well tolerated. In terms of pain and tenderness at the site of inoculation, DNA inoculations have been indistinguishable from those of placebo inoculations. Following MVA inoculations, approximately 70% participants experienced transient mild pain and 25% experienced transient moderate pain at the site of injection. Systemic symptoms were similar to those in placebo recipients.

Figure 20 compares the overall immune responses prompted by the GOVX-B11 vaccine (green bars) and the partially protective RV144 vaccine (gray bars). Data show that both vaccines had largely similar response rates for CD4+ T cells (the helper cells for immune responses); that GOVX-B11 elicited a higher CD8+ T cell response rate than was elicited in RV144; and that both vaccines had similarly high response rates for Ab to the Env of HIV.

Figure 20

OVERALL IMMUNE RESPONSE WITH GOVX-B11 AND RV144

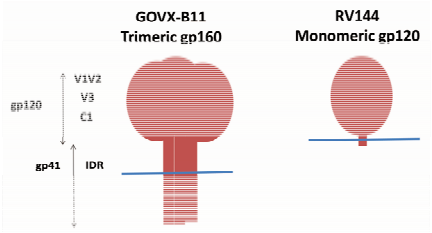


Source: GeoVax, Inc.

As shown in Figure 21, the forms of Env used for eliciting Ab in the GOVX-B11 and RV144 vaccines are very different. The Env displayed by the GOVX-B11 prime is a native trimer of the complete Env glycoprotein (gp160). The gp160 form of Env consists of a gp120 receptor binding subunit and a gp41 stalk subunit that anchors Env in the viral membrane. The gp120 subunit has high sequence variability, whereas gp41 is relatively conserved. In RV144, the Env displayed in the prime consists of the gp120 subunit fused to the transmembrane region of the stalk subunit. Both GOVX-B11 and the RV144 vaccine elicit responses to protective specificities in gp120, designated V1V2, V3 and C1 (Figure 22). However, RV144 elicited higher response rates to the V1V2 region of Env than elicited by GOVX-B11. In contrast, only GOVX-B11 elicited anti-gp41 Ab. This Ab to gp41 included a high response rate to the conserved immunodominant region of gp41, which is a known target for protective Ab-dependent cell-mediated killing.

Figure 21

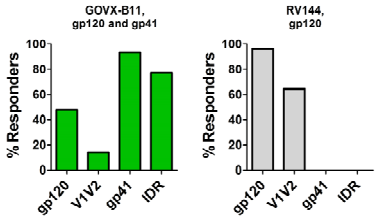
ENV IMMUNOGENS, GOVX-B11 VERSUS RV144 PRIMES



Source: GeoVax, Inc.

Figure 22

AB SPECIFICITY: GOVX-B11 AND RV144



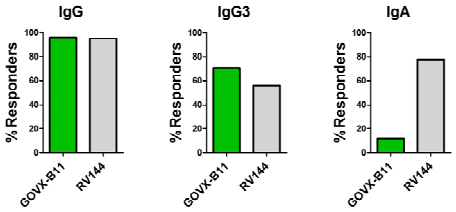
Source: GeoVax, Inc.

Figure 23 shows response rates for IgG1, IgG3 and IgA elicited by GOVX-B11 (green) and in RV144 (grey). In RV144, protection waned as the levels of Ab contracted. Positively, GOVXB11 elicited much more durable Ab than RV144. Antibodies belong to different classes (isotypes) and subgroups within isotypes. These isotypes and subgroups determine how Ab binds lytic factors (C') in serum and signals white blood cells for the engulfment or killing of a virus or infected cell. GOVX-B11 and RV144 both elicited essentially 100% response rates for Env-specific Ab of the IgG1 subgroup of IgGs. IgG1 is a favorable subgroup for initiating cell-mediated killing. GOVX-B11 elicited slightly higher response rates than RV144 for IgG3, the most favorable IgG subgroup for protection. However, more importantly, GOVX-B11 elicited a much lower serum IgA response rate than elicited in RV144 (15% as opposed to 80% response rate). In RV144, Serum IgA showed a strong negative correlation with vaccine efficacy. In RV144, the ratio of IgG3 to IgA in plasma was a strong correlate for reduced risk of infection. The ratio of these response rates is almost 10 times more favorable for GOVX-B11 than RV144 (6.0 as opposed to 0.75).

In Figure 24, Ab response rates are presented as heat maps. Different regions of Env are listed to the left of the heat maps. The heat maps compare response rates at peak vaccine response with those present six months later. Data for GOVX-B11 are presented in the left panels and data for RV144 in the right panels. Reduction in Ab response, indicated by reduction in intensity of color in a given row, is much greater for RV144 than for GOVX-B11. For GOVX-B11, deep rust holds and other colors drop by only one category in the first six months-post vaccination. For RV144, all colors drop by more than one category in this same time period. This difference, in part, reflects the fact that Ab responses to gp41, a major target for Ab elicited by GOVX-B11, were much more durable than Ab responses to gp120, the only Env target for Ab in RV144. However, responses for gp120 were also more durable for GOVX-B11 than in RV144 (4th row from top, Figure 24).

Figure 23

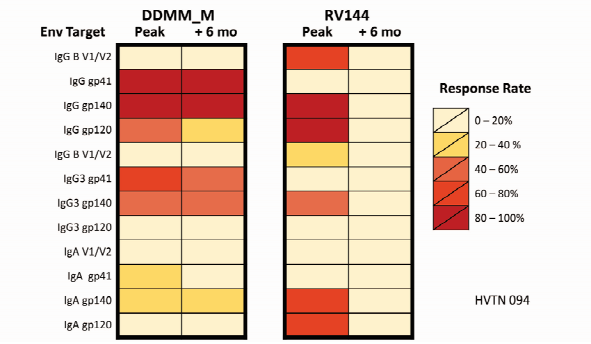
ENV SPECIFIC AB ISOTYPES, CONS GP140 AG



Source: GeoVax, Inc.

Figure 24

AB DURABILITY: GOVX-B11>>RV144

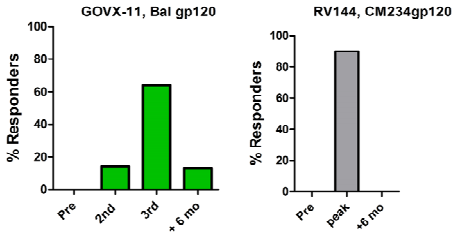


Source: GeoVax, Inc.

Figures 25 and 26 depict the response rates for **antibody dependent cellular cytotoxicity (ADCC)** elicited by the GOVX-B11 vaccine. In Figure 25, ADCC is measured for gp120. Note the increase in the response rate with the third MVA boost. The 64% response rate observed is lower than the 70-90% response rate observed in RV144. However, the GOVX-B11 elicited response was still scoring at six months post the peak vaccine response, whereas the response elicited in RV144 had declined to undetectable levels by this time. Figure 26 shows an assay where responses score both gp120 and gp41 epitopes exposed during viral entry. The response is highest after the third MVA boost. The 85% response rate is also higher than the 64% response rate seen for gp120 alone.

Figure 25

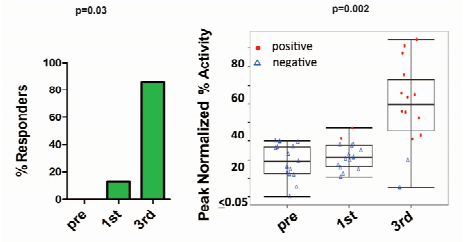
ADCC BOUND GP120, 64% RESPONSE RATE



Source: GeoVax, Inc.

Figure 26

ADCC BOUND VIRION, 85% RESPONSE RATE



Source: GeoVax, Inc.

GeoVax's GOVX-B11 is a VLP-expressing DNA/MVA vaccine that elicits a broad-based Ab and T-cell response capable of providing preclinical protection against a heterologous challenge. Based on the partially successful RV144 trial (described on page 29), the Ab responses elicited by GOVX-B11 have solid features for reducing the risk of infection. These features include exceptional IgG3 to IgA ratios, outstanding durability, multiple target specificities (including the highly conserved immunodominant region of gp41), and excellent activity in assays for antibody-dependent cellular cytotoxicity. Testing of this vaccine in a pivotal efficacy trial is expected to continue to be supported by the NIH.

Summary of Clinical Trials

Figure 27 provides a summary of clinical trials to date for GeoVax's GOVX-B11 clade B Vaccine.

Figure 27
CLINICAL TRIALS, GOVX-B11 CLADE B VACCINE

Trial	Indication	Phase	Prime	Boost	IND held by	Status
HVTN 045 n=22	Preventive	1	GEO-D01	None	NIAID	Completed
HVTN 065 n=120	Preventive	1	GEO-D02	MVA62B	NIAID	Completed
			MVA62B	MVA62B	NIAID	Completed
HVTN 205 n=300	Preventive	2a	GEO-D02	MVA62B	NIAID	Completed
			MVA62B	MVA62B	NIAID	Completed
HVTN 094 n=48	Preventive	1	GEO-D03	MVA62B	NIAID	Completed
GV-TH-01 n=9	Therapeutic	1	GEO-D02	MVA62B	GeoVax	Completed
HVTN 114 n=~100	Preventive	1	Late protein (AIDSVAX) boost of HVTN 205		NIAID	Started Jan 2017
HVTN TBD n= 144	Preventive	1	GEO-D02	MVA62B + gp120 protein	NIAID	Start Q1 2018

Source: GeoVax Labs, Inc.

In January 2017, HVTN began the next human clinical trial (HVTN 114) in the path toward human efficacy trials. HVTN 114 is to test the ability of "late boosts" to increase the antibody responses elicited by GOVX-B11. These "late boosts" will consist of the GeoVax MVA vaccine with or without a gp120 protein vaccine. HVTN 114 is being conducted with funding from NIAID by HVTN. Data produced from this trial is intended to contribute to the design of additional human clinical trials testing GeoVax's vaccine in the presence and absence of the gp120 proteins.

Importantly, during 2016, NIAID awarded GeoVax a Staged Vaccine Development contract of up to $7.8 million for producing the DNA vaccine component of GOVX-B11 in sufficient quantities to use in future clinical trials. The Company is also developing DNA/MVA vaccines designed for use against the clade C subtype of HIV (predominant in South Africa and India). In support of this effort, NIAID has further awarded GeoVax Small Business Innovative Research (SBIR) grants.

GeoVax's HIV Immunotherapy Program

Discovering a cure for HIV/AIDS, while incredibly challenging, is the goal. Present day ART, while very effective at suppressing HIV viral load, cannot eliminate latent forms of HIV that are invisible to the immune system and inaccessible to ART drugs. As well, long-term use of ART can lead to loss of drug effectiveness and can carry significant side effects. Furthermore, lifetime costs for medical treatments for an HIV-infected patient in the U.S. is over $350,000. Consequently, any new treatments that would enable HIV patients the ability to reduce, modify, or discontinue their ART may offer measurable quality of life benefits to the patient and incredible value within the marketplace.

Collaboration with American Gene Technologies International Inc. (AGT)

In March 2017, GeoVax entered into a collaboration with American Gene Technologies International Inc. (AGT)—a developer of advanced genetic technologies to cure major human diseases, such as cancers, metabolic disorders, and infectious diseases, whereby AGT intends to conduct a Phase 1 human clinical trial with the companies' combined technologies. The GeoVax vaccine will be used to stimulate virus-specific CD4 T cells *in vivo*, which will then be harvested from the patient, genetically modified *ex vivo* using AGT's technology, and reinfused to the patient.

The primary objectives of the trial are to assess the safety and efficacy of the therapy, with secondary objectives to assess the immune responses as a measure of efficacy. The overall goal of the program is to develop a functional cure for the HIV infection. In a previous Phase 1 clinical trial (GV-TH-01), GeoVax demonstrated that its vaccine stimulates production of CD4+ T cells in HIV infected patients—the intended use of the MVA-VLP HIV vaccine in the proposed AGT study.

GeoVax's Hemorrhagic Fever (HF) Vaccine Program

Ebola, Sudan, Marburg, and Lassa Fever Viruses

Ebola (EBOV, previously designated as Zaire ebolavirus), Sudan (SUDV), and Marburg viruses (MARV) are the most infectious species of the Filoviridae family, with up to a 90% fatality rate in humans, and epizootic in Central and West Africa with 28 outbreaks since 1976. In particular, the 2013-2016 Ebola outbreak caused 28,616 cases and 11,310 deaths (a 40% fatality rate). On May 12, 2017, a new cluster of Ebola outbreak was detected in Democratic Republic of Congo, resulting in 18 cases and 4 deaths (as of June 8, 2017).

Lassa fever virus (LASV), a member of the **Arenaviridae family**, also causes severe and often fatal hemorrhagic illnesses in an overlapping region with Ebola. In contrast to the unpredictable epidemics of filoviruses, LASV is endemic in West Africa with an annual incidence of over 300,000, and leading to 5,000 to 10,000 deaths. Recent study data suggests that the number of annual LASV cases may in fact be significantly higher, with three million infections and 67,000 deaths (placing upwards of 200 million individuals at risk).

While timing of the next filovirus outbreak is unknown, it is certain that one will occur due to the following factors: the zoonotic nature of the virus, weak healthcare systems, high population mobility, cultural beliefs and burial practices, and endemic infectious diseases such as malaria and Lassa fever that mimic early Ebola symptoms in those at natural risk (and for those not at natural risk from the aforementioned factors, the risk of intentional release by a bioterrorist).

GeoVax believes that an ideal vaccine against major filoviruses and LASV must activate both humoral and cellular arms of the immune system. As well, it should include the induction of antibodies to slow the initial rate of infection and a cellular immune response to help clear the infection. Furthermore, it needs to address strain variations via broad coverage against potential epizootic filovirus strains, and, at the same time, be safe for healthy individuals (e.g. travelers or healthcare workers) as well as those individuals who are immunocompromised (e.g., HIV infected), along with fundamental health issues.

GeoVax's Approach

GeoVax is currently developing a novel **Tetravalent Hemorrhagic Vaccine (THV)** utilizing its established MVA-VLP platform to address the need for a product that can respond to future filovirus epidemics and potentially end LASV infections in West Africa. The Company is addressing strain variations, and induction of broad humoral and cellular response in developing four monovalent vaccines, which perhaps with only a single dose, can be combined to provide broad coverage. The MVA vector has proven to be highly safe as it was originally developed as a smallpox vaccine for use in immunocompromised patients (described on page 22). GeoVax's THV vaccine is expected to not only protect at-risk individuals against EBOV, SUDV, MARV, and LASV, but could reduce or modify the severity of other re-emerging filovirus pathogens, including Bundibugyo, Ivory Coast, and Reston viruses, based on antigenic cross reactivity and the elicitation of T cells to the more conserved matrix proteins. A summary of the development status of GeoVax's THV vaccine is provided in Figure 28 (page 38).

GeoVax's MVA-VLP-TV strategy is to provide a novel and unique combination of advantages to achieve breadth and safety of a LASV vaccine. Beyond the Africa market, GeoVax's development efforts are also intended to prevent the spread of the disease to the U.S., as well as offer protection against possible bioterrorist threats. The initial markets for the TV vaccine are both non-governmental agencies (NGOs), such as the GAVI vaccine alliance and the Bill & Melinda Gates Foundation, along with U.S. and foreign governments. GeoVax's preliminary preclinical studies in rodents and nonhuman primates for its first vaccine candidate (EBOV) has shown 100% protection against a lethal dose of Ebola virus upon a single immunization.

Figure 28

DEVELOPMENT STATUS OF GEOVAX THV VACCINE

Vaccine	Construction	In vitro testing		Efficacy in rodents	Efficacy in NHP
		WB	VLP		
EBOV (MVA/Z-VLP)	✓	✓	✓	✓	✓
SUDV (MVA/S-VLP)	✓	✓	✓		
MARV (MVA/M-VLP)	✓	✓	✓		
LASV (MVA/L-VLP)	✓	✓	✓	✓	

Tasks: Completed TBD

Source: GeoVax Labs, Inc.

The HF Vaccine Landscape

While incredible progress has been made within clinical trials of some experimental vaccines (Figure 29), 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 prove dangerous to immunocompromised individuals (including those with HIV). The adeno-vectored vaccine candidates, which are not as far along, may require relatively cumbersome heterologous prime/boost regimens (e.g. with MVA) to elicit durable protective immunity. The use of Ad5 vectors has also been associated with concerns over increased susceptibility to HIV infection in areas with high HIV incidence. While rVSV-ZEBOV has demonstrated some promise during the 2013-2015 epidemic, it would ultimately be more beneficial to be prepared with a multivalent, safer vaccine that could prevent or alleviate the next epidemic's effects.

There is currently only one vaccine approved for filoviruses or HF, which is for Ebola, though it is being utilized for emergency use by Merck and under regulatory approval by the FDA covering one strain of Ebola (the Zaire strain). Because it is unknown when the next epidemic of Ebola will come and what strain will be epidemic, GeoVax has made a construct and is evaluating this construct in preclinical testing so they are able to create a monovalent vaccine for Lassa, Sudan, Marburg, or Ebola, or mixing them as a cocktail in order to vaccinate the endemic area and provide universal protection.

Figure 29

COMPARISON OF CURRENT HFV VACCINE TECHNOLOGIES

Vaccine*	Target Pathogens	Antigen	VLPs	Non Replicating	Efficient Homologous Prime-Boost	Required Dose	Self Adjuvanted	Phase
MVA-VLP GOVX-E303	TV (EBOV, SUDV, MARV, LASV)	Bivalent GP, VP40/Z	Formed in vivo	+	+	High	+	Pre-clinic
Rec. protein Novavax	EBOV	Monovalent GP	Synthetic Liposomes	+	+	High	-	1
Ad26	EBOV	Monovalent GP	-	+	-	Very High	+	2b
rVSV-ZEBO NewLink/Merck	EBOV	Monovalent GP	-	-	+	Medium	+	3
DNA Bivalent	BI (EBOV, SUDV)	Monovalent GP	-	+	+	High	-	1
ChAd3-ZEBOV, MVA GSK (Bivalent)	BI (EBOV, SUDV)	Monovalent GP	-	+	-	Very High	+	2/3
MVA-BN Filo, BN	Tri (EBOV, SUDV, MARV)	Monovalent GP	-	+	-	High	+	2
Ad26/MVA-BN Filo NIH	Tri (EBOV, SUDV, MARV)	Monovalent GP	-	+	-	Very High	+	1

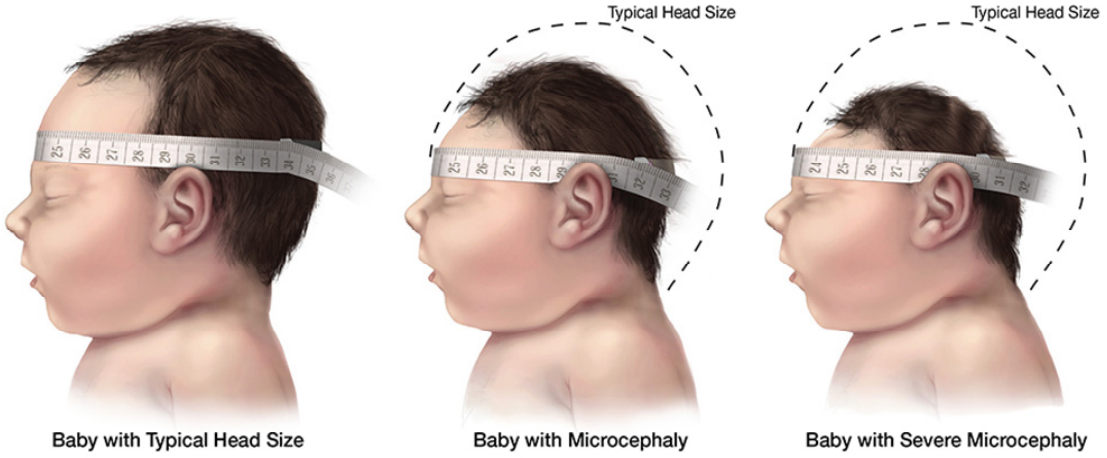
Source: GeoVax Labs, Inc.

GeoVax's Zika Virus (ZIKV) Vaccine Program

Zika Virus (ZIKV)

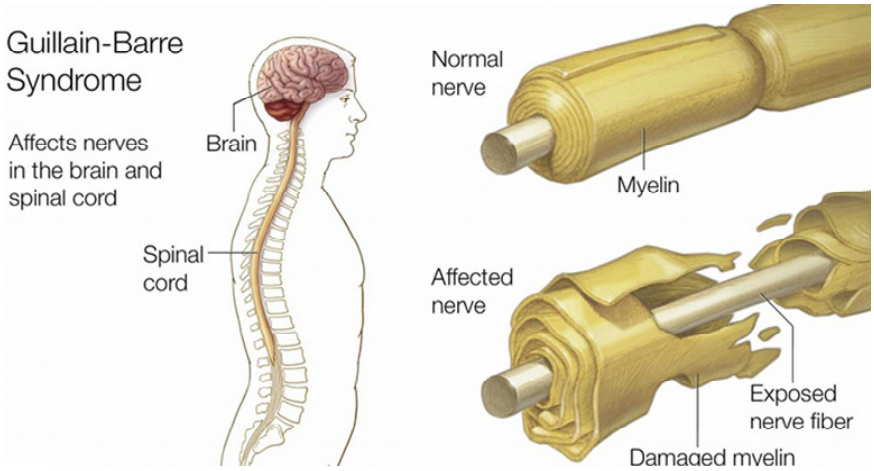
Caused by the Zika virus (ZIKV), Zika disease is an emerging rapidly-spreading mosquito-borne infectious disease that has been linked to an increase in microcephaly in infants, a condition in which a baby's head is significantly smaller than expected (Figure 30), often due to abnormal brain development, and Guillain-Barré syndrome in adults, a condition in which the immune system attacks the nerves (Figure 31). 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. Protection against mosquito bites and vector control remain the key preventive measures currently available to fight ZIKV infections.

Figure 30
CONGENITAL ZIKA SYNDROME



Source: Centers for Disease Control and Prevention.

Figure 31
GUILLAIN-BARRE SYNDROME

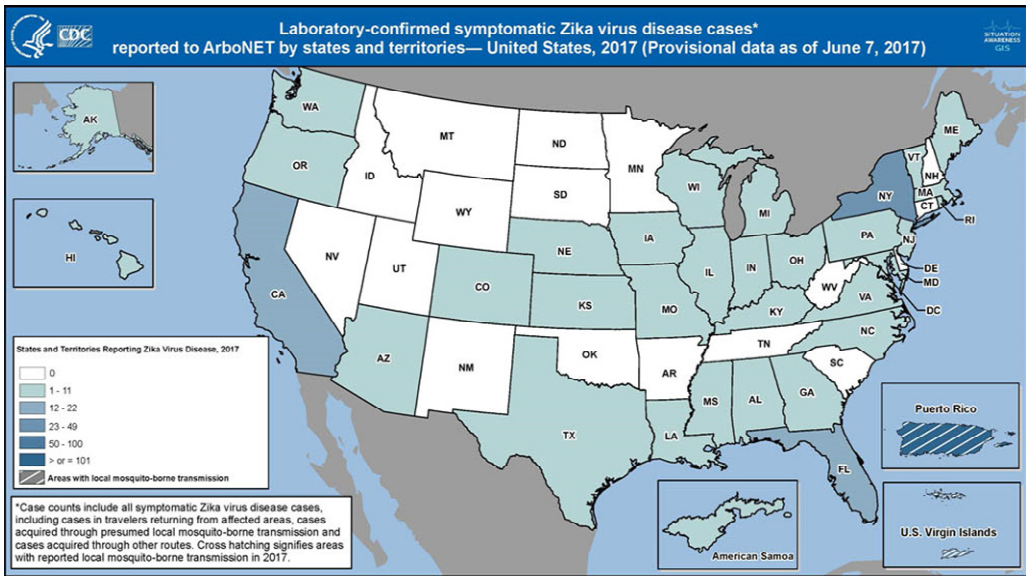


Source: Centers for Disease Control and Prevention.

As of June 7, 2017, there have been 5,283 symptomatic ZIKV disease cases reported in the U.S., including 5,011 cases in travelers returning from affected areas, 224 cases acquired through presumed local mosquito-borne transmission; and 48 cases acquired through other routes, including sexual transmission (N=46), laboratory transmission (N=1), and person-to-person through an unknown route (N=1). In U.S. territories, there have been 36,587 symptomatic ZIKV disease cases reported, including 143 cases in travelers returning from affected areas and 36,444 cases acquired through presumed local mosquito-borne transmission. In 2016, there were 58 liveborn with birth defect from ZIKV infected pregnant mothers in U.S. states. Figure 32 depicts Zika cases by state and territory.

Figure 32

ZIKA CASES BY STATE AND TERRITORY



Source: Centers for Disease Control and Prevention.

History of ZIKV

First discovered in 1947 in the Zika forest of Uganda, ZIKV was considered only a minor public health concern for 60 years. In 2007, a large epidemic occurred on Yap Island in Micronesia, followed by a 2013 outbreak in French Micronesia. Currently, due to its arrival and rapid spread across the Americas, it has developed into a serious threat with pandemic potential—raising the profile of Zika as an emerging infectious disease. ZIKV is transmitted to people mainly by infected *Aedes* mosquitoes (*A. aegypti* and *A. albopictus*), the same species that transmit dengue and chikungunya viruses. In approximately 80% of cases, ZIKV infection is asymptomatic. In those with symptoms, however, these historically have been mild—usually lasting no more than one week—and include fever, rash, arthralgia, and conjunctivitis. The most recent Zika epidemic, however, has shown this disturbing and serious link between the Zika infection and fetal brain abnormalities, such as microcephaly.

Current Development Efforts

There are no approved preventive or therapeutic products on the market to address the Zika epidemic, which was declared an International Public Health Emergency by WHO in February 2016. Because of this, public health officials have recommended delaying pregnancies and following basic supportive care (fluids, rest, and acetaminophen) should a person become infected. Development of a safe and effective vaccine against ZIKV is an urgent global health priority due to the virus' rapid spread and its ability to cause serious complications. Multiple vaccines are in development (detailed in Figure 35 (page 43), *The Zika Vaccine Landscape*); however, all known vaccines in advanced development are based on viral envelope proteins (PrM and E), potentially capable of inducing Antibody Dependent Enhancement (ADE) of infection—a phenomenon experienced with other flaviviruses that have tropism for myeloid leukocytes and recently documented in ZIKV.

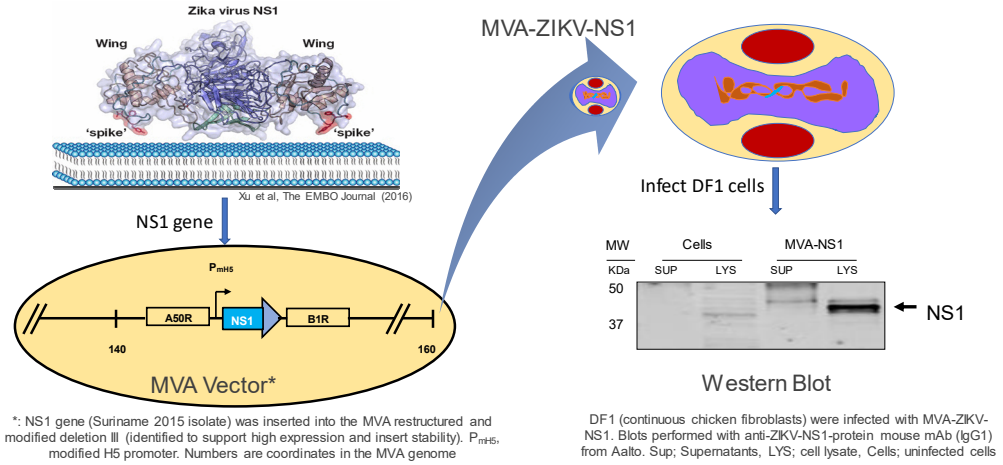
GeoVax's Approach

GEO-ZM02: Zika Vaccine

As a medical countermeasure to Zika, GeoVax is developing its GEO-ZM02 vaccine built in the Company's MVA platform, which has demonstrated great promise in the Company's HIV and Ebola vaccines. This vaccine has demonstrated 100% protection against lethal challenge after a single dose in a rigorous mouse model. GEO-ZM02 has the unique advantage of conferring protection using a ZIKV antigen (NS1), which does not carry the risk of ADE. Moreover, the NS1 protein is abundantly secreted into the blood of a ZIKV-infected individual and plays a critical role in flavivirus acquisition by mosquitoes by overcoming the immune barrier of the mosquito midgut. Thus, GEO-ZM02 may not only protect populations against ZIKV infections but could also importantly block further transmission of ZIKV from humans back to its mosquito host.

Using the Company's platform technology, an MVA vaccine that expresses ZIKV NS1 in host cells was constructed, leading to both endogenous expression and secretion of NS1 (the Company's current candidate, GEO-ZM02). The design of these vaccines is illustrated in Figure 33. The MVA vaccine candidates were constructed using shuttle vectors developed in the laboratory of Dr. Bernard Moss (described on page 23) and licensed by the NIAID to GeoVax for use with ZIKV. These shuttle vectors have proven to give stable vaccine inserts with high, non-toxic, levels of expression in the Company's work with HIV and HF virus vaccines.

Figure 33
MVA-NS1 VACCINE



*: NS1 gene (Suriname 2015 isolate) was inserted into the MVA restructured and modified deletion III (identified to support high expression and insert stability). P_{mH5}, modified H5 promoter. Numbers are coordinates in the MVA genome

DF1 (continuous chicken fibroblasts) were infected with MVA-ZIKV-NS1. Blots performed with anti-ZIKV-NS1-protein mouse mAb (IgG1) from Aalto. Sup; Supernatants, LYS; cell lysate, Cells; uninfected cells

Source: GeoVax, Inc.

NS1 was inserted into a restructured and modified deletion III between the A50R and B1R genes. Inserted sequences have been edited for vaccinia-specific terminators to remove motifs that could lead to premature termination. The insert is placed under the modified H5 early/late vaccinia promoter. Vectors were prepared in a dedicated room at GeoVax, with full traceability and complete documentation of all steps using Bovine Spongiform encephalopathy/Transmissible Spongiform Encephalopathy (BSE/TSE)-free raw materials. The expression of full-length NS1 was confirmed by western blot (WB) shown in Figure 33 (right).

To date, GeoVax's MVA platform has shown a tremendous safety record, which is key due to the need to include women of child-bearing age and newborns among the vaccinated population. The Company expects its features to lead to a safe, highly-effective vaccine that is appropriate to deliver a potent immunity against ZIKV infection. GeoVax believes that its approach is in line with WHO's recommendation as MVA-ZIKV vaccines match the safety profile of non-live/inactivated vaccines without the need for an adjuvant, and additionally offer the potential for high levels of immunogenicity and efficacy following a single dose.

MVA vaccines are replication competent in avian cells used for vaccine production, yet replication deficient in mammalian cells making them safe for humans, including immunocompromised individuals. MVA has been shown to be safe in >120,000 individuals, including HIV-infected individuals, and has shown no reproductive toxicity in studies in pregnant rats. Figure 34 provides a summary of those traits that would make the ideal Zika vaccine candidate.

Figure 34

AN IDEAL ZIKA VACCINE

- Safe for use in pregnant women, infants, elderly, and immune compromised
- Induces rapid onset of humoral and cellular responses
- Generates durable protective responses
- Protects after a single dose
- Does not bear the risk of ADE
- Block transmission of ZIKV in mosquito vector
- Cost-effective manufacturing
- Does not require an adjuvant
- Able to be lyophilized

Source: GeoVax Labs, Inc.

With Proof of Concept (PoC) demonstrated, GeoVax's GEO-ZM02 vaccine is now ready for scale-up and cGMP production followed by good laboratory practice (GLP) safety testing and Phase 1 clinical studies. With a network of partners/collaborators, including the contract manufacturing organization (CMO) Emergent BioSolutions, GeoVax has the capability to advance GEO-ZM02 into clinical trials.

GeoVax has collaborations with the CDC to develop a lethal challenge model in mice to test this vaccine candidate. To date, GeoVax has demonstrated 100% protection in mice against a lethal challenge after a single dose vaccination. ZIKV and reagents are supplied by the University of Texas Medical Branch (UTMB).

Recent Announcement that Single Dose of Zika Vaccine Provided 100% Protection in Lethal Challenge Model with a Single Immunization

In early June 2017, GeoVax presented research showing that a single dose of its Zika vaccine gave 100% protection in mice challenged with a lethal dose of ZIKV. This announcement is important as it represents the first report of a Zika vaccine based on the ZIKV NS1 protein, and single-dose protection against ZIKV using an immunocompetent lethal mouse challenge model. Details of the study were presented by Farshad Guirakhoo, Ph.D., GeoVax's chief scientific officer (biography on page 17), at the American Society for Microbiology (ASM) Microbe conference in New Orleans—a showcases of the best microbial sciences in the world, including seven tracks, 500+ sessions and 575+ speakers from 96 countries covering topics from basic science to translation and application. The vaccine was tested at the CDC in Fort Collins, CO with funding by a grant from the CDC. In the study, outbred immunocompetent mice were exposed to a lethal challenge dose of ZIKV delivered directly into the brain. A single dose of GeoVax's NS1 vaccine candidate protected 100% of vaccinated animals. In contrast, 80-90% of sham-immunized control animals died within 7-10 days.

The Zika Vaccine Landscape

Analysis of the ZIKV vaccine landscape (summarized in Figure 35) by the WHO revealed that more than 18 entities have an active ZIKV vaccine program, most of which use either inactivated (PIV, e.g. Bharat, NewLink), live-attenuated (LAV, e.g. NIH, CDC, Sanofi), or both approaches in parallel (Bio-Manguinhos/Fiocruz, Butantan). Both PIV and LAV approaches have proven successful for other flavivirus vaccines. PIV, however, are expensive, poorly immunogenic (requiring adjuvants), require two doses for primary immunizations, and generally boosters every 3-5 years, making PIV impractical for broad use in large epidemics that require rapid immunity. For LAV, determinants of ZIKV pathogenicity and neurovirulence must be determined to strike a balance between safety and immunogenicity, expanding development timelines. LAV also require extensive safety testing before use in pregnant women and infants.

Figure 35
ZIKA VACCINE LANDSCAPE

Vaccine/ Vector	Developer/s	Antigens	Non Replicating	Inherent safety	Potential single- dose	Durable immunity	Self Adjuvant	Lack of ADE risk	Platform approved in humans
MVA	GeoVax	NS1	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Measles	Themis	prME	No	Yes	Yes	Yes	Yes	No	Yes
Chimeric/live	NIAID, Sanofi, CDC, Fiocruz, Takeda	Whole virus	No	No	Yes	Yes	Yes	No	Yes
DNA, RNA	Inovio, NIH/GSK	prME	Yes	Yes	Y/N	Y/N	Y/N	No	No
PIV	NewLink, Bharat, Butantan	Whole virions	Yes	Yes	No	Y/N	No	No	Yes

Source: GeoVax Labs, Inc.

The U.S. Government (USG) is currently funding the development of several vaccine candidates. These include a live attenuated vaccine from the Instituto Butantan; whole-virus inactivated vaccines from Sanofi Pasteur, Takeda, and Walter Reed; nucleic acid vaccines from GlaxoSmithKline, the National Institutes of Health Vaccine Research Center, and Moderna Therapeutics; and a recombinant viral vaccine from Harvard. Notably, all the vaccine candidates being advanced with USG funding include the E protein; therefore, all have the possibility to induce ADE. Though vaccines containing or expressing the ZIKV E protein are likely to be immunogenic and well tolerated, all such vaccines may induce ADE.

An alternative product that cannot induce ADE would be a highly valuable tool in the USG's portfolio. Another benefit of an NS1-based vaccine for Zika is its potential to block the transmission of the virus in mosquitos since the NS1 protein enables ZIKV replication by disabling mosquitoes' innate immune response. Thus, the NS1-based vaccine could protect both humans and mosquitoes against Zika infections, providing higher vaccine efficacy at lower coverage. The GeoVax NS1-expressing vaccine, therefore, meets a need that is not met by any of the other vaccines currently being advanced with USG funding.

Financial Impact

The impact from Zika could prove tremendous—ranging from $183 million to $1.2 billion—depending on infection rates from several at-risk states in the south. The key problem is that there is no active surveillance for Zika along the Gulf Coast, so it is unknown as to the true number of cases that occurred last year. This is likely to remain unknown until babies are born with birth defects.

GeoVax's Cancer Immunotherapy Program

Cancer Immunotherapy

Surpassed only by heart disease, cancer is the second most common cause of death in the U.S., where by 2030, there will be approximately 22 million new cases per year. There is, at present, only one FDA-approved cancer vaccine, PROVENGE® (sipuleucel-T), a personalized therapy for prostate cancer patients, which prolongs survival times by approximately four months.

Overview of MVA-VLP vectors for Cancer Immunotherapy

Based on the favorable efficacy and low side effect profile of immunotherapies, the field of immune-oncology has received greater attention. In particular, the recent development of monoclonal antibodies (Mabs) that are immune checkpoint inhibitors (ICIs) has further advanced the field. 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), which act as a mechanism of immune resistance, especially against T cells that are specific for tumor antigens and can kill cancer cells. ICIs block the interaction of immune checkpoints with their ligands on tumor cells, allowing poorly functional T cells to resume proliferation and cytokine production, thus killing tumor cells.

The first known immune checkpoints were Cytotoxic T-Lymphocyte-Associated antigen 4 (CTLA4), programmed cell death protein 1 (PD1), and the PD1 ligand (PDL1). The approval of the first anti CTLA4 Mab, YERVOY® (ipilimumab), in 2011 for treatment of melanoma, was followed by anti PD1 Mabs, OPDIVO® (nivolumab) and KEYTRUDA® (pembrolizumab) in 2014 for melanoma and then in 2015 for non-small cell lung cancer (NSCLC). ICIs are currently being combined with many types of oncology products, such as chemotherapies, small molecules, therapeutic vaccines, cell-based therapies, or even with other ICIs, in order to demonstrate improvements in safety and efficacy over monotherapies.

Unlike conventional therapies (e.g., radiation, chemotherapy, antibody, etc.), cancer vaccines have the potential to induce responses that not only result in the control and clearance of tumors but also to establish immunological memory that can suppress and prevent tumor recurrence. Convenience, safety, and low toxicity of cancer vaccines make them invaluable tools to be included in future immunotherapy approaches for treating tumors. Currently, there are only a few vectored cancer vaccines being tested in combination with ICIs, all of which are in early clinical stages. A summary of select immunotherapy development efforts, where information has been made available, is provided in Figure 36 (page 46).

GeoVax's Approach

GeoVax's approach to cancer immunotherapy is to utilize a combination approach, for which each component has already shown some promising results in preclinical models. A selected vaccine regimen will be used to elicit antibody and T cell responses to MUC1 in patients without the need to remove or pretreat any plasma fractions. Prior to vaccination, patients will undergo their standard of care (SOC) treatments, such as chemotherapy or radiation. ICIs will be used at reduced doses or frequencies (to reduce adverse reactions and costs) to activate suppressed T cells and enable the patients' immune system to respond to VLP-delivered MUC1 antigens, with the goal of causing tumor regression.

Upon completion of Proof of Concept (PoC) studies in mice, GeoVax now is exploring the addition of other tumor-associated antigens (TAAs) to its vaccine candidate to determine whether such antigens could further enhance efficacy for specific cancer indications. An IND with the FDA along with the initiation of a Phase 1 trial is anticipated by 2019.

GeoVax has established a collaboration with Dr. Olivera Finn, a leading expert in cancer immunotherapy at the University of Pittsburgh. She was the first to show that many tumors express an abnormal form of cell surface-associated Mucin 1 (MUC1) protein that could be recognized by the immune system as foreign. Given this, GeoVax is using its MVA-VLP vaccine platform to deliver abnormal forms of MUC1 (e.g., hypo-glycosylated forms found in tumors), with the goal of raising protective anti-tumor antibodies and T cell responses in cancer patients. The Company is also collaborating with ViaMune that has developed a fully synthetic MUC1 vaccine candidate (MTI) for the treatment of cancer. In this collaboration, the Company is assessing each company's vaccine platform separately, and in combination, with the goal of developing a tumor MUC1 vaccine that can produce a broad spectrum of anti-tumor antibody and T cell responses. The resulting MUC1 vaccine will be combined with ICIs as a novel vaccination strategy for cancer patients with advanced MUC1+ tumors.

The Company has produced an MVA-VLP-Muc1 vaccine candidate, demonstrated VLP production by electron microscopy using MUC1 immunogold staining, as well as has shown that the VLPs express a hypo-glycosylated form of MUC1 in human cell lines. Preclinical PoC is being established via the Company's collaboration with ViaMune and University of North Carolina at Charlotte, using engineered murine human MUC1 models. Contingent on the outcome of the preclinical studies, GeoVax believes that it may be able to file an IND with the FDA in two years and subsequently initiate a Phase 1 trial in a limited number of oncology patients.

Well Documented Antigenic Target

GeoVax' novel therapeutic cancer vaccine strategy is based on the MVA-VLP platform to deliver the TAA MUC1 in a highly immunogenic format (e.g. VLP), in combination with SOC and ICIs. The MVA-VLP-MUC1 recombinant virus was created to express: a sequence consisting of the MUC1 extracellular ectodomain with multiple variable number of tandem repeats (VNTRs), the transmembrane domain of a matrix protein, and the intracellular domain of MUC1. The ectodomain of MUC1 is expressed in cells and on the surface of VLPs, and serves as a target antigen for the vaccine.

Among healthy individuals, MUC1 transmembrane protein is heavily glycosylated, lines the epithelial surfaces, protects the body from pathogens, and is involved in cell signaling. Over-expression and hypo-glycosylation of MUC1 is associated with multiple myeloma as well as all human adenocarcinomas (including breast, colon, ovarian, prostate, pancreatic, and lung). Because MUC1 is abnormally glycosylated in tumor cells, it is subject to immune surveillance resulting in spontaneous induction of anti-tumor antibodies and T cells.

The presence of antibodies to altered MUC1 at diagnosis is associated with clinical benefits. Since its discovery as a TAA, MUC1 has been used as a promising antigen for passive (e.g., antibody) and active immunizations (e.g. vaccines) in a number of clinical trials with some success, though this success has been limited by the immunosuppressive microenvironment of advanced cancer that affects cytotoxic and helper T cell responses, upregulation of checkpoint inhibitors (e.g. high expression of PDL1 by tumors and PD1 on responding T cells), and consequently, production of low levels of anti-MUC1 IgG antibodies.

Immunizations against MUC1 induces some CD8+ and CD4+ T cell responses in humans and causes tumor regression in preclinical models. DNA vaccination with MUC1 has also shown efficacy in preclinical models. Moreover, MVA delivered MUC1 +IL2 (TG4010) was tested in non-small cell lung cancer (NSCLC), prostate, renal cell carcinoma (RCC), and lung cancer, which yielded the best results (6-month improvement versus chemotherapy thought only in Phase 2 studies). MUC1 antigen is now being tested in >60 trials, though most are early phase trials, with only a few in Phase 2b and none in combination with a DNA vaccine, vectored VLP, or ICIs.

Because both MVA-MUC1 and newly approved ICIs have shown only modest efficacy as monotherapies for cancer treatment, GeoVax intends to combine its MVA-VLP-MUC1 vaccine with ViaMune's synthetic peptide vaccine (MTI), SOC, and ICIs to maximize success. There is currently no company in clinical testing utilizing a MVA-VLP vector approach in combination with a synthetic MUC1 vaccine, SOC (e.g. chemotherapy and radiation), and ICIs. This combination approach may enhance efficacy while reducing adverse reactions due to extensive use of SOC and ICIs.

Market Opportunity for GeoVax's Solution

The cancer vaccine market is set to almost triple from $2.5 billion in 2015 to $7.5 billion by 2022, representing a compounded annual growth rate (CAGR) of 16.93% (Source: GBI Research). Therapeutic vaccines (a type of immunotherapy with lower toxicity than traditional chemotherapies) are expected to increase the overall survival of poor-performance-status patients and enable increased rounds of treatments. Therapeutic vaccines are a relatively new form of cancer treatment, with the first FDA approval granted to PROVENGE® in 2010 (described below). Prophylactic vaccines have not yet faced patent expiry, where the threat of generics/biosimilars would restrict revenue growth. In certain instances, ICIs have demonstrated stronger efficacy than cancer vaccines. While cancer vaccines may have more favorable safety profiles than ICIs, they may be promising candidates for combination therapy in the future, which could substantially enhance sales.

The therapeutics portion represents the most rapidly expanding area, expected to grow from $48 million in 2010 to more than $4.8 billion by the end of 2018 (Source: GlobalData Healthcare). As the only FDA approved cancer vaccine, PROVENGE® is indicated to treat castration-resistant prostate cancer, and is a one patient/one vaccine approach, which cannot be produced at large scale manufacturing required for a worldwide distribution. Moreover, PROVENGE® requires complex manufacturing involving multiple leukaphereses of blood, transferring blood to manufacturing facilities, stimulation of antigen presenting cells *in vitro*, and infusion of autologous stimulated cells into the donor patient. Recently, cancer immunotherapies have received a boost with the approval of ICIs, such as YERVOY® (an anti CTLA4 Mab) as well as OPDIVO® and KEYTRUDA® (anti PD1 Mabs) originally for melanoma and more recently for NSCLC. Both the cancer vaccine PROVENGE® and ICIs prolong patients' survival time by only 4-6 months and are expensive (>$100,000 per patient per year), limiting their broad applications. ICIs also cause various adverse reactions at the same or higher rate than seen in chemotherapy patients.

Market Development Efforts (MUC1-Positive Cancer Types)

While other cancer vaccines have been tested in advanced clinical trials, none have had a significant impact on tumor regression or overall survival. TG4010 (MVAMUC1+ IL2) and Prostvac (vaccinia-PSA+TRICOM), both poxvirus-based prostate cancer vaccines being tested in Phase 2/3 trials may not be highly effective without the addition of ICIs. Numerous Phase 1 clinical trials are currently underway evaluating combinations of ICIs with other cancer drugs, chemotherapies, small molecules, and vaccines. For cancer, there are a significant number of companies developing various types of therapeutic vaccines or other immunotherapy approaches to treat cancer including, among others, Advaxis, Immune Design, Oncothyreon, Bavarian Nordic, Roche Pharmaceuticals, Merck & Co, Bristol Myers Squibb, AstraZeneca plc, and Medimmune, LLC. Figure 36 provides a summary of MUC1 cancer vaccine candidates, where information has been made available.

Figure 36

MUC1 CANCER VACCINE COMPETITIVE LANDSCAPE

Vaccine	Sponsor	Form	Target	Status
MUC1 Peptide Vaccine	Olivera Finn	100-mer MUC1 peptide + PolyIC adjuvant	NSCLC	In Phase 1 & 2 clinical trials
MUC1 DC Vaccine	Olivera Finn	Dendritic cells pulsed with MUC1 peptides	Patients with resected pancreatic and biliary tumors	Successful Phase 1/2 clinical trial
PANVAC-VF	Therion Biologics	Poxvirus-express Muc1 & CEA & costimulatory molecules	Metastatic pancreatic cancer	Dropped product in Phase 3 clinical trials after failing to meet primary efficacy endpoint
TG4010	Regional Center for Lung Disease, Poznan, Poland	Bivalent MVA encoding MUC1 + IL2	NSCLC	Inadequately effective in Phase 2 clinical trial; now back in pre-clinical development
Stimuvax (Tecemotide)	Merck/Oncothyreon	Synthetic lipopetide formulated in lipsomes	NSCLC	Failed Phase 3 clinical trials
ImMucin	Vaxil Biotherapeutics	Synthetic peptides from MUC1 signal sequence	Multiple myeloma	Positive results from Phase 1/2 clinical trials
Oxidized Mannan-MUC1	Burnet Institute	Peptide conjugated to oxidized mannan	Breast cancer	Positive results from pilot Phase 3 clinical trial
AS1402	UTMD Anderson	Anti-MUC1 Antibody	Breast cancer	Well tolerated in Phase 1 dose escalation study
AS1402 + Letrozole	UTMD Anderson	Anti-MUC1 Antibody + aromatase inhibitor	Advanced/metastatic breast cancer	Failed to meet primary endpoints in Phase 2 clinical trial

Source: GeoVax Labs, Inc.

GeoVax's Hepatitis B Virus (HBV) Vaccine Program

Hepatitis B

Caused by the Hepatitis B virus (HBV), Hepatitis B is a contagious liver disease that is transmitted person-to-person by blood, semen, or other bodily fluids. Transmission can take place through sexual contact, needle sharing, or mother-to-infant transmission during birth. Hepatitis B can be an acute (short-term) illness for some people; however, for others, it can become a long-term (chronic) infection that may lead to serious health issues, including cirrhosis or liver cancer.

The risk of chronic infection is related to age at infection. About 90% of infected infants will develop chronic infections; however, as a child gets older, this risk declines. Approximately 25%-50% of children infected between ages 1 and 5 develop chronic hepatitis. The risk drops to 6%-10% when a person is infected at over 5 years of age. Globally, the majority of individuals 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 U.S. have chronic HBV infections, with roughly 20,000 new infections every year.

A large number of people are unaware that they are infected or may not show any symptoms. As a result, they never seek the attention of medical or public health officials. Worldwide, chronic HBV affects more than 240 million people and contributes to nearly 686,000 deaths each year. While a preventive HBV vaccine is available, fewer than 5% of chronic HBV infections are cured.

GeoVax's Approach

There is an urgent medical need to treat chronic HBV infections as these infections afflict hundreds of millions of individuals around the world. There are vaccines available today that protect against HBV infection though they are not helpful to patients who already have the disease.

While chronic HBV can be treated with medications, the treatments are not able to cure 95% of patients as they cannot induce strong neutralizing antibodies and cellular responses, which are needed to break tolerance to HBV antigens and clear infections; they only suppress the replication of the virus. As a result, a significant number of people who start treatments must continue on them for life. In addition, diagnosis and treatment options are very limited in resource/low income-constrained populations, resulting in many patients dying within months of diagnosis.

GeoVax's combination therapeutic vaccine strategy encompasses multivalent vaccine antigens delivered by DNA and MVA-VLP in combination with the SOC treatment to induce functional antibodies and CD4+, CD8+ T cell responses—designed to clear infection and break tolerance needed toward a functional cure. GeoVax seeks to significantly increase the cure rate of HBV infections while reducing the duration of drug therapy, overall treatment costs, side effects, and potential drug resistance.

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

Market Development Efforts (HBV)

For HBV, there are currently no commercial vaccines to treat this chronic infection. Multiple vaccines exist to protect against HBV infection, though they are not able to help patients already diagnosed with the disease. While 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 rather only suppress the replication of the virus.

Oxxon Pharmaccines entered Phase 2 trials with its H1-8 HBV therapeutic vaccine, containing 2 doses of DNA plasmid primes and two modified MVA boosts, both vectors expressing the same HBV surface antigen. The Phase 2a study concluded that this novel, disease-specific therapeutic vaccine was well tolerated and appeared capable of inducing HBeAg seroconversion (4/21, 19%) and reduced the HBV viral load in HBeAg seroconverters. Oxxon was acquired by Oxford Miomedica in 2007 and HBV program does not exist in their portfolio anymore. Meanwhile, PowderMed designed a plasmid DNA (ppdpSC18) expressing both the HBcAg and HBsAg antigens and is carrying both HBcAg and HBsAg antigens and Ph 1 in Hong Kong, Singapore, Thailand, and the U.S. Figure 37 provides a summary of select development efforts underway for HBV vaccines, where information has been made available.

Figure 37

HBV DEVELOPMENT LANDSCAPE

Company	Antigens	Phase	Comments
Abivax 203	2 VLP proteins, S and C, licensed from CIGB Cuba	2/3	57M Eu funding in 2015, 276 patients, results Q416, may not meet its primary endpoint due to lack of adjuvant, additional Ag, etc. ABX 203 is not listed on its website
GSK	HBsAg plus novel adjuvant and Lamivudine	2	Failed
GlobeImmune-GS-4774/Gilead	X-S-Core-fusion protein expressing yeast	2	Did not meet primary endpoint reduction in HBsAg
Guangzhou biotech	DNA	2	Failed 2014, Virus load reduced to 18% vs 7% controls
Fuqiang, New Biomed	DNA	2	No info
Chongqing Jiachen	Peptides (epsilon PA-44) include HBVeAg	2	No info
ANRS (Fr Age for Res on AIDS and Viral Hepatitis)	DNA, PrS2-S	2	Vaccine did not reduce virus rebound, no response to C, planning to add C and Pol and use with checkpoint inhibitors
Inovio-1800	DNA, S and C antigens clades A and C	1	Internal program
Dynavax DV-601	S+C+CpG	1b	Some lymphoproliferative response and C- specific IFN-gamma
Genexine	DNA	1	Weaker response in human compared to mice
PowderMed/Pfizer	DNA (s and C)	1	Pfizer acquired PowderMed, HBV not in 2016 pipeline
Transgene, TG1050	Ad5 (S, C, Pol)	1	50:50 equity JV with Tasly (Tianjin) Biopharmaceutical
Vaxine Pty	S? use CH based adjuvant Advax	Preclinical	
Altravax	Molecular breeding, S and C proteins?	Preclinical	Technology did not work for dengue vaccine
Big DNA (bacteriophage), Ichor, Mologen, Lipoxen	DNA vaccines	Disco	

Source: GeoVax Labs, Inc.

GeoVax's Malaria Vaccine Program

Malaria

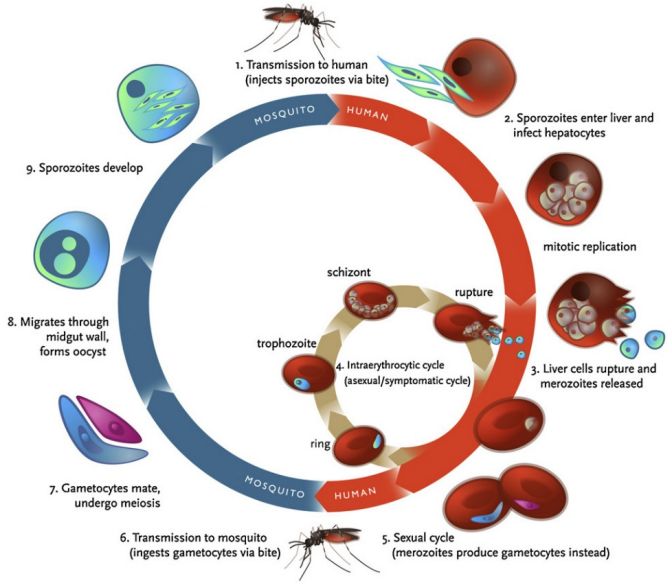
Caused by *Plasmodium* parasites, malaria is a mosquito-borne disease that causes symptoms of fever, chills, sweating, vomiting, and flu-like illness. If not effectively treated, severe complications can result, such as severe anemia, cerebral malaria, and organ failure, which will result in death. Today, more than 3 billion people in 106 countries and territories are at risk for developing a malaria infection. The latest World Health Organization (WHO) data estimates that 214 million new cases of malaria were recorded worldwide in 2015, leading to 438,000 deaths. In the U.S., there are approximately 1,500 cases (due to travelers returning home). Kids under age five are predominantly susceptible to malaria illness, infection, and death, where in 2015, 306,000 children succumbed to disease worldwide. Present day treatments include bed net distributions, drug treatment, and mosquito spraying; however, the malaria parasite has developed resistance to some drugs and insecticides.

While vaccines have shown to be the most cost effective ways to fight and eliminate infectious diseases (Smallpox, polio, etc.)—with decades of R&D in this area—there is still no commercial malaria vaccine available on the market, noting that even at an efficacy of 30-50%, such a vaccine would thwart hundreds of thousands of deaths annually. Current vaccine candidates largely consist of subunit proteins, are poorly immunogenic, based on limited number of antigens (generally 4-5 antigens), do not target the multi-stages of the parasite's life cycle, and do not induce strong durable functional antibodies and T cell responses. Because of this, identifying appropriate antigens and vaccine technologies is necessary to develop an effective malaria vaccine.

GeoVax's Approach

GeoVax believes that the perfect malaria vaccine candidate should contain antigens from multiple stages of the malaria life cycle (shown in Figure 38); should induce functional antibodies (predominantly IgG1 and IgG3 subtypes shown to be associated with protection); and should have strong cell mediated immunity (e.g. Th1 biased CD4+ ad CD8+) to reduce parasitemia by clearing infected cells (liver cells or erythrocytes). The Company has shown both in animal models and humans that its MVA-VLP vaccines induce a Th1-biased response with both durable functional antibodies (IgG1 and IgG3) and CD4+ and CD8+ T cell responses—both of which are hallmarks of an ideal malaria vaccine.

Figure 38
LIFECYCLE OF MALARIA PARASITE



Source: Klein EY. Antimalarial drug resistance: a review of the biology and strategies to delay emergence and spread. Int J Antimicrob Agents (2013), http://dx.doi.org/10.1016/j.ijantimicag.2012.12.007.

GeoVax has a collaboration with the Burnet Institute, a leading infectious diseases research institute in Australia, to develop 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 in combination with malaria *Plasmodium falciparum* and *Plasmodium vivax* sequences identified by the Burnet Institute. The vaccine design, construction, and characterization is to be performed by GeoVax with further characterization and immunogenicity studies in animal models conducted at Burnet Institute using their unique functional assays, which provide important information on the efficacy of the vaccine.

Market Development Efforts

For malaria, there are currently no commercialized vaccines to prevent this infection. A first generation infection-blocking malaria vaccine, RTS,S, is under regulatory review. It requires four 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 the 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.

U.S. Government Support

Contracts and Grants

GeoVax has received multiple federal grants and contracts supporting its vaccine development programs, as described in the accompanying section. The most recent awards are summarized as follows:

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

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

- *SBIR Grant No. 1R43AI120887-01/02.* In June 2015, NIAID awarded the Company an SBIR grant entitled "*Directed Lineage Immunizations for Eliciting Broadly Neutralizing Antibody*." The initial grant award was $299,585 for the first year of a two-year project period, beginning July 1, 2015. In June 2016, NIAID awarded GeoVax $294,038 for the second year of the project period.

- *SBIR Grant No. 5R43AI106422-01-02.* In July 2013, NIAID awarded the Company an SBIR grant entitled "*Enhancing Protective Antibody Responses for a GM-CSF Adjuvanted HIV Vaccine*." The initial grant award was $276,690 for the first year of a two-year project period, beginning August 1, 2013. In July 2014, the NIH awarded GeoVax $289,641 for the second year of the project period.

Clinical Trial Support

Human clinical trials to date for all of GeoVax's preventive HIV vaccines, including the newly initiated HVTN 114 trial, have been conducted by the HVTN and funded by NIAID. Financial support has been provided by NIAID directly to the HVTN; therefore, it is not recognized on the Company's financial statements.

Other Federal Support

GeoVax also has received additional in-kind federal support through collaborative and intramural arrangements with CDC for its Zika vaccine program; the Rocky Mountain Laboratory facility of NIAID for its HF virus vaccine program; and the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) for its HF virus vaccine program. This support generally has been for the conduct or support of preclinical animal studies on behalf of GeoVax.

Investment Summary

Figure 39 provides a summary of key investment considerations for GeoVax.

Figure 39
INVESTMENT OPPORTUNITY

GOVX-B11 Preventive HIV Vaccine

- Most clinically advanced HIV vaccine candidate for high-value commercial markets
- NIH/NIAID clinical trial support

GOVX-ZM01 Zika Vaccine

- A novel vaccine candidate
- High-profile effort with world-class collaborators at CDC

GOVX-E303 Hemorrhagic Fever Vaccine

- Four vaccines covering all major hemorrhagic fevers (Ebola, Sudan, Marburg, Lassa)
- Collaborative effort with NIAID Rocky Mountain Lab and IHV University of Maryland

Immuno-Oncology Program

- Multiple high-value targets
- Novel clinical strategy
- Collaboration with University of Pittsburgh and ViaMune

HBV Therapeutic program

Multiple vaccine antigens

Collaboration with Georgia State University and Peking University

Malaria Program

Vaccine antigens covering all three stages of malaria infection

Testing in June 2017 in collaborator. Laboratory at Burnet Institute - Australia

MVA-VLP Technology Platform

Proven vector safety; manufacturing advantages and scalability

Proven preclinical protection in HIV, Zika and Ebola

Disease target expansion (CMV, dengue, RSV, HSV, others)

Solid IP protection

Source: GeoVax, Inc.

Competition

GeoVax's current programs are focused on the development of preventive vaccines against Human Immunodeficiency Virus (HIV), Hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), ZIKV, and malaria. The Company has also initiated programs to develop therapeutic vaccines to treat chronic HBV infections and MUC1-positive cancer types. The biotechnology and pharmaceutical industries are highly competitive, with companies, universities, and research organizations actively engaged in researching and developing products that may be competitive to those being developed by GeoVax.

As the Company continues to develop and eventually commercialize its product candidates, it is likely to face competition from pharmaceutical and biotechnology companies marketing or developing products that target the same indications. In addition, GeoVax is likely to face competition from initiatives supported by private and government entities, including the National Institute of Allergy and Infectious Diseases (NIAID) (part of the U.S. National Institutes of Health [NIH]), the U.S. Military, the International Aids Vaccine Initiative (IAVI), the European Vaccine Initiative (EVI), and the South African AIDS Vaccine Initiative (SAAVI), among others.

To the Company's knowledge, there are currently no U.S. Food and Drug Administration (FDA)-licensed and commercialized preventive HIV vaccines, Zika vaccines, or HF virus vaccines available anywhere in the world. The Company is aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, who are engaged in vaccine research and development within these areas, as outlined below. Many of these entities and their efforts have been mentioned throughout this report within their respective sections. Therefore, this list, as well as those companies/entities mentioned within the Core Story, is not intended to be an exhaustive collection of potential competitors to GeoVax; however, it is believed to represent the type of competition the Company may encounter as it seeks to further develop and commercialize its product candidates.

HIV Vaccines Competitive Landscape

HIV vaccines are in varying stages of research, testing, and clinical trials. GeoVax is developing one of the leading vaccine candidates within this therapeutic arena. Three other vaccines for the clade B subtype of HIV are under development by Harvard/Janssen, the Institute of Human Virology/Profectus, and Inovio. Two of the more advanced prophylactic HIV vaccine clinical trial efforts are the NIAID-led collaboration between GlaxoSmithKline (GSK) and Sanofi Pasteur, as well as the ViiV Healthcare Phase 3 study of its HIV product candidate, cabotegravir.

NIAID—HVTN 702 Trial

The NIAID has begun a large clinical trial to test a new vaccine regimen for clade C, which according to the organization, would be the first efficacy study for an HIV vaccine in seven years and the most advanced efficacy trial of an HIV vaccine candidate. This new study, called HVTN 702, is designed to determine whether the regimen is safe, tolerable, and effective at preventing HIV infection among South African adults. Under a collaboration that includes GSK and Sanofi Pasteur, the NIAID started a Phase 2b/3 trial of the new vaccine regimen in South Africa among 5,400 sexually active men and women aged 18 to 35 who do not have the infection, but are considered at risk for infection. Results from the trial are expected in late 2020. The vaccine regimen consists of two experimental vaccines combined with a GSK-supplied adjuvant, called MF59. The first vaccine, ALVAC-HIV, is supplied by Sanofi Pasteur and consists of a viral vector containing genetically engineered versions of three HIV genes. The second is a protein vaccine supplied by GSK, which is expected to create an immune response to GP120, an essential component for the HIV virus to enter into the host cells.

The new vaccine is a modified version of the RV144 experimental HIV vaccine that was part of a 2009 clinical trial conducted by the U.S. Military HIV Research Program in Thailand (described on page 29). The trial, known as the RV144 trial, used a prophylactic vaccine combination, which was found to be safe and somewhat effective. Results from that test showed the experimental vaccine lowered the rate of infection by 31.2% compared to a placebo during a 3.5-year follow-up period. Although this reduction was not considered enough to prompt wide use of this vaccine, it provided the first proof that a vaccine could stop HIV-1 infection, and provided researchers the ability to study the mechanisms of action that resulted in the protective effect. The candidate for the HVTN 702 study was

adapted from the RV144 experimental vaccine to target HIV subtype C, the most common in southern African countries. The regimen was modified as well, to provide a longer protection period. The start of HVTN 702 follows in the footstep of a smaller initial trial, HVTN 100. This Phase 1/2 trial was co-funded by the NIH and the Bill & Melinda Gates Foundation. After the initial success observed in the HVTN 100 trial, this larger trial aims to determine whether the vaccine can really provide effective protection in South Africa and other neighboring countries (e.g. Namibia, Zimbabwe, Botswana etc.), which are particularly affected by HIV/AIDS.

ViiV Healthcare—HPTN 083 Trial

ViiV Healthcare—a global specialist HIV company majority-owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders—is conducting Phase 3 studies on cabotegravir, an injectable vaccine for the prevention of HIV. The study is designed to evaluate injections of cabotegravir given every two months compared to daily oral Pre-Exposure Prophylaxis (PrEP) with Truvada®, and is being conducted through a public-private collaboration of ViiV Healthcare, the HIV Prevention Trials Network (HPTN), NIAID, and Gilead Sciences. The global Phase 3 study, called HPTN 083, will seek to enroll 4,500 men who have sex with men, and transgender women who have sex with men, at more than 40 sites in North and South America, Asia, and Africa. A second Phase 3 study, to evaluate long-acting cabotegravir for the prevention of HIV infection in young women, is anticipated to start in 2017.

Outside of these trials, HIV vaccine research at earlier stages continues to remain a focus for teams around the world. Western University in Canada moved onto Phase 2 clinical trial in 2017 on a new vaccine candidate—SAV001—after Phase 1 trials showed that it was safe to use in humans. The new vaccine candidate is to be tested in 600 people in North America. Additionally, the Scripps Research Institute signed on to test Yisheng Biopharma's adjuvant in conjunction with its own HIV vaccine technology. Other players in the space include the University of Massachusetts, University of Maryland, Texas Biomed, Duke University, Johnson & Johnson, as well as different biotechnology startups. In Europe, authorities established a €23 million collaboration that involved 22 companies and organizations working on a HIV vaccine.

Sanofi Pasteur SA (a subsidiary of Sanofi S.A.)

Sanofi, a global healthcare leader, is involved on the discovery, development, and commercialization of a wide range of therapeutic solutions through the operation of its five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur, and Consumer Healthcare. Sanofi Pasteur, the vaccines division of Sanofi, is the largest company entirely dedicated to vaccines and a leader in the vaccine industry, with a broad range of vaccines protecting against infectious diseases. In addition to its HIV development efforts in partnership with NIAID and GSK, on October 2016 Sanofi Pasteur agreed to collaborate with the Brazilian Oswaldo Cruz Foundation (Fiocruz) and the Walter Reed Army Institute of Research—U.S. Department of Defense Laboratory (WRAIR) for the development of a Zika vaccine candidate. Other Sanofi Pasteur pipeline candidates include an anti-malarial Phase 2 vaccine (ferroquine/OZ439), being developed in collaboration with Medicines for Malaria Venture (MMV). Sanofi Pasteur is headquartered in Lyon, France.

GlaxoSmithKline plc (GSK)

GlaxoSmithKline (GSK) is one of the world's leading research-based pharmaceutical and healthcare companies, with products and product candidates across multiple therapeutic classes, including respiratory and antiviral, as well as vaccines and healthcare-related consumer products. Its prophylactic vaccine pipeline includes product candidates targeting Ebola (Phase 2), Hepatitis C (Phase 2), and malaria (Phase 2), among others. GSK's RTS,S/AS01—trade name Mosquirix™—is a malaria vaccine approved for use by European regulators in July 2015. Final results from the Phase 3 efficacy trial of RTS,S, published in *The Lancet*, showed that the vaccine candidate helped protect children and infants from clinical malaria for at least three years after the first vaccination. According to the company, this represents not only the world's first licensed malaria vaccine, but the first vaccine licensed for use against a parasitic disease of any kind. The World Health Organization Regional Office for Africa (WHO/AFRO) announced on April 24, 2017, that Ghana, Kenya, and Malawi will partner with WHO in the Malaria Vaccine Implementation Programme (MVIP) that will make the RTS,S vaccine available in selected areas of the three countries, beginning in 2018. In addition, the company is involved in the development of a prophylactic vaccine for HIV through its dual efforts in partnership with NIAID and Sanofi, as well as its involvement in ViiV

Healthcare. GSK is also commercializing Engerix®, a vaccine indicated for prevention of infection caused by all known subtypes of HBV. GSK is headquartered in Brentford, London, UK.

GeneCure LLC

GeneCure is a private biotechnology company developing novel human vaccines based on its patented lentiviral delivery platform. The mission of the company is to develop safe, potent, and simple-to-use human vaccines to manage chronic viral infections and cancers. GeneCure's lead product is a therapeutic HIV vaccine—HIVAX™—currently being tested as a first-in-human, proof-of-concept (PoC) therapy for HIV infected patients. According to the company, HIVAX™ can provide both therapeutic and protective benefits to vaccines, and has been proven safe for use in clinical studies. Other products in the pipeline include therapeutic Hepatitis C and B vaccines for chronic infected patients. GeneCure is headquartered in Norcross, Georgia.

Inovio Pharmaceuticals, Inc.

Inovio Pharmaceuticals, a clinical stage biopharmaceutical company, develops active DNA immunotherapies and vaccines in combination with proprietary delivery devices to prevent and treat cancers and infectious diseases. Its SynCon immunotherapy design has the ability to break the immune system's tolerance of cancerous cells and facilitate cross-strain protection against known, as well as new unmatched strains of pathogens, such as influenza. Inovio's product pipeline includes clinical programs of its proprietary SynCon immunotherapies for HPV-caused pre-cancers and cancers (Phase 1); therapeutic vaccines for HBV (INO-1800) and hepatitis C (INO-8000), both in Phase 1; preventive and therapeutic vaccines for HIV (through its PENNVAX® platform, in Phase 1), preventive vaccine for Ebola (INO-4212) in Phase 1, and preventive vaccines for Zika (GLS-5700) in Phase 1. Inovio Pharmaceuticals was founded in 1979 and is headquartered in Plymouth Meeting, Pennsylvania.

Janssen Pharmaceutical Companies of Johnson & Johnson (a subsidiary of Johnson & Johnson)

Janssen is a pharmaceutical company involved in the development of treatments for a wide range of conditions, including its development of vaccines targeting infectious diseases, such as HIV, hepatitis, and HFs. Janssen, in collaboration with international health organizations, including the World Health Organization (WHO) and NAIAD, is developing a vaccine regimen for Ebola. The vaccine regimen includes a prime-boost combination of two components that are based on Janssen's AdVac® technology and the MVA-BN® technology from Bavarian Nordic, a biotechnology company based in Denmark. Phase 1 clinical trial data published in *The Journal of the American Medical Association (JAMA)* showed that the vaccine regimen induced a durable immune response in 100% of healthy volunteers one year following vaccination, with no vaccine-associated serious adverse events. Janssen is also involved on the development of a HIV vaccine that works by first priming the immune system to fight the virus, then boosting it again for an even more potent response. Last year, the company published a study in the journal *Science* showing that its HIV candidate offered significant protection against HIV infection, with about 60% of non-human primates administered the vaccine and exposed six times to the simian immunodeficiency virus (SIV) remaining disease-free. Janssen launched a global 400 volunteer-study to evaluate a similar vaccine in humans, starting in Rwanda, South Africa, Thailand, and Uganda.

Merck & Co, Inc.

Merck is one of the largest pharmaceutical companies in the world. Merck's pipeline includes a Phase 3 Ebola vaccine. The product candidate, designated V920 or rVSV-ZEBOV, was originally developed by the Public Health Agency of Canada and was subsequently licensed to NewLink Genetics Corporation. Merck then licensed V920 from NewLink Genetics to accelerate the development, licensure, and availability of the vaccine. Although research evaluating V920 is ongoing, data from a 2015 study conducted in Guinea reported 100% efficacy following vaccination with a single dose, with vaccinated individuals protected against the Ebola virus infection within six to 10 days of vaccination. In July 2016, the FDA granted the vaccine breakthrough therapy designation, and the European Medicines Agency (EMA) provided the vaccine PRIME (PRIority MEdicines) status. Merck's pipeline also includes MK-1439, a Phase 3 investigational orally available candidate being evaluated for the treatment of HIV infection. In addition, the company is commercializing RECOMBIVAX HB®, a vaccine indicated for prevention of infection caused by all known subtypes of HBV. Merck is headquartered in Kenilworth, New Jersey.

NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company focused on discovering, developing, and commercializing immunotherapeutic products for the treatment of cancer and infectious disease. Its portfolio includes biologic product candidates based on its HyperAcute cellular immunotherapy technology, which is designed to stimulate the human immune system to attack cancer cells; and small-molecule product candidates that are focused on breaking the immune system's tolerance to cancer. Its infectious disease program includes replication-competent recombinant vesicular stomatitis virus, a vaccine technology to treat Ebola and Marburg viruses. The investigational vaccine rVSV-ZEBOV for Ebola (licensed to Merck & Co.) received the Best Prophylactic Vaccine award at the 15th Annual World Vaccine Congress on April 8, 2015, in Washington, DC. The company has license and collaboration agreements with Genentech, Inc. and Merck, Sharpe, and Dohme Corp. NewLink Genetics Corporation was founded in 1999 and is headquartered in Ames, Iowa.

Novavax, Inc.

Novavax is a clinical-stage biotechnology company committed to delivering novel products to prevent a broad range of infectious diseases. Its Ebola vaccine candidate—Ebola GP—is currently in Phase 1 development. Data from its Phase 1 clinical trial in 230 healthy adults showed the vaccine to be well tolerated and to provoke high ebolavirus antibody responses. According to Novavax, these data, together with two positive challenge studies in non-human primates, suggest that the Ebola GP Vaccine would be protective in humans. Novavax is headquartered in Gaithersburg, Maryland with additional facilities in Rockville, Maryland and Uppsala, Sweden.

Profectus Biosciences, Inc.

Profectus BioSciences is a clinical-stage company developing preventive and therapeutic vaccines for infectious diseases and oncolytic vaccines for cancer immunotherapy. Profectus vaccines are based on the company's proprietary VesiculoVax™ and DNA vaccine delivery platforms. Used alone, VesiculoVax™-vectored vaccines lead to rapid expansion of B cells to provide protection against emerging infectious diseases of public health and biodefense importance, such as Ebola, Marburg, Chikungunya, and the Equine Encephalitis viruses. When used as a boost after priming the immune system with pDNA vaccines, VesiculoVax™-vectored vaccines lead to the expansion of primed T cells into effector cells that are uniquely suited to killing virally infected cells and cancers. Current programs using the Prime/Boost System of Vaccines (PBS Vax™) strategy include HBV, human papilloma virus (HPV), herpes simplex virus type 2 (HSV-2), and HIV. Profectus is based in Baltimore, Maryland.

Protein Sciences Corporation

Protein Sciences is a biotechnology company developing vaccines and biopharmaceuticals using its proprietary BEVS platform technology to produce the next generation of vaccines for the prevention and treatment of a wide range of diseases. Its preclinical Zika vaccine is based on production of recombinant variations of the E protein from the ZIKV. This vaccine is similar to vaccine candidates produced at Protein Sciences against West Nile Virus and Japanese Encephalitis Virus, which are close relatives of the ZIKV, that have previously been shown to neutralize their respective viruses in preclinical studies. Protein Sciences is based in Meriden, Connecticut.

Historical Financial Results

Figures 40, 41, and 42 (pages 57-59) provide a summary of GeoVax's key historical financial statements for the year ended December 31, 2017

Figure 40

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2016	2015	2014
Grant revenue	$ 828,918	$ 428,081	$ 882,956
Operating expenses:			
Research and development	1,970,859	1,693,102	1,812,969
General and administrative	2,131,426	1,429,731	1,807,605
Total operating expenses	4,102,285	3,122,833	3,620,574
Loss from operations	(3,273,367)	(2,694,752)	(2,737,618)
Other income:			
Interest income	1,666	5,465	4,063
Total other income	1,666	5,465	4,063
Net loss	$ (3,271,701)	$ (2,689,287)	$ (2,733,555)
Basic and diluted:			
Loss per common share	$ (0.08)	$ (0.08)	$ (0.10)
Weighted average shares outstanding	41,516,514	31,950,813	26,645,140

Source: GeoVax, Inc.

Figure 41

CONSOLIDATED BALANCE SHEETS

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 454,030	$ 1,060,348
Grant funds receivable	28,074	119,978
Prepaid expenses and other current assets	62,275	56,649
Total current assets	544,379	1,236,975
Property and equipment, net	54,828	83,608
Other assets	11,010	11,010
Total assets	$ 610,217	$ 1,331,593
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 75,607	$ 100,935
Accrued expenses	294,240	26,055
Total current liabilities	369,847	126,990
Commitments (Note 6)		
Stockholders' equity:		
Preferred stock, $.01 par value:		
Authorized shares – 10,000,000		
Series B convertible preferred stock, $1,000 stated value; 100 shares issued and outstanding at December 31, 2016 and 2015, respectively	76,095	76,095
Series C convertible preferred stock, $1,000 stated value; 2,868 and 3,000 shares issued and outstanding at December 31, 2016 and 2015, respectively	940,705	983,941
Common stock, $.001 par value:		
Authorized shares – 300,000,000 and 150,000,000 at December 31, 2016 and 2015, respectfully		
Issued and outstanding shares – 55,235,233 and 31,950,813 at December 31, 2016 and 2015, respectively	55,235	31,951
Additional paid-in capital	34,914,963	32,587,543
Accumulated deficit	(35,746,628)	(32,474,927)
Total stockholders' equity	240,370	1,204,603
Total liabilities and stockholders' equity	$ 610,217	$ 1,331,593

Source: GeoVax, Inc.

Figure 42

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$(3,271,701)	$(2,689,287)	$(2,733,555)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	28,780	28,935	69,037
Stock-based compensation expense, including common stock issued for services	967,667	67,905	479,103
Changes in assets and liabilities:			
Grant funds receivable	91,904	(40,637)	61,568
Prepaid expenses and other current assets	(5,626)	(12,146)	(934)
Accounts payable and accrued expenses	242,857	(60,033)	(125,326)
Total adjustments	1,325,582	(15,976)	483,448
Net cash used in operating activities	(1,946,119)	(2,705,263)	(2,250,107)
Cash flows from investing activities:			
Purchase of property and equipment	-	(15,850)	(35,503)
Net cash used in investing activities	-	(15,850)	(35,503)
Cash flows from financing activities:			
Proceeds from sale of common stock	1,339,801	-	873,400
Proceeds from sale of preferred stock	-	2,679,810	-
Net cash provided in financing activities	1,339,801	2,679,810	873,400
Net decrease in cash and cash equivalents	(606,318)	(41,303)	(1,412,210)
Cash and cash equivalents at beginning of period	1,060,348	1,101,651	2,513,861
Cash and cash equivalents at end of period	$ 454,030	$ 1,060,348	$ 1,101,651

Source: GeoVax, Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by GeoVax, Inc. ("GeoVax" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in GeoVax's statements on Forms 10-K, 10-Q, and 8-K as well as other forms filed from time to time.

The content of this report with respect to GeoVax has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. GeoVax is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by GeoVax or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA will have been compensated by the Company in cash of forty-eight thousand dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about GeoVax's business, as described below. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in GeoVax's SEC filings are not the only risks that the Company faces. Additional risks and uncertainties not presently known to GeoVax or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, GeoVax's business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved in an investment in the Company as well as for copies of this report, please contact GeoVax by calling (678) 384-7220.

Risks Related to GeoVax's Business

The Company has a history of operating losses, and expects losses to continue for the foreseeable future.

GeoVax has had no product revenue to date and there can be no assurance that the Company will ever generate any product revenue. The Company has experienced operating losses since it began operations in 2001. As of March 31, 2017, GeoVax had an accumulated deficit of approximately $36.3 million. The Company expects to incur additional operating losses and expects cumulative losses to increase as its research and development, pre-clinical, clinical, manufacturing, and marketing efforts expand. Its ability to generate revenue and achieve profitability depends on the ability to successfully complete the development of its product candidates, conduct pre-clinical tests and clinical trials, obtain the necessary regulatory approvals, and manufacture and market the resulting products. Unless GeoVax is able to successfully meet these challenges, the Company will not be profitable and may not remain in business.

GeoVax has received a going concern opinion from its auditors.

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

The Company's business will require continued funding. If GeoVax does not receive adequate funding, it will not be able to continue its operations.

To date, the Company has financed its operations principally through the sale of its equity securities and through NIH grants and clinical trial support. GeoVax will require substantial additional financing at various intervals for its 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 the Company or at all.

If GeoVax is not able to secure the significant funding that is required to maintain and continue its operations at current levels, or at levels that may be required in the future, the Company may be required to delay clinical studies or clinical trials, curtail operations, or obtain funds through collaborative arrangements that may require it to relinquish rights to some of its products or potential markets. The costs of conducting all of GeoVax's human clinical trials to date for its preventive HIV vaccine have been borne by the HIV Vaccine Trials Network (HVTN), with funding by the NIH, and the Company expects NIH support for additional clinical trials. GeoVax incurs costs associated with manufacturing the clinical vaccine supplies and other study support.

The Company cannot predict the level of support it will receive from the HVTN or the NIH for any additional clinical trials of its HIV vaccines. GeoVax's operations are also partially supported by the NIH grants awarded to it to support its HIV/AIDS vaccine program. As of March 31, 2017, there was approximately $868,000 of unused grant funds remaining and available for use during 2017 and early 2018. The Company is pursuing additional support from the federal government for its vaccine programs. However, as the Company progresses to the later stages of its 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 GeoVax to look to other sources of funding to finance its development activities.

GeoVax will need to raise additional funds to significantly advance its vaccine development programs and to continue operations. In order to meet the Company's operating cash flow needs, it plans to seek sources of non-dilutive capital through government grant programs and clinical trial support. The Company may also plan additional offerings of its equity securities, debt, or convertible debt instruments. Should the financing it requires to sustain the Company's working capital needs be unavailable or prohibitively expensive when it is required, the consequences could have a material adverse effect on GeoVax's business, operating results, financial condition, and prospects.

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

GeoVax's products are still being developed and are unproven. These products may not be successful.

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

Whether GeoVax is successful will be dependent, in part, upon the leadership provided by its management. If the Company were to lose the services of any of these individuals, its business and operations may be adversely affected.

Whether the Company's business will be successful will be dependent, in part, upon the leadership provided by its officers, particularly its president and chief executive officer and its chief scientific officer. The loss of the services of these individuals may have an adverse effect on the Company's operations. Further, its employees, including its executive officers and directors, are not subject to any covenants not to compete against the Company, and the Company's business could be adversely affected if any of its employees or directors engaged in an enterprise competitive with the Company.

Regulatory and legal uncertainties could result in significant costs or otherwise harm the Company's business.

To manufacture and sell GeoVax's products, the Company must comply with extensive domestic and international regulation. In order to sell its products in the U.S., 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. GeoVax cannot predict whether its products will be approved by the FDA. Even if they are approved, the Company 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, GeoVax cannot predict if or when it may obtain these regulatory approvals. If the Company cannot demonstrate that its products can be used safely and successfully in a broad segment of the patient population on a long-term basis, its products would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

GeoVax faces intense competition and rapid technological change that could result in products that are superior to the products it 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. The Company has numerous competitors in the U.S. and abroad, including, among others, large companies with substantially greater resources than it. If any of the Company's competitors develop products with efficacy or safety profiles significantly better than its products, the Company may not be able to commercialize its products, and sales of any of its commercialized products could be harmed. Some of GeoVax's competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing, and human resources than the Company does. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by the Company. GeoVax will seek to expand its technological capabilities to remain competitive; however, research and development by others may render its technologies or products obsolete or noncompetitive, or result in treatments or cures that are superior.

GeoVax's product candidates are based on new medical technology and, consequently, are inherently risky. Concerns about the safety and efficacy of the Company's products could limit its future success.

The Company is 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 GeoVax creates will not be effective, that its product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals, and that GeoVax's 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 GeoVax's products. The responses of potential physicians and others to information about complications could materially affect the market acceptance of the Company's products, which in turn would materially harm its business.

GeoVax may experience delays in its clinical trials that could adversely affect the Company's financial results and its commercial prospects.

The Company does not know whether planned clinical trials will begin on time or whether it will complete any of its clinical trials on schedule, if at all. Product development costs will increase if GeoVax has delays in testing or approvals or if it needs to perform more or larger clinical trials than planned. Significant delays may adversely affect its financial results and the commercial prospects for its products, and delay the Company's ability to become profitable.

GeoVax relies heavily on the HVTN, independent clinical investigators, and other third party service providers for successful execution of its clinical trials, but does not control many aspects of their activities. The Company is responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires the Company 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. GeoVax's reliance on third parties that it does not control does not relieve the Company of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct clinical trials in accordance with regulatory requirements or the Company's stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of GeoVax's product candidates. There is also a risk of changes in clinical trial strategy and timelines due to the HVTN and the NIH altering their trial strategy.

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

None of the Company's vaccines are approved by the FDA for sale in the U.S. or by other regulatory authorities for sale in foreign countries. To exploit the commercial potential of its technologies, GeoVax is 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 the Company's ability to commercialize its technology or products. Any such failure may severely harm GeoVax's business. In addition, any approvals obtained by GeoVax 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 the Company 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 the Company is in full compliance with these laws, it could face enforcement action, fines, and other penalties and could receive adverse publicity—all of which could harm its business.

Recently enacted and future legislation may increase the difficulty and cost for GeoVax to obtain marketing approval of and commercialize its drug candidates and affect the prices that the Company may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of GeoVax's drug candidates, restrict or regulate post-approval activities, and affect the Company's ability to profitably sell any drug candidates for which it obtains marketing approval. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and expanding access. In the U.S., the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives.

GeoVax may not be successful in establishing collaborations for product candidates it seeks to commercialize, which could adversely affect its ability to discover, develop, and commercialize products.

The Company expects 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 GeoVax's vaccine's safety and efficacy profile. If the Company is unable to reach agreements with suitable collaborators for any product candidate, GeoVax will be forced to fund the entire development and commercialization of such product candidates itself and may not have the resources to do so. If resource constraints require the Company to enter into a collaboration agreement early in the development of a product candidate, GeoVax may be forced to accept a more limited share of any revenues this product may eventually generate. The Company may face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. The Company may not be successful in its efforts to establish collaborations or other alternative arrangements for any product candidate. Even if GeoVax is successful in establishing collaborations, the Company may not be able to ensure fulfillment by collaborators of their obligations or GeoVax's expectations.

GeoVax does not have manufacturing, sales, or marketing experience.

GeoVax does not have the facilities or expertise to manufacture any of the clinical or commercial supplies for its own products. To be successful, its products must be manufactured in commercial quantities in compliance with regulatory requirements and at an acceptable cost. To date, the Company has not commercialized any products, nor has it demonstrated that it can manufacture commercial quantities of its product candidates in accordance with regulatory requirements.

If the Company cannot manufacture products in suitable quantities and in accordance with regulatory standards, either on its 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 GeoVax's competitive position and its chances of achieving profitability.

The Company cannot be sure that it can manufacture, either on its own or through contracts with third parties, such products at a cost or in quantities that are commercially viable. GeoVax currently relies on and intends to continue to rely on third-party contract manufacturers to produce vaccines needed for research and clinical trials. The Company has arrangements with third party manufacturers for the supply of its DNA and MVA vaccines for use in its planned clinical trials. These suppliers operate under the FDA's current Good Manufacturing Practices (cGMPs) and (in the case of European manufacturers) similar regulations of the European Medicines Agency.

GeoVax anticipates that these suppliers will likely be able to provide sufficient vaccine supplies to complete its currently planned clinical trials. Various contractors are generally available in the U.S. and Europe to manufacture 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 the Company were to switch to other contractors.

GeoVax's vaccines under development may not gain market acceptance.

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

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

GeoVax 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. The Company may face substantial product liability exposure in human clinical trials and for products that it sells after regulatory approval. The Company carries product liability insurance and expects to continue such policies. However, product liability claims, regardless of their merits, could exceed policy limits, divert management's attention, and adversely affect the Company's reputation and the demand for its products.

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

Market acceptance of vaccines GeoVax develops, 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. The Company cannot be certain that reimbursement will be available for any vaccines that it may develop. Also, GeoVax cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for the Company's vaccines. If reimbursement is not available or is available on a limited basis, the Company may not be able to successfully commercialize vaccines that it develops.

Risks Related to GeoVax's Intellectual Property

The Company could lose its license rights to its own important intellectual property if it does not fulfill its contractual obligations to its licensors.

GeoVax's rights to significant parts of the technology it uses in its vaccines are licensed from third parties and are subject to termination if the Company does not fulfill its contractual obligations to its licensors. Termination of intellectual property rights under any of GeoVax's license agreements could adversely impact the Company's ability to produce or protect its vaccines. The Company's obligations under its license agreements include requirements that GeoVax makes milestone payments to its licensors upon the achievement of clinical development and regulatory approval milestones, royalties as the Company sells commercial products, and reimbursement of patent filing and maintenance expenses. Should GeoVax become bankrupt or otherwise unable to fulfill the Company's contractual obligations, its licensors could terminate the Company's rights to critical technology that it relies upon.

Other parties may claim that GeoVax infringes their intellectual property or proprietary rights, which could cause the Company to incur significant expenses or prevent it from selling products.

The Company's success will depend in part on its 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 GeoVax's products or its licensors' products, product candidates, or other technologies. Future or existing patents issued to third parties may contain patent claims that conflict with the Company's products. GeoVax expects to be subject to infringement claims from time to time in the ordinary course of business, and third parties could assert infringement claims against the Company in the future with respect to its current products or with respect to products that it may develop or license.

Litigation or interference proceedings could force GeoVax 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 the Company's key management and technical personnel.

Any inability to protect intellectual property rights in the U.S. and foreign countries could limit GeoVax's ability to manufacture or sell products.

The Company will rely on trade secrets, unpatented proprietary know-how, continuing technological innovation and, in some cases, patent protection to preserve its competitive position. The Company's 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 the Company. GeoVax and its 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 the Company.

If patents containing competitive or conflicting claims are issued to third parties, GeoVax 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. The Company may not be able to prevent third parties from infringing or using its intellectual property, and the parties from whom GeoVax may license intellectual property may not be able to prevent third parties from infringing or using the licensed intellectual property.

The Company generally will attempt to control and limit access to, and the distribution of, its product documentation and other proprietary information. Despite efforts to protect this proprietary information, unauthorized parties may obtain and use information that the Company 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 U.S., 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 GeoVax's proprietary rights.

Risks Related to Regulations

Regulation by U.S. governmental and foreign authorities is a significant factor in GeoVax's ongoing R&D activities, as well as in the manufacture of its products under development. Complying with these regulations involves considerable expertise, time, and expense. In the U.S., drugs are subject to rigorous federal and state regulation. GeoVax's products are regulated under the Federal Food, Drug and Cosmetic Act, as amended (FD&C Act), and the regulations promulgated thereunder, and other federal and state statutes and regulations. These laws govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising, and promotion of medications and medical devices. Product development and approval within this regulatory framework is difficult to predict, takes several years, and involves great expense. The steps required before a human vaccine may be marketed in the U.S. include:

- pre-clinical laboratory tests, *in vivo* pre-clinical studies, and formulation studies;
- manufacturing and testing of the product under strict compliance with current cGMP regulations;
- submission to the FDA of an Investigational New Drug (IND) application for human clinical testing which must become effective before human clinical trials can commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- the submission of a Biologics License Application to the FDA, along with the required user fees;
- FDA approval of the Biologics License Application prior to any commercial sale or shipment of the product; and
- post-marketing requirements imposed by FDA.

Each of these steps is described further below. Before marketing any drug or biologic for human use in the U.S., the product's sponsor must obtain FDA approval. As well, each manufacturing establishment must be registered with the FDA and must pass a Pre-Approval Inspection (PAI) before introducing any new drug or biological product into commercial distribution. Since GeoVax does not manufacture vaccines for human use within its own facilities, the Company must ensure compliance both in its own operations and in the outsourced manufacturing operations.

All FDA-regulated manufacturing establishments (both domestic establishments and foreign establishments that export products to the U.S.) are subject to inspections by the FDA and must comply with the FDA's cGMPs for products, drugs, and devices. The 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, or potentially criminal charges for the most serious violations.

Preclinical Testing

Preclinical testing includes laboratory evaluation of chemistry and formulation, along with cell culture and animal studies, to assess the safety and potential efficacy of the product. Preclinical safety tests and certain other pivotal preclinical studies need to be conducted by laboratories that comply with the FDA's Good Laboratory Practices (GLPs). The results of pre-clinical testing are submitted to the FDA as part of the IND application and are reviewed by the FDA prior to beginning human clinical trials. Unless the FDA objects to an IND, the IND becomes effective 30 days following its receipt by the FDA.

cGMP-Compliant Manufacturing and Testing

The FDA has issued, and often updates, extensive regulations on current cGMP's. Any drug, biologic, or device for human use, whether commercial or investigational, must be manufactured under these regulations. CGMP regulations include a wide variety of requirements covering personnel, documentation, facilities, equipment, testing procedures, and many other aspects of manufacturing and testing.

Clinical Trials

Clinical trials involve the administration of investigational drugs to volunteers or to patients under the supervision of a qualified, medically trained clinical investigator. These trials are conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the trial, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol and the qualifications of the investigators who plan to carry it out must be submitted to the FDA as part of the IND.

As well, each clinical trial must be conducted under the auspices of an independent institutional review board at the institution where the trial is to be conducted. The institutional review board will consider, among other things, ethical factors, the safety of human subjects, and the possible liability of the institution. Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

In the Phase 1 clinical trial (the initial introduction of the product into healthy human subjects), the vaccine is tested for safety (including adverse side effects) and dosage tolerance. The Phase 2 clinical trial is the proof of principal stage and involves trials in a limited patient population to determine whether the product induces the desired effect (for GeoVax's vaccines, whether there is an immune responses) and to better determine optimal dosage. The continued identification of possible safety risks is also a focus. When there is evidence that the product may be effective and has an acceptable safety profile in Phase 2 clinical trials, Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety within an expanded patient population. Phase 3 trials are completed using multiple clinical study sites which are geographically dispersed. The manufacturer or the FDA may suspend clinical trials at any time if either party believes that the individuals participating in the trials are being exposed to unacceptable health risks.

Biologics License Application and FDA Approval Process

The results and details of the pre-clinical studies and clinical trials are submitted to the FDA in the form of a Biologics License Application (BLA), which is equivalent to the New Drug Application (NDA) submitted by companies seeking to market new drugs. If the BLA is approved, the manufacturer may market the product in the U.S. under the Prescription Drug User Fee Act (PDUFA). The FDA charges user fees to applicants to offset the costs of its operations. The PDUFA user fee for a new vaccine is over $2 million (unless the applicant obtains a waiver or reduction through programs designed to encourage development of certain types of products).

Post-marketing Requirements

The FDA often imposes post-marketing requirements as a condition of NDA or BLA approval. Common post-marketing requirements include additional clinical trials (Phase 4 trials) or observational studies. Post-marketing requirements are especially relevant to the Company's Ebola and Marburg vaccines. GeoVax expects to seek approval of these vaccines using the accelerated approval process, in which FDA grants approval based on performance against a criterion other than actual protection against the disease but requires the manufacturer to monitor and submit data on efficacy of the approved product.

Unlike pathogens like human papillomavirus, Ebola and Marburg are not constantly in circulation. Rather, they occur in sporadic but enormously deadly outbreaks. For this reason, it would be impractical and potentially unethical to attempt to perform a traditional Phase 3 trial in which vaccinated participants are compared against unvaccinated participants to determine the efficacy of the vaccine in preventing infection with Ebola or Marburg.

The accelerated approval process allows the FDA to approve a new medicine based on its performance against a surrogate endpoint (in the case of Ebola or Marburg, its performance in raising immune responses). GeoVax has stated that as a condition of receiving accelerated approval, the Company would agree to monitor the real-world performance of its Ebola and Marburg vaccines.

International Approval

Whether or not the FDA has approved the drug, approval of a product by regulatory authorities in foreign countries must be obtained before a company begins commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval.

Other Regulations

In addition to FDA regulations, GeoVax's business activities may also be regulated by the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state, or local regulations. Violations of regulatory requirements at any stage may result in various adverse consequences, including regulatory delay in approving or refusal to approve a product, enforcement actions, including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions and/or civil or criminal penalties. Any product developed by GeoVax's must receive all relevant regulatory approvals or clearances prior to being marketed.

Risks Related to the Company's Common Stock

The market price of GeoVax's common stock is highly volatile.

The market price of the Company's common stock has been, and is expected to continue to be, highly volatile. Certain factors, including announcements of new developments by the Company or other companies, regulatory matters, new or existing medicines or procedures, concerns about GeoVax's 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 the Company's stock. In addition, potential dilutive effects of future sales of shares of common stock by the Company, and subsequent sales of common stock by the holders of warrants and options could have an adverse effect on the market price of its shares.

GeoVax's common stock does not have a vigorous trading market and investors may not be able to sell their securities when desired.

The Company has a limited active public market for its common shares. A more active public market, allowing investors to buy and sell large quantities of the Company's 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.

The Company has never paid dividends and has no plans to do so.

Holders of shares of GeoVax's common stock are entitled to receive such dividends as may be declared by its Board of Directors. To date, the Company has paid no cash dividends on its shares of common stock and does not expect to pay cash dividends on its common stock in the foreseeable future. The Company intends to retain future earnings, if any, to provide funds for operations of its business. Therefore, any potential return investors may have in its common stock will be in the form of appreciation, if any, in the market value of their shares of common stock.

If the Company fails to maintain an effective system of internal controls, it may not be able to accurately report its financial results or prevent fraud.

GeoVax is subject to reporting obligations under the U.S. 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 the Company to produce reliable financial reports and are important to help prevent fraud. As a result, failure to achieve and maintain effective internal controls over financial reporting could result in the loss of investor confidence in the reliability of the Company's financial statements, which in turn could negatively impact the trading price of its stock.

If GeoVax fails to remain current in its reporting requirements, the Company's securities could be removed from the OTC Market, which would limit the ability of broker-dealers to sell its securities and the ability of stockholders to sell their securities in the secondary market.

U.S. 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 the Company fail to remain current on its reporting requirements, it could be removed from the OTC Market. As a result, the market liquidity for the Company's securities could be severely adversely affected by limiting the ability of broker-dealers to sell its securities and the ability of stockholders to sell their securities in the secondary market.

GeoVax needs additional capital, and the sale of additional shares or other equity securities could result in additional dilution to its stockholders.

In order to meet its operating cash flow needs, the Company plans additional offerings of its equity securities, debt, or convertible debt instruments. The sale of additional equity securities could result in additional dilution to the Company's 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 the Company sells 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 Company operations. GeoVax cannot assure investors that financing will be available in amounts or on terms acceptable to the Company, if at all.

The exercise of options or warrants or conversion of GeoVax's Series B, Series C, or Series D Preferred Stock may depress its stock price and may result in significant dilution to the Company's common stockholders.

There are a significant number of outstanding warrants and options to purchase GeoVax stock and the Company has issued Series B, Series C, and Series D Convertible Preferred Stock that is convertible into its Common Stock. If the market price of the Company's Common Stock exceeds the exercise price of outstanding warrants and options or the conversion prices of the preferred shares, holders of those securities may be likely to exercise their warrants and options or convert their preferred shares and sell the Common Stock acquired upon exercise or conversion of such securities, as applicable, in the open market.

Sales of a substantial number of shares of the Company's Common Stock in the public market by holders of warrants, options, or preferred shares may depress the prevailing market price for GeoVax's Common Stock and could impair its ability to raise capital through the future sale of the Company's equity securities. Additionally, if the holders of outstanding options, warrants, or preferred shares exercise those options or warrants or convert those preferred shares, as applicable, the Company's common stockholders will incur dilution in their relative percentage ownership. The prospect of this possible dilution may also impact the price of GeoVax's Common Stock.

The Company's outstanding options and warrants include warrants to purchase up to 27,822,910 shares with an exercise price of $0.015 per share. These warrants contain anti-dilution provisions, which may, under certain circumstances, reduce the exercise price (but have no effect on the number of shares subject to the warrants) to match if the Company sells or grants options to purchase, including rights to reprice its common stock or common stock equivalents at a price lower than the exercise price of the warrants, or if the Company announces plans to do so. This potential reduction in exercise price could reduce the funds the Company receives upon exercise of the warrants, and increase the likelihood that a dilutive issuance will occur.

GeoVax's common stock is and likely will remain subject to the SEC's "penny stock" rules, which make it more difficult to sell.

The Company's common stock is currently and may remain classified as a "penny stock." The SEC rules regarding penny stocks may have the effect of reducing trading activity in its 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 the Company's securities and may result in a lower trading volume of its common stock and lower trading prices.

Certain provisions of GeoVax's 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.

GeoVax's certificate of incorporation authorizes its Board of Directors to issue up to 10,000,000 shares of preferred stock. The Company has issued 100 shares of Series B Convertible Preferred Stock. 2,846 shares of its Series C Convertible Preferred Stock and 1,000 shares of its Series D Convertible Preferred Stock. GeoVax believes 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 the Company's 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 the Company's common stock, and therefore could reduce the value of its common stock. In addition, specific rights granted to future holders of preferred stock could be used to restrict the Company's ability to merge with, or sell assets to, a third party. The ability of GeoVax's 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 the Company's common stock.

Provisions contained in certain of the Company's outstanding warrants may make it more difficult for a third party to effect a change in control.

The Company's outstanding warrants include warrants to purchase up to 27,822,910 shares which contain provisions permitting the holders to require the payment to them of an amount of cash equal to the value (based on a Black-Scholes computation) of the remaining unexercised portion of the warrants on the date of the consummation of a fundamental transaction (as defined, but generally a change in control of the Company) that is (i) an all cash transaction; (ii) a "going private" transaction; or (iii) a transaction involving a person or entity not traded on a national securities exchange. The prospect of making such payments may discourage a potential third party acquirer.

Glossary

Adjuvants—A substance (such as one added to a vaccine) that enhances the body's immune response to an antigen.

Antibody—Also known as an immunoglobulin, is a large, Y-shaped protein produced mainly by plasma cells that is used by the immune system to neutralize pathogens, such as bacteria and viruses.

Antibody dependent cellular cytotoxicity (ADCC)—A type of immune defense reaction in which a target cell or microbe is coated with antibodies and killed by certain types of white blood cells. The white blood cells bind to the antibodies and release substances that kill the target cells or microbes.

Antibody Dependent Enhancement (ADE)—A process in which antiviral proteins facilitate virus entry into host cells, leading to increased infectivity in the cells. The most widely known example of ADE occurs in the setting of infection with the dengue virus.

Antigens—A toxin or other foreign substance that induces an immune response in the body, especially the production of antibodies.

Antiretroviral Therapies (ART)—The combination of several antiretroviral medicines used to slow the rate at which HIV makes copies of itself (multiplies) in the body. A combination of three or more antiretroviral medicines is more effective than using just one medicine (monotherapy) to treat HIV.

Arenaviridae family—A family of viruses (arenovirus) whose members are generally associated with rodent-transmitted diseases in humans. At least eight arenaviruses are known to cause human disease, including hemorrhagic fever (HF) syndromes, such as Lassa fever.

CD4+ T cells—T-helper cells with CD4 receptor that recognizes antigens on the surface of a virus-infected cell and secretes lymphokines that stimulate B cells and killer T cells. T-helper cells help suppress or regulate immune responses and assist other white blood cells in immunologic processes. T cells are infected and killed by the HIV virus.

current Good Manufacturing Practice (cGMP)—Regulations enforced by the U.S. Food and Drug Administration (FDA). CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.

Chick Embryo Fibroblast (CEF)—A fibroblast is a type of cell that synthesizes the structural framework for animal tissues and plays a critical role in wound healing. Fibroblasts are the most common cells of connective tissue in animals. Primary cultures of chick embryo fibroblasts are widely used for the cultivation of viruses.

Clade—A clade is a group of organisms that consists of a common ancestor and all its lineal descendants, and represents a single “branch” on the “tree of life” or genealogy tree.

Deoxyribonucleic Acid (DNA)—The molecule that carries genetic information in all living systems. The DNA molecule is formed in the shape of a double helix from a great number of smaller molecules (nucleotides).

Ebola—An infectious and frequently fatal type of HF marked by severe gastrointestinal distress, high fever, and internal bleeding, spread through contact with infected body fluids by a filovirus (Ebola virus), whose normal host species is unknown.

Epizootic—Relating to or denoting a disease that is temporarily prevalent and widespread in an animal population. A disease event in a non-human animal population, analogous to an epidemic in humans.

Filoviridae—A family of filamentous single-stranded threadlike RNA viruses that cause diseases in humans and nonhuman primates (monkeys and chimpanzees). The virus family is defined by their unique appearance and reproductive strategies, and include the Ebola and Marburg viruses.

Flaviviridae—A family of single-stranded RNA viruses transmitted especially by ticks and mosquitoes and include the causative agents of dengue, hepatitis C, hog cholera, Saint Louis encephalitis, West Nile virus, and yellow fever.

Flavivirus—Any member of the Flaviviridae virus family that cause a number of serious human diseases, including yellow fever, dengue, various types of encephalitis, and hepatitis C.

Guillain-Barré syndrome—An uncommon, usually self-limited form of polyneuritis, occurring after a viral illness or immunization and manifested by loss of muscle strength, loss of or altered sensation, and sometimes paralysis.

Hemorrhagic Fever (HF) viruses—A diverse group of viruses that cause viral hemorrhagic fevers (VHFs). VHFs are a group of animal and human viral illnesses characterized by sudden onset, fever, bleeding of the internal organs, and shock. Some of the VHF agents cause relatively mild illnesses, while others, such as Ebola virus, can cause severe, life-threatening disease.

Hepatitis B (HBV)—A severe form of liver infection caused by the Hepatitis B virus (HBV), normally transmitted in infected blood. It occurs in both rapidly developing (acute) and long-lasting (chronic) forms, and is one of the most common chronic infectious diseases worldwide.

HIV Vaccine Trials Network (HVTN)—A non-profit organization which connects physicians and scientists with activists and community educators for the purpose of conducting clinical trials seeking a safe and effective HIV vaccine.

Human Immunodeficiency Virus (HIV)—A retrovirus that occurs as two types: HIV-1 and HIV-2. Both types are transmitted through direct contact with HIV-infected body fluids, such as blood, semen, and genital secretions. HIV attacks the body's immune system, specifically the CD4+ T cells, weakening the body's ability to fight infection and other disease. AIDS is a syndrome that is the most advanced stage of HIV infection.

Hypoglycosylated—Reduced, or insufficient glycosylation. Glycosylation is an essential process by which sugars are attached to proteins and lipids. Because of the widespread function of glycosylation, inherited disorders of glycosylation are multisystemic. There are over 40 different congenital protein hypoglycosylation diseases.

Immune Checkpoint Inhibitors (ICIs)—A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. These proteins help keep immune responses in check and can keep T cells from killing cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells better.

Immunogenicity—The ability of a particular substance, such as an antigen or epitope, to provoke an immune response in the body of a human or animal.

Immuno-oncology—A therapy that uses drugs known as immunotherapies that target the body's immune system to help fight cancer.

Lassa Fever—A viral hemorrhagic disease that is caused by the Lassa virus and is characterized by a high fever, headaches, mouth ulcers, muscle aches, small hemorrhages under the skin, heart and kidney failure, and a high mortality rate.

Malaria—An infectious disease characterized by cycles of chills, fever, and sweating, caused by the parasitic infection of red blood cells by a protozoan of the genus Plasmodium. The parasite is transmitted by mosquitoes in many tropical and subtropical regions

Malaria Plasmodium Falciparum—A protozoan parasite, one of the species of Plasmodium that cause malaria in humans. It is transmitted by the female Anopheles mosquito. Almost every malarial death is caused by Plasmodium falciparum.

Marburg—Marburg disease is an acute, often fatal, form of hemorrhagic fever. It is caused by a filovirus (Marburg virus) that normally lives in African monkeys and certain bats.

Microcephaly—Abnormal smallness of the head, a congenital condition associated with incomplete brain development.

Modified Vaccinia Ankara Virus-Like Particle (MVA-VLP)—The Modified Vaccinia Ankara (MVA) is an attenuated strain of vaccinia virus that was developed towards the end of the campaign for the eradication of smallpox. MVA is widely considered as the vaccinia virus strain of choice for clinical investigation because of its high safety profile, and holds great promise as a vaccine platform or delivery system. MVA can encode one or more foreign antigens and thus functions as a multivalent vaccine. A virus-like particle (VLP) are small particles that resemble viruses, but are non-infectious because they contain no viral genetic material.

Monoclonal Antibodies (Mabs)—An antibody produced in the laboratory by a single clone of cells or cell line and consisting of identical antibody molecules, designed so that it binds to only one substance, such as cancer cells. Monoclonal antibodies are being used to treat some types of cancer.

Monovalent—Monovalent vaccine is a vaccine directed at only one pathogen, and designed to immunize against a single antigen or single microorganism.

Multivalent—A multivalent or polyvalent vaccine is designed to immunize against two or more strains of the same microorganism, or against two or more microorganisms.

NS1 (Nonstructural Protein)— A protein encoded by a virus but that is not part of the viral particle. Non-structural protein 1 (NS1) is an RNA-binding protein that is required for virus replication. NS1 antigen test (nonstructural protein 1) is a test for dengue that was introduced in 2006. It allows rapid detection on the first day of fever, before antibodies appear some five or more days later.

Parasitemia—The demonstrable presence of parasites in the blood.

Plasmodium Vivax Sequences—Plasmodium vivax is a protozoal parasite and a human pathogen. The most frequent and widely distributed cause of recurring malaria, Plasmodium vivax is one of the five species of malaria parasites that commonly infect humans. The Plasmodium vivax sequence refers to the virus' genome sequencing, or the order of the DNA nucleotides, or bases, in its genome that make up the organism's DNA.

Ryan White Act—The Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Act is the largest federal program focused specifically on providing HIV care and treatment services to people living with HIV. The legislation, first enacted in 1990 as the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, provides a comprehensive system of care for people living with HIV who are uninsured or underinsured, and also allocates part of the resources to fund technical assistance, clinical training, and the development of innovative models of care.

Sudan Virus—One of five known viruses within the genus Ebolavirus that causes Ebola virus disease (EVD) in humans and other primates; it is the sole member of the species Sudan ebolavirus.

Tetravalent Hemorrhagic Vaccine (THV)—A vaccine designed to immunize against four strains of a microorganism that causes hemorrhagic fever. In particular, a tetravalent dengue vaccine targets the four serotypes of dengue that possess the ability to cause disease.

Tetravalent Vaccine (TV)—A tetravalent vaccine is designed to immunize against four strains of the same microorganism or virus.

Virus-like particle (VLP)—Small particles that resemble viruses, but are non-infectious because they contain no viral genetic material.

Zika Virus (ZIKV)—A mosquito-borne flavivirus that causes the infectious disease Zika fever, also known as Zika virus disease. Although symptoms of Zika can be mild and may include fever, red eyes, joint pain, headache, and a skin rash, there is scientific consensus that ZIKV is a cause of microcephaly and Guillain-Barré syndrome. Links to other neurological complications are also being investigated.

Intentionally Blank

Intentionally Blank

Intentionally Blank

CRYSTAL
RESEARCH ASSOCIATES
FACTS WITHOUT FICTION

About Our Firm: For the past decade, Crystal Research Associates, LLC (www.crystalra.com) has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

Crystal Research Associates is led by Wall Street veterans, Jeffrey Kraws and Karen Goldfarb. Together, Kraws and Goldfarb have built a unique business model, capitalizing on decades of experience as an award-winning sell-side analyst team to produce institutional-quality industry and market research in a manner that is easily understood by investors and consumers. Our firm's approach has been proven successful over the years as our products are published and available on Bloomberg, Thomson Reuters/First Call, Capital IQ, FactSet, Yahoo! Finance, and scores of other popular forums.

880 Third Avenue, 6th Floor, New York, NY 10022
Office: (212) 851-6685
www.crystalra.com