

Company Description

GeoVax Labs, Inc. (“GeoVax” or “the Company”) is a uniquely-positioned clinical-stage biotechnology company developing preventative and therapeutic human vaccines against infectious diseases and cancer. The Company’s 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 individual 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 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 (immunooncology). GeoVax believes its expertise is complementary to a range of other human diseases for which there is an unmet medical need, and consequently, 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 with financial and operational support from the National Institutes of Health (NIH). The next planned clinical trial of GOVX-B11 is expected to be an additional Phase 1 trial, evaluating the safety and immunogenicity of a prime-boost regimen of GOVX-B11 with and without two additional protein boosts. This trial is to be conducted by HVTN with funding from NIAID, with an anticipated start date of mid-2018.
- The Company’s HIV vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the Centers for Disease Control and Prevention (CDC). The technology 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.
- GeoVax’s novel preclinical Zika vaccine (GEO-ZM02) is designed to avoid safety concerns shown with other Zika vaccines in development. During the quarter, the Company presented data at multiple conferences showing that a single dose of GEO-ZM02 gave 100% protection in mice challenged with a lethal dose of Zika virus (ZIKV) delivered directly into the brain.
- 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 (having received >\$50 million to date from the NIH).
- GeoVax remains focused on transitioning its technologies into Phase 1 clinical trials for three vaccines targets—Zika, Lassa Fever, and its immunooncology program. The Company has promising preclinical data and is focused on fund raising to bring about the next stage of development. By means of working with multiple collaborators on a variety of vaccine candidates, GeoVax is able to manage development risk by creating many paths on the road to selecting the best vaccine candidate.



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GOVX (OTC.BB) One-Year Chart



Ticker (Exchange)	GOVX (OTC.BB)
Recent Price (03/01/18)	\$0.042
52-week Range	\$0.0248 to \$0.1049
Shares Outstanding	~131.7 million
Market Capitalization	~\$5.53 million
Avg. 10-day Volume	841,283
EPS (Qtr. ended 09/30/17)	(\$0.01)
Employees	9

DEVELOPMENT UPDATE

Continued Validation of MVA-VLP Vaccine Platform

GeoVax's product pipeline is based on its Modified Vaccine Ankara (MVA) Virus-Like Particle (VLP) vaccine platform, which supports in vivo production of non-infectious VLPs from the cells of the actual person receiving the vaccine. This technology mimics a natural infection and stimulates both the humoral and cellular arms of the immune system to recognize, prevent, and control target infections. The Company's original application of its technology was to develop preventive HIV vaccines. Recently, it has expanded to preventive vaccines for Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines for HIV, chronic Hepatitis B infections, and cancers. GeoVax continues to add to an encouraging data set for its MVA-VLP platform, with preclinical proof-of-concept in four disease indications (HIV, Zika, Lassa, and Ebola). As well, the data has demonstrated excellent safety and immunogenicity in clinical trials of its HIV vaccine in 500 individuals, providing the basis for expecting clinical efficacy for the current vaccine development programs. In addition, this data shows promise as it relates to future pipeline expansion for further disease indications.

HIV Preventive Vaccines

The Company's most advanced program is a prophylactic vaccine (GOVX-B11) for the clade B subtype of HIV, the most common form of HIV in North America, Western Europe, Australia, and Japan. This program has completed Phase 1 and Phase 2a human clinical trials, which were conducted by the HIV Vaccine Trials Network (HVTN) with funding from the National Institute of Allergy and Infectious Diseases (NIAID). In January 2017, the HVTN initiated a Phase 1 human clinical trial of GOVX-B11 to evaluate the durability of immune responses elicited by the vaccine and the effects of late boosts (additional vaccinations) on the antibody responses elicited by the GOVX-B11.

The next planned clinical trial of GOVX-B11 is expected to be an additional Phase 1 trial, evaluating the safety and immunogenicity of a prime-boost regimen of GOVX-B11 with and without two additional protein boosts. This trial is expected to be conducted by HVTN with funding from NIAID, with an anticipated start date of mid-2018. Both this trial as well as HVTN 114 are intended to contribute critical data to determine the regimen for use in a future Phase 2b efficacy trial.

The Company is also continuing preclinical work funded by grants from the NIAID for its vaccine for the clade C HIV subtype, which is prevalent in Africa. In October 2017, GeoVax reported the elicitation of a key precursor for a broadly neutralizing antibody for the HIV CD4 binding site—a material advantage in advancing HIV vaccine development. The findings were published in the peer-reviewed open access journal PLOS ONE (<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177863>).

HIV Therapeutic Vaccine ("Functional Cure" Program)

GeoVax began a collaboration with American Gene Technologies International, Inc. (AGT) in March 2017 with the goal of developing a functional cure for HIV infection through AGT's gene therapy technology combined with GeoVax's HIV vaccine. The Company expects AGT to file an Investigation New Drug (IND) application in early 2018 and to initiate human clinical trials of the companies' combined technologies in mid-2018.

Zika Vaccine

GeoVax presented data at multiple conferences showing that a single dose of its Zika vaccine (GEO-ZM02) gave 100% protection in mice challenged with a lethal dose of Zika virus (ZIKV) delivered directly into the brain. These conferences included the American Society for Microbiology (ASM) conference (ASM MICROBE 2017) in New Orleans, LA in June 2017 and later in August at the 5th Annual Meeting of Cambridge Healthtech Institute, Immunology-Oncology Summit, in Boston, MA, as well as in October 2017, at the 18th World Vaccine Congress Europe in Barcelona, Spain. This is the first report of (1) a Zika vaccine based on the ZIKV non-structural (NS1) protein, and (2) single-dose protection against ZIKV using an immunocompetent lethal mouse challenge model. The vaccine was tested at the Centers for Disease Control and Prevention (CDC) in Ft. Collins, CO with funding from the CDC. GeoVax's approach to a Zika vaccine uniquely uses the non-structural protein NS1 instead of the commonly used

structural proteins for immunogens, avoiding potential Antibody Dependent Enhancement (ADE) of infection—a safety concern for Zika vaccines based on structural proteins.

Preclinical efficacy of GEO-ZM02 was published in the peer-reviewed open access journal Scientific Reports by Nature Research under the title of “*A Zika Vaccine Targeting NS1 Protein Protects Immunocompetent Adult Mice in a Lethal Challenge Model*” (<http://rdcu.be/yasq>). As well, in June 2017, the National Institutes of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), awarded GeoVax a Small Business Innovative Research (SBIR) grant of \$600,000 to support advanced preclinical testing, including non-human primate studies, for its Zika vaccine development program to prepare for a Phase 1 human clinical study.

Lassa Fever Vaccine

GeoVax made significant strides, as announced in July 2017, in developing a vaccine candidate to protect against Lassa hemorrhagic fever virus (LASV). Efficacy testing in a murine challenge model (using a chimeric LASV reassortant) showed a single intramuscular dose of GEO-LM01 provided 100% protection to mice infected with a lethal dose of the challenge virus directly delivered into the brain. The study was conducted, and successfully repeated, at the Institute of Human Virology at the University of Maryland School of Medicine. The Company further expanded its LASV vaccine development efforts through a collaboration with The Scripps Research Institute located in San Diego, CA. In October 2017, at the International Society for Vaccines, at the Institute Pasteur in Paris, France, GeoVax presented updates on efficacy data of its single dose vaccine for Lassa fever virus. In December 2017, GeoVax announced that it is collaborating with the U.S. Naval Research Laboratory (USNRL) to develop high-quality antibodies useful for detection of LASV and potentially as a treatment for Lassa Fever (LF). Because there is no vaccine currently available, LASV continues to kill more than 5,000 people each year in West African countries where the virus is endemic. The Company expects that it could receive government SBIR fast track for the Lassa Fever program.

A single dose of GeoVax’s Ebola (EBOV) vaccine has been shown to protect 100% of rhesus monkeys against death. The Company is also developing vaccines against Sudan virus (SUDV) and Marburg virus (MARV), two other lethal hemorrhagic fever viruses for which no effective vaccine currently exists. In addition to developing the four individual hemorrhagic fever vaccines (EBOV, LASV, SUDV, MARV), GeoVax seeks to combine the vaccines into a single tetravalent vaccine to provide broad protection for individuals at-risk for these viruses. In October 2017, together with its collaborators at Rocky Mountain Laboratories of NIH, GeoVax submitted a manuscript for publication to a prestigious peer reviewed journal describing efficacy data for its MVA-VLP-Ebola vaccine.

Immuno-oncology Program

In August 2017, at the 5th Annual Meeting of Cambridge Healthtech Institute, Immuno-Oncology Summit, in Boston, MA, and in October 2017, at the 18th World Vaccine Congress Europe in Barcelona, Spain, GeoVax presented preliminary results from studies of its cancer vaccine in collaboration with ViaMune, Inc. The studies were performed by the laboratory of Dr. Pinku Mukherjee, PhD, at the University of North Carolina at Charlotte. GeoVax and ViaMune are each developing products that target an abnormal form of the cell surface-associated protein, Mucin 1 (MUC1), which is overexpressed in metastatic cancers (e.g. breast, pancreatic, lung, and ovarian cancers) and circulating tumor cells and which is often used as a diagnostic marker for cancer progression. In a human MUC1 colon adenocarcinoma mouse tumor model, groups of hMUC1 transgenic mice with established tumors were treated with MTI (ViaMune’s synthetic vaccine), MVA-VLP-MUC1 (GeoVax’s viral-vectored vaccine), or a combination of both. All treatment groups received an immune checkpoint inhibitor in the form of an anti-PD-1 antibody. Results from two studies indicate that a combined vaccine approach increases the therapeutic potential of anti-PD-1 therapy, affording scientific justification to pursue additional investigation of this cancer vaccine candidate. In January 2018, GeoVax announced that it is collaborating with Vaxeal Holding SA on the expansion of GeoVax’s cancer immunotherapy program. The collaboration between GeoVax and Vaxeal will include the design, construction, characterization, and animal testing of vaccine candidates using Vaxeal’s antigens in GeoVax’s MVA-VLP vaccine platform.

Malaria Vaccine

In January 2017, GeoVax initiated a program to develop a malaria vaccine with its MVA-VLP viral vector platform via a collaboration with The Burnet Institute in Australia. The Company has completed construction of four vaccine candidates, which have been shipped to The Burnet Institute and are being evaluated in preclinical proof-of-concept studies.

Chronic Hepatitis B (HBV) Immunotherapy

During the first quarter 2017, GeoVax added Georgia State University and Peking University as collaborators to develop a therapeutic vaccine for chronic hepatitis B infection. Preclinical proof-of-concept studies are ongoing. In February 2018, the Company announced that it is collaborating with CaroGen Corporation on the development of a combination immunotherapy treatment for chronic hepatitis B virus (HBV) infection. The project will include testing GeoVax's MVA-VLP-HBV vaccine candidate in combination with CaroGen's HBV virus-like vesicles (VLVs) vaccine candidate in prophylactic and therapeutic animal models of HBV.

Potential Milestones

Zika

- Determine immunogenicity and efficacy in non-human primates (funded by NIH SBIR grant)
- Determine correlation of protection by passive protection studies in mice
- Produce GMP vaccine
- File IND with the FDA
- Initiate Phase 1 clinical trial

HIV

- Initiate Phase 1 HIV clinical trial by AGT (gene therapy cure trial), (H2 2018)
- Complete evaluation of patient inoculations for HVTN 114 Phase 1 trial testing the ability of “late boosts” to increase the antibody responses elicited by GOVX-B11 (H1 2018)
- Initiate Phase 1 HIV protein boost clinical trial by HVTN (pathway to efficacy trial), (Q3 2018)

Cancer Immunotherapy

- Continue its collaboration with ViaMune, Inc. to co-develop the companies’ respective cancer immunotherapy programs. Encouraging preliminary data were presented in August 2017; follow-on studies are being planned

Malaria

- Preclinical data on efficacy of malaria vaccine via relationship with Burnett Institute (Q2 2018)

Summary of Recent Events

February 7, 2018—Announced that the Company is collaborating with Carogen Corporation on the development of a combination immunotherapy treatment for chronic hepatitis B virus (HBV) infection. The project will include testing GeoVax’s MVA-VLP-HBV (Modified Vaccinia Ankara-Virus Like Particle-Hepatitis B Virus) vaccine candidate in combination with Carogen’s HBV virus-like vesicles (VLVs) vaccine candidate in prophylactic and therapeutic animal models of HBV. Therapeutic experiments may be carried out in combination with anti-viral drugs, TLR agonists, or immune checkpoint inhibitors, which are currently in use (or anticipated to be used in future) as part of the standard of care for treatment of this difficult to treat disease. This collaboration with Carogen complements GeoVax’s existing collaboration with Georgia State University, increasing its chances of success. The strategy is to use both vaccines as part of a combination strategy with current or future HBV treatments to induce functional antibodies as well as CD4+, CD8+ T cell responses to break tolerance to HBV antigens and clear the infection. The ultimate goal is to significantly increase the current cure rate of chronic HBV infection while reducing the duration of drug therapy, overall treatment costs, side effects, and potential drug resistance.

January 31, 2018—Announced that its Chief Scientific Officer, Farshad Guirakhoo, PhD, delivered a talk, entitled “From A to Z: Development of Vaccines for AIDS and Zika and Many More In Between, Using a Novel MVA Vector Platform Technology,” during the 2018 American Society for Microbiology (ASM) Biothreats Conference, being held February 12-14, 2018 in Baltimore, MD.

January 16, 2018—Announced publication of its manuscript entitled “A Single-Dose of Modified Vaccinia Ankara Expressing Ebola Virus Like Particles Protects Nonhuman Primates from Lethal Ebola Virus Challenge.” The paper is published in the peer-reviewed open access journal Scientific Reports by Nature Research, and can be viewed at www.nature.com/articles/s41598-017-19041-y. In this study, GEO-EM01 was administered as either a single IM inoculation (prime) or as two IM inoculations at a four-week interval (prime-boost) to groups of four rhesus macaques each. A control group received the MVA vector without Ebola virus protein inserts. Four weeks after inoculation, animals in all three groups were exposed to a lethal dose of Ebola virus. Three of the four unvaccinated animals died within 12 days, while all of the vaccinated animals survived. Researchers at Rocky Mountain Laboratories, part of the National Institute of Allergy and Infectious Diseases (NIAID), collaborated in the study.

January 3, 2018—Announced that it is collaborating with Vaxeal Holding SA on the expansion of GeoVax’s cancer immunotherapy program. The collaboration between GeoVax and Vaxeal will include the design, construction, characterization, and animal testing of vaccine candidates using GeoVax’s MVA-VLP vaccine platform. Vaccine antigens will include Vaxeal’s proprietary designed sequences. This project is intended to be complementary and mutually exclusive to the Company’s ongoing collaboration with ViaMune, Inc. for co-developing cancer immunotherapies based on the MUC1 tumor-associated antigen.

January 2, 2018—Announced that its Chief Scientific Officer, Farshad Guirakhoo, PhD, delivered a presentation at the China Showcase during the Biotech Showcase 2018 conference.

December 18, 2017—Announced the scheduling of investor and corporate partnering meetings during the J.P. Morgan 36th Annual Healthcare Conference, to be held in San Francisco on January 8-11, 2018.

December 12, 2017—Announced that it is collaborating with the U.S. Naval Research Laboratory (USNRL) to develop high-quality antibodies useful for detection of Lassa virus (LASV), and potentially as a treatment for Lassa Fever (LF). The U.S. Department of Defense has an interest in the early detection of the presence of LASV to better protect and treat troops that may be in areas where exposure may occur.

November 15, 2017—Announced that the HIV Vaccine Trials Network (HVTN) has closed enrollment for the phase 1 human clinical trial evaluating late boosts of GeoVax’s preventive vaccine (GOVX-B11) for clade B HIV. The trial, designated HVTN 114, is being conducted by the HVTN and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The HVTN is the world’s largest publicly funded multi-disciplinary international collaboration facilitating the development of vaccines to prevent HIV/AIDS.

November 13, 2017—Announced that its Chief Scientific Officer, Farshad Guirakhoo, PhD, delivered a talk, entitled “*Development of Novel and Safe Single-Dose Vaccines; Preclinical Efficacy Data for Zika, Ebola and Lassa Fever,*” during the Third International Conference on Vaccines Research and Development, on Tuesday, November 14 in Washington, DC.

November 9, 2017—Announced its financial results for the quarter ended September 30, 2017 and provided an update of its research and development programs.

November 7, 2017—Announced publication of its manuscript entitled “A Zika Vaccine Targeting NS1 Protein Protects Immunocompetent Adult Mice in a Lethal Challenge Model.” The paper is published in the peer-reviewed open access journal Scientific Reports by Nature Research, and can be viewed at <http://rdcu.be/yasq>. The published paper reports research showing that a single intramuscular dose of GeoVax’s Zika vaccine (GEO-ZM02) provided 100% protection in normal mice challenged with a lethal dose of Zika virus (ZIKV) delivered directly into the brain. This is (1) the only Zika vaccine in development based solely on the ZIKV NS1 protein, and (2) the first report of single-dose vaccine that afforded full protection against ZIKV using an immunocompetent lethal mouse challenge model. The vaccine was tested at the Division of Vector-Borne Diseases, Centers for Disease Control and Prevention (CDC) in Fort Collins, Colorado with funding 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 ZIKV NS1 vaccine protected 100% of vaccinated animals. In contrast, 80-90% of sham-immunized control animals died within ~7 days. Currently, no approved vaccine or therapeutic medicine exists for the prevention or treatment of infection from the ZIKV. GEO-ZM02 uses GeoVax’s proven MVA vaccine platform that has been shown to be safe and to induce durable antibody and T-cell responses in multiple human clinical trials for GeoVax’s prophylactic HIV vaccine.

Third Quarter 2017 Financial and Operating Results

In November 2017, its most recently reported quarter, GeoVax reported a net loss of \$588,787 (\$0.01 per share) for the three months ended September 30, 2017 versus \$464,200 (\$0.01 per share) for the same period in 2016. For the nine months ended September 30, 2017, the Company’s net loss was \$1,653,979 (\$0.03 per share) versus \$2,336,314 (\$0.06 per share) in 2016.

Grant and collaboration revenues were \$247,997 and \$895,866 for the three-month and nine-month periods of 2017, respectively, versus \$440,106 and \$653,986 reported for the comparable periods of 2016. As of September 30, 2017, there is \$744,769 in approved grant funds remaining and available for use.

Research and development (R&D) expenses were \$498,200 and \$1,568,093 for the three-month and nine-month periods of 2017, respectively, versus \$683,939 and \$1,519,519 for the comparable periods of 2016. R&D expenses include direct costs funded by NIH grants, as well as other vaccine manufacturing and testing costs. General and administrative (G&A) expenses were \$340,143 and \$985,001 for the three-month and nine-month periods of 2017, respectively, versus \$220,707 and \$1,472,030 for the comparable periods of 2016.

GeoVax reported cash balances of \$343,826 at September 30, 2017 versus \$454,030 at December 31, 2016.

Company Background

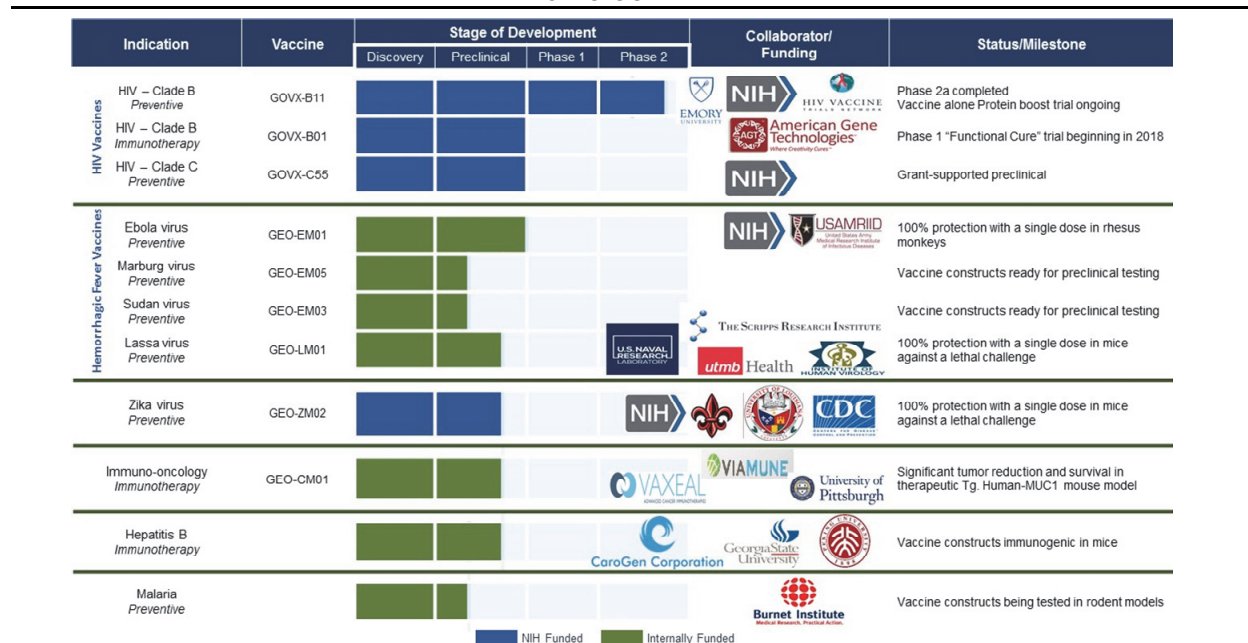
GeoVax Labs, Inc. is a clinical-stage biotechnology company focused on developing human vaccines—both preventative and therapeutic—against infectious diseases as well as cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) vector vaccine platform. The Company’s proprietary 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 of our base report, <https://www.crystalra.com/research-library/geovax-0-0> (pages 21-52).

Figure 1
TECHNOLOGY PIPELINE



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 led 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. Historically, 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.

HIV (Therapeutic Vaccine)

In March 2017, GeoVax announced a collaboration with American Gene Technologies International Inc. (AGT) 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, expected to begin in mid-2018, 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, PhD, GeoVax's chief scientific officer, emeritus, 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 a series of vaccines utilizing its MVA-VLP platform to address the unmet need for products 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, potentially with a single dose. The MVA vector has historically 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.

Beyond protecting people in Africa, GeoVax's hemorrhagic fever vaccine program 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 hemorrhagic fever vaccines 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. And in July 2017, the Company announced 100% single-dose protection in rodents for its LASV vaccine.

ZIKA Virus (ZIKV) Vaccine Program

During the Zika epidemic in 2016, GeoVax began developing an MVA-Zika vaccine (GEO-ZM02). The Company collaborated with the CDC to develop a lethal challenge model in mice to test its vaccine candidates, with ZIKV and reagents 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. 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. In June 2017, NIAID awarded GeoVax a \$600,000 SBIR grant to support its preclinical studies.

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.

In early February 2018, the Company announced that it is collaborating with CaroGen Corporation on the development of a combination immunotherapy treatment for chronic hepatitis B virus (HBV) infection. The project is to include testing GeoVax's MVA-VLP-HBV (Modified Vaccinia Ankara-Virus Like Particle-Hepatitis B Virus) vaccine candidate in combination with CaroGen's HBV virus-like vesicles (VLVs) vaccine candidate in prophylactic and therapeutic animal models of HBV. Therapeutic experiments may be carried out in combination with anti-viral drugs, TLR agonists, or immune checkpoint inhibitors, which are currently in use (or anticipated to be used in future) as part of the standard of care for treatment. CaroGen's vaccine candidate employs a transformative VLV platform technology developed at Yale University School of Medicine and exclusively licensed by CaroGen for the development and commercialization of immunotherapies worldwide.

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 immunoncology program is being developed pursuant to a collaboration with ViaMune, Inc. 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.

Figure 2
VACCINE DEVELOPMENT COLLABORATIONS

<p>— HIV</p> <ul style="list-style-type: none"> ● Duke University ● NIH/NIAID ● HVTN ● American Gene Technologies, Inc. <p>— Zika</p> <ul style="list-style-type: none"> ● CDC – Ft. Collins ● UTMB ● NIH/NIAID <p>— Lassa fever</p> <ul style="list-style-type: none"> ● University of Maryland ● The Scripps Research Institute 	<p>— Oncology</p> <ul style="list-style-type: none"> ● University of NC – Charlotte ● ViaMune, Inc. ● University of Pittsburgh ● Vaxeal <p>— HBV Therapeutic</p> <ul style="list-style-type: none"> ● Georgia State University ● Peking University ● CaroGen <p>— Malaria</p> <ul style="list-style-type: none"> ● Burnet Institute, Australia
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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, 2018. GeoVax currently employs nine 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.

Risks and Disclosures

This Quarterly Update 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 the base report and for quarterly updates.

Investors should carefully consider the risks and information about GeoVax’s business, as described in the base report, available at <https://www.crystalra.com/research-library/geovax-0-0>. 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.

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