

Company Description

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines and immunotherapies using its novel viral vector platform technology 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 hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), Zika virus (ZIKV), malaria, and human immunodeficiency virus (HIV). 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). Furthermore, GeoVax is collaborating with Emory University to develop a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). GeoVax believes its expertise is complementary to a range of other human diseases for which there is an unmet medical need, with plans to expand its pipeline.

Key Points

- GeoVax announced its selection as a finalist in two award categories at this year's 12th Vaccine Industry Excellence (ViE) Awards program, held in conjunction with the 19th World Vaccine Congress. GeoVax's immuno-oncology product was selected as a finalist for the "Best Therapeutic Vaccine Award" and its novel MVA-VLP vaccine platform was selected as a finalist for the "Best New Vaccine Technology Award." The ViE Awards will be announced on April 15th, 2019. In 2018, GeoVax received the "Best Biotech" ViE award and was a finalist in the "Best Prophylactic Vaccine" category for its Zika virus vaccine.
- GeoVax's most advanced vaccine program is focused on preventing the clade B subtype of HIV prevalent in the larger commercial markets of the Americas, Western Europe, Japan, and Australia. This program is currently undergoing human clinical trials in the U.S. with support from NIH/NIAID. In October 2018, positive results from HVTN 114, a Phase 1 trial of GeoVax's preventive HIV vaccine, were presented at the HIVR4P conference in Madrid.
- In seeking to develop a functional cure for HIV, the Company has a collaboration with American Gene Technologies International, Inc. (AGT) to use its vaccine in combination with AGT's gene therapy, which is on track to enter a Phase 1 trial sponsored by AGT. AGT anticipates starting the trial during the second half of 2019.
- In 2018, GeoVax started with a single program within the field of immuno-oncology for tumor-associated MUC1 vaccines. This program continued to be supported by two collaborations (University of Pittsburgh and ViaMune). During 2018, GeoVax added four additional collaborations to expand its presence within this space: (1) Vaxeal Holding SA (Cyclin B1 tumor-associated antigen), (2) Emory University (HPV-related head and neck cancers), (3) Virometix AG (also for HPV-related cancers), and (4) Leidos, Inc. (multiple potential cancer targets).
- GeoVax and Enesi Pharma have recently collaborated to develop solid-dose needle-free vaccine formulations utilizing GeoVax's MVA-VLP vaccine platform combined with Enesi's ImplavaX[®] technology. The collaboration is expected to include development of thermostable solid-dose needle-free vaccines for a variety of infectious diseases and evaluation of the potential to generate improved vaccine responses with simplified administration and reduced storage and distribution costs.
- On March 27, 2019, GeoVax reported a net loss for the year ended December 31, 2018 of \$2.6 million, or (\$0.02) per share; for the year ended December 31, 2017, the Company had reported a loss of \$2.2 million, or (\$0.03) per share. At December 31, 2018, GeoVax's cash and cash equivalents were \$259,701 and total assets were \$642,064.



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GOVX (OTC.BB) One-Year Chart



Ticker (Exchange)	GOVX (OTC.BB)
Recent Price (03/29/19)	\$0.0092
52-week Range	\$0.0090 - 0.0500
Shares Outstanding	~258.04 million
Market Capitalization	~\$2.5 million
Avg. 10-day Volume	3.14 million
EPS (Qtr. ended 12/31/18)	(\$0.02)
Employees	9

RECENT DEVELOPMENTS

GeoVax's development programs continue to progress, with a growing list of world-class government, academic, and corporate collaborators (as highlighted on page 3, Current Collaborations). The Company continues to assess options to secure the capital needed to proceed with its business plan and advance its programs into human clinical testing, which is key to overall corporate development. GeoVax continues to progress toward having multiple clinical programs underway, addressing various infectious diseases and cancer indications, and having a capital structure in place to support continued implementation of its business plan. Highlights from 2018 and early 2019 include:

- **Immuno-oncology.** The Company began with a single program in this area in 2018 (tumor-associated MUC1 vaccines), which was supported by two collaborations (University of Pittsburgh and ViaMune), with this work continuing to expand and advance. During 2018, GeoVax added four additional collaborations to expand its presence within this space: (1) Vaxeal Holding SA (Cyclin B1 tumor-associated antigen), (2) Emory University (HPV-related head and neck cancers), (3) Virometix AG (also for HPV-related cancers), and (4) Leidos, Inc. (multiple potential cancer targets). Immuno-oncology represents a significant area of development for GeoVax, with the Company seeking to continue to develop these programs, contingent on raising sufficient capital.
- **Defense Department Grant.** The U.S. Department of Defense (DoD) awarded GeoVax a \$2.4 million grant to support its Lassa Fever vaccine program. The DoD has also committed to fund testing of the Company's vaccine by U.S. Army scientists at USAMRIID under a separate sub-award. This grant represents a key area for advancement by GeoVax into biodefense in applying its technology and expertise.
- **HIV "Cure" Program.** GeoVax's collaboration with American Gene Technologies International, Inc. (AGT) to use its vaccine in combination with AGT's gene therapy to develop a functional cure for HIV is on track to enter a Phase 1 trial sponsored by AGT. AGT anticipates starting the trial during the second half of 2019. GeoVax is also in discussions with two other groups to possibly use the Company's vaccine in similar efforts toward developing a cure for HIV. One or both of these studies could begin in late 2019 or early 2020.
- **HIV "Prevention" Program.** In October 2018, positive results from HVTN 114, a Phase 1 trial of GeoVax's preventive HIV vaccine, were presented at the HIVR4P conference in Madrid. The clinical trial program for the Company's preventive HIV vaccine continues to be supported by the NIH and the HIV Vaccine Trials Network (HVTN), with the next study (HVTN 132) expected to commence later this year. Worth noting is that during President Trump's recent State of the Union address, he committed to pursuing the elimination of HIV within the next decade; GeoVax's preventive vaccine developments could be critical to his core initiative.
- **NIH Support for the Lassa Fever and Zika Programs.** In April 2018, the NIH awarded GeoVax a Fast-Track Phase I/II SBIR grant for its Lassa Fever vaccine with an anticipated total project budget of up to \$1.9 million. In May 2018, the Company received \$300,000 for the second year of the NIH SBIR grant for its Zika vaccine. Both of these grants support preclinical testing of GeoVax's vaccines in non-human primates to prepare for human clinical trials.
- **New Collaborations.** In addition to the new collaborations described above, the Company is working with the Burnet Institute in Australia on its malaria vaccine program and with Georgia State University on its Hepatitis B immunotherapy program. GeoVax has further added new collaborations with Scripps Research, Institute of Human Virology, the Geneva Foundation for its Lassa Fever program, and with Enesi Pharma for developing a novel vaccine delivery platform utilizing several of its vaccines. The Company also recently expanded its relationship with Leidos, adding a malaria program to its existing cancer collaboration. These collaborations provide multiple opportunities for success and demonstrate the high level of interest its MVA-VLP platform generates within the scientific and business development community.

- **Scientific and Peer Recognition.** GeoVax’s accomplishments have been recognized through its selection for the 2018 “Best Biotech” Vaccine Industry Excellence (VIE) Award, and a finalist for the “Best Prophylactic Vaccine” for its Zika vaccine candidate at the 18th World Vaccine Congress in Washington DC, as well as a finalist for 2018 Pipelines of Promise at the Buzz of BIO in Boston.
 - In 2019, GeoVax has made it through as a finalist in two categories for this year’s VIE Awards on April 15, at the 19th World Vaccine Congress: for the “Best Therapeutic Vaccine Award” (MVA-VLP-MUC1 cancer) and “Best New Vaccine Technology Award” (MVA-VLP platform). This marks two consecutive years of recognition by industry peers of its continued progress in applying GeoVax’s expertise and technology to advance highly promising vaccines for the benefit of people worldwide.

RECENT FINANCIAL RESULTS

On March 27, 2019, GeoVax reported a net loss for the year ended December 31, 2018 of \$2.6 million, or (\$0.02) per share based on 163.6 million weighted average shares outstanding. For the year ended December 31, 2017, the Company reported a loss of \$2.2 million, or (\$0.03) per share based on 68.6 million weighted average shares outstanding. Grant and collaboration revenues of \$1.0 million for 2018 compares to \$1.1 million in 2017. Research and development expenses were \$1.9 million in 2018 versus \$2.0 million in 2017. General and administrative expenses were \$1.6 million in 2018 versus \$1.2 million in 2017. At December 31, 2018, GeoVax had cash and cash equivalents of \$259,701 and total assets of \$642,064 versus \$312,727 and \$490,235, respectively, at December 31, 2017.

CURRENT COLLABORATIONS

GeoVax’s collaborators and partners include the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), the HIV Vaccines Trial Network (HVTN), Centers for Disease Control and Prevention (CDC), U.S. Department of Defense (DoD), U.S. Army Research Institute of Infectious Disease (USAMRIID), U.S. Naval Research Laboratory (USNRL), Emory University, University of Pittsburgh, Georgia State University Research Foundation (GSURF), University of Texas Medical Branch (UTMB), the Institute of Human Virology (IHV) at the University of Maryland, the Scripps Research Institute (Scripps), Burnet Institute in Australia, the Geneva Foundation, American Gene Technologies International, Inc. (AGT), ViaMune, Inc., Vaxeal Holding SA, Virometix AG, Enesi Pharma, and Leidos, Inc.

TIMELINE OF RECENT EVENTS THIS QUARTER

- **March 27, 2019**—GeoVax announced financial results for the year ended December 31, 2018 (see page 3, Recent Financial Results).
- **March 19, 2019**—The Company announced the publication of a manuscript entitled “Single Dose Protection Against Lethal Ebola Virus Challenge.” The article is published in the open-access journal Atlas of Science and can be viewed at <https://atlasofscience.org/single-dose-protection-against-lethal-ebola-virus-challenge>.
- **March 12, 2019**— The Company announced its selection as a finalist in two award categories at this year’s 12th Vaccine Industry Excellence (ViE) Awards program, held in conjunction with the 19th World Vaccine Congress. The Company’s unique immuno-oncology product (GeoVax MVA-VLP-MUC1) was selected as a finalist for the “Best Therapeutic Vaccine Award” and GeoVax’s novel MVA-VLP vaccine platform was selected as a finalist for the “Best New Vaccine Technology Award.” The ViE Awards will be announced on April 15th.
- **March 11, 2019**—GeoVax provided an update on its progress and development programs (as outlined on pages 2 and 3).
- **March 4, 2019**— The Company announced that it has expanded its collaboration activities with Leidos, Inc. to develop malaria vaccine candidates. The work will be supported under a contract to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). Leidos has been tasked by USAID to advance promising vaccine candidates against *P. falciparum* malaria and selected the GeoVax MVA-VLP platform as part of this development effort.
- **February 14, 2019**—GeoVax published an open letter to U.S. Department of Health and Human Services (HHS) Secretary Alex Azar in response to the HHS initiative “Ending the HIV Epidemic: A Plan for America.” Click the following link to view the letter <https://www.geovax.com/news/entry/2019/02/14/geovax-issues-open-letter-to-hhs-secretary-alex-azar.html>.
- **February 7, 2019**—GeoVax commemorated National Black HIV/AIDS Awareness Day celebrating the progress toward the development of a vaccine against HIV, recognizing the work yet to be done, and bringing attention to the continued HIV epidemic in the U.S. and the disproportionate impact of the disease on African-Americans.
- **February 6, 2019**—GeoVax’s President and CEO, David Dodd responded to the State of the Union address by President Donald Trump, in which he asked Congress to support his goal of eliminating the HIV epidemic in America within 10 years. GeoVax stated:

“We applaud President Trump for using such a high-profile setting to bring attention to the continued HIV epidemic in the United States...Tremendous strides have been made in HIV awareness and treatment over the past three decades. However, despite the availability of effective HIV medications and the best efforts of community education and prevention programs, the tide of new HIV infections has not been reversed.” ...“In his budget proposal to Congress, I encourage President Trump to make vaccine development a central pillar of his HIV elimination strategy, and to take lessons from the private sector by encouraging calculated risks by public health policy decision-makers. Our country should set higher goals for addressing the U.S. HIV epidemic, ones that seek a cost-effective eradication approach and not just expensive and never-ending chronic disease management.”
- **January 24, 2019**— The Company announced the publication of a manuscript entitled “A Vaccine Candidate for Zika with Potential for Reduced Risk of Antibody-Dependent Enhancement (ADE).” The article is published in the open-access journal Atlas of Science and can be viewed at <http://atlasofscience.org/a-vaccine-candidate-for-zika-with-potential-for-reduced-risk-of-antibody-dependent-enhancement-ade/#more-27090>. The article reports a major step forward in the development of a vaccine for protection against Zika virus (ZIKV). Testing in a highly rigorous challenge model showed the GeoVax vaccine, GEO-ZM02, provided 100% protection to mice infected with a lethal dose of ZIKV delivered directly into the brain. The study was funded by a grant from the U.S. Centers for Disease Control and Prevention (CDC), which also provided technical assistance. GEO-ZM02 not

only has the potential of 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 serotypes 1-4.

- **January 22, 2019**—GeoVax reported that Senior Scientist, Mary Hauser, PhD, was to deliver a presentation, entitled “Development of a Safe and Effective Single-Dose Vaccine for Emerging Infectious Diseases, Preclinical Data for Zika, Ebola and Lassa Fever as Examples,” during the 2019 American Society for Microbiology (ASM) Biothreats Conference, being held January 29-31, 2019 in Arlington, Virginia. Dr. Hauser discussed GeoVax’s “Plug and Play” vaccine platform, which utilizes its recombinant Modified Vaccinia Ankara (MVA) vector to express foreign antigens on virus-like particles (VLPs) in the person being vaccinated.
- **January 2, 2019**—GeoVax and Enesi Pharma announced a collaboration to develop solid-dose needle-free vaccine formulations utilizing GeoVax’s novel MVA-VLP vaccine platform in combination with Enesi’s Implava[®] device and formulation technology. The collaboration is expected to include development of thermostable solid-dose needle-free vaccines for a variety of infectious diseases and evaluation of the potential to generate improved vaccine responses with simplified administration and reduced storage and distribution costs.
- **December 12, 2018**—The Company commented on the ongoing Ebola outbreak in the Democratic Republic of the Congo (DRC), stating “The ongoing Ebola outbreak in DRC is now among the deadliest in history, second only to the 2014-16 outbreak in several African nations that infected 28,652 people and killed 11,325. As of December 8, 2018, there have been 446 confirmed cases of Ebola in the Congo with 235 deaths, which disproportionately affected women and young children. The scenario is likely to worsen, as the disease has spread to a major city of 1 million people (Butembo) with 25 confirmed cases so far.” There is currently no licensed vaccine to protect people from the Ebola virus. An experimental vaccine with a limited supply is being used in a “ring vaccination” approach. This vaccine can protect after a single dose but has caused mild to moderate adverse effects that included headache, fatigue, and muscle pain in half of the vaccinated subjects. The experimental vaccine also has the logistical challenge of limited stability under conditions of normal refrigeration or room temperature storage. GeoVax’s Ebola vaccine (GEO-EM01), has shown promise for a safer and more heat stable vaccine. GEO-EM01 consists of a replication incompetent vector, modified vaccinia Ankara (MVA) that has been engineered to express non-infectious Ebola virus-like particles. GEO-EM01 also generates a protective immune response after a single dose in non-human primates but has the advantages of added safety and the ability to be stored at normal refrigerated temperature. The occurrence of two major Ebola outbreaks since 2014 highlights the need for routine vaccination in areas at risk for Ebola emergence. GeoVax is working to advance its Ebola vaccine into human clinical trials.
- **December 3, 2018**—The Company noted its observance of World AIDS Day 2018. World AIDS Day is a global initiative to raise awareness, fight prejudice, and improve education about HIV and AIDS. GeoVax is committed to an AIDS-free generation through vaccine development, and recognized and thanked its many collaborators and partners, both current and past, who have helped advance its vaccine candidates.
- **November 28, 2018**—The Company provided an update of the clinical development plan for its preventive vaccine (GOVX-B11) for clade B HIV. The HIV Vaccine Trials Network (HVTN) is moving forward with plans for a Phase 1 trial, designated HVTN 132, which will be a multi-center, randomized, double-blind trial, enrolling up to 70 healthy adults. The primary objectives of the trial will be to assess the safety, tolerability, and immunogenicity (elicited antibody responses) of a prime-boost regimen of GOVX-B11, in combination with protein boosts. HVTN 132 is expected to commence patient enrollment in mid-2019.
- **November 19, 2018**—GeoVax announced that it is collaborating with Leidos, Inc. on a research program evaluating the combination of the companies’ respective technologies. The project will include the design, construction, and characterization of multiple immunotherapeutic vaccine candidates using GeoVax’s MVA-VLP vaccine platform combined with certain novel peptide PD-1 checkpoint inhibitors developed by Leidos. The vaccine design, construction, and characterization will be performed at GeoVax with further analysis conducted by Leidos.

POTENTIAL MILESTONES

Zika

- Determine immunogenicity and efficacy in non-human primates (funded by NIAID SBIR grant)
- 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), (2019)
- Initiate Phase 1 HIV protein boost clinical trial by HVTN (pathway to efficacy trial), (mid-2019)
- Enter into additional collaborative efforts for HIV functional cure

Cancer Immunotherapy

- Continue and expand collaborations to develop cancer immunotherapy programs. Encouraging preliminary data were presented in August 2017; follow-on studies are being planned. Goal is to eventually proceed into Phase I human clinical trials

Malaria

- Preclinical data on efficacy of malaria vaccine via relationship with Burnet Institute

HPV

- Begin testing therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC) via new collaboration with Emory University to test GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV

Hepatitis B

- Continue to compile data on its Hepatitis B vaccine, with some data expected to be reported in the near term

Corporate

- Move one or two of its programs into Phase 1 human trials, and subsequently pursue a licensure
- Establish strategic collaboration resulting in capital investment and acceleration of specific development program(s)

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. It has since 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. The platform has the following manufacturing advantages: (1) no purification issues such as associated with synthetic VLPs produced in vitro; (2) no adjuvant needed; and (3) no vector immunity (no smallpox vaccine in routine use).

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 NIAID. In January 2017, the HVTN initiated a Phase 1 human clinical trial (HVTN 114) 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. In October 2018, positive results from HVTN 114 were presented at the HIVR4P conference in Madrid.

In November 2018, GeoVax provided an update of the clinical development plan for GOVX-B11, whereby the HIV Vaccine Trials Network (HVTN) is moving forward with plans for a Phase 1 trial, designated HVTN 132, which will be a multi-center, randomized, double-blind trial, enrolling up to 70 healthy adults. The primary objectives of the trial will be to assess the safety, tolerability, and immunogenicity (elicited antibody responses) of a prime-boost regimen of GOVX-B11, in combination with protein boosts. HVTN 132 is expected to commence patient enrollment in mid-2019.

Both HVTN 132 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. This program is on track to enter a Phase 1 trial sponsored by AGT. AGT expects the trial to begin during the second half of 2019.

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.

In May 2018, it was announced that the NIAID had awarded the Company a grant award of \$300,000 to fund the second year of a two-year project period with a total budget of \$600,000. The grant, entitled “Advanced Preclinical Testing of a Novel Recombinant Vaccine Against Zika Virus”, supports advanced preclinical testing of GeoVax's vaccine candidate. In January 2019, GeoVax announced the publication of a manuscript entitled “A Vaccine Candidate for Zika with Potential for Reduced Risk of Antibody-Dependent Enhancement (ADE).” The article is published in the open-access journal Atlas of Science and can be viewed at <http://atlasofscience.org/a-vaccine-candidate-for-zika-with-potential-for-reduced-risk-of-antibody-dependent-enhancement-ade/#more-27090>. The article reports a major step forward in the development of a vaccine for protection against Zika virus (ZIKV).

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 Scripps Research 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.

In April 2018, GeoVax announced that it was awarded a Fast-Track Phase I/II SBIR grant by the NIAID to advance its Lassa Fever vaccine (GEO-LM01). The \$300,000 initial grant is for Phase I of the project, with an expected total project budget of up to \$1.9 million. This grant is to enable preclinical testing of the Company's vaccine candidates in preparation for human clinical trials. The work is being performed in collaboration with the Institute of Human Virology at the University of Maryland, The Scripps Research Institute, and the University of Texas Medical Branch.

In September 2018, GeoVax announced that the U.S. Department of Defense (DoD) awarded the Company a \$2.4 million cooperative agreement in support of its Lassa Fever vaccine development program. The grant was awarded by the U.S. Army Medical Research Acquisition Activity pursuant to the Peer Reviewed Medical Research Program (PRMRP), part of the Congressionally Directed Medical Research Programs (CDMRP). In addition, DoD will also fund

testing of the GeoVax vaccine by U.S. Army scientists under a separate subaward. The project award, entitled “Advanced Preclinical Development and Production of Master Seed Virus of GEO-LM01, a Novel MVA-VLP Vaccine Against Lassa Fever”, will support generation of immunogenicity and efficacy data for GeoVax’s LF vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock to prepare for human clinical trials. The work will be performed in collaboration with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the Geneva Foundation, and Advanced Bioscience Laboratories (ABL). The work funded by this award is expected to significantly advance the development of GeoVax’s vaccine candidate, GEO-LM01, which has already demonstrated impressive preclinical results. These studies will be complementary to those being funded by the separate SBIR grant from NIAID/NIH, which is supporting development of a potentially “universal” LF vaccine by eliciting broadly neutralizing antibodies to the Lassa virus (LASV) glycoprotein designed by Scripps Research.

Ebola Vaccine

The Company published excellent results from a rigorous preclinical study of its Ebola vaccine in the peer-reviewed open access Nature journal’s Scientific Reports. In this study, GeoVax demonstrated (for the first time) that a single-dose of an MVA-Ebola vaccine provided full protection to rhesus macaques challenged with a lethal dose of live Ebola virus. The article can be viewed at www.nature.com/articles/s41598-017-19041-y. Furthermore, the GeoVax announced in March 2019 the publication of a manuscript entitled “Single Dose Protection Against Lethal Ebola Virus Challenge.” The article is published in the open-access journal Atlas of Science and can be viewed at <https://atlasofscience.org/single-dose-protection-against-lethal-ebola-virus-challenge/>.

Immuno-oncology Program

In August 2017, 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. This project is complementary to GeoVax’s ongoing collaboration with ViaMune, Inc. for co-developing cancer immunotherapies. GeoVax is also collaborating with the University of Pittsburgh and their Professor, Dr. Olja Finn, to use combined technologies for abnormal MUC1 secreting tumors.

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. GeoVax continued to work on its malaria multi antigen vaccine program in collaboration with the Burnet Institute in Australia. To date, there has been encouraging preclinical proof of concept immunogenicity data. In early March 2019, Geo Vax announced that it had expanded its collaboration activities with Leidos to develop malaria vaccine candidates. The work will be supported under a contract to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). Leidos has been tasked by USAID to advance promising vaccine candidates against *P. falciparum* malaria and selected the GeoVax MVA-VLP platform as part of this development effort.

Chronic Hepatitis B (HBV) Immunotherapy

In early 2018, GeoVax began a collaboration with CaroGen Corporation to develop a combination immunotherapy treatment for chronic hepatitis B virus (HBV) infection. This project includes 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 infection. Data is also being compiled for GeoVax's own HBV vaccine design, which is being tested in animal models at Georgia State University.

Human Papillomavirus (HPV) Infection Vaccine

GeoVax announced in August 2018 that it was collaborating with Emory University on the development of a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). The GeoVax/Emory collaboration is to include testing GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV in the laboratory of Dr. Rafi Ahmed, Director of the Emory Vaccine Center. Dr. Ahmed, a member of the National Academy of Sciences, is a world-renowned immunologist whose work during the past decade has been highly influential in shaping understanding of memory T cell differentiation and T and B cell-mediated antiviral immunity. This is important research area as there are currently no medical treatments for chronic HPV infections, which can lead to the formation of cancerous tumors.

In November 2018, GeoVax announced the expansion of its collaborative efforts in this area through a collaboration with Virometix AG. The collaboration is to include preclinical animal testing of GeoVax's MVA-vectored HPV vaccine candidates in combination with Virometix' synthetic HPV vaccine candidate. This collaboration complements the Company's ongoing collaboration with Emory University for HPV-related head and neck cancers in patients who express oncogene products of HPV16, E6, and E7 proteins. Like the strategy GeoVax is utilizing in its clinical trials for HIV and preclinical testing of its cancer vaccines (e.g. vector and protein combination), GeoVax believes the combination of its MVA-vectored HPV vaccines and Virometix' SVLP-based HPV vaccine will likely bring a synergy that significantly increases the therapeutic potential of each platform.

Company Background

GeoVax is 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.

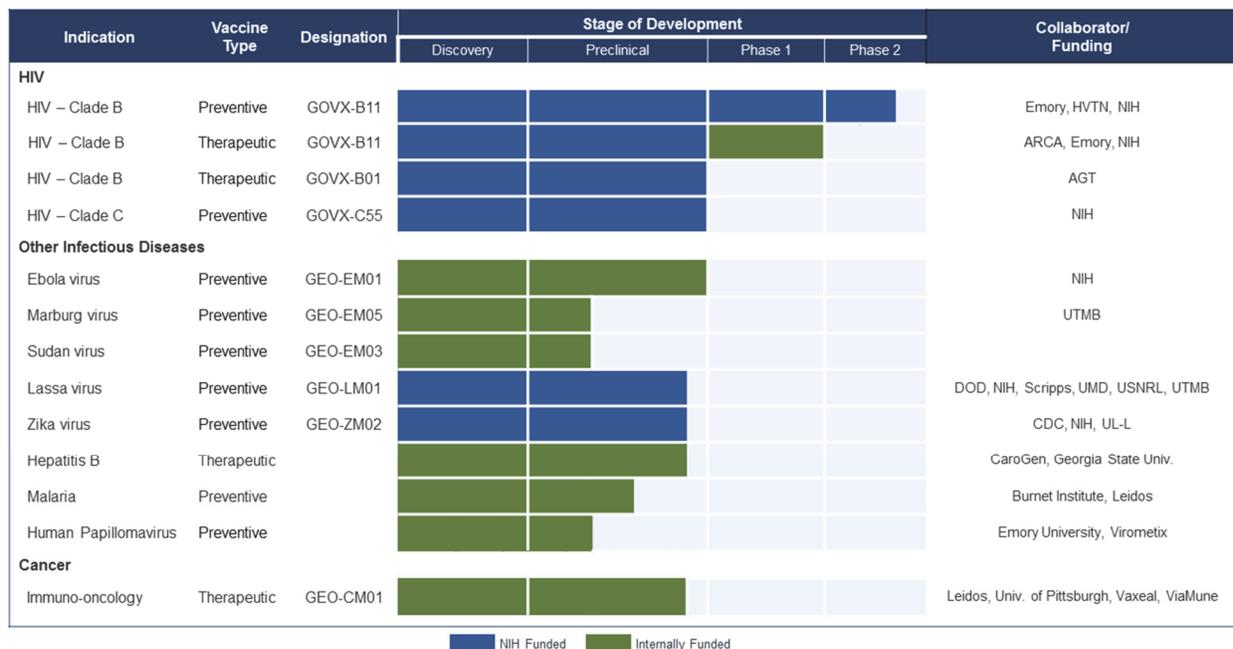
The Company’s development efforts are focused on preventive vaccines within the following important areas: human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), and malaria. GeoVax is also developing therapeutic vaccines for chronic 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). Large pharmaceutical or biotechnology companies typically do not have a significant interest in sponsoring early-stage activity in HIV until the development 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. A summary of the Company’s current MVA-VLP-based technology pipeline is provided in Figure 1.

Figure 1
MVA-VLP TECHNOLOGY PIPELINE AND COLLABORATORS



Source: GeoVax Labs, 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.

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. Recently, GeoVax announced the start of a collaboration to develop a therapeutic vaccine for human papillomavirus (HPV) infection, including preclinical animal testing of GeoVax’s MVA-vectored HPV vaccine candidates in combination with Virometix’ synthetic HPV vaccine candidate. Furthermore, during the quarter, the Company announced that it is collaborating with PharmaJet, Inc., on the evaluation of PharmaJet’s needle-free injection system for administration of GeoVax’s Zika vaccine. The Company further began a collaboration with Vaxeal Holding SA, expanding its cancer vaccine program to include the design, construction, characterization, and animal testing of vaccine candidates using GeoVax’s MVA-VLP vaccine platform with Vaxeal’s proprietary designed genetic sequences. A summary of the Company’s current vaccine research collaborations is provided in Figure 2.

Figure 2
NATIONAL & INTERNATIONAL RESEARCH COLLABORATORS



Source: GeoVax Labs, 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.

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, 2019. 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, CRA has been compensated by the Company in cash of forty-eight thousand dollars for its services in creating the base report and for quarterly updates.

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