

## Company Description

GeoVax Labs, Inc. (“GeoVax” or “the Company”) is a clinical-stage biotechnology company developing preventive and therapeutic human vaccines against infectious diseases and cancer. The Company’s proprietary GV-MVA-VLP™ vector vaccine technology utilizes a Modified Vaccinia Ankara (MVA) vector, a large virus capable of carrying several vaccine antigens, that are expressed as non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (in vivo). VLPs mimic a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection through durable immune responses. GeoVax is capitalizing on the safety and efficacy of its technology platform to address the urgent need for a COVID-19 vaccine and is also developing vaccines against human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa Fever), and malaria. Furthermore, the Company is applying its MVA-VLP technology to cancer immunotherapy (immuno-oncology).

## Key Points

- GeoVax announced financial results for the quarter ended September 30, 2020 and delivered an update on its corporate developments on November 5, 2020. The Company reported a net loss of \$570,648 for the three months ended September 30, 2020 versus a net loss of \$424,434 for the year ago period. For the nine months ended September 30, 2020, the net loss was \$1,621,546 versus net loss of \$1,780,036 for the year ago period in 2019.
- The Company reported grant and collaboration revenues of \$415,458 and \$1,572,037 for the three-month and nine-month periods of 2020, respectively, versus \$333,209 and \$907,382 for the year ago periods. These largely relate to GeoVax’s grant from the U.S. Department of Defense (DoD) for its Lassa Fever vaccine and its collaboration with Leidos, Inc. for its malaria vaccine program. As of September 30, 2020, \$417,121 of approved funds are accessible from GeoVax’s grant from the DoD.
- During the quarter, GeoVax was focused on obtaining capital needed to further progress its product development, with a specific focus on its COVID-19 vaccine as well as its cancer immunotherapy programs. On September 29, 2020, the Company closed a \$12.8 million public offering and listing its common stock (GOVX) and warrants (GOVXW) on NASDAQ.
- The Company has constructed multiple novel COVID-19 vaccine candidates and is running preclinical animal studies to identify and select one candidate to advance to a Phase 1 human clinical trial. This program is based on the Company’s MVA-VLP technology, enabling insertion of multiple antigen fragments, potentially allowing for broad-spectrum virus prevention. GeoVax is targeting the second half of 2021 to be ready to move into the clinic with its candidate.
- GeoVax recently announced the signing of a Patent and Biological Materials License Agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), in support of the Company’s development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The Patent License Agreement includes access to NIAID’s patent rights in the stabilized SPIKE protein, which is the protein that SARS-CoV-2 uses to enter human tissue.
- 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, which has a documented safety profile and is highly immunogenic, has been tested successfully through a Phase 2a human clinical trial and is being used in a follow-on clinical trial run by the HIV Vaccine Trial Network (HVTN).
- GeoVax reported cash balances of \$11,580,594 as of September 30, 2020 versus \$283,341 as of December 31, 2019.



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**GOVX (NASDAQ) One-Year Chart**



Ticker (Exchange)	GOVXD (NASDAQ)
Recent Price (11/11/2020)	\$2.90
52-week Range	\$2.30 - 60.00
Shares Outstanding	3.6 million
Market Capitalization	\$10.5 million
Avg. 10-day Volume	2.4 million
EPS (Qtr. ended 09/30/20)	(\$0.73)
Employees	8

## RECENT DEVELOPMENTS

The Company is using proceeds from its recent \$12.8 million offering to accelerate the development of its COVID-19 vaccine and immuno-oncology programs. Furthermore, GeoVax remains focused on several additional programs to continue to advance through partnering and collaborative efforts that require nominal capital investment and additional resources from the Company, as described below.

- **HIV Preventive Vaccine.** The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), is funding a clinical trial which includes GeoVax's HIV preventive vaccine (GOVX-B11) through the HIV Vaccine Trials Network (HVTN). The next trial (HVTN-132) is expected to begin in early 2021, which would further evaluate the safety and immunogenicity of adding "protein boost" components to this vaccine.
- **HIV Functional Cure Program.** Through GeoVax's mutual collaboration, American Gene Technologies International, Inc. (AGT) intends to conduct a Phase 1 human clinical trial with the combined technologies with the ultimate goal of developing a functional cure for HIV infection. GeoVax expects this vaccine to be added to an arm of the AGT trial in 2021.
- **HIV Combination Therapy.** In a program that entered clinical trials in August 2020, a consortium led by researchers at the University of California, San Francisco (UCSF) is using GeoVax's vaccine as part of a combinational therapy intended to induce remission in HIV-positive individuals.
- **Lassa Fever Vaccine.** GeoVax's Lassa Fever vaccine is progressing with funding under a cooperative agreement with the U.S. Department of Defense. The project award supports generation of immunogenicity and efficacy data for this vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparation for human clinical trials. This work is in collaboration with U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation.
- **Sudan, Marburg, and Ebola Vaccines.** GeoVax announced a multi-party collaboration for the development of its Sudan ebolavirus (SUDV) and Marburg virus (MARV) vaccine candidates in August 2020. The collaboration between the Company, researchers at the University of Texas Medical Branch (UTMB), and Battelle Memorial Institute will utilize the suite of preclinical services from NIAID, where the candidates will be tested for immunogenicity and efficacy in the benchmark nonhuman primate model. The studies are to include two vaccine regimens—single dose and prime/boost immunization—for each vaccine tested. This builds upon earlier studies in rodents and nonhuman primates for GeoVax's Ebola virus (EBOV) vaccine candidate that demonstrated 100% protection against a lethal dose of EBOV with a single immunization (conducted with support from NIAID and USAMRIID).
- **Malaria Vaccine.** The Company continues to collaborate separately with Leidos, Inc. and the Burnet Institute to develop malaria vaccine candidates using its GV-MVA-VLPTM vaccine platform. The collaboration with Leidos has been funded by a grant to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). The vaccine candidates have recently entered initial animal testing with results expected as early as year-end 2020.
- **FDA Tropical Disease Priority Review Voucher (PRV) Program.** Each one of GeoVax's development programs is focused on areas of considerable medical need and commercial opportunities. Six of the Company's vaccine programs (e.g., Ebola, Lassa, Marburg, Sudan, Malaria, and Zika) address medical areas within the FDA Priority Review Voucher (PRV) program, providing considerable potential value should any of them succeed. Section 524 of the FD&C Act authorizes the FDA to award PRVs to sponsors of approved tropical disease product applications that meet certain criteria, where with the priority review, the FDA aims to render a decision in 6 months.

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## RECENTLY ANNOUNCED LICENSE AGREEMENT WITH NIH TO SUPPORT COVID-19 VACCINE DEVELOPMENT

GeoVax announced on October 26, 2020 the signing of a Patent and Biological Materials License Agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), in support of GeoVax's development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The Patent License Agreement to GeoVax includes access to NIAID's patent rights in the stabilized SPIKE protein, which is the protein that SARS-CoV-2 uses to enter human tissue.

This Agreement allows GeoVax to use these materials and patent rights owned by agencies of the United States Department of Health and Human Services (HHS) in combination with the Company's proprietary technology to create a preventive Modified Vaccinia Ankara Virus-Virus Like Particle (MVA-VLP) vaccine that primes and/or boosts the immune system against COVID-19. The Agreement provides GeoVax with nonexclusive rights to develop, manufacture, and commercialize its COVID-19 vaccine (noting that the financial terms of this Agreement were not disclosed).

GeoVax has designed and constructed four COVID-19 vaccine candidates to date, with the goal that one will provide a single-dose, universal vaccine effective against multiple coronavirus strains. Preclinical small animal studies for the first candidate are currently being conducted in collaboration with researchers at the University of Texas Medical Branch at Galveston (UTMB), with GeoVax anticipating to accelerate small animal testing (with initial results expected near term). Furthermore, GeoVax continues active discussions and negotiations related to additional funding support, as well as securing the necessary manufacturing resources to proceed into clinical development as soon as possible.

Despite their being vaccines that have entered various stages of clinical testing (using different approaches and vector platforms than GeoVax), there is increasing evidence that alternative vaccine approaches, including those from various cohort populations will be necessary to successfully address COVID-19 and various coronaviruses. GeoVax is targeting the second half of 2021 to be ready to move into the clinic with its candidate. This timing, however, will depend on what the Company reports with its animal results, which could come in the latter part of first quarter or into early part of second quarter.

## COVID-19 DEVELOPMENT UPDATE

With over 200 COVID-19 vaccines in various development stages (according to the World Health Organization), crucial challenges remain as to the timing of public use and distribution, attributes of the various vaccines, and long-term preparation readiness for potential future pandemic challenges. The initial COVID-19 vaccines and clinical trials being funded by BARDA under Operation Warp Speed are largely focused on vaccine technologies, with existing established relationships between the federal government and specific vaccine developers. Since those vaccine technologies are largely unproven, significant questions exist regarding the safety, efficacy, and durability, in addition to the eventual public acceptance based on their performance profiles—including the feasible distribution of populations across the world.

RNA and DNA vaccines, such as those from Moderna, Pfizer, and Inovio, merely allow for specific genetic fragments, meaning that they could potentially result in a tight, narrow focus such as the COVID-19 virus as protein as the target for preventive success.

### ***Pfizer Announcement***

In an important announcement, on November 9, 2020, Pfizer announced positive early results from its late-stage vaccine trial, saying its vaccine was more than 90% effective in preventing COVID-19 among volunteers who had no evidence of prior infection. Pfizer's vaccine results are good news across the board though its crucial to determine safety and efficacy of the vaccine in subgroups, including older people, African Americans, and people with preexisting conditions. Phase three trials are the important last steps needed to get the vaccines submitted to the FDA for potential authorization and distribution. Of the 47 vaccines in clinical trials worldwide, there are currently four U.S.-backed frontrunners in Phase Three: Pfizer, Moderna, AstraZeneca, and Johnson & Johnson's. As well, Novavax, expects to begin its late-stage trial in the U.S. by months end.

Geovax believes its vaccine design and characteristics may offer improvements versus the frontrunners in terms of safety for use in immune-compromised individuals, single-dose administrations (the Pfizer vaccine requires two doses), vaccine durability, and storage/distribution logistics.

## **RECENT FINANCIAL RESULTS**

GeoVax reported a net loss of \$570,648 for the three months ended September 30, 2020 versus a net loss of \$424,434 for the same period in 2019. For the nine months ended September 30, 2020, the Company's net loss was \$1,621,546 versus a net loss of \$1,780,036 in 2019.

The Company reported grant and collaboration revenues of \$415,458 and \$1,572,037 for the three-month and nine-month periods of 2020, respectively, versus \$333,209 and \$907,382 for the comparable periods of 2019. These amounts primarily relate to GeoVax's grant from the U.S. Department of Defense (DoD) for its Lassa Fever vaccine and its collaboration with Leidos, Inc. for its malaria vaccine program. As of September 30, 2020, there were \$417,121 of approved funds remaining and available for GeoVax's grant from the DoD.

Research and development (R&D) expenses were \$416,756 and \$1,687,113 for the three-month and nine-month periods of 2020, respectively, versus \$467,674 and \$1,474,619 for the comparable periods of 2019. Variations in R&D expenses are largely attributable to the timing of expenditures related to the DoD grant. General and administrative (G&A) expenses were \$435,013 and \$1,364,650 for the three-month and nine-month periods of 2020, respectively, versus \$291,475 and \$1,214,189 for the comparable periods of 2019.

The Company's cash position as of September 20, 2020 was \$11,580,594 versus \$283,341 as of December 31, 2019. Contributing to the increase in cash balances were the sale of convertible preferred stock in January 2020 for proceeds of \$300,000, the issuance of a note payable in April 2020 for proceeds of \$170,200, the sale of convertible debentures in June 2020 for net proceeds of \$888,500, and net proceeds of approximately \$11.2 million from the September 2020 offering. Related to the September 2020 offering, an estimated \$1.2 million of convertible debentures and accrued interest were converted into the Company's equity securities. A well, \$1.5 million of accumulated amounts owed to the Company's current and former executive officers and directors were converted to equity.

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## RECENT TIMELINE OF EVENTS

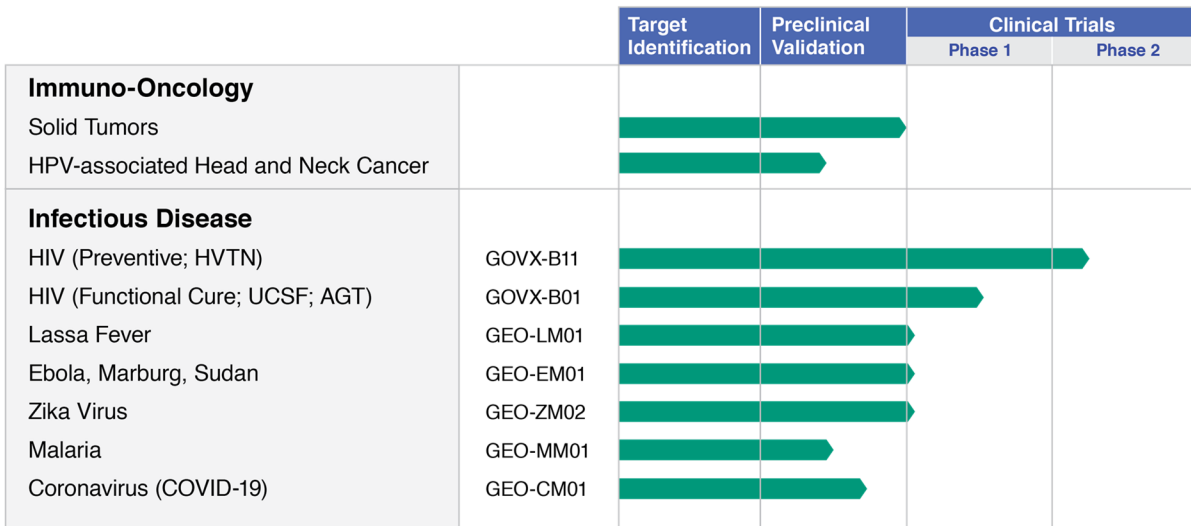
- **November 5, 2020**—GeoVax announced financial results for the quarter ended September 30, 2020 and provided an update on its corporate developments.
- **October 28, 2020**—Announced that CEO and Chairman David Dodd was to participate in an upcoming virtual webinar titled, “What COVID-19 Vaccines Teach Us About All Tech Transfers.” Sponsored by Outsourced Pharma ([www.outsourcedpharma.com](http://www.outsourcedpharma.com)). The event was held on Wednesday, November 4, 2020 at 2:00pm ET. Discussion topics included the lessons learned and best practices from the COVID-19 vaccine efforts that can be applied to technology transfers.
- **October 26, 2020**—Announced the signing of a Patent and Biological Materials License Agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), in support of GeoVax’s development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The Patent License Agreement to GeoVax includes access to NIAID’s patent rights in the stabilized SPIKE protein, which is the protein that SARS-CoV-2 uses to enter human tissue.
- **September 29, 2020**—Announced the closing of its underwritten public offering of 2,560,000 units of its common stock, pre-funded warrants, and warrants for gross proceeds of \$12.8 million before deducting underwriting discounts and commissions and other estimated offering expenses.
- **September 25, 2020**—Announced the pricing of its underwritten public offering of 2,560,000 units at a price to the public of \$5.00 per unit. Each unit issued in the offering consists of one share of common stock (or pre-funded warrant to purchase common stock in lieu thereof) and one warrant to purchase one share of common stock at an exercise price of \$5.00. The common stock and warrants are to begin trading on the Nasdaq Capital Market, on September 25, 2020, under the symbols “GOVX” and “GOVXW,” respectively. Concurrent with the offering, the Company effectuated a reverse split of its issued and outstanding common stock at a ratio of 1-for-20. The reverse stock split was effective at 12:01 a.m., Eastern Time, on Friday, September 25, 2020.
- **September 15, 2020**—Announced that its Chief Scientific Officer Emeritus, Harriet L. Robinson, PhD, was an invited speaker at the 20<sup>th</sup> Annual World Vaccine Congress, September 28<sup>th</sup> to October 1<sup>st</sup>. Dr. Robinson spoke on September 28<sup>th</sup> at 2:55 p.m. EDT in the session “Why the World Needs HIV Vaccines”. The title of her presentation is “Non-Neutralizing Antibody and HIV Vaccines, Clinical and Preclinical Experience”.
- **September 3, 2020**—Announced the publication of peer-reviewed data of a new vaccine candidate utilizing the Company’s GV-MVA-VLPTM platform against Marburg virus in animal models. The study, based on research conducted in 2019, was published on September 2, 2020 in *Nature Partner Journals (NPI) Vaccines*.
- **August 26, 2020**—Announced the appointment of Mark J. Newman, Ph.D. as Chief Scientific Officer. Dr. Newman, who previously served the company as vice president of research and development from 2010 to 2013, joins GeoVax on a half-time basis. The other portion of his working time will be devoted primarily to his work at NewMark Diagnostics, which he founded in 2016.
- **August 24, 2020**—Announced initiation of a Phase 1 clinical study of a combination therapy in HIV-positive patients utilizing GeoVax’s novel boost component MVA62B. The study is a collaboration of researchers led by Dr. Steven Deeks, Professor of Medicine in Residence at the University of California San Francisco (UCSF) and a faculty member in the Division of HIV, Infectious Diseases and Global Medicine at Zuckerberg San Francisco General Hospital. The study is designed to induce remission in HIV-positive individuals, also known as a “functional cure.” It is being funded by amfAR, The Foundation for AIDS Research.
- **August 13, 2020**—Announced a multi-party collaboration for the development of Sudan ebolavirus (SUDV) and Marburg virus (MARV) vaccine candidates. The collaboration between GeoVax, researchers at the University of Texas Medical Branch (UTMB), and Battelle Memorial Institute, and will utilize the suite of preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

## Company Background

GeoVax Labs, Inc. is a clinical-stage biotechnology company focused on developing human vaccines—both preventive and therapeutic. Its technology, targeting infectious diseases and cancer, employs the Company’s proprietary GV-MVA-VLP™ vector vaccine technology platform. This GV-MVA-VLP™ vector vaccine technology utilizes a Modified Vaccinia Ankara (MVA) vector, a large virus capable of carrying several vaccine antigens. MVA is a replication-defective live vector that expresses non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (*in vivo*). VLPs mimic a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection through durable immune responses.

The Company’s development efforts are focused on preventive vaccines within the following areas (shown in Figure 1): human immunodeficiency virus (HIV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), Zika virus (ZIKV), and malaria. GeoVax is capitalizing on the safety and efficacy of its technology platform to address the urgent need for a COVID-19 vaccine—currently a high-priority program for the Company. Moreover, the Company is applying its MVA-VLP technology to cancer immunotherapy and plans to accelerate this program with proceeds from its recent financing. Greater Company details can be found in the base report, Executive Informational Overview (<https://bit.ly/3IjIBC0>).

Figure 1  
DEVELOPMENT PIPELINE



Source: GeoVax Labs, Inc.

GeoVax’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, 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 National Institutes of Health (NIH)). Every one of GeoVax’s preventive vaccine trials have been sponsored by the NIH, with the NIH (through the HIV Vaccine Trials Network [HVTN], [www.hvtn.org](http://www.hvtn.org)) running the Company’s trials—something that is unusual within the biotechnology space.

### MVA-VLP TECHNOLOGY PLATFORM

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. Newer vaccines largely use recombinant DNA technology to produce vaccine antigens from specific portions of the DNA sequence of the target pathogen. The most successful of these purified antigens have been non-infectious VLPs, used in vaccines such as the hepatitis B vaccines (Merck’s Recombivax® and GlaxoSmithKline’s [GSK’s] Enderix®) and human papillomavirus vaccine (GSKs Cervarix® and Merck’s Gardasil®).



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 induced by vaccinia vectors. Human clinical trials of the Company's HIV vaccines have demonstrated that its VLPs, expressed from the cells of the vaccinated individual, are safe and produce both strong and durable humoral and cellular immune response.

VLPs train the body's immune system to identify and attack the authentic virus should it appear, and 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 the same way it would an authentic virus. The GeoVax technology drives the production of the VLPs in the body of the person being vaccinated (*in vivo*), thereby more closely mimicking a viral infection and inducing the appropriate types of immune responses.

Multiple studies have demonstrated the VLPs for enveloped viruses, such as HIV, Ebola, Sudan, Marburg, or Lassa fever, produced using the MVA-VLP platform are identical in appearance to the authentic virus because they include viral protein antigens and the viral envelope, consisting of membranes from the vaccinated individual's cells. In contrast, VLPs produced externally have no envelope or an envelope derived 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 recognize the authentic virus more readily. In addition, GeoVax's MVA-VLP platform has unique advantages, summarized below and further described within the report in context.

- *Safety.* Clinical testing of the GeoVax's HIV vaccines have documented an optimal safety profile. This is consistent with the safety profile for MVA used as a smallpox vaccine and documented in more than 120,000 subjects throughout Europe.
- *Durability.* The Company's vaccine technology promotes highly-durable and long-lasting immune responses.
- *Limited pre-existing immunity to vector.* Following the eradication of smallpox in 1980, smallpox vaccinations ended, which left individuals born after 1980 (except for 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 using the most modern technologies that support scalability, 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. The vaccine consists of a recombinant DNA vaccine (used to prime immune responses) and a recombinant MVA vaccine (used to boost the primed responses), with both the DNA and MVA vaccines producing non-infectious VLPs. The vaccine was developed by Emory University, the NIH, and the CDC, and was licensed by GeoVax for commercialization.

GOVX-B11 has successfully completed Phase 1 and Phase 2a human clinical trials, in which the vaccine was demonstrated to be safe and potent, inducing high level and durable antibody and cellular immune responses. These trials are supported by the NIH and conducted by the HVTN—the world's largest publicly-funded international collaborative effort focused on developing HIV vaccines.

The most recently completed trial (HVTN 114) was designed to test the ability of booster vaccinations, given on average 6.9 years after the original, to increase the antibody responses induced by GOVX-B11. This trial demonstrated that late protein boosts significantly enhanced the antibody responses by more than 600-fold for the most effective regimen tested, which might play a role in protecting individuals against HIV.

GOVX-B11 has successfully completed Phase 1 and Phase 2a human clinical trials, in which the vaccine was demonstrated to be safe and potent, inducing high level and durable antibody and cellular immune responses. The GOVXB11 vaccine was subsequently used to test multiple innovative prime-boost strategies and GeoVax is awaiting the start of a new Phase 1 trial (HVTN 132) to further evaluate the HIV vaccine strategies. The HIV vaccine clinical efforts are all supported by the NIH and conducted by the HIV Vaccine Trials Network (HVTN)—the world’s largest publicly-funded international collaborative effort focused on developing HIV vaccines. GeoVax has also developed similar vaccines designed for use against the clade C subtype of HIV that predominate in Africa, Asia, and India.

#### *HIV (Therapeutic Vaccine)*

GeoVax believes that its vaccine platform may prove useful as a component of a combination therapy to provide a cure for HIV. To this end, the Company entered into a collaboration with American Gene Technologies International, Inc. (AGT) to test GeoVax’s vaccines in combination with AGT’s gene therapy technology, as well as a separate functional cure collaborative effort led by the University of California, San Francisco (UCSF), with funding from amfAR, The Foundation for AIDS Research.

#### American Gene Technologies Collaboration

In March 2017, GeoVax announced a collaboration with AGT to develop a functional cure for the HIV infection utilizing the companies’ combined technologies. In late 2019, AGT submitted an Investigational New Drug (IND) application to the FDA for its lead HIV program, AGT103-T, a lentiviral vector-based gene therapy, which, once approved, would allow AGT to initiate a Phase 1 clinical trial. GeoVax will provide its novel MVA-VLP-HIV vaccine (MVA62B) for evaluation in combination with AGT103-T. AGT recently announced that the FDA had cleared their Phase 1 trial to begin. GeoVax expects its vaccine to be added to the AGT trial in early 2021.

#### Collaboration with UCSF

In November 2019, GeoVax entered into an agreement with the University of California, San Francisco (UCSF), for a collaborative effort to develop a functional cure for HIV. On August 24, 2020, GeoVax announced the initiation of the Phase 1 clinical study to test a therapeutic regimen involving a combination of vaccinations (DNA priming and MVA boosting), administration of broadly neutralizing antibodies (bNAbs), and a toll-like receptor 9 (TLR9) agonist. As with the AGT trial, GeoVax will provide its novel boost component (MVA62B) for use in the studies.

#### **Hemorrhagic Fever (HF) Vaccine Programs**

Ebola (EBOV), Sudan (SUDV), and Marburg viruses (MARV) are 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). Lassa fever virus (LASV) also causes severe and often fatal hemorrhagic illnesses in an overlapping region to that of Ebola, but is endemic, with an annual rate of >300,000 infections and leading to 5,000-10,000 deaths.

In agreement with the WHO, GeoVax believes that an ideal vaccine against major filoviruses and LASV must provide protection with a single dose. The MVA-VLP vaccines are well suited to meet this goal because they induce both antibody and cellular immune responses, which are needed to control and clear the infections. GeoVax’s preclinical studies in rodents and non-human primates have demonstrated 100% single-dose protection in lethal challenge models for its EBOV, SUDV, and LASV vaccines. On August 13, 2020, GeoVax announced a collaboration with University of Texas Medical Branch (UTMB) and Battelle, supported by NIAID, to further develop its SUDV and MARV vaccine candidates, and the Company has an ongoing grant from the U.S. Department of Defense supporting development of its LASV vaccine. Clinical development of the Company’s EBOV vaccine will initiate as priorities and resources are allocated in support of this program.



### **ZIKA Virus (ZIKV) Vaccine Program**

GeoVax is developing an MVA-Zika vaccine (GEO-ZM02). To date, the Company has demonstrated 100% protection of mice vaccinated with a single-dose of the Zika vaccine and exposed to a lethal dose of ZIKV. Continued development of the ZIKV vaccine will occur as priorities and resources are allocated in support of this program. Potential collaboration in the development of the Company's Zika vaccine remains within the Southern Hemisphere where the virus continues to present a critical risk.

### **Malaria Vaccine Program**

Worldwide, malaria causes 214 million infections and 438,000 deaths every year. The Company believes that the optimal malaria vaccine candidate should contain antigens from multiple stages of the malaria life cycle, and should induce functional antibodies associated with protection and strong cell mediated immunity—all attributes that GeoVax's MVA-VLP malaria vaccine candidates have demonstrated in animal models. GeoVax is collaborating with the Burnet Institute, a leading infectious disease research institute in Australia, as well as with Leidos, Inc. (under a contract from United States Agency for International Development [USAID] Malaria Vaccine Development Program) for the development of a vaccine to prevent both malaria infection and transmission.

### **Coronavirus (COVID-19) Vaccine Program**

In January 2020, GeoVax announced initiation efforts to develop a vaccine against Coronavirus Disease 2019 (COVID-19) caused by the SARS-CoV-2 coronavirus. COVID-19 is an infectious disease first identified in Wuhan, China in December 2019, and has resulted in an ongoing worldwide pandemic. As of November 9, 2020, more than 50 million cases have been reported, resulting in nearly 1.3 million deaths. The U.S. is currently considered one of the epicenters of the disease, with roughly 10.1 million cases and 238,000 deaths so far. The World Health Organization (WHO) declared COVID-19 a global pandemic on March 11, 2020. GeoVax has constructed novel candidate vaccines against SARS-CoV-2 based on the MVA-VLP platform designed to: (1) induce both neutralizing antibodies and cellular immune response; (2) induce a Th1 based cellular immune response to prevent immunopathology; (3) potentially cross-protect against other coronaviruses; and (4) induce full protection after a single dose in less than two weeks.

GeoVax is in discussions with the Biomedical Advanced Research and Development Authority (BARDA) and other entities to support and accelerate its COVID-19 vaccine development efforts. While other COVID-19 vaccine candidates are in later stages of development, the GV-MVA-VLP™ platform offers unique advantages, including safety and breadth of responses. This makes the Company's platform ideal for immunization of those most vulnerable, including the immunocompromised and comorbid. GeoVax's recently completed financing will allow it to aggressively pursue preclinical evaluation of its vaccine candidates while continuing negotiations in support of clinical development.

### **Cancer Immunotherapy Vaccine Program**

GeoVax is also developing the next generation of immunotherapies to address unmet medical needs in cancer. The Company believes that its MVA-VLP vector platform is well-suited for development of therapeutic cancer vaccines. From an investment perspective, the Company sees these efforts as a key component for strengthening the valuation of the Company and providing future value growth opportunities. To fully exploit its immuno-oncology program, GeoVax intends to focus on the advancement of its immuno-oncology programs and to seek additional, complementary technologies and clinical-stage products in the oncology space. GeoVax intends to use a portion of the proceeds from its recent financing to accelerate development of its immuno-oncology program. GeoVax's internal oncology programs include a cancer vaccine strategy for the treatment of solid tumors, combining: MVA-VLP cancer vaccines to stimulate an immune system response; immune check-point inhibitors (ICIs) to reverse immune tumor tolerance; and select peptides.

### *Solid Tumors*

The Company is collaborating with ViaMune, which has developed a fully synthetic MUC1 peptide vaccine candidate (MTI). The collaboration will assess each companies' vaccine platform, separately, and in combination, with the goal of developing a tumor MUC1 vaccine that can produce a broad spectrum of anti-tumor antibody and T cell responses. GeoVax intends to combine its MVA-VLP-MUC1 vaccine with ViaMune's synthetic peptide vaccine (MTI), standard of care (SOC), and ICIs to maximize the chances for success. Preclinical studies to test the combined MTI and MVA-VLP-MUC1 vaccines, conducted at the University of North Carolina at Charlotte, yielded positive result measures as significantly arrested tumor growth and tumor regression in a mouse model for colorectal cancer.

### *HPV*

In July 2018, GeoVax began collaborating with Emory University in developing a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). The GeoVax/Emory collaboration will include testing GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV. Furthermore, in November 2018, GeoVax announced a collaboration with Swiss-based Virometix AG, a company developing next-generation Synthetic Virus-Like Particle (SVLP™)-based vaccines, to develop a therapeutic vaccine for HPV infection. The collaboration includes preclinical animal testing of GeoVax's MVA-vectored HPV vaccine candidates in combination with Virometix's synthetic HPV vaccine candidate.

### **Partnerships**

Through its development efforts, the Company has achieved significant partnerships. Current and recent collaborators and partners include the NIAID/NIH, the HVTN, the 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, AGT, ViaMune, Inc., Virometix AG, Enesi Pharma, Leidos, Inc., and UCSF, among others.

### **Patent Portfolio**

GeoVax has a patent portfolio that consists of 58 granted or pending patents covering the Company's vaccine technology, manufacturing methods, and applications. The Company has acquired its global patent position through its research operations, collaborations, and license agreements. GeoVax's current patent portfolio includes applications directed to DNA and MVA-based HIV vaccines, their genetic inserts expressing multiple HIV protein components, composition, structure, claim of immunization against multiple subtypes of HIV, routes of administration, and safety and other related factors and methods of therapeutic and prophylactic use, including administration regimens.

### **Corporate Background**

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

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved in an investment in the Company as well as for copies of this report or the updated Base Report from October 22, 2020, please contact GeoVax by calling (678) 384-7220.



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