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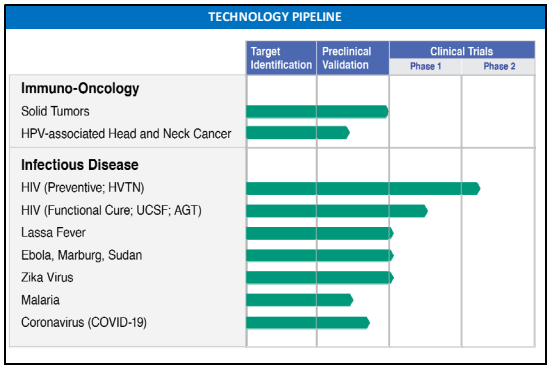
Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (10/22/2020)	$3.19
Shares Outstanding*	3.8 million
Market Capitalization	$11.4 million
Average 3-month Volume	377,347
Insider Ownership +>5%	6.9%
Institutional Ownership	25%
EPS (06/30/2020)*	($0.66)
Employees	8

* EPS figure for Q2 2020 has been restated for the 1:20 reverse split in September 2020.

GeoVax Labs, Inc. (GOVX-NASDAQ)



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's recently completed $12.8 million public offering and its uplist to Nasdaq give it the financial resources it has lacked in recent years to significantly advance its new key programs, with a focus on COVID-19 and immuno-oncology.
- 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's HIV vaccine technology was developed in collaboration with researchers at Emory University, the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC). The technology is exclusively licensed to GeoVax from Emory. GeoVax also has nonexclusive licenses to certain patents owned by the NIH used to develop the Company's other vaccines.
- GeoVax constructed multiple novel COVID-19 vaccine candidates and is running preclinical animal studies to identify and select one to advance to a Phase 1 human clinical trial.
- 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 clinical trials. GeoVax's HIV program receives substantial federal support (>$50 million to date from the NIH).
- By working with multiple collaborators on a variety of vaccine candidates, GeoVax manages its risk by providing many paths on the road to selecting the best vaccine candidate.

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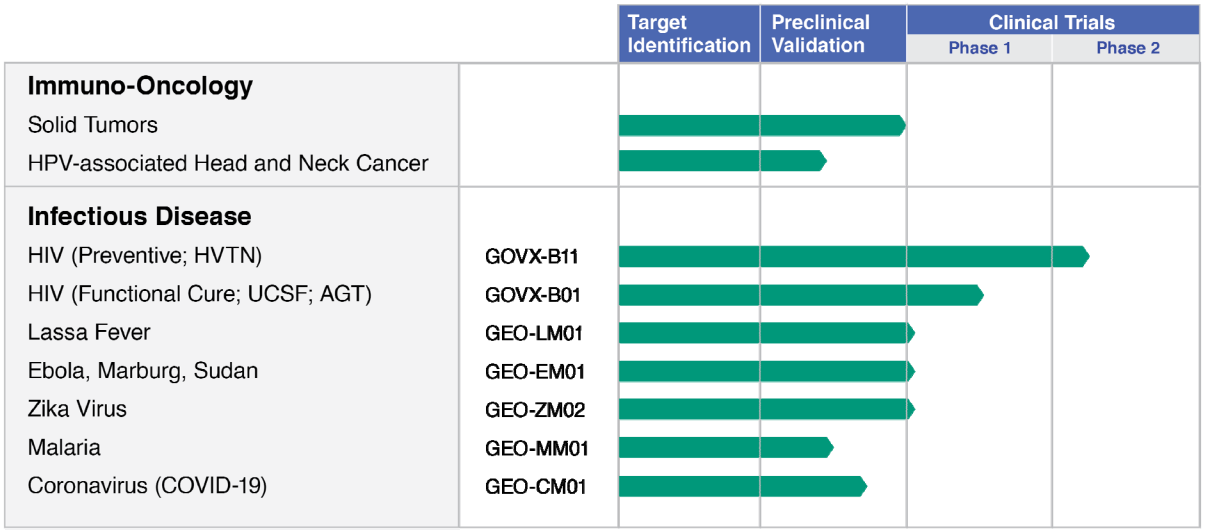
Executive Overview

GeoVax Labs, Inc. ("GeoVax" or "the Company") 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

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) 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] Engerix®) 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.

<u>American Gene Technologies Collaboration</u>

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.

<u>Collaboration with UCSF</u>

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 October 21, 2020, more than 41 million cases have been reported across 216 countries, resulting over 1.13 million deaths. The U.S. is currently considered one of the epicenters of the disease, with roughly 8.3 million cases and 221,000 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 breath 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.

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.

Milestones

GeoVax's MVA-VLP vaccine platform continues to advance by means of a growing list of corporate and academic collaborators (Figure 27, page 45), delivering promising preclinical and clinical results, as described below.

Infectious Disease Programs

HIV Vaccines (Preventive)

- GeoVax has developed a preventive HIV vaccine (GOVX-B11) from preclinical studies to human clinical trials, which has been financially supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

HIV Vaccines (Therapeutic)

- GeoVax is participating in a planned clinical trial led by researchers at American Gene Technologies (AGT) to develop a therapy aimed at eliminating HIV from infected people (a functional cure).

- GeoVax is also participating in a collaborative effort led by researchers at the University of California, San Francisco (UCSF) to develop a combinational therapy aimed at inducing remission in HIV-positive individuals (another approach toward a functional cure).

Lassa Fever Vaccine (supported by U.S. Dept. of Defense)

- GeoVax's Lassa fever vaccine continues to progress toward nonhuman primate testing and manufacturing process development in preparation for human clinical trials through grant support from the U.S. Department of Defense.

Ebola Vaccine

- GeoVax has completed efficacy testing in NHPs and is ready for cGMP manufacture and Phase 1 human trials.

Marburg and Sudan Vaccines

- These vaccines are slated to be tested in NHPs by NIH (no cost to GeoVax).

Zika Vaccine

- This vaccine has completed efficacy testing in NHPs and is ready for cGMP manufacture and Phase 1 human trials

Malaria Vaccine (collaboration with Leidos, Inc.)

- In February 2020, GeoVax expanded its ongoing collaboration with Leidos, Inc. to develop malaria vaccine candidates.

Other Emerging Infectious Disease Vaccines

- GeoVax has developed vaccines for several other pathogens, including Ebola, Sudan, Marburg and Zika virus—each representing a threat to world populations. In preclinical animal models, the Company has demonstrated 100% protection with its vaccines against each of these viruses. On August 13, 2020, GeoVax announced a collaboration with UTMB and Batelle, supported by NIAID, to further develop its SUDV and MARV vaccine candidates

FDA Tropical Disease Priority Review Voucher (PRV) Program

- Section 524 of the FD&C Act authorizes the FDA to award priority review vouchers (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. GeoVax believes that its vaccine programs in Ebola, Sudan, Marburg, Lassa Fever, Malaria, and Zika may each be eligible for a PRV and intends to apply for a PRV at the appropriate time.

- Since the first PRV was granted in 2009, there have been approximately 35 PRVs granted. Beginning in 2014, the first PRV was sold; in total 18 PRVs have been sold since 2014 for an average value of approximately $135 million. GeoVax's vaccine candidate indications that are included in the FDA PRV Program include: Ebola, Lassa, Marburg, Sudan, Malaria and Zika.

Coronavirus (COVID-19) Vaccine

- The Company's GV-MVA-VLP™ vaccine platform is being used to construct four vaccine candidates for COVID-19. The platform has a track record of safety in humans via the HIV vaccine program, with the preclinical testing results seen with its HIV vaccine, as well as its emerging infectious disease vaccines (Ebola, Sudan, Marburg and Zika). GeoVax seeks to narrow its focus to one vaccine candidate based on the safety, immunogenicity, and protective efficacy of its PreMaster Seed Viruses observed upon conducting animal studies. Subsequently, GeoVax expects to proceed directly to manufacturing and initial human clinical testing for safety and immunogenicity (pending adequate resources).

- The Company expects to have its efforts accepted through the inclusion of its vaccine in the "Draft Landscape of COVID-19 Candidate Vaccines" by the World Health Organization (WHO). While other vaccines may be advancing more rapidly toward clinical trials, GeoVax's vaccine could provide excellent safety and, due to its multi-antigen components, broader efficacy than other candidates produced using rapid platform technologies.

Financing and Uplisting to Nasdaq

On September 29, 2020, GeoVax announced the closing 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 (or pre-funded warrants to purchase common stock in lieu thereof) and warrants are immediately separable and will be issued separately.

The common stock and warrants began trading on the Nasdaq Capital Market on September 25, 2020, under the symbols "GOVX" and "GOVXW," respectively. GeoVax received gross proceeds of $12.8 million, before deducting underwriting discounts and commissions and other estimated offering expenses. Concurrent with the offering, the Company effectuated a reverse split of its issued and outstanding common stock at a ratio of 1-for-20, effective at 12:01 a.m., Eastern Time, on Friday, September 25, 2020.

Maxim Group LLC acted as sole book-running manager for the offering and Joseph Gunnar & Co., LLC acted as co-manager for the offering. GeoVax has granted the underwriters a 45-day option to purchase up to an additional 384,000 shares of common stock, pre-funded warrants, and/or warrants at the public offering price to cover over-allotments, if any.

Company Leadership

Executive Management

Key members of GeoVax's management team are profiled below.

David A. Dodd, Chairman, President and Chief Executive Officer (CEO)

Mr. Dodd joined the GeoVax Board of Directors in March 2010 and was elected Chairman in January 2011. His executive management experience in the pharmaceutical and biotechnology industries spans more than 40 years. He is a recognized leader with a high level of experience and expertise in transforming and restructuring public and private companies, and establishing strong governance processes and operational discipline. This has resulted in operational improvements, significant revenue, and enterprise value growth. During his career, he has overseen the approval of over 10 NDAs, over 15 acquisitions/divestitures, in excess of $2.5 billion in financial transactions, and over $5 billion in incremental enterprise growth. Mr. Dodd's achievements have also included the successful achievements of IPO listings, re-capitalizations, and corporate developments in multiple international jurisdictions. During Mr. Dodd's six-year tenure as President, CEO, and Director of Serologicals Corporation, the market value of that company increased over $1 billion—from $85 million when he joined SERO to an all-cash sale to Millipore Corporation of $1.5 billion, accomplished within 6 years. Mr. Dodd served as President, CEO, and Director of Solvay Pharmaceuticals, Inc., during which the enterprise value increased over $2 billion—from $100 million to $2.5 billion over a five-year period. As President, CEO, and Director of Aeterna Zentaris, Mr. Dodd led the development of an FDA approval of Macrilen™, the first and only product successfully developed and receiving regulatory approval in the history of that company. Mr. Dodd also served in executive roles with Wyeth-Ayerst Laboratories (now part of Pfizer), Bristol-Myers Squibb Company, and Abbott Laboratories. He is a frequently invited speaker and panelist at business and economic development conferences, as well as various conferences focused on the life sciences and pharmaceutical industry. Mr. Dodd is a recipient of the Oglethorpe Award for UK-US Business Relationships recognized by the British American Business Council, the Georgia BIO Industry Growth Award, and a multi-year recipient of the FastTech 50 Growth Company Award (2000-2006) while leading Serologicals Corporation. In addition, he has served on a development committee of the MacArthur Foundation, as an advisor to the First Minister of Scotland, as the Chair of the American Foundation for Suicide Prevention, as a member of the External Advisory Board of the Petit Institute for Bioengineering & Biosciences (GaTech), as the Chair of GaBio, as a board member on the Harvard Business School Healthcare Alumni Association, and in leadership roles with numerous additional organizations. Mr. Dodd holds Bachelor of Science and Master of Science degrees from Georgia State University and completed the Harvard Business School of Advanced Management Program.

Mark W. Reynolds, Chief Financial Officer (CFO)

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

Mark J. Newman, Ph.D., Chief Scientific Officer (CSO)

Dr. Newman has more than 30 years' experience in the biotechnology sector serving in senior management roles at GeoVax (Atlanta, GA), PaxVax (San Diego, CA), Pharmexa (Horsholm, Denmark), Epimmune (San Diego, CA), Vaxcel (Atlanta, GA), Apollon (Philadelphia, PA), and Cambridge Biotech (Boston, MA), where he directed research, development, and early stage clinical testing of protein, peptide, plasmid DNA and viral vectored vaccines, and multiple vaccine adjuvants. He participated with or directed teams responsible for the transition of 10 vaccine or vaccine-related products from the research stage to Phase 1 and 2 clinical testing. He also served as the primary

scientific director for multiple corporate teams that completed due diligence reviews, technology assessments, and intellectual property review and portfolio management to support strategic planning, technology in-licensing and out-licensing, corporate partnering and mergers and acquisitions. Dr. Newman has co-authored more than 100 scientific papers, reviews, and book chapters during his professional career. He is a named co-inventor on multiple issued U.S. and PCT patents, all related to vaccine technologies. He served as the Principal Investigator on multiple U.S. government and foundation grants and contracts and has served as a grant and contract review expert for more than 20 years for National Institutes of Health (NIH). Dr. Newman is a graduate of the Ohio State University (B.Sc. and M.Sc.) and received his Ph.D. in Immunology from the John Curtin School of Medical Research, the Australian National University (Canberra, Australia). He completed four years post-doctoral training at Cornell University and the Uniformed Services University of Health Sciences under contract with the National Cancer Institute, National Institutes of Health. He also served four years as a full-time member of the Louisiana State University faculty at the School of Veterinary Medicine prior to joining the biotechnology industry in 1989.

Board of Directors

Key members of GeoVax's Board of Directors are profiled below.

David A. Dodd, Chairman of the Board

Biography on page 10.

Randal D. Chase, Ph.D.

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

Dean G. Kollintzas

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

Robert T. McNally, Ph.D.

Dr. McNally joined the Board of Directors in December 2006 and was appointed as the Company's President and CEO from April 1, 2008 to his retirement on August 31, 2018. From 2000 to March 2008, Dr. McNally served as CEO of Cell Dynamics LLC, a cGMP laboratory services company. Previously, Dr. McNally was a co-founder and Senior Vice President of Clinical Research for CryoLife, Inc., a pioneering company in transplantable human tissues. He has over 35 years of experience in academic and corporate clinical investigations, management, research, business, quality and regulatory affairs. Dr. McNally is a Fellow of the American Institute for Medical and Biological Engineering, serving on the advisory boards of the Petit Institute for Bioengineering and Dupree College of

Management at the Georgia Institute of Technology, and is a former Chairman of Georgia Bio, a trade association. Dr. McNally graduated with a Ph.D. in biomedical engineering from the University of Pennsylvania.

John (Jack) N. Spencer, Jr.

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

Scientific Advisory Board

GeoVax seeks advice from its Scientific Advisory Board and Advisors, which consist of leading scientists and medical professionals, as profiled below.

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

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

Olivera (Olja) J. Finn, PhD, Scientific Advisory Board

Dr. Finn is University of Pittsburgh Distinguished Professor of Immunology and Surgery and Founding Chair of the Department of Immunology, a position she held from 2001 to 2013. She was Program Leader of the Cancer Immunology Program at the University of Pittsburgh Cancer Institute from 1991 to 2014. After receiving her PhD in Immunology at Stanford University in 1980, and completing her postdoctoral training there, Dr. Finn moved to Duke University and in 1991 to the University of Pittsburgh. She gained prominence through her original focus on transplantation biology and later through her basic and applied research focused on tumor antigens and the development of cancer vaccines. She has an extensive track record of research accomplishments reported in over 170 peer-reviewed papers and book chapters. She is the discoverer of the MUC1 tumor antigen and has published extensively and continuously for the last 25 years on her basic and preclinical work on the development and evaluation of MUC1 cancer vaccines. She has been a co-investigator on a dozen clinical trials of various MUC1 vaccines in pancreatic, colon, breast, prostate, and lung cancers. Dr. Finn and her team also identified cyclin B1 as a tumor antigen and published several papers on its excellent potential as a cancer vaccine. She is on the editorial board of various cancer journals, and on the advisory board of numerous cancer centers and several companies. She is an active member of the American Association of Immunologists, where she served seven years as Council member and one year as President; a member of the American Association for Cancer Research; and past Chair of the Steering Committee of the AACR Cancer Immunology (CIMM) Working Group.

Barney S. Graham, MD, PhD, Scientific Advisory Board

Dr. Graham is Senior Investigator at the Vaccine Research Center (VRC), NIAID, NIH, Bethesda, MD. Dr. Graham is an immunologist, virologist, and clinical trials physician whose primary interests are viral pathogenesis, immunity, and vaccine development. His work is focused on respiratory syncytial virus (RSV), influenza, coronaviruses, HIV, and other emerging viral diseases. After graduating from Rice University, Houston, TX, he obtained his MD from the University of Kansas School of Medicine in 1979. He then completed residency and two chief residencies in Internal Medicine, a fellowship in Infectious Diseases, and a PhD in Microbiology and Immunology at Vanderbilt University School of Medicine, Nashville, TN, where he rose to the rank of Professor of Medicine with a joint appointment in the Department of Microbiology and Immunology. In 2000, he became one of the founding investigators for the NIAID VRC at NIH, where he is now the Deputy Director and Chief of the Viral Pathogenesis Laboratory and oversees the advanced development of VRC candidate vaccine products. He serves as a consultant for organizations involved in vaccine development for HIV, Tb, malaria, RSV, and emerging viral pathogens. His laboratory investigates basic mechanisms by which T cells affect viral clearance and immunopathology, explores mechanisms of antibody-mediated viral neutralization, and develops vaccine approaches against respiratory virus infections and emerging viral diseases.

Stanley A. Plotkin, MD, Scientific Advisory Board

Dr. Plotkin is Professor Emeritus at the University of Pennsylvania in Philadelphia, PA and Adjunct Professor at the Johns Hopkins University, Baltimore, MD. Until 1991, he was Professor of Pediatrics and Microbiology at the University of Pennsylvania, Professor of Virology at the Wistar Institute, and at the same time, Director of Infectious Diseases and Senior Physician at the Children's Hospital of Philadelphia. In 1991, Dr. Plotkin left the University to join the vaccine manufacturer Pasteur-Mérieux-Connaught (now Sanofi Pasteur), based in Marnes-la-Coquette (outside Paris), where he held the title of Medical and Scientific Director for seven years. Dr. Plotkin developed the rubella vaccine now in standard use throughout the world, is co-developer of the pentavalent rotavirus vaccine, and has worked extensively on the development and application of other vaccines, including anthrax, oral polio, rabies, varicella, and cytomegalovirus. Dr. Plotkin's bibliography includes nearly 800 articles, and he has edited several books, including the standard textbook on vaccines – Vaccines'– now in its 6th edition. He is a consultant to vaccine manufacturers, biotechnology companies, and non-profit research organizations as principal of Vaxconsult, LLC. Dr. Plotkin attended New York University, where he received a B.A. degree, and the State University of New York Medical School in Brooklyn, where he received an M.D. degree in 1956. He has been chairman of the Infectious Diseases Committee and the AIDS Task Force of the American Academy of Pediatrics, liaison member of the Advisory Committee on Immunization Practices, and Chairman of the Microbiology and Infectious Diseases Research Committee of the National Institutes of Health. Dr. Plotkin has been the recipient of numerous awards and honors during his distinguished career.

Scott C. Weaver, PhD, Scientific Advisory Board

Dr. Weaver is Director of the University of Texas Medical Branch (UTMB) Institute for Human Infections and Immunity and the Scientific Director of the Galveston National Laboratory. An internationally recognized virologist and vector biologist, Dr. Weaver studied arthropod-borne viruses (arboviruses), their transmission by mosquitoes, and develops vaccines to control the diseases that they cause. His research encompasses the ecology and epidemiology of enzootic arbovirus transmission cycles, virus-mosquito interactions, pathogenesis, and emergence mechanisms of epidemic strains. He has also developed promising new vaccines against several alphaviruses; the chikungunya vaccine developed in his laboratory, licensed to Takeda Pharmaceuticals and patented in 19 countries, is in late preclinical development. Dr. Weaver's research has led to over 270 peer-reviewed publications in scientific journals, and 75 reviews and book chapters. In 2014, Dr. Weaver received the Walter Reed Medal, awarded every three years by the American Society of Tropical Medicine and Hygiene for distinguished career accomplishments in tropical medicine research. His many national and international leadership roles include his current role as Chair of the Global Virus Network's Chikungunya and Zika Task Forces. He also serves as an editor for several major tropical medicine and microbiology journals.

Intellectual Property

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 regimes.

GeoVax's patent portfolio also includes patent applications directed to preventive vaccines against hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), Zika virus, human papilloma virus (HPV), and malaria, and use thereof; and immuno-oncology vaccine compositions and methods of use. The Company has a pending U.S. application directed to its virus-like particle (VLP) platform technology and recently filed several provisional patent applications directed to various MVA-based vaccines for the treatment of SARS CoV-2.

GeoVax is the exclusive, worldwide licensee of several patents and patent applications, which the Company refers to as the Emory Technology, owned, licensed, or otherwise controlled by Emory University for HIV or smallpox vaccines pursuant to a license agreement originally entered into on August 23, 2002 and restated on June 23, 2004. Through the Emory License, GeoVax is also a non-exclusive licensee of four issued United States patents owned by the NIH related to the ability of the Company's MVA vector vaccine to operate as a vehicle to deliver HIV virus antigens, and to induce an immune response in humans.

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

A summary of the Company's patent portfolio is provided in Figures 2 and 3 (pages 15 and 16), including its in-licensed and Company-owned patent rights. This is followed by Figure 4 (page 17), which provides pending in-licensed patents and patent applications.

MVA-COVID-19 Vaccine Intellectual Property Strategy

Most recently, provisional patent applications were filed in February, March, and May 2020 covering current GEO-CM0X vaccine candidates and backups employing enhanced antigenic VLP display strategies and construct design. The creation of the GEO-CM0X vaccines was made possible through the contribution of materials and methods developed in the laboratory of Dr. Bernard Moss of the National Institute of Allergy and Infectious Diseases (NIAID), Laboratory of Viral Diseases (LVD).

Figure 2

COMPANY-OWNED PATENT RIGHTS

Patent Family	Jurisdiction	Patent	Effective Filing	Status	Expiration
GEO-300 **Ebola/Marburg/Lassa Virus Compositions**	USSN 15/543,139		12Jan16	Pending	12Jan36 (est.)
GEO-400 **Multivalent HIV Vaccine Boost (SBIR Ph2)**	USSN 16/077,215		16Feb17	Pending	16Feb37 (est.)
	EP 17753803.0		16Feb17	Pending	
	CA 3,014,419		16Feb17	Pending	
GEO-500 **MUC1 Vaccine**	USSN 16/068,527		9Jan17	Pending	9Jan37 (est.)
	USSN 16/796,350		9Jan 17	Pending	
	EP 17736506.1		9Jan17	Pending	
	CA 3,011,014		9Jan17	Pending	
	IN 201817026156		9Jan17	Pending	
	AU 2017206102		9Jan17	Pending	
	CN 201780016086.9		9Jan17	Pending	
	JP 2018-554658		9Jan17	Pending	
GEO-800 **Zika Virus Vaccine Compositions**	US 16/074,947		3Feb17	Pending	3Feb37 (est.)
GEO-900 **Malaria Vaccine**	US 16/648,693		19Sep18	Pending	19Sep38 (est.)
GEO-1000 **Lassa Vaccine Compositions**	US 16/631,489		18Jul18	Pending	18Jul38 (est.)
GEO-1100 **Immuno-Oncology Vaccine**	US 16/641,728		24Aug18	Pending	24Aug38 (est.)
GEO-1400P **Cancer Vaccine**	PCT/US20/35995		03Jun20	Pending	03Jun40
19101-002 **Vaccine and Use Thereof to Induce an Immune Response to 2019 Novel Coronavirus**	US 62/976,913		14Feb20	Pending	14Feb41 (Est.)
	US 62/977,402		16Feb20	Pending	
	US 62/992,710		20Mar20	Pending	
	US 63/026,580		18May20	Pending	14Feb41 (Est.)

GEOVAX/GEORGIA STATE CO-OWNED PATENT APPLICATIONS

Patent Family	Jurisdiction	Patent	Effective Filing	Status	Expiration
GEO-600 **HBV Vaccine Compositions**	CA 3,026,054		30May17	Pending	30May37 (est.)
	CN 201780047473.9		30May17	Pending	
	EP 17807327.6		30May17	Pending	
	US 16/305,305		30May17	Pending	

Source: GeoVax Labs, Inc.

Figure 3
IN-LICENSED PATENT RIGHTS

Patent Family	Jurisdiction	Patent	Effective Filing	Status	Expiration
0008 **Parent DNA Family (Emory University, NIH, CDC)** DNA Expression Vectors and Methods of Use	USSN 11/009,063	7,795,017	9Dec04	Issued	←10Jan23
	CA	2,401,974	2Mar01	Granted	2Mar21
	IN	245,816	2Mar01	Granted	
2084 **Emory 2nd CIP Family (Emory University, NIH, CDC)**	USSN 10/336,566	8,623,379	3Jan03	Issued	← 3Jan23
	USSN 14/137,095	9,254,319	20Dec13	Issued	10Mar23
	AU	2003,220111	10Mar03	Granted	
	CA	2,478,371	10Mar03	Granted	
	IN	248,360	10Mar03	Granted	
	EP 1010184784 (DE, FR, GB)	2368985	10Mar03	Granted	
2080 **NIH Filed 1st MVA Family (Emory, NIH)** MVA Expressing Modified HIV Envelope, GAG and POL genes	USSN 12/018,150	7,867,982	22Jan08	Issued	←19Apr22
	USSN 12/987,791	8,916,172	10Jan11	Issued	
	JP	4,554,887	1Mar02	Granted	1Mar22
	EP (DE, FR, GB)	1,372,710	1Mar02	Granted	
	CA	2,454,959	1Mar02	Granted	
6056 **NIH Filed 2nd MVA Family (Emory, NIH)** Recombinant MVA Viruses Expressing Clade A/G, Clade B, and Clade C Modified HIV ENV, GAG and POL genes	USSN 11/574,285	9,453,239	29Aug05	Granted	←21Aug28
92001 **NIH Background MVA (NIH)** Recombinant Vaccinia Virus Containing a Chimeric Gene Having Foreign DNA Flanked by Vaccinia Regulatory DNA nonexclusive license	USSN 07/987,546	7,045,313	7Dec92	Issued	14Feb23
	USSN 08/470,360	6,998,252	6Jun95	Issued	14Feb23
	USSN 08/470,359	7,045,136	6Jun95	Issued	16May23
	USSN 08/470,357	7,015,024	6Jun95	Issued	21Mar23

Source: GeoVax Labs, Inc.

Pending In-Licensed Patents and Patent Applications

The MVA backbone that the Company uses in its vaccines was provided by the laboratory of Dr. Bernard Moss of the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The Company has agreed on the material terms for a non-exclusive commercial license to the NIH MVA backbone for its SARS CoV-2 vaccine with the NIH, which includes the use of the patents and patent applications listed below. The Company has also agreed on material terms for a non-exclusive research and development license to use the MVA backbone and its listed patents and applications for its other vaccine candidates. The licenses have been approved by the appropriate committees within the NIH and are awaiting final signature. If GeoVax elects to proceed with one or more vaccines developed under the research and development license, the Company will negotiate appropriate commercialization licenses.

Figure 4
PENDING IN-LICENSED PATENTS AND PATENT APPLICATIONS

U.S. Patent/Patent Application	Title	Estimated Expiration Date
U.S. 6,998,252	Recombinant poxviruses having foreign DNA expressed under the control of poxvirus regulatory sequences.	Feb. 2023
U.S. 7,015,024	Compositions containing recombinant poxviruses having foreign DNA expressed under the control of poxvirus regulatory sequences.	Mar. 2023
U.S. 7,045,136	Methods of immunization using recombinant poxviruses having foreign DNA expressed under the control of poxvirus regulatory sequences.	May 2023
U.S. 7,045,313	Recombinant vaccinia virus containing a chimeric gene having foreign DNA flanked by vaccinia regulatory DNA.	Feb. 2023
U.S. 9,133,480	Recombinant modified vaccinia ankara (MVA) vaccinia virus containing restructured insertion sites.	Mar. 2032
U.S. 9,879,231	Recombinant modified vaccinia ankara (MVA) vaccinia virus containing restructured insertion sites.	Oct. 2031
U.S. 9,133,478	Modified vaccinia Ankara (MVA) virus recombinants comprising heterologous coding sequences inserted into the intergenic regions between essential genes	Jun. 2031
U.S. 10,421,978	Intergenic sites between conserved genes in the genome of modified vaccinia ankara (MVA) vaccinia virus	Aug. 2027
U.S. App. No. 16/344,774	Prefusion coronavirus spike proteins and their uses.	Oct. 2037
U.S. App. No. 16/579,276	Intergenic Sites Between Conserved Genes in the Genome of Modified Vaccinia Ankara (MVA) Vaccinia Virus	Aug. 2027
U.S. Prov. App. No. 62/972,886	2019-nCoV vaccine.	Feb. 2041

Source: GeoVax Labs, Inc.

Core Story

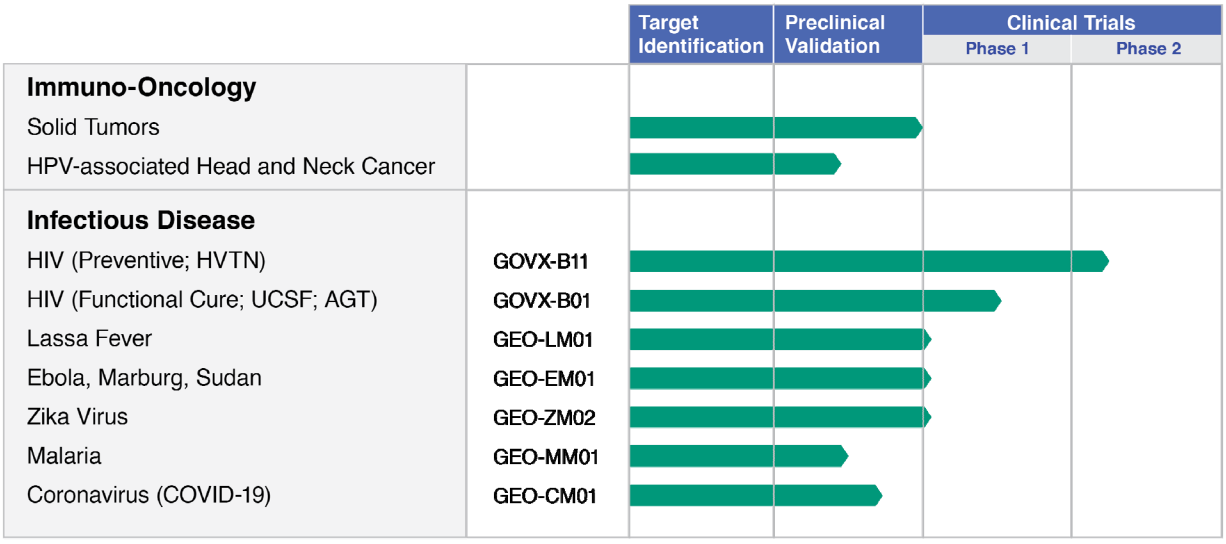
GeoVax Labs, Inc. is a clinical-stage biotechnology company developing safe and effective vaccines and immunotherapies against infectious diseases and cancer using its innovative and patented Modified Vaccinia Ankara Virus-Like Particle (MVA-VLP) vaccine platform technology. The Company's MVA-VLP vector vaccine technology (GV-MVA-VLP™) combines two key components:

(1) the safety of a replication-defective live vector technology (MVA—a large virus capable of carrying multiple vaccine antigens); and

(2) the immunogenicity of virus-like particles (VLPs)—small particles that resemble viruses but are non-infectious because they contain no viral genetic material). Upon vaccination, MVA-VLPs mimic a natural infection in which target proteins are displayed on the surface of the VLPs produced by the vaccine. The VLP-displayed proteins stimulate both humoral and cellular arms of the immune system to recognize, prevent, and control the target infections, while maintaining the safety characteristics of a replication-defective vector. GeoVax's platform results in highly immunogenic, long-lasting, and safe vaccines. Key attributes of this platform include the need for only a single dose with no adjuvant, durable immunity, and cost-effective manufacturing that is conducive to affordable scale-up for use in both epidemic response and routine vaccination.

GeoVax's development programs include preventive and therapeutic vaccines against human immunodeficiency virus (HIV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), Zika virus (ZIKV), and malaria. The Company is also looking to capitalize on the safety and efficacy of its technology platform to address the urgent need for a COVID-19 vaccine. GeoVax is moreover applying its MVA-VLP technology to cancer immunotherapy (immuno-oncology). Figure 5 summarizes the Company's pipeline, followed by greater details of each development effort.

Figure 5
TECHNOLOGY PIPELINE



Source: GeoVax Labs, Inc.

According to the Company, its MVA-VLP technology offers a platform that is well suited for use against a wide range of cancers and infectious diseases. GeoVax believes that its technology and vaccine development expertise is compatible with a variety of human diseases for which there is an unmet medical need. The Company seeks to advance its product candidates through human clinical testing and subsequently pursue partnership or licensing arrangements to achieve regulatory approval and commercialization. GeoVax also engages third party resources through collaborations and partnerships for preclinical and clinical testing with multiple government, academic, and corporate entities.

MVA-VLP has distinct advantages, including the ability to use single inoculations to achieve protection for HF and ZIKV, the ability to generate both antibody and T-cell responses, and the production of durable immune responses. The Company's vaccines for HIV, HF viruses, and ZIKV have proven safe, immunogenic, and protective in preclinical trials, with the HIV vaccine demonstrating outstanding safety and immunogenicity in clinical trials; it is now being prepared for efficacy testing in the presence and absence of a protein boost.

MVA-VLP and MVA Platform Technology

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

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

Origination of MVA

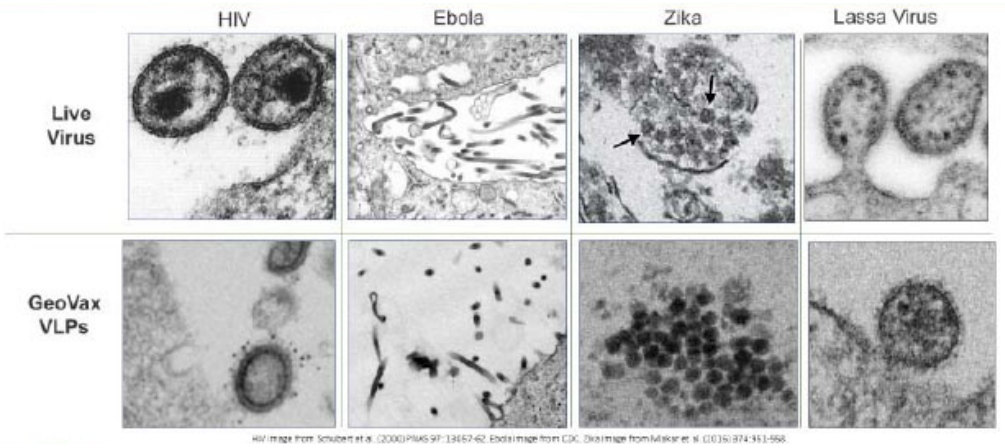
MVA is an attenuated form of the smallpox vaccine developed for use in individuals considered to be at risk for the standard smallpox inoculation. MVA originated from the dermovaccinia strain of vaccinia virus (smallpox vaccine) that was retained for many years at the Ankara Vaccination Station in Turkey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

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

VLPs are small particles that resemble viruses but are non-infectious because they contain no viral genetic material. VLPs impersonate the viral presentation of these antigens and thus generate strong and specific immune responses to a wide variety of viruses. Most VLPs exit cells using the pathways of their parent virus. Figure 6 (page 21) illustrates examples of thin section electron micrographs of actual viruses and VLPs for these viruses expressed by GeoVax's MVA-VLP vaccines. The MVA vectors can also be used to express proteins that do not form VLPs.

Figure 6

GEOVAX'S VLPs MIMIC NATIVE VIRUS STRUCTURE



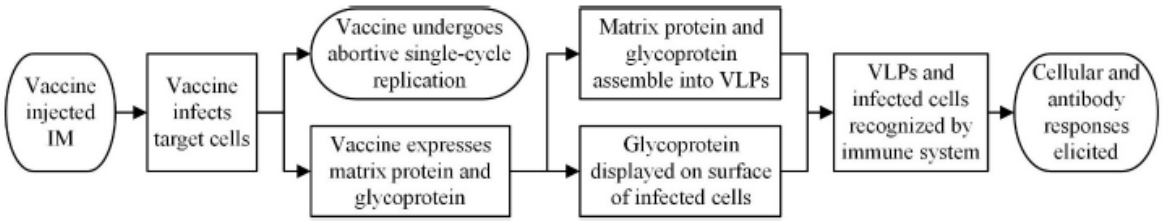
Source: GeoVax Labs, Inc.

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

Each MVA-VLP vaccine has up to two expression cassettes, each expressing one or more antigens selected from pathogens of interest. At a minimum, each vaccine expresses two antigens required for VLP formation; in the case of HIV and HF vaccines, a viral matrix protein and an envelope glycoprotein. GeoVax use a synthetic early/late promoter that provides high (non-lethal) levels of insert expression, which is initiated immediately after infection. The process by which MVA-VLP vaccines elicit cellular and humoral immune responses is shown in Figure 7, assuming intramuscular injection (noting that vaccines administered by other routes function by the same mechanism).

Figure 7

ELICITATION OF IMMUNE RESPONSES BY MVA-VLP VACCINE



Source: GeoVax Labs, Inc.

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

GeoVax's Approach

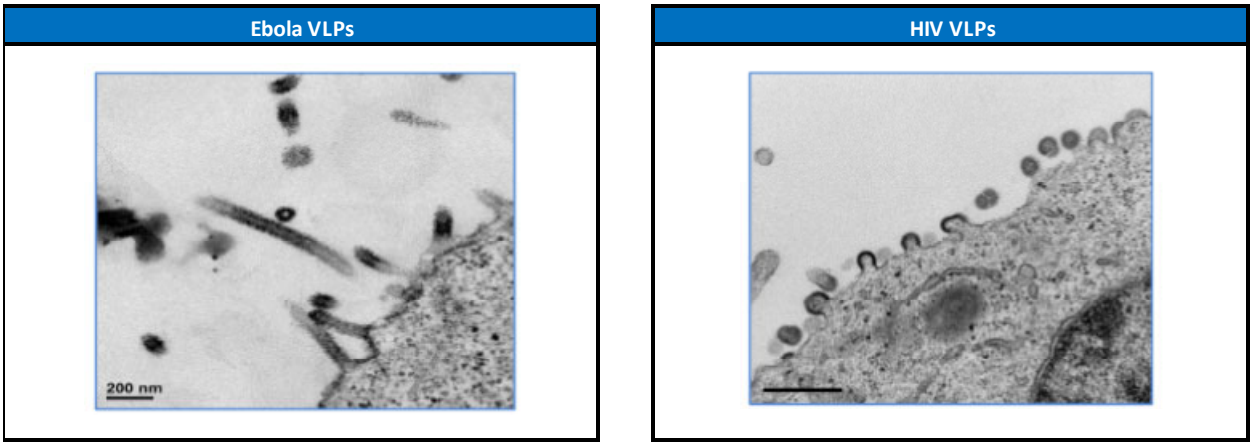
The approach employed by GeoVax uses recombinant DNA or recombinant MVA to produce VLPs within the individual being vaccinated *(in vivo*). Human clinical trials of the Company's HIV vaccines have demonstrated that its VLPs, expressed from the cells of the vaccinated individual, are safe and produce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

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

Figure 8 shows the Ebola VLPs (left) self-assemble into the rod-like shape of the actual Ebola virus, while the HIV VLPs (right) assume the spherical shape of the actual HIV virus. Thus, both types of VLPs display what GeoVax believes to be the native form of the respective viral envelope glycoproteins—something which the Company feels is critical to producing an effective humoral immune response. MVA was selected by GeoVax for the live viral component of its vaccines due to its well-known safety record along with the vector's ability to carry adequate viral proteins in order to produce VLPs.

Figure 8

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



Source: GeoVax Labs, Inc.

Proven Delivery Platform

GeoVax has successfully tested its MVA-based VLP platform in preclinical models for HIV and Ebola vaccines, as well as in Phase 1 and Phase 2 clinical trials for an HIV vaccine. The advantages of MVA-VLP versus other MVAs and vaccinia viruses, as summarized in Figures 9 and 10 (pages 23 and 24), include: VLP formation, immunogenicity, safety, and transgene stability.

Figure 9

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

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

++ High + Medium - Low

Source: GeoVax Labs, Inc.

Platform Advantages

Since the 1980s, MVA vaccines have been under development in academic as well as commercial settings. GeoVax is focused on developing MVA vaccines expressing VLPs, which is unique. Other companies also use MVA as a vaccine vector (e.g., Bavarian Nordic and Transgene, among others). In addition, the Jenner Institute of Oxford University (among other research organizations) has an active MVA program in which MVA vaccines are being used primarily as heterologous boosts. GeoVax believes that its MVA platform affords the following unique advantages, as summarized below and in greater detail in Figure 10 (page 24):

- *Safety.* GeoVax's HIV vaccines have demonstrated exceptional safety in multiple human clinical trials. In general, safety for MVA has been shown in over 120,000 subjects in Europe, including immunocompromised individuals, during the initial development of MVA and its use as a safer vaccine against smallpox.

- *Durability.* GeoVax's technology raises highly-durable (long-lasting) vaccine responses, the most durable in the field of vectored HIV vaccines.

- *Limited pre-existing immunity to vector.* Following the eradication of smallpox in 1980, smallpox vaccinations subsequently ended, leaving all but those born before 1980 and selected populations (medical workers, first responders) unvaccinated and without pre-existing immunity to MVA-derived vaccines.

- *No need for adjuvants.* MVA generally stimulates strong innate immune responses and does not require the use of adjuvants.

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

- *Genetic stability and manufacturability.* If appropriately engineered, MVA is genetically stable and can reliably be manufactured in either the established Chick Embryo Fibroblast cell substrate, or novel continuous cell lines that support scalability as well as greater process consistency and efficiency.

Figure 10

ADVANTAGES OF THE GEOVAX MVA PLATFORM

Feature	Advantage
Safety in all targeted populations, including immunocompromised individuals	MVA vaccines are expected to be safe in all targeted populations, including the immunocompromised, based on the safety of GeoVax's HIV vaccines in clinical trials. Safety for the MVA vector has been shown in more than 120,000 subjects in Europe, including immunocompromised individuals during the initial development of MVA and more recently with the development of MVA as a safer vaccine against smallpox.
Rapid elicitation of protective immunity after a single dose	GeoVax MVA vaccines are expected to elicit protective immunity after a single dose based on GeoVax results against Ebola challenge in macaques. In the Ebola study, antibody responses reached levels generally considered to be protective in under two weeks.
Durability of immune response	GeoVax/NIAID rMVA technology raises highly durable Ab responses, the most durable in the field of vectored HIV vaccines. The Company hypothesizes that elicitation of durable vaccine responses is conferred on responding B cells by the vaccinia parent of MVA, which raises highly durable responses for smallpox.
Elicitation of both humoral and cellular immune responses	Extensive experience with MVA vectors has demonstrated their ability to raise humoral and cellular immune responses, and has provided strong precedent for safe and effective use against multiple indications.
Rapid production of prototype vaccines	MVA is well established as a vaccine vector, and vaccines can be constructed quickly and easily using standard molecular biology techniques.
High "carrying capacity" to express multiple viral antigens	GeoVax has had success expressing multiple HIV-1 proteins with a single MVA vector. Immunogenicity and safety have been demonstrated for other MVA vaccines expressing up to four antigens from a single construct.
Thermostable formulation	MVA is stable in both liquid and lyophilized dosage forms. Precedent for lyophilization of MVA-vectored vaccines suggest that a lyophilized MVA vaccine would be highly thermostable and suitable for long term storage at refrigerator temperature.
No need for adjuvants	MVA stimulates strong innate immune responses and does not require the use of adjuvants.
Limited pre-existing immunity to vector, suitability for repeated use	Following the eradication of smallpox in 1980, smallpox vaccinations subsequently ended, leaving all but those born before 1980 and selected populations (such as vaccinated laboratory works, first responders) unvaccinated and without pre-existing immunity. Repeated immunizations with rMVA have been shown to boost responses, including neutralizing antibody
Robust, flexible, and scalable manufacturing processes	A scalable, cell culture-based process, which uses single-use bioreactor technology for robust flexible and scalable upstream manufacturing process combined with downstream process, which uses industry standard product and impurity binding membranes, also leveraging the Company's disposables-based approach for flexible manufacturing. The manufacturing process developed for other MVA-based vaccines has been demonstrated to support most constructs produced to date.
Genetic stability in manufacturing	If appropriately engineered, MVA can reliably be manufactured in Chicken Embryo Fibroblasts (CEFs) or novel continuous cell lines that support scalability as well as greater process consistency and efficiency.

Source: GeoVax Labs, Inc.

Infectious Disease Programs

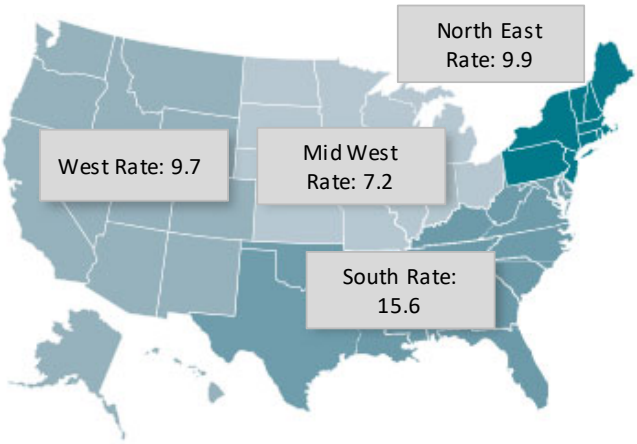
HIV/AIDS VACCINE PROGRAM

With an estimated 38 million people living with HIV worldwide and roughly 1.7 million newly infected annually, HIV/AIDS is considered by key opinion leaders (KOLs) in the scientific and medical community to be the most lethal infectious disease in the world and is the fifth leading cause of death globally. Since the start of the HIV pandemic in 1981, more than 75 million people have been infected with the HIV virus and about 32 million people infected with virus have died (Source: UNAIDS' *Global HIV & AIDS statistics—2020 fact sheet*). The U.S. has an estimated 1.2 million individuals infected with HIV, with roughly 38,000 new infections per year. Worldwide, there are roughly 690,000 deaths per year, with approximately 15,800 of these in the U.S. (Source: HIV.gov).

HIV affects every corner of the U.S., though the rate (number of diagnoses per 100,000 people) is highest in the South (15.6 per 100,000 people), followed by the Northeast (9.9), West (9.7) and the Midwest (7.2), as depicted in Figure 11. Most of the new HIV infections happen in men who have sex with men (MSM) of all races and ethnicities, followed by African American heterosexual women. By race/ethnicity overall, African Americans are the most heavily affected population (with 39.2% of new infections occurring in African Americans), followed by Latinos (Source: U.S. Centers for Disease Control and Prevention [CDC]).

Figure 11

RATES OF HIV DIAGNOSES PER REGION, 2018



Source: U.S. Centers for Disease Control and Prevention (CDC).

HIV remains a significant health problem in the U.S., particularly among gay and bisexual men, who bear the greatest burden by risk group, accounting for 69% of the new HIV diagnoses and 86% of diagnoses among males in 2018 (Source: CDC's *HIV in the United States and Dependent Area).*

Several AIDS-causing HIV virus subtypes, or clades, are found throughout different regions of the world. These clades are identified as clade A, clade B, and so on. The predominant clade found in Europe, North America, parts of South America, Japan and Australia is clade B, whereas the predominant clades in Africa are clades A and C. In India, the predominant clade is clade C. Genetic differences between the clades could mean that vaccines or treatments developed against HIV of one clade may be only somewhat effective or in fact, ineffective against HIV of other clades. Therefore, a geographical focus to designing and developing HIV vaccines is important.

HIV Treatment Landscape

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

Importantly, there is no approved HIV vaccine. Current antiretroviral therapies (ARTs) do not eliminate HIV infection and infected individuals must remain on these drugs for life. Successful long-term adherence to therapy is also limited, where only about 30% of infected individuals remain on HIV care with their viral load sufficiently suppressed to prevent spread of HIV. As well, the financial load to U.S. taxpayers for HIV education, prevention, and treatment costs is expected to reach over $25 billion annually.

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

History of HIV Vaccines and the RV144 Trial

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

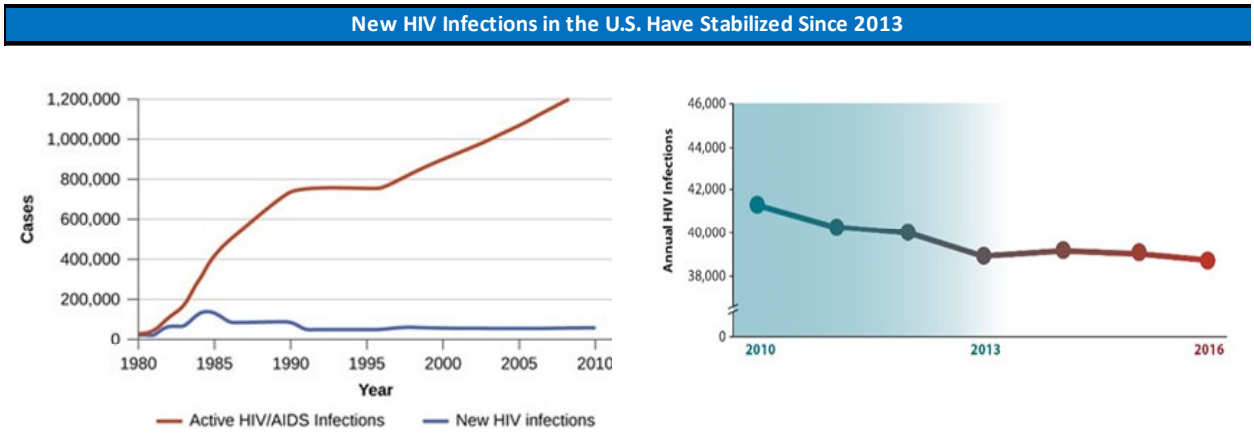
On February 3, 2020, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), announced the halt of the HVTN 702 clinical trial, which had been underway in South Africa since 2016. Although there were no safety concerns, an independent data and safety monitoring board (DSMB) found during an interim review that the regimen did not prevent HIV infection. The HVTN 702 vaccine regimen consisted of two experimental vaccines supplied by Sanofi Pasteur and GSK. The Sanofi Pasteur vaccine was based upon the vaccine used in the RV144 trial, the only vaccine to date to demonstrate HIV prevention. For HVTN 702, the vaccine regimen was adapted to the HIV subtype Clade C—most common in southern Africa, where the pandemic is most pervasive.

The Need for an HIV/AIDS Vaccine

The CDC estimates that there are approximately 1.2 million people in the U.S. living with HIV, with about one in seven of these individuals unaware that they are infected. Efforts to prevent HIV have led to hopeful declines in new diagnoses among certain populations, including African Americas, gay and bisexual men, and heterosexuals, along with a steadying in new diagnoses among Hispanics. According to the CDC, and as illustrated in Figure 12 (page 27), since the peak of the epidemic in the mid-1980s, the number of new HIV infections every year in the U.S. has been reduced by over 70%—from roughly 130,000 in 1985 to approximately 38,000 in 2018. Due to treatment advances since the late 1990s, the number of people living with HIV (HIV prevalence) has increased dramatically. However, despite increasing HIV prevalence and more opportunities for HIV transmission, the number of new infections has remained relatively stable since 2013.

Figure 12

HIV PREVALENCE AND NEW INFECTIONS

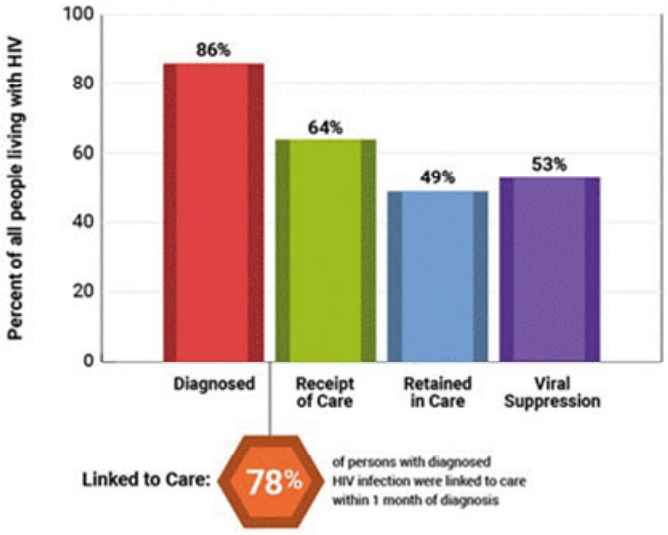


Sources: Lumen Microbiology and the CDC.

As shown in Figure 13, of the 1.2 million individuals who are known or suspected of being infected with HIV, only 53% ultimately remain in viral control.

Figure 13

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



Source: HIV.gov.

Financial Impacts of HIV

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

According to the CDC, for every HIV infection that is prevented, an estimated $379,668 is saved in lifetime medical care—a significant cost-savings for the U.S. federal government that spent $27.5 billion on domestic HIV research, care, and treatment in 2016, through numerous federal programs and departments, including the **Ryan White Act** (the largest federally funded program in the U.S. for people living with HIV/AIDS), Medicare, Medicaid, the NIH, the CDC, and the U.S. Department of Veterans Affairs (VA), among others (Sources: CDC and the U.S. Department of Health & Human Services' HIV.gov).

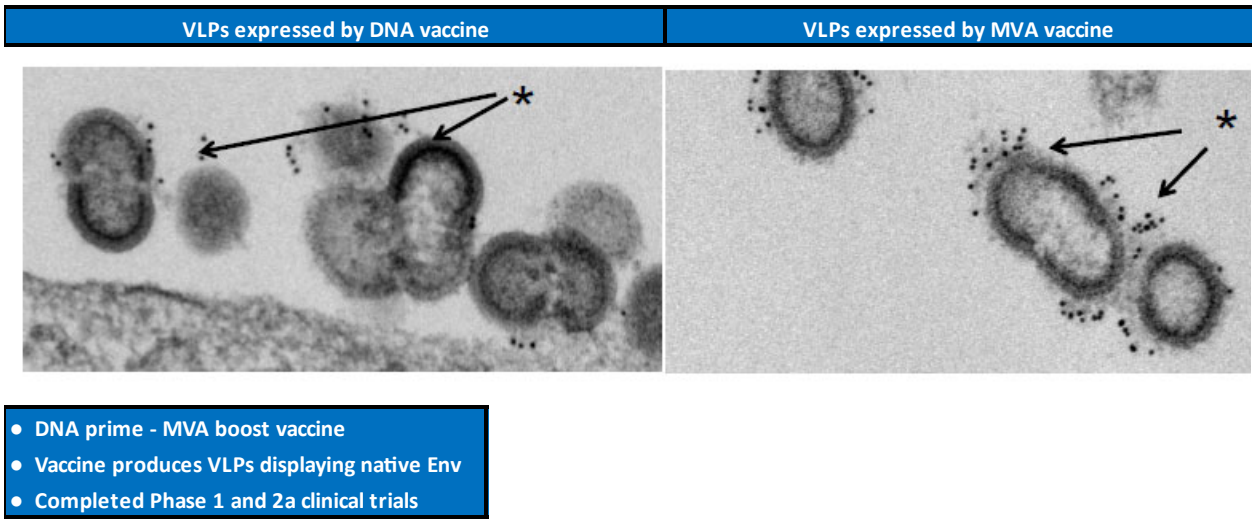
GeoVax's Preventive HIV Vaccine Program

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

GeoVax's most advanced vaccine, GOVX-B11, is designed to protect against the clade B subtype of the HIV virus, which is prevalent in the Americas, Western Europe, Japan, and Australia. The vaccine consists of a recombinant DNA vaccine (used to prime immune responses) and a recombinant MVA vaccine (used to boost the primed responses), where both the DNA and MVA vaccines produce non-infectious VLPs in the cells of the vaccinated person (Figure 14). This vaccine was developed by scientists at Emory University, the NIH, and the CDC, and has been licensed by GeoVax for commercialization.

Figure 14

GOVX-B11: A CLADE B HIV VACCINE



Source: GeoVax Labs, Inc.

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

The development of GOVX-B11 from preclinical studies to human clinical trials has been financially supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The HIV Vaccine Trials Network (HVTN) with support from NIAID, has conducted multiple human clinical trials of the Company's preventive HIV vaccine candidates, and continues advancing the vaccine in clinical studies. Based on previous trial results from GeoVax's vaccines in non-human primate studies and human trials, the Company is planning for a new human clinical trial (designated HVTN 132) to further assess the safety, tolerability, and immunogenicity (elicited antibody responses) of a prime-boost regimen of GOVX-B11, in combination with protein boost vaccines. Although the start of HVTN 132 has been delayed due to clarification of components not related to the Company's vaccine, GeoVax currently expects HVTN to commence patient enrollment in 2021. The GeoVax HIV Vaccine Program has been supported primarily by non-dilutive funding from NIH/NIAID.

Phase 1 and 2a Clinical Trials

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

In Phase 1 and 2a clinical trials, conducted by the HVTN, the vaccine had consistent safety and reproducible immunogenicity. Administration of GOVX-B11, composed of MVA (MVA 62B) and DNA vaccines encoding HIV envelope (Env) and matrix proteins, led to production of VLPs. In a group that received a regimen consisting of three MVA 62B vaccinations and no DNA, 98.4% of subjects had binding antibodies to Env. Additionally, 64.4% of patients in this group had detectable neutralizing antibody responses against a tier 1 isolate—more than double that observed for groups primed with DNA then boosted with MVA. For the same group, there was a 43.1% and 14.9% response rate for polyfunctional CD4+ and CD8+ T cells, respectively. Six months after vaccination with MVA 62B, the proportion of responders as assessed by binding antibody did not decline, in contrast to the DNA plus MVA regimen, whereas the magnitude of the response of both groups declined 2.7-fold. Following MVA inoculations, about 70% of participants had transient mild pain and 25% transient moderate pain at the site of injection. Systemic symptoms (most frequently malaise, fatigue, myalgia, headache, and nausea) have been similar to those in placebo recipients.

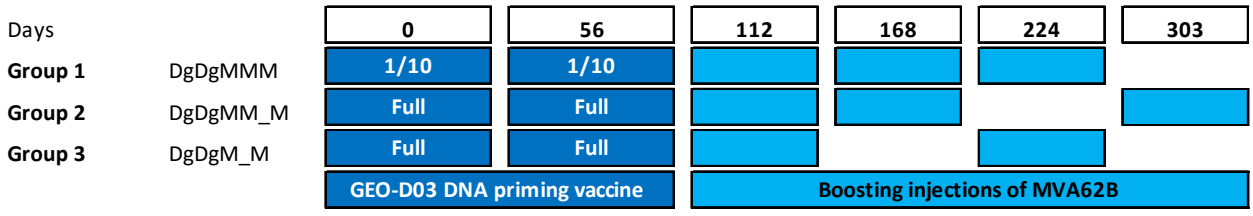
HVTN 094 Clinical Trial

The Phase 1 trial of GeoVax's clade B HIV vaccine in HIV-uninfected adults evaluated the safety and immune response of a prime-boost regimen of two HIV vaccines: two injections of GEO-D03 DNA priming vaccine (Dg), followed by either two or three boosting injections of modified vaccinia Ankara MVA 62B Boosts (M).

This study enrolled 48 healthy, HIV-1-uninfected, vaccinia-naive adults into 1 of 3 groups. Participants within each group were randomly assigned to receive either the study vaccine (40 total participants) or placebo (8 total participants). The vaccination schedule, illustrated in Figure 15, was as follows: Group 1 participants received 1/10th dose of the GEO-D03 DNA priming vaccine on Days 0 and 56 followed by three boosting injections of MVA 62B at days 112, 168, and 224 (DgDgMMM); Group 2 participants received full dose priming vaccine on Days 0 and 56 followed by three boosting injections of MVA 62B at days 112, 168, and 303 (DgDgMM_M); and Group 3 received full dose priming vaccine on Days 0 and 56 followed by two boosting injections of MVA 62B at days 112 and 224 (DgDgM_M). Peak immunogenicity was measured two weeks post-last vaccination.

Figure 15

HVTN 094 VACCINATION SCHEDULE

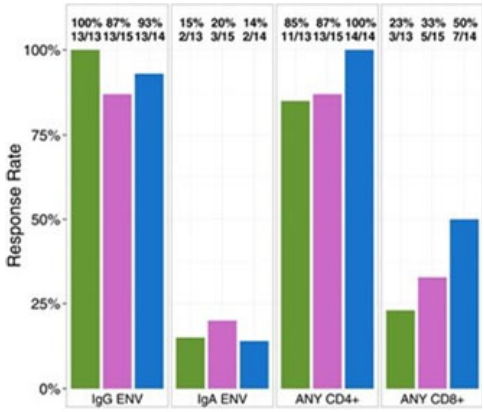


Source: PLoS One Vo.12(7):e0179597, 2017.

All regimens were well tolerated and safe, with mild to moderate local reactogenicity in all arms, and no serious adverse effects reported. Participants receiving full dose vaccine regimens (Group 2 and 3) did not have significantly more local or systemic reactogenicity than those in the 1/10 dose arm (Group 1). Because the full-dose regimens were safe and tolerable and will likely be considered or modified in future trials, all immunogenicity results presented compare data within or between the two full-dose arms.

Figure 16

IMMUNE RESPONSE IN HVTN 094



Source: PLoS One Vo.12(7):e0179597, 2017.

These GEO-D03/MVA regimens induced a durable, functional HIV-1 humoral immune response profile that included Env IgG1 and IgG3 binding responses, high antibody avidity, and low level ADCC and neutralizing antibody responses, without substantial IgA; the cellular immune response was biased toward **CD4+ T cells**. Overall rates of humoral and cellular immune responses are depicted in Figure 16.

Both regimens induced high rates of IgG while IgA response rates were low (<20%) in all vaccine groups. Full dose DgDgM_M (Group 3) and DgDgMM_M (Group 2) regimens generated Env-specific IgG to HIV-1 Env in >90%, IgG3 in >80%, and IgA in <20% of participants. The third MVA dose (Group 2) appeared to improve both the quality and longevity of the antibody response. There were no positive responses among the placebo recipients in any of these assays. Overall CD4+ T cell response rates were higher than CD8+ T cell responses within each vaccine group and were not significantly different between groups.

Of note, the RV144 trial had a similar immune profile but targeted different epitopes and had a more short-lived immune response. IgG3, an independent predictor of reduced HIV-1 infection and putatively of the level of vaccine efficacy in the RV144 trial, nearly disappeared at 6 months post-vaccination in RV144, while in HVTN 094, approximately one-half of the participants in each full-dose arm, still had IgG3 responses by 6 months post-vaccination, and response rates and magnitudes dropped only slightly from 6- to 12-months post-vaccination. These data suggest that the GEO-D03/MVA HIV62B regimens produce a more durable response than was seen in RV144.

GeoVax believes that the immune system responses elicited by GOVX-B11 in its clinical trials show encouraging features when compared to the data generated in the RV144 trial. These features include the durability of the elicited antibody and T-cell responses and the highly favorable IgG3/IgA ratio. GOVX-B11 is ready to progress into a pivotal trial to determine safety and efficacy in populations at risk.

HVTN 114 Clinical Trial

In January 2017, HVTN began the next human clinical trial (HVTN 114) in the path toward human efficacy trials. HVTN 114 enrolled 27 individuals who previously participated in the HVTN 205 Phase 2a trial of the GOVX-B11 vaccine, which concluded in 2012. Participants of HVTN 205 received the Geo-DO2 priming vaccine followed by MVA62B boosts. HVTN 114 is designed to test the ability of "late boosts" (additional vaccinations given on average 6.9 years after the original) to increase the antibody responses elicited by GOVX-B11. These "late boosts" consisted of the GeoVax MVA62B vaccine with or without a HIV-1 gp120 protein vaccine candidate. The gp120 protein candidate, AIDSVAX® B/E, includes the same glycoproteins used to boost immune responses in the partially protective RV144 trial and is being used in HVTN 114 to assess the effect of adding a protein vaccine to GOVX-B11. Participants in HVTN 114 received either (a) another MVA62B boost, (b) a combined boost of MVA62B and AIDSVAX® B/E, or (c) AIDSVAX® B/E alone. HVTN 114 was completed during 2018 and results were presented during the HIV Research for Prevention (HIVR4P) conference in Madrid, Spain in October 2018.

HVTN 114 demonstrated that combining GOVX-B11 with a protein boost significantly enhanced the antibody response, which might play a role in protecting the individuals against HIV. The study results showed the most effective boost to be the combination of MVA62B live vector and AIDSVAX B/E proteins, which increased titers of antibodies to the HIV envelope glycoproteins by more than 600-fold. This trial was designed to develop regimens for a Phase 2b efficacy trial and highlight the use of a vector plus protein boost strategy.

Summary of Clinical Trials

Figure 17 provides a summary of clinical trials to date for GeoVax's GOVX-B11 clade B Vaccine.

Figure 17
CLINICAL TRIALS, GOVX-B11 CLADE B VACCINE

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

Source: GeoVax Labs, Inc.

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

Upcoming HVTN 132 Clinical Trial

GeoVax is planning for a new Phase 1 human clinical trial (HVTN 132) designed to further assess the safety, tolerability, and immunogenicity (elicited antibody responses) of a prime-boost regimen of GOVX-B11, in combination with protein boost vaccines. The trial builds on the preliminary results from HVTN 114 that demonstrated that late protein boosts significantly enhanced the antibody responses by more than 600-fold for the most effective regimen tested. HVTN 132 is designed to further evaluate the prime-boost strategy with newly developed proteins. HVTN 132, being conducted with operational support from the HVTN and funding from NIAID, is a multi-center, randomized, double-blind trial, which is enrolling up to 70 healthy adults. The start of HVTN 132 was delayed due to clarification of components (unrelated to GeoVax vaccine), but GeoVax anticipates the trial to start during 2021, following delays in recruitment due to the trial sites being utilized for COVID-19 vaccine testing. The study aims to evaluate the durability of the immune responses elicited by GOVX-B11 and the effects of late MVA, protein, or MVA+protein boosts. The protein boosts to be evaluated in the trial (B.63521Δ11gp120mutC gp120 protein and the gp120-based IHV01 vaccine) were developed by the Center for HIV/AIDS Vaccine Immunology-Immunogen Design Duke University and by the Institute of Human Virology of the University of Maryland School of Medicine, respectively. Data produced from this trial is intended to contribute to the design of additional human clinical trials testing GeoVax's vaccine in the presence and absence of the gp120 proteins.

Clade C Preventive HIV Vaccine Program

The Company is also developing DNA/MVA vaccines designed for use against the clade C subtype of HIV that predominate in South Africa and India. NIAID has awarded GeoVax Small Business Innovative Research (SBIR) grants in support of this effort, with further development dependent upon additional funding support.

GeoVax's HIV Immunotherapy Program

Discovering a cure for HIV/AIDS is exceptionally challenging. Present day ART, while highly effective at suppressing HIV viral load, cannot eliminate latent forms of HIV that are invisible to the immune system and inaccessible to ART drugs. As well, long-term use of ART can lead to loss of drug effectiveness and can carry significant side effects. Furthermore, lifetime costs for medical treatments for an HIV-infected patient in the U.S. is over $300,000. Consequently, any new treatments that would enable HIV patients the ability to reduce, modify, or discontinue their ART may offer measurable quality-of-life benefits to the patient and exceptional value within the marketplace.

GeoVax believes that its HIV vaccine platform may prove useful as a necessary 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. 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. The Company's HIV vaccine has also been selected for inclusion in a separate "functional cure" collaborative effort led by the University of California, San Francisco, with funding from amfAR, The Foundation for AIDS Research; that trial commenced patient enrollment in August 2020.

Collaboration with American Gene Technologies International Inc. (AGT)

In March 2017, GeoVax entered into a collaboration with American Gene Technologies International Inc. (AGT)—a developer of advanced genetic technologies to cure major human diseases, such as cancers, metabolic disorders, and infectious diseases—whereby AGT intends to conduct a Phase 1 human clinical trial with the companies' combined technologies.

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. Upon clearance by the FDA, this IND will allow AGT to initiate a Phase 1 clinical trial that will investigate the safety of AGT103-T in humans, measure key biomarkers, and explore surrogate markers of efficacy. GeoVax is expected to provide its novel MVA-VLP-HIV vaccine (MVA62B) for evaluation in an arm of the clinical trial in combination with AGT103-T. The primary objectives of the trial are to assess the safety and efficacy of the therapy, with secondary objectives to assess the immune responses as a measure of efficacy. The overall goal of the program is to develop a functional cure for the HIV infection. AGT recently announced that the FDA had accepted their IND in support of their Phase 1 trial; GeoVax expects its vaccine to be added to the AGT trial in early 2021.

MVA62B is the boosting component for GeoVax's preventive HIV vaccine (GOVX-B11), which has successfully completed a Phase 2a clinical trial and is awaiting funding in support of a Phase 2b pivotal trial. The GeoVax vaccine will be used to stimulate virus-specific CD4+ T cells *in vivo*, which will then be harvested from the patient, genetically modified *ex vivo* using AGT's technology, and reinfused to the patient as a therapeutic cell product. In a previous Phase 1 clinical trial (GV-TH-01), GeoVax demonstrated that its vaccine stimulates production of CD4+ T cells in HIV infected patients—the intended use of the MVA-VLP HIV vaccine in the proposed AGT study.

Collaboration with UCSF

In November 2019, GeoVax entered into an agreement with the University of California, San Francisco (UCSF), to participate in a collaborative effort led by researchers at UCSF to develop a combinational therapy aimed at inducing remission in HIV-positive individuals (i.e., a functional cure). The studies, a collaboration of researchers led by Dr. Steven Deeks, Professor of Medicine in Residence at the UCSF and a faculty member in the Division of HIV, Infectious Diseases and Global Medicine at Zuckerberg San Francisco General Hospital, will be conducted with funding from amfAR, The Foundation for AIDS Research, and will involve a combination of vaccines, drugs, and biologics.

On August 24, 2020, GeoVax announced the initiation of the Phase 1 clinical study to test a combination therapy in HIV-positive patients utilizing GeoVax's novel boost component MVA62B. The single-arm, open-label study is to enroll 20 HIV-infected adults who are on stable and effective **antiretroviral therapy (ART)**. The therapeutic regimen to be tested involves 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.

The primary objectives of the trial will be to assess the safety and tolerability of the combinational therapy and to determine the viral load "set-point" during a treatment interruption. Secondary objectives will be to assess immune responses and changes in viral reservoir status.

HEMORRHAGIC FEVER (HF) VACCINE PROGRAM

Ebola, Sudan, Marburg, and Lassa Fever Viruses

Ebola (EBOV, previously designated as Zaire ebolavirus), Sudan (SUDV), and Marburg viruses (MARV) are highly infectious species of the Filoviridae family, with up to a 90% fatality rate in humans, and epizootic in Central and West Africa with 29 outbreaks since 1976. In particular, the 2013-2016 Ebola outbreak caused 28,616 cases and 11,310 deaths (a 40% fatality rate).

In August 2018, the Ministry of Health of the Democratic Republic of the Congo declared a new outbreak of Ebola virus disease in North Kivu Province. Despite responses from the Ministry of Health, WHO, and its partners to contain this outbreak, there were 3,470 cases, with 2,287 people dying after contracting the disease and 1,183 patients recovering (case fatality rate of 66%). The outbreak, the second-largest outbreak in history, was declared over by the World Health Organization (WHO) on June 25, 2020. However, a new unrelated Ebola outbreak in the Democratic Republic of the Congo was declared on June 1, 2020.

Lassa fever virus (LASV), a member of the **Arenaviridae family**, also causes severe and often fatal hemorrhagic illnesses in an overlapping region with Ebola. In contrast to the unpredictable epidemics of filoviruses, LASV is endemic in West Africa with an annual incidence of over 300,000, leading to 5,000 to 10,000 deaths. Recent study data suggests that the number of annual LASV cases may actually be significantly higher, with three million infections and 67,000 deaths (placing upwards of 200 million individuals at risk). Lassa fever (LF), a zoonotic disease caused by Lassa virus (LASV), can lead to acute hemorrhagic fever with a case fatality rate (CFR) of up to 50%

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

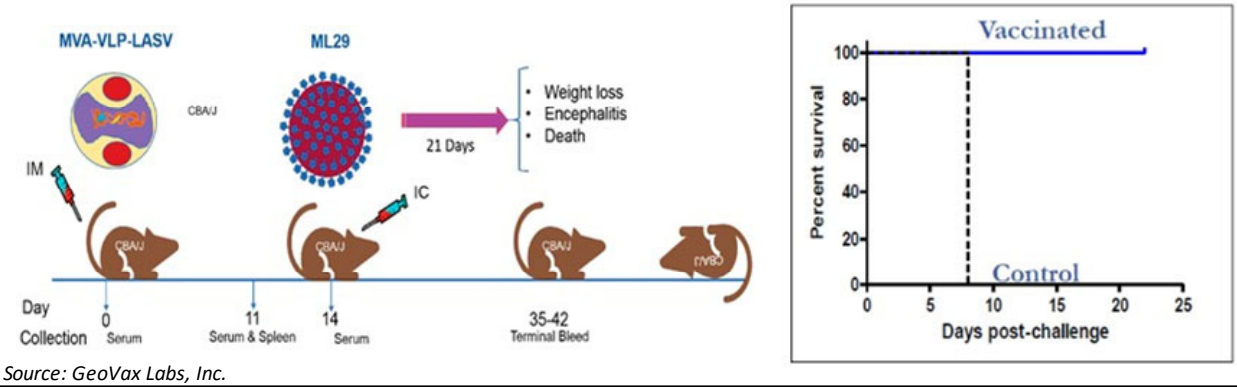
GeoVax believes that an ideal vaccine against major filoviruses and LASV must activate both humoral and cellular arms of the immune system. As well, it should include the induction of antibodies to slow the initial rate of infection and a cellular immune response to help clear the infection. Furthermore,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

GeoVax's Lassa Fever Vaccine Candidate (GEO-LM01)

GeoVax's initial preclinical studies for its LASV vaccine candidate in rodents have shown 100% single-dose protection against a lethal dose of LASV challenge composed of a **reassortant** virus delivered directly into the brain (Figure 18, page 34). The study was conducted at the Institute of Human Virology at the University of Maryland School of Medicine in Baltimore. Multiple repeats of the study confirmed the findings. The vaccine induced low levels of antibodies, but more importantly, Lassa-specific CD4+ and CD8+ T cell responses.

Figure 18

LASSA RODENT PRECLINICAL STUDY



Source: GeoVax Labs, Inc.

Subsequent to these initial findings, in April 2018, the NIAID awarded the Company a $300,000 Small Business Innovative Research (SBIR) grant in support of further advancing its Lassa vaccine development program. The work was 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.

Furthermore, in September 2018, the U.S. Department of Defense (DoD) awarded GeoVax a $2,442,307 cooperative agreement in support of its LASV vaccine development program. The grant was awarded by the U.S. Army Medical Research Acquisition Activity pursuant to the Peer Reviewed Medical Research Program (PRMRP), part of the Congressionally Directed Medical Research Programs (CDMRP). In addition to the grant funds provided directly to GeoVax, DoD will also fund testing of the GeoVax vaccine by U.S. Army scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) under a separate sub-award. The grant funds and supports generation of immunogenicity and efficacy data for the Company's vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparation for human clinical trials. The work is being performed in collaboration with USAMRIID and the Geneva Foundation, and IDT Biologika (IDT). Further development of the Company's Lassa Fever vaccine beyond the work being funded by the U.S. DoD will be dependent upon additional funding and/or partnering support.

GeoVax's Filovirus (Ebola, Sudan, Marburg) Vaccine Program (GEO-EM01)

The Company's EBOV vaccine is a novel recombinant MVA-based vaccine combining the EBOV matrix protein VP40 and the glycoprotein (GP). GP is one of the main targets for protective response and its display on the VLP surface efficiently elicits protective humoral and adaptive immune response similar to EBOV infection. GeoVax's Ebola vaccine has completed efficacy testing in rodents and non-human primates—where it showed 100% protection against a lethal dose of EBOV upon a single immunization—and is ready for GMP manufacture and Phase 1 human trials. The preclinical trials were conducted with support from NIAID and USAMRIID.

The Company analyzed the protective efficacy of its novel EBOV vaccine in two well-established animal disease models for EBOV infection; the guinea pig and macaques. Young adult guinea pigs were prime and boost vaccinated with MVA-EBOV at week 0 (prime) and week 4 (boost) and were challenged at week 8 with a lethal dose of EBOV. While the guinea pigs in the unvaccinated and placebo-vaccinated control groups developed signs of disease and were euthanized after reaching the humane endpoint, the MVA-EBOV vaccinated guinea pigs showed little to no body weight changes after challenge and achieved 100% survival (left side of Figure 19, page 35).

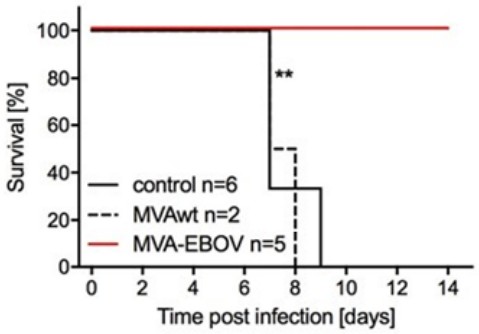
Given these results, the efficacy of MVA-EBOV was tested next in macaques against lethal challenge with EBOV-Makona. Twelve rhesus macaques were divided into three groups of four animals resulting in a control group (MVAwt), a MVA-EBOV prime/boost, and a MVA-EBOV prime only group. Both immunization schemes, single dose as well as prime/boost vaccination, resulted in 100% protection in the animals (right side of Figure 19, page 35). In contrast, all the animals in the control group developed Ebola hemorrhagic fever (EHF), with three animals reaching euthanasia criteria and one animal recovering. The vaccine elicited a variety of antibody responses to both antigens, including neutralizing antibodies and antibodies with antibody-dependent cellular cytotoxic activity

specific for GP. This is the first report that a replication-deficient MVA vector can confer full protection against lethal EBOV challenge after a single dose vaccination in macaques (Source: *Scientific Reports* Vol. 8: 864, 2018).

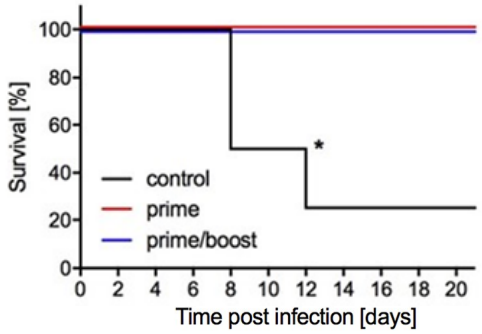
Figure 19

GEOVAX EBOLA VACCINE SURVIVAL BENEFITS

GUINEA PIG MODEL



NON-HUMAN PRIMATES



Source: Scientific Reports Vol. 8: 864, 2018.

Overall, complete protection was offered by a single-dose of GV-MVA-VLP™-EBOV in non-human primates, with challenged animals **aviremic**, as determined by virus titration. Potent anti-EBOV antibody responses were seen after single or prime-boost immunization regimens.

GeoVax has also designed and constructed vaccine candidates for SUDV and MARV. In July 2019, the Company reported positive results (100% protection) from preclinical challenge studies of its MARV vaccine candidate. In this study, the MARV vaccine candidate was administered by intramuscular (IM) inoculations to guinea pigs, with a control group receiving saline injections. Eight weeks after inoculation, animals in each group were exposed to a lethal dose of MARV. Within eight days post-challenge, all animals in the control group had developed moribund conditions and needed to be euthanized. At the conclusion of the study (21 days post-challenge), all vaccinated animals survived, with no weight loss or other health issues, and no virus detectable in serum. The study was conducted in collaboration with researchers at the University of Texas Medical Branch at Galveston (UTMB).

On August 13, 2020, GeoVax announced a multi-party collaboration between GeoVax, researchers at UTMB, and Battelle Memorial Institute for the development of its SUDV and MARV vaccine candidates. The researchers are also planning to utilize the suite of preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). According to the Company, this collaboration would enable it to advance the two vaccine candidates through nonhuman primate testing.

Under the collaboration, GeoVax's SUDV and MARV vaccine candidates will be tested for immunogenicity and efficacy in the benchmark nonhuman primate model. The studies will include two vaccine regimens—single-dose and prime/boost immunization—for each vaccine tested. Animals will receive a lethal dose of either SUDV or MARV following corresponding vaccine inoculations and monitored for morbidity and mortality. Additionally, the humoral and cellular immune responses to vaccination will be evaluated in detail. The studies are to be funded under NIAID contract no. HHSN272201800131.

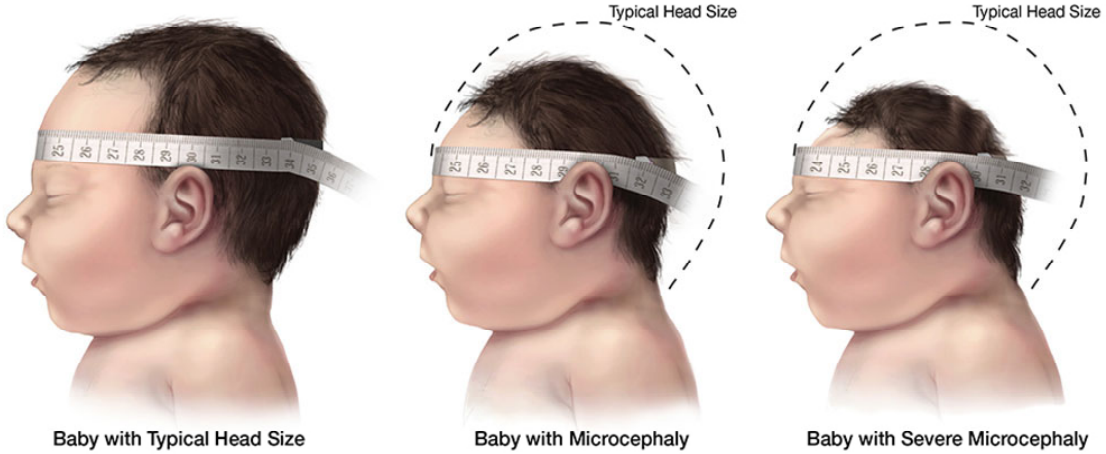
GeoVax believes that its MVA-VLP vaccine platform is well suited for the construction of vaccines for filoviruses. In a recent independent, peer-reviewed paper, the authors concluded that the MVA-VLP-EBOV and MVA-VLP-SUDV vaccines are the best-in class vaccine in development. This is because the Company's MVA-VLP-EBOV construct co-express both GP and VP40, which protected chimeric mice challenged with EBOV to a greater extent than a vector expressing GP alone (Source*: Journal of Virology* Vol. 92(11): e00363-18, 2018). Further development of the Company's filovirus vaccines is dependent upon additional funding support.

ZIKA VIRUS (ZIKV) VACCINE PROGRAM

Zika Virus (ZIKV)

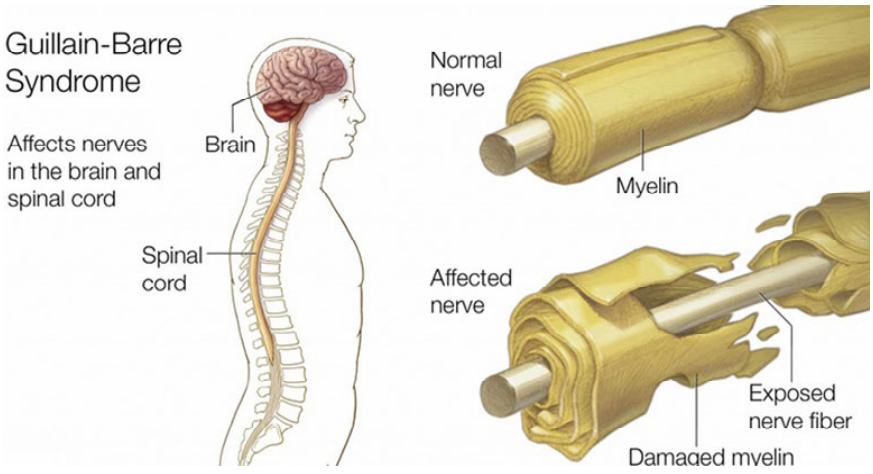
Caused by the Zika virus (ZIKV), Zika disease is an emerging rapidly-spreading mosquito-borne infectious disease that has been linked to an increase in **microcephaly** in infants, a condition in which a baby's head is significantly smaller than expected (Figure 20), often due to abnormal brain development, and **Guillain-Barré syndrome** in adults, a condition in which the immune system attacks the nerves (Figure 21). ZIKV is a member of the **Flaviviridae** family, which includes medically important pathogens, such as dengue fever, yellow fever, Japanese encephalitis, tick-borne encephalitis, and West Nile viruses. Protection against mosquito bites and vector control remain the key preventive measures currently available to fight ZIKV infections.

Figure 20
CONGENITAL ZIKA SYNDROME



Source: Centers for Disease Control and Prevention.

Figure 21
GUILLAIN-BARRE SYNDROME



Source: Centers for Disease Control and Prevention.

History of ZIKV

First discovered in 1947 in the Zika forest of Uganda, ZIKV was considered only a minor public health concern for 60 years. In 2007, a large epidemic occurred on Yap Island in Micronesia, followed by a 2013 outbreak in French Micronesia. ZIKV is transmitted to people mainly by infected *Aedes* mosquitoes (*A. aegypti* and *A. albopictus*), the same species that transmit dengue and chikungunya viruses. In approximately 80% of cases, ZIKV infection is asymptomatic. In those with symptoms, however, these historically have been mild—usually lasting no more than one week—and include fever, rash, arthralgia, and conjunctivitis.

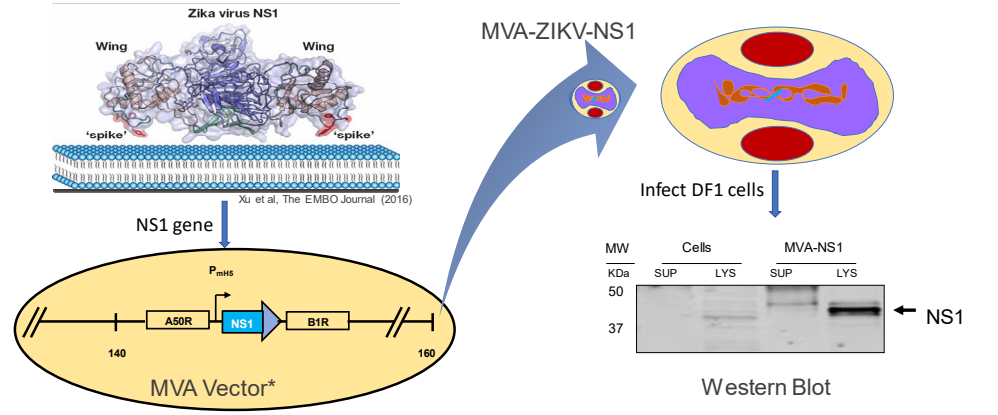
However, due to its arrival and rapid spread across the Americas in 2015, it has developed into a serious threat with pandemic potential—raising the profile of Zika as an emerging infectious disease. In 2015 and 2016, large outbreaks of Zika virus occurred in the Americas, resulting in an increase in travel-associated cases in US states, widespread transmission in Puerto Rico and the US Virgin Islands, and limited local transmission in Florida and Texas. This epidemic showed a disturbing and serious link between the Zika infection and fetal brain abnormalities, such as microcephaly.

GEO-ZM02: Zika Vaccine

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

Using the Company's platform technology, an MVA vaccine that expresses ZIKV NS1 in host cells was constructed, leading to both endogenous expression and secretion of NS1 (the Company's current candidate, GEO-ZM02). The design of these vaccines is illustrated in Figure 22. The MVA vaccine candidates were constructed using shuttle vectors developed in the laboratory of Dr. Bernard Moss (described on page 14) and licensed by the NIAID to GeoVax for use with ZIKV. These shuttle vectors have proven to give stable vaccine inserts with high, non-toxic, levels of expression in the Company's work with HIV and HF virus vaccines.

Figure 22
MVA-NS1 VACCINE



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

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

Source: GeoVax Labs, Inc.

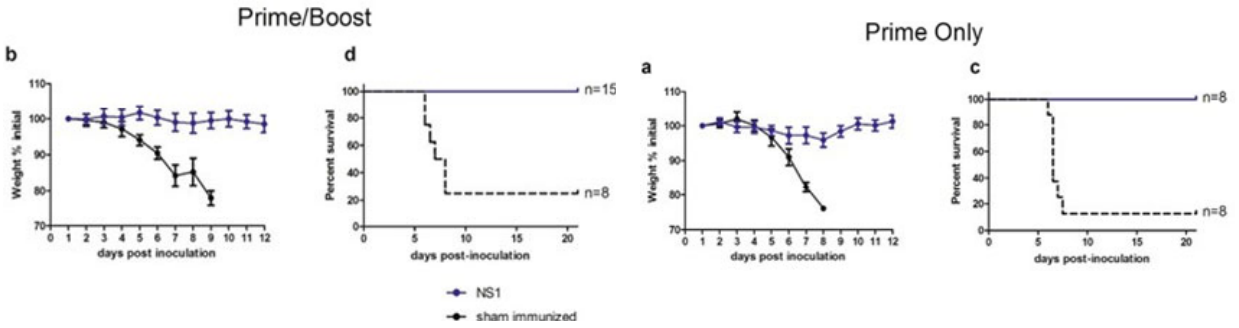
To date, GeoVax's MVA platform has shown a tremendous safety record, which is key due to the need to include women of child-bearing age and newborns among the vaccinated population. The Company expects its features to lead to a safe, highly-effective vaccine that is appropriate to deliver a potent immunity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

GEO-ZM02 Preclinical Testing

In 2017, GeoVax presented research showing that a single dose of its Zika vaccine gave 100% protection in mice challenged with a lethal dose of ZIKV. This announcement represented the first report of a Zika vaccine based on the ZIKV NS1 protein, and single-dose protection against ZIKV using an immunocompetent lethal mouse challenge model. In the study, mice were injected a lethal dose of ZIKV. Immunized mice were fully (100%) protected after both prime-only and prime-boost immunizations. No significant symptoms or weight loss were observed in any vaccinated animal. In contrast, most sham-immunized animals lost weight, demonstrated signs of neurological disease, and were euthanized according to approved IACUC protocols (~70–80% mortality), as seen in Figure 23. (Source: *Scientific Reports* Vol. 7, 14769, 2017). The study was conducted and funded by the US Centers for Disease Control and Prevention (CDC), which also provided technical assistance.

Figure 23

ZIKA VACCINE PRECLINICAL RESULTS



Source: Scientific Reports Vol. 7, 14769, 2017.

Subsequent to these initial findings, in June 2017, NIAID awarded the Company a Small Business Innovative Research (SBIR) grant in support of further advancing its development program. The $600,000 two-year grant supported preclinical testing of the ZIKV vaccine in nonhuman primates in preparation for human clinical trials. With Proof of Concept (PoC) demonstrated, GeoVax's GEO-ZM02 vaccine is now ready for scale-up and cGMP production followed by good laboratory practice (GLP) safety testing and Phase 1 clinical studies. Further development will initiate as collaborations are potentially established.

MALARIA VACCINE PROGRAM

Malaria

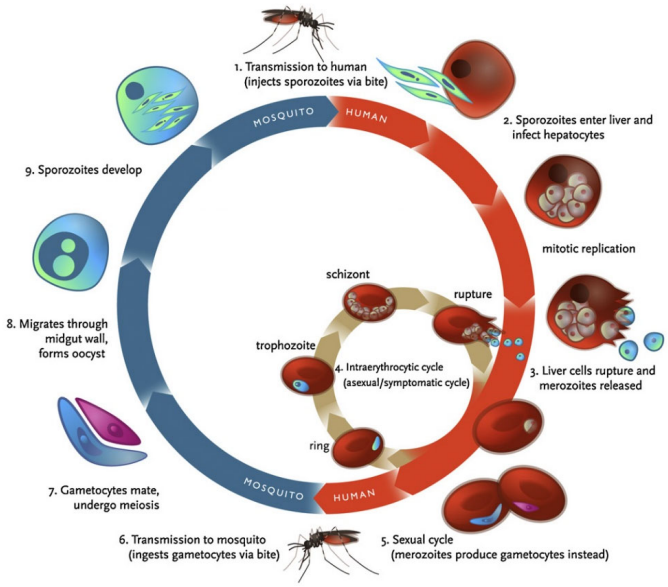
Caused by *Plasmodium* parasites, malaria is a mosquito-borne disease that causes symptoms of fever, chills, sweating, vomiting, and flu-like illness. If not effectively treated, severe complications can result, such as severe anemia, cerebral malaria, and organ failure, which results in death. Today, more than 3 billion people in 106 countries and territories are at risk for developing a malaria infection. The latest World Health Organization (WHO) data estimates that 228 million new cases of malaria were recorded worldwide in 2018, leading to 405,000 deaths. In the U.S., there are approximately 2,000 cases every year (due to travelers returning home). Kids under age five are predominantly susceptible to malaria illness, infection, and death, where in 2018 they accounted for 67% (272,000) of all malaria deaths worldwide. Present day treatments include bed net distributions, drug treatment, and mosquito spraying; however, the malaria parasite has developed resistance to some drugs and insecticides (Sources: World Health Organization and the CDC).

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

GeoVax's Approach

GeoVax believes that the perfect malaria vaccine candidate should contain antigens from multiple stages of the malaria life cycle (shown in Figure 24); should induce functional antibodies (predominantly IgG1 and IgG3 subtypes shown to be associated with protection); and should have strong cell mediated immunity (e.g. Th1 biased CD4+ ad CD8+) to reduce **parasitemia** by clearing infected cells (liver cells or erythrocytes). The Company has shown both in animal models and humans that its MVA-VLP vaccines induce a Th1-biased response with both durable functional antibodies (IgG1 and IgG3) and CD4+ and CD8+ T cell responses—both of which are hallmarks of an ideal malaria vaccine.

Figure 24
LIFECYCLE OF MALARIA PARASITE



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

Market Development Efforts

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) to develop a vaccine to prevent both malaria infection and transmission by targeting antigens derived from multiple stages of the parasite's life cycle. The Company's vaccine constructs are currently being evaluated in small animal models.

GeoVax has a collaboration with the Burnet Institute, a leading infectious disease research institute in Australia, to develop a vaccine to prevent malaria infection. The project includes the design, construction, and characterization of multiple malaria vaccine candidates using GeoVax's MVA-VLP vaccine platform in combination with malaria *Plasmodium falciparum* and ***Plasmodium vivax*** **sequences** identified by the Burnet Institute. The vaccine design, construction, and characterization is to be performed by GeoVax with further characterization and immunogenicity studies in animal models conducted at Burnet Institute using their unique functional assays, which provide important information on the efficacy of the vaccine.

In March 2019, GeoVax began a collaboration with Leidos, Inc. to develop malaria vaccine candidates. The work is supported under a contract to Leidos from the 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 GV-MVA-VLP™ platform as part of this development effort. The collaboration with Leidos complements GeoVax's ongoing malaria vaccine development project with Burnet Institute and offers a separate opportunity for success. The collaboration also expands upon the Company's existing relationship with Leidos for GeoVax's cancer immunotherapy program.

CORONAVIRUS PROGRAM

GeoVax seeks to capitalize on the safety and efficacy of its technology platform to address the urgent need for a COVID-19 vaccine through the development of a novel GV-MVA-VLP™ vaccine candidate.

Coronavirus Disease 2019 (COVID-19)

Coronaviruses are a large family of viruses that usually cause mild to moderate upper-respiratory tract illnesses, like the common cold. However, three new coronaviruses have emerged from animal reservoirs over the past two decades to cause serious and widespread illness and death. SARS coronavirus (SARS-CoV) emerged in November 2002 and caused severe acute respiratory syndrome (SARS). That virus disappeared by 2004. Middle East respiratory syndrome (MERS) is caused by the MERS coronavirus (MERS-CoV). Transmitted from an animal reservoir in camels, MERS was identified in September 2012 and continues to cause sporadic and localized outbreaks. The third novel coronavirus to emerge in this century, called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), causes Coronavirus Disease 2019 (COVID-19) (Source: NIH's National Institute of Allergy and Infectious Diseases).

COVID-19 is an infectious disease first identified in Wuhan, China in December 2019, and has resulted in an ongoing global pandemic. As of October 21, 2020, more than 41 million cases have been reported across 216 countries, resulting over 1.13 million deaths. The U.S. is currently considered one of the epicenters of the disease, with over 8.3 million cases and 221,000 deaths as of October 21, 2020. The World Health Organization (WHO) declared the COVID-19 a global pandemic on March 11, 2020.

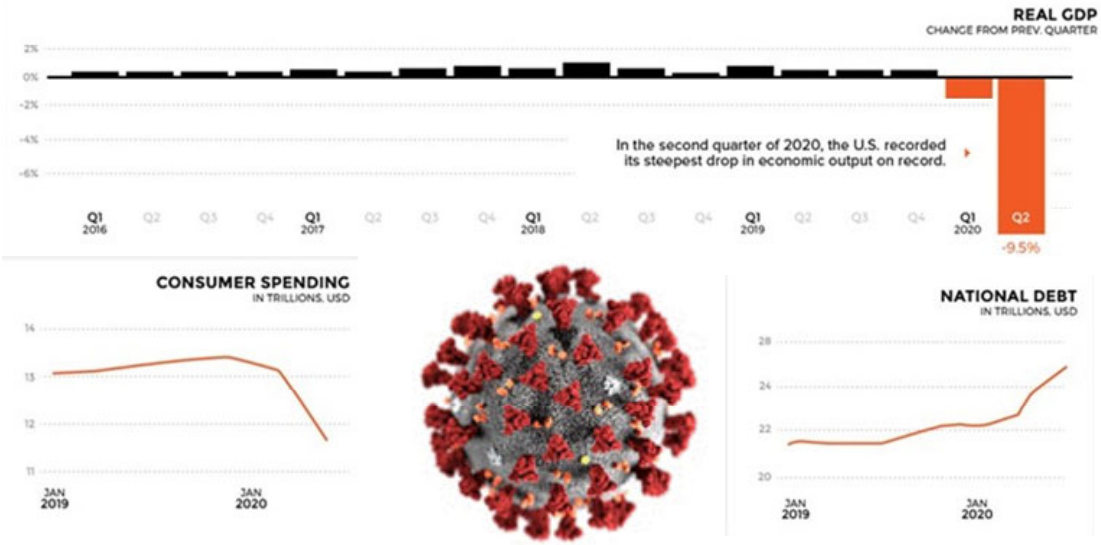
While COVID-19 causes mild symptoms in most people, with common symptoms including fever, cough, fatigue, shortness of breath, and loss of smell and taste, some people develop acute respiratory distress syndrome (ARDS) possibly precipitated by cytokine storm, multi-organ failure, septic shock, and blood clots. The time from exposure to onset of symptoms may range from two to fourteen days. The virus is spread primarily via nose and mouth secretions, including small droplets produced by coughing, sneezing, and talking.

There are no proven vaccines nor specific antiviral treatments or a universal standard of care (SOC) for COVID-19. Management of the disease normally involves the treatment of symptoms, supportive care, isolation, and experimental measures. The scientific research community is racing to develop **medical countermeasures (MCM)** against this pathogen. Initial work has focused on repurposing existing drugs to fight COVID-19; however, no product has yet demonstrated clear efficacy. A safe and effective vaccine to control this new pathogen is desperately needed.

In addition to the health and mortality effects of the disease, measures taken by countries to curtail the transmission of the disease, such as lockdowns, social distance measures, travel restrictions, and school and business closures, among others, have resulted in a significant impact on the global economy, at a cost in the trillions of dollars. COVID-19 has caused severe repercussions for economies across the world, with unusually high and rapid increases in unemployment in many countries. In the U.S. specifically, well over 50 million people are still out of the workforce as businesses shutter permanently and restrictions continue in many parts of the country, with new unemployment claims exceeding 1 million for 19 consecutive weeks. In the second quarter of 2020, the U.S. recorded a 9.5% drop in GDP, its steepest drop in economic output on record, with historical quarterly GDP never exceeded even a 3% drop since record keeping began in 1947 (Figure 25 [page 42]). U.S. consumer spending, which accounts for more than two-thirds of the U.S. economy, decreased sharply in April 2020, declining by 12.6%, despite the weekly $600 payments provided through the CARES Act, which helped bolster household income and partially offset steeper losses (Source: Visual Capitalist's Charts: *The Economic Impact of COVID-19 in the U.S. So Far*, July 2020).

Figure 25

ECONOMIC IMPACT OF COVID-19



Sources: Visual Capitalist and statnews.com.

GeoVax's COVID-19 Development Efforts

In January 2020, GeoVax announced initiation efforts to develop a vaccine against the novel coronavirus disease (COVID-19) caused by the SARS-CoV-2 coronavirus. The Company's vaccine program has been included in the "Draft Landscape of COVID-19 Candidate Vaccines" by the World Health Organization (WHO).

Development Plans

GeoVax designed, constructed, and characterized four vaccine candidates in preparation for advancement to animal testing, manufacturing scale-up, and initial human clinical trials. Following the animal testing, GeoVax plans to focus on one vaccine candidate based on the safety, immunogenicity, and protective efficacy observed in animal studies. The Company then plans to proceed directly to manufacturing and initial human clinical testing for safety and immunogenicity. However, this accelerated development schedule leading to human clinical trials will be dependent upon additional fundraising and/or support from U.S. funding agencies.

GeoVax has submitted applications to Biomedical Advanced Research and Development Authority (BARDA) and other entities requesting funding support of its COVID-19 vaccine development efforts. While other COVID-19 vaccine candidates have more rapidly progressed to human testing, designed using unproven technology platforms or platforms that consistently require adjuvants and/or boosters, the Company believes that its GV-MVA-VLP™ platform has been well validated in providing vaccines with excellent efficacy, safety, and durability—critical attributes of any COVID-19 vaccines that might be eventually approved and distributed worldwide. GeoVax's recently completed financing will allow the Company to aggressively pursue preclinical evaluation of its vaccine candidates while awaiting additional third-party funding support for advanced development.

In light of the current epidemic and of BARDA's focus on stockpiling products eligible for Emergency Use Authorizations (EUAs) rather than funding development of products through licensure, GeoVax intends to bring its coronavirus vaccine to the point of EUA readiness, which requires regulatory (data in animals and humans, development of manufacturing and analytical processes, and completion of regulatory processes), as well as production prerequisites (manufacturing of adequate quantities to support distribution and use under an EUA). For FDA approval, the Company plans to follow either the traditional regulatory approval pathway or through accelerated approval (using a surrogate immunological measurement as the efficacy endpoint and following Phase 3 efficacy studies with Phase 4 post-marketing trials to confirm the clinical benefit of the vaccine candidate). The choice of regulatory path will depend on the incidence and scientific knowledge of COVID-19 by the time the Company begins to determine the efficacy endpoints of its study in conjunction with the FDA.

Vaccine Candidate

GeoVax has constructed four novel candidate vaccines against SARS-CoV-2 (GEO-CM01, GEO-CM02, GEO-CM03, and GEO-CM04), shown in Figure 26. All vaccine candidates are designed to display the following features: (1) induce VLPs in the host, having superior immunogenicity and protection profiles compared to their non-VLP versions; (2) induce a Th1-based immune response, which is a minimum requirement for a vaccine candidate against SARS-CoV-2, which could avoid an enhanced disease attributed to other SARS-CoVs; and (3) induce strong antibody and T cell responses and full protection after a single dose in less than two weeks.

Figure 26
GEOVAX COVID-19 VACCINE CANDIDATES

Vaccine	SARS-Cov-2 Antigens	Goals
GEO-CM01 (S+E+M)		VLPs form naturally using three native SARS-2 proteins, S, M & E, broadening the breadth of immune response beyond Spike only
GEO-CM02 (Stab. S+E+ M)		VLP expression of stabilized Spike with two-point mutations locking S into the pre-fusion state, shown to generate higher levels of neutralizing antibodies
GEO-CM03 (RBD+ E + M)		Receptor binding domain (RBD) engineered to be displayed on VLPs containing native M and E, will narrow antibody response to neutralizing domain of Spike
GEO-CM04 (Multi-antigen linked VLP)		Cross-reactive epitopes potentially to provide protection against multiple HCoV strains, engineered into a dual presentation strategy (VLP & non-VLP) – a single dose "universal coronavirus vaccine" is the goal

Source: GeoVax Labs, Inc.

The first vaccine candidate, GEO-CM01 (expressing three antigens from SARS-CoV2), is designed to produce a broader immunity than those vaccine candidates utilizing a single protective antigen, such as the S protein (e.g. DNA vaccines, mRNA vaccines, Adeno-vectored vaccines, VSV-vectored vaccines). The second construct, GEO-CM02, is similar to GEO-CM01 but its construct includes encoding 2 proline residues in the S antigen to produce prefusion-stabilized spikes in their native structure, shown to possess higher immunogenicity that a wild-type S protein. GE-CM03 is designed to express the RBD of SARS-Cov-2 that is shown not only to induce cross reactive neutralizing antibodies that are higher than those induced by the full length S, but also could potentially avoid immunopathology that was shown with SARS and MERS to be associated with immunodominant epitopes within the S2 subunit. Coronaviruses possess RNA genomes that are prone to mutate, as evidenced by the new dominant circulating strain of SARS-CoV-2 containing a D614G mutation within the Spike protein. The Company's fourth candidate (GEO-CM04) serves as a candidate offering cross protection against emerging mutant variants of SARS-CoV-2. This construct delivers conserved linear B and T cell epitopes in VLP format using GeoVax proprietary matrix protein alternatives.

GEO-CM04 candidates are designed to contain conserved sequences capable of offering broad protection against SARS-Cov-2 and other SARS-CoV (serving as a universal coronavirus vaccine to stem future potential epidemics caused by closely related strains). Although other vaccine candidates have been discussed in the public record, GeoVax believes that the GV-MVA-VLP™ platform may provide candidates with excellent efficacy, safety, and durability—all critical attributes of any COVID-19 vaccine. GeoVax believes its COVID-19 program displays the following advantages over competitive alternatives:

- Expedited vaccine construction through proprietary single-cycle recombination technology;
- In vivo proof of concept in hACE2 transgenic mouse model: preclinical investigators identified and animal study designed;
- Accelerated seed banking and Phase 1a/1b vaccine production using platform processes available at the Company's manufacturing partner sites;
- Early interactions with FDA: little to no toxicology testing likely based on safety record of MVA platform; and
- Scale up for EUA readiness during Phase 1a/1b clinical trial.

Production

Construction of the Company's COVID-19 vaccine candidates is complete. All steps are performed under aseptic conditions in specific-pathogen-free chick embryo fibroblast (CEF) cells. In this process, the antigen sequences are inserted into plasmid DNA shuttle vectors, which are then recombined with MVA in cultures of CEF cells. Recombinant viruses expressing the antigens are plaque-purified, and then the clones are further purified and amplified in serial cultures of CEF cells. The Company believes that the complexity required for the generation of the viral vectors required for its vaccine candidates represents a competitive advantage that could prevent other companies from trying to emulate its COVID-19 approach. Compared to vaccine candidates based on small molecules—whose manufacturing is relatively easy to achieve—there are a limited number of manufacturers that have experience with the viral vectors used by the Company's technology.

Alignment with BARDA Priorities

The objectives of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) are outlined in the PHEMCE Strategy and Implementation Plan (SIP), last updated in December 2017. The Company's proposed project aligns well with the goals and objectives of the PHEMCE SIP. Specifically, GeoVax proposes to address a critical Medical Countermeasures (MCM) gap for the American civilian population through development of MCMs for individuals at risk for COVID-19 (Goal 4, Objective 4.2). Additionally, the Company's platform technology is expected to be useful not only against COVID-19, but also to provide a robust and sustainable pipeline of GV-MVA-VLP vaccines that are both commercially viable and applicable to use in routine public health (Goal 1, Objective 1.3).

In a March 2020 update to its Broad Agency Announcement (BAA) BAA-18-100-SOL-00003, BARDA suspended all Areas of Interest unrelated to SARS-CoV-2 or COVID-19 and indicated that, until further notice, it will accept only submissions related to this outbreak. The Company's proposed project is clearly responsive to Area of Interest 8.3, COVID-19 Vaccine. With scalable manufacturing technology, a robust manufacturing process, and all operations based in the U.S., GeoVax's proposed project meets the requirements of the BAA.

PARTNERSHIPS AND U.S. GOVERNMENT SUPPORT

Through its development efforts, the Company has achieved significant partnerships, as summarized in Figure 27 and described in the accompanying section.

Figure 27
GEOVAX COLLABORATIONS

PROGRAM	COLLABORATORS
HIV Preventative Vaccine	NIH, HVTN
HIV Therapeutic Vaccine	AGT, UCSF
Hemorrhagic Fever Vaccine	NIH, USAMRIID, UTMB, Battelle
Lassa Fever Vaccine	
Zika Vaccine	Univ. of Georgia, CDC, NIAID
Malaria Vaccine	Burnet Institute, Leidos
Coronavirus (COVID-19)	
Immuno-oncology (solid tumors)	Univ. of Pittsburgh, ViaMune, Leidos
Immuno-oncology (HPV head and neck cancer)	Emory

Source: GeoVax Labs, Inc.

Contracts and Grants

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

- *Malaria Contract with Leidos*. In March 2019, GeoVax entered into a $196,126 subcontract with Leidos, Inc., supported by 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 GV-MVA-VLP™ platform as part of this development effort. In January 2020, the work was extended through an additional subcontract for $385,193.

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

- *Lassa SBIR Grant.* In April 2018, NIAID awarded GeoVax a $300,000 SBIR grant entitled "Construction and efficacy testing of novel recombinant vaccine designs for eliciting both broadly neutralizing antibodies and T cells against Lassa virus."

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

- *HIV Staged Vaccine Development Contract.* In August 2016, NIAID awarded GeoVax a Staged Vaccine Development contract to produce the Company's preventive HIV vaccine for future clinical trial use. The award included a base contract of $199,442 for the initial twelve-month period, beginning August 1, 2016, to support process development, as well as $7.6 million in additional development options that can be exercised by NIAID. Prior to the end of the base period, NIAID notified that GeoVax that did not plan to exercise the additional development option under the contract due to funds availability and NIAID's programmatic needs. GeoVax does not expect this to have an impact on the human clinical trials of its preventive HIV vaccine currently being conducted by the HVTN, or future trials being planned.

- *HIV SBIR Grant.* In April 2016, NIAID awarded the Company a Small Business Innovation Research (SBIR) grant entitled "Enhancing Protective Antibody Responses for a DNA/MVA HIV Vaccine." The initial grant award was $740,456 for the first year of a two-year project period, beginning April 15, 2016, with a total project budget of $1,398,615. In March 2017, NIAID awarded GeoVax $658,159 for the second year of the project period and the Company subsequently received a one-year no cost extension of the project period, which was completed during 2019.

Clinical Trial Support

Human clinical trials to date for all of GeoVax's preventive HIV vaccines, including the newly initiated HVTN 114 trial and the HVTN 132 trial currently planned, have been or are expected to be conducted by the HVTN and funded by NIAID. Financial support has been provided by NIAID directly to the HVTN; therefore, it is not recognized on the Company's financial statements.

Other Federal Support

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

Cancer Immunotherapy Program

GeoVax is developing the next generation of vaccines and immunotherapies to address unmet medical needs in cancer and infectious disease. The Company believes that its MVA-VLP vector platform is well-suited for development of therapeutic cancer vaccines based on the expression of tumor-associated antigens, such as MUC1, Cyclin B1, or others. To fully capitalize on the Company's MVA-VLP platform applications in the area of oncology, the Company is considering a separate financing effort in support of these programs and sees these efforts as a key component for strengthening the valuation of GeoVax and providing future value growth opportunities.

CANCER IMMUNOTHERAPY BACKGROUND

Cancer is a major burden of disease and among the leading causes of death worldwide. In 2019, there were an estimated 18.1 million new cases and 9.6 million cancer-related deaths globally. In 2020, more than 1.8 million new cancer cases are expected to be diagnosed in the U.S.—equivalent to more than 4,900 new cases each day—with 606,520 deaths (translating into about 1,660 deaths per day). Cancer is the second most common cause of death in the U.S., exceeded only by cardiovascular disease (Source: American Cancer Society's *Cancer Facts & Figures 2020*). As population aging continues, cancer is expected to remain a significant health problem and become the leading cause of death (Source: *CA: A Cancer Journal for Clinicians*; Vol. 68 (6): 394-424, 2018).

The oncology market is one of the largest pharmaceutical markets and, with the introduction of improved treatments, it is expected to continue to expand. Globally, the oncology market is forecast to grow at an average annual growth rate of 12.3% to $196.2 billion in 2026, up from $77.3 billion in 2018 (Source: Coherent Market Insights' *Oncology Drugs Market Analysis*, December 2018). Cancer also represents a significant economic burden. The cost of cancer care is expected to reach almost $174 billion by 2020, with costs likely to rise as the population ages and cancer prevalence increases. Costs are also expected to increase as new, and often more costly treatments are adopted as standards of care (Source: U.S. National Institutes of Health's National Cancer Institute).

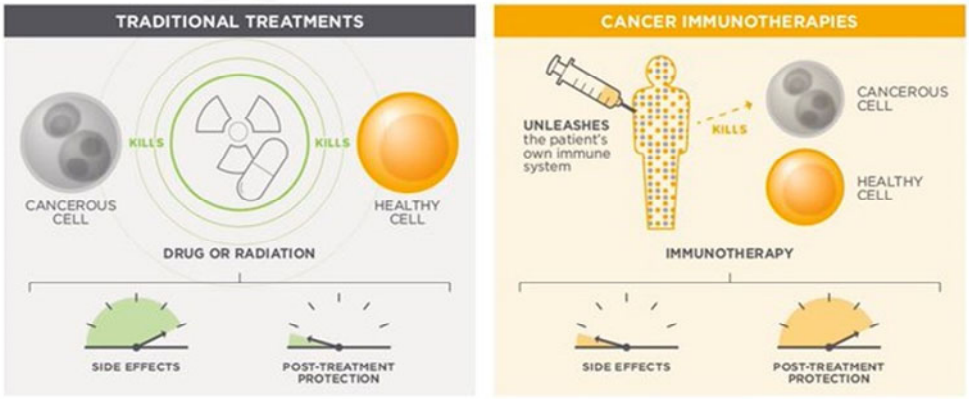
Cancer Immunotherapy Overview

To counteract the severe toxicities and stagnant survival rates normally associated with current cancer treatments, researchers are developing new cancer therapies with improved efficacies and more favorable safety profiles that selectively attack only the cancer cells without harming surrounding healthy cells. One prominent method, called immunotherapy, utilizes the body's own immune system to fight the disease. Immunotherapy, or biological therapy, is a type of cancer treatment that boosts the body's natural defenses to fight, helping the patient's body fight cancer by eliciting the following effects: (1) stop or slow the growth of cancer cells; (2) stop cancer from spreading to other parts of the body; and (3) help the immune system work better at destroying cancer cells.

Immunotherapies also provide significant advantages over conventional cancer treatments, such as chemotherapy or radiation. Since immunotherapy can train the immune system to recognize and remember cancer cells, this "immunomemory" may result in longer-lasting remissions. Clinical studies on long-term overall survival have shown that the beneficial responses to cancer immunotherapy treatment are maintained even after treatment is completed. Furthermore, since cancer immunotherapy is focused on the immune system and may be more targeted than conventional cancer treatments, it normally presents a better safety profile when it comes to side effects. Conventional chemical or radiological cancer therapy normally affects both the cancerous cells as well as healthy tissues, which results in common side effects, such as hair loss and nausea, but also can cause immunosuppression, weakening the body's immune system and affecting the body's post-treatment protection against infections and recurrent cancers, as seen in Figure 28 (page 48), (Source: Cancer Research Institute).

Figure 28

IMMUNOTHERAPY VS. CHEMOTHERAPY



Source: Adaptive Biotechnologies.

In the past few years, the field of immuno-oncology has received new momentum with the discovery and FDA approval of immune checkpoint inhibitors (ICIs). Since cancer cells are not foreign substances, but rather are derived from the body's own cells, the immune system does not always recognize them as foreign, an event called **tumor tolerance**. Moreover, even if the immune system distinguishes tumor cells and attempts to attack them, the response is often inadequate. One reason for this is that tumors protect themselves by secreting substances that suppress the activation of the body's anti-tumor killer cells, eliminating cellular components that the immune system uses to recognize diseased or cancerous cells.

Adaptive immune cells, like T-cells, roam the body looking for foreign cells by using protein receptors located on their surface to exchange signals with other cells and help them differentiate healthy cells from cancer cells. During this exchange of signals, called a checkpoint, a cell's surface proteins bind together with the T-cell, telling the immune system they are normal cells and sending an "off" signal to the T-cell. However, many types of cancer cells can send deceptive signals at checkpoints that bind to the protein receptors of the T-cells, making them appear as normal cells. ICIs work by blocking the receptors that cancer cells use to send signals to T-cells. This prevents the "off" signal from being sent, allowing the T-cells to launch an attack and kill cancer cells. However, while relatively well tolerated, ICIs stimulate the immune system, which may cause immune cells to attack healthy cells, triggering a variety of side effects, mostly immune related (Source: Cancer Research Institute).

In 2011, the FDA approved the first checkpoint inhibitor immunotherapy for the treatment of cancer—ipilimumab (Yervoy®) for melanoma. As of 2020, seven checkpoint inhibitors have been approved for multiple cancer types. In particular, two check point inhibitors received FDA approval for the treatment of head and neck cancer: Pembrolizumab (Keytruda®) by Merck & Co., for the treatment of head and neck squamous cell cancer; and Nivolumab (Opdivo®), by Bristol-Myers Squibb Company, for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). Due to their potential to enhance the effectiveness of immune responses, many different checkpoint inhibitors are currently being evaluated, both alone and in combination with other treatments, in a variety of cancer types in clinical trials (Source: ONS Voice).

Cancer Vaccine Background

Unlike traditional vaccines intended to directly prevent diseases, such as polio, smallpox, or measles, cancer vaccines do not prevent cancer but are used to treat specific cancers and prevent conditions that may cause cancer. Vaccines for cancer come in two categories: prophylactic and therapeutic. There are currently four vaccines that are approved by the FDA that can help prevent cancer (prophylactic), in addition to three FDA-approved vaccines for the treatment of cancer (therapeutic), as seen in Figure 29 (page 49).

Figure 29

FDA-APPROVED CANCER VACCINES

Prophylactic		
Name	Protects against HPV strains	Can help prevent the development of HPV-related:
Cervarix® (HPV)	16 and 18	Anal, cervical, head and neck, penile, vulvar, and vaginal cancers
Gardasil® (HPV)	16, 18, 6, and 11	Anal, cervical, head and neck, penile, vulvar, and vaginal cancers
Gardasil-9® (HPV)	16, 18, 31, 33, 45, 52, 58, 6, 11	Anal, cervical, head and neck, penile, vulvar, and vaginal cancers
HEPLISAV-B (HBV)	HBV	Liver cancer
Therapeutic		
Name	Type	
Bacillus Calmette-Guérin	Weakened bacteria	Approved for patients with early-stage bladder cancer
Sipuleucel-T (Provenge®)	Autologous dendritic cells	Approved for prostate cancer
talimogene laherparepvec (T-VEC, or Imlygic®)	Oncolytic (virus based)	Approved for melanoma that cannot be operated on;

Source: Cancer Research Institute.

Prophylactic or preventive vaccines attack viruses that may cause cancer. The human papillomavirus (HPV) vaccine, for example, targets the high-risk strains of HPV responsible for most cases of cervical cancer and linked to some throat, anal, vaginal, vulvar, and penile cancers. The hepatitis B virus (HBV) vaccine targets the disease that has been linked to an increase risk for liver cancer in people who have chronic (long-term) infections with the virus. Thus, vaccinating certain people against HPV and HBV could have a positive effect in protecting against the types of cancers linked to each condition.

Therapeutic cancer vaccines are a type of immunotherapy that treats cancer by stimulating the immune system to attack cancer in a specific location of the body. Unlike cancer prevention vaccines, cancer treatment vaccines are designed to make the immune system attack a disease that already exists. Therapeutic cancer vaccines either delay or stop cancer cell growth, shrink the tumor, and prevent tumor growth. They work by presenting the immune system with antigens it will recognize as foreign or dangerous. The three FDA-approved vaccines for the treatment of cancer (therapeutic) are:

- *PROVENGE® (Sipuleucel-T)*. This vaccine is used to help treat advanced prostate cancer. Each dose is made specifically for each patient using the patient's own immune dendritic cells to seek and attack prostate cancer cells. This treatment typically takes six weeks and is administered in three infusions every two weeks and prolongs survival times by approximately four months.

- *Bacillus Calmette–Guérin (BCG) vaccine.* Originally developed for tuberculosis, the BCG vaccine is approved to treat bladder cancer. BCG is live bacteria injected into the bladder via a catheter. The bacterium attracts immune cells, which then attack cancer cells.

- *Talimogene laherparepvec.* This vaccine, which is approved to treat advanced melanoma skin cancer, can be considered a different type of cancer treatment vaccine, called oncolytic virus therapy, which uses a virus that infects and breaks down cancer cells but does not harm normal cells. It is made from herpes simplex virus type 1. Although this virus can infect both cancer and normal cells, normal cells are able to kill the virus while cancer cells cannot.

The cancer vaccine market is expected to surpass $15 billion by 2025. In recent years, the cancer vaccine segment has emerged as the next growth frontier for the various companies involved in the research, development, and commercialization of cancer therapeutics. Rising vaccines usage, combined with other therapies, is expected to drive market growth, with growing occurrence of different types of cancer and the introduction of new vaccines anticipated to raise product demand over the next seven years (Source: ResearchAndMarkets.com's Global Cancer Vaccine Market & Clinical Trial Insight 2025, 2018).

CANCER IMMUNOTHERAPY TECHNOLOGY

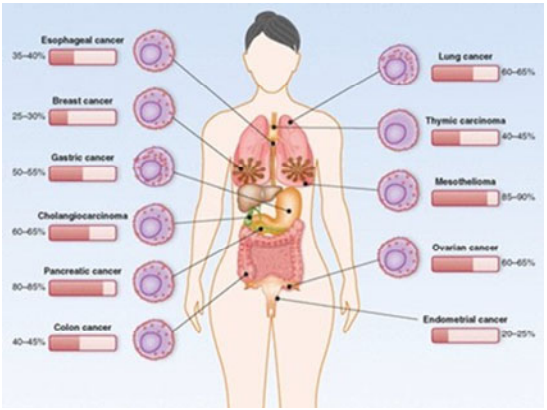
Based on the favorable efficacy and low side effect profile of immunotherapies, the field of immune-oncology has received greater attention. In particular, the recent development of **monoclonal antibodies (Mabs)** that are ICIs has further advanced the field. Tumors hijack the body's natural immune checkpoints by over-expressing immune checkpoint ligands (proteins that bind to and activate the inhibitory activity of immune checkpoints), which act as a mechanism of immune resistance, especially against T cells that are specific for tumor antigens and can kill cancer cells. ICIs block the interaction of immune checkpoints with their ligands on tumor cells, allowing poorly functional T cells to resume proliferation and cytokine production, thus killing tumor cells.

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

Unlike conventional therapies (e.g., radiation, chemotherapy, antibody, etc.), cancer vaccines have the potential to induce responses that not only result in the control and clearance of tumors but also establish immunological memory that can suppress and prevent tumor recurrence. Convenience, safety, and low toxicity of cancer vaccines make them invaluable tools to be included in future immunotherapy approaches. Currently, there are only a few vectored cancer vaccines being tested in combination with ICIs, all of which are in early clinical stages.

GeoVax's Approach

Figure 30
SOLID CANCERS



Source: Cancer Discovery Vol. 6 (2), 2016

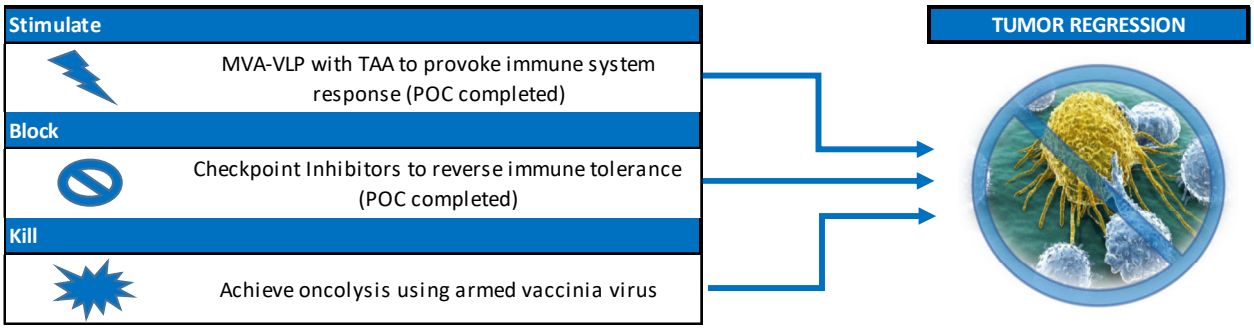
GeoVax believes that its MVA vector platform is well-suited for development of therapeutic cancer vaccines based on the expression of tumor-associated antigens. Utilizing its technology, GeoVax is developing a combination cancer vaccine strategy for the treatment of solid tumors (Figure 30), for which each component has already shown some promising results in preclinical models. GeoVax's approach to cancer immunotherapy uses combinations of:

- MVA-VLP cancer vaccines;
- Select proteins, peptides (e.g., MUC1; Cyclin B1), and
- Immune check-point inhibitors (e.g., anti-PD1)

The combination of the three components is expected to help the immune system fight and destroy cancer cells by eliciting the following three steps in order to achieve tumor regression, as shown in Figure 31 (page 51): (1) the use of the Company's MVA-VLP to stimulate the immune system and provoke a response (proof of concept completed); (2) the use of ICI to reverse immune tumor tolerance (proof of concept completed); and (3) the use of armed vaccinia virus to achieve oncolysis of cancer cells.

Figure 31

GEOVAX IMMUNOTHERAPY APPROACH



Source: GeoVax Labs, Inc.

Well-Documented Antigenic Target

GeoVax's cancer vaccine portfolio is based on the identification and expression of tumor-associated antigens in order to elicit an immune response against the cancer cells. The Company is initially targeting the following antigenic targets

- MUC1
  - aberrantly glycosolated in many cancers
  - In collaboration with ViaMune and University of Pittsburgh
- Cyclin B1
  - overexpressed in certain cancers
- HPV Head and Neck cancers
  - E6/E7 antigens
- Oncolytic vaccinia virus
  - To be used in conjunction with yet undisclosed immune checkpoint receptors

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

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

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

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

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

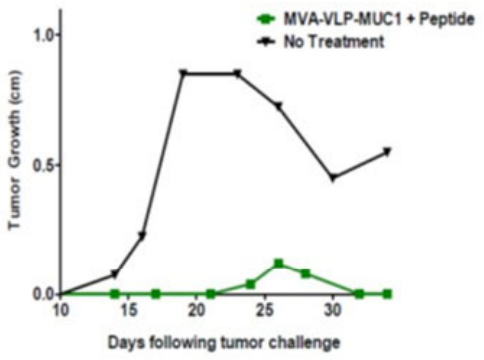
In addition to MUC1, GeoVax has expanded its oncology program to target other cancer antigens through collaborations with Emory University for HPV-associated head and neck cancers, and Leidos, Inc. for combination with novel peptide checkpoint inhibitors developed by Leidos. Each of these oncology programs have the potential to yield multiple vaccine candidates against various types of cancers.

Collaboration with Leidos, Inc.

In November 2018, the Company began collaborating with the Explorations of Global Health Division of Leidos, evaluating the combination of the companies' respective technologies in the field of cancer immunotherapy. The GeoVax/Leidos collaboration includes the design, construction, and characterization of multiple immunotherapeutic vaccine candidates using GeoVax's GV-MVA-VLP™ vaccine platform combined with certain novel peptide PD-1 ICIs developed by Leidos. The vaccine design, construction, and characterization is to be performed at GeoVax, with further analysis conducted by Leidos. The Company believes that the use of ICI in combination with its vaccines may overcome some of the challenges associated with the use of immune checkpoint inhibitors in cancers or other chronic infectious disease, including the need for multiple injections, significant side effects, and the development of drug resistance by the patients. According to GeoVax, this effort may lead to expanded efforts in cancer immunotherapy, or other diseases where an immunological-based therapeutic approach would be beneficial.

Solid Tumor Cancers Candidates

Figure 32
TUMOR PREVENTION EXPERIMENT



Source: GeoVax Labs, Inc.

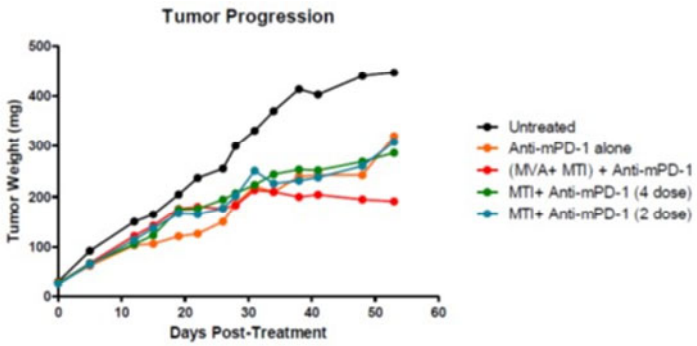
GeoVax is collaborating with Dr. Olivera Finn, a leading expert in cancer immunotherapy at the University of Pittsburgh. Dr. Finn was the first to show that many tumors express an abnormal form of cell surface-associated Mucin 1 (MUC1) protein that is recognized by the immune system as foreign. Given this, GeoVax has produced an MVA-VLP-Muc1 vaccine candidate designed to deliver abnormal forms of MUC1 (e.g., **hypo-glycosylated** forms found in tumors), with the goal of raising protective anti-tumor antibodies and T cell responses in cancer patients.

The Company has demonstrated VLP production by electron microscopy using MUC1 immunogold staining, and has shown that the VLPs express a hypo-glycosylated form of MUC1 in human cell lines. Mucin 1 (MUC1) protein is associated with a wide range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung. The Company has also shown that a combination of its MVA-VLP-MUC1 vaccine candidate with a MUC1 peptide was capable of breaking tumor tolerance to human MUC1 tumors in transgenic mice and to protect them against in a lymphoma tumor model, achieving tumor prevention, as shown in Figure 32.

The Company is also collaborating with ViaMune, which has developed a fully synthetic MUC1 vaccine candidate (MTI). The collaboration is intended to 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. Because both MVA-MUC1 and newly approved ICIs have shown only modest efficacy as monotherapies for cancer treatment, GeoVax intends to combine its MVA-VLP-MUC1 vaccine with ViaMune's synthetic peptide vaccine (MTI), SOC, and ICIs to maximize success. To GeoVax's knowledge, there is currently no company in clinical testing utilizing a MVA-VLP vector approach in combination with a synthetic MUC1 vaccine, SOC (e.g. chemotherapy and radiation), and ICIs. This combination approach may result in a novel vaccination strategy for cancer patients that could enhance efficacy while reducing adverse reactions due to extensive use of SOC and ICIs.

Preclinical studies of the combined MTI and MVA-VLP-MUC1 vaccines conducted at the University of North Carolina at Charlotte have shown the combination of the Company's vaccine with MTI and ICI have significantly reduced the tumor burden in a mouse model for colorectal cancer. Figure 33 illustrates the combination of MVA, MTI, and an ICI arrested tumor growth and shrank tumors.

Figure 33
THERAPUTIC USE



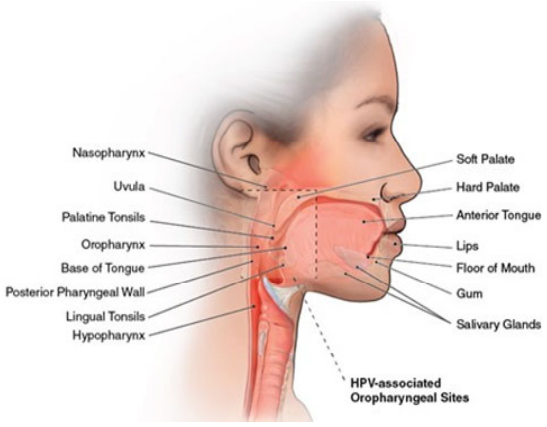
Source: GeoVax Labs, Inc.

GeoVax's clinical approach to developing its immuno-oncology program is to use standard-of-care (SOC) treatments, vaccination, and immune checkpoint inhibitors (ICIs) to unleash a patient's immune system to fight their cancer. A selected vaccine regimen will be used to elicit antibody and T cell responses to MUC1 in patients without the need to remove or pretreat any plasma fractions. Prior to vaccination, patients will undergo their SOC treatments, such as chemotherapy or radiation. ICIs will be used at reduced doses or frequencies (to reduce adverse reactions and costs) to activate suppressed T cells and enable the patients' immune system to respond to VLP-delivered MUC1 antigens, with the goal of causing tumor regression.

Preclinical PoC is being established via the Company's collaboration with ViaMune and University of North Carolina at Charlotte, using engineered murine human MUC1 models. Contingent on the outcome of the preclinical studies, GeoVax believes that it may be able to file an IND with the FDA within two years and subsequently initiate a Phase 1 trial in a limited number of oncology patients.

Human Papilloma Virus (HPV) – Associated Head and Neck Cancers

Figure 34
COMMON HEAD AND NECK CANCER SITES



Source: Centers for Disease Control and Prevention (CDC).

Head and neck cancers are the sixth most frequently occurring cancer worldwide. Approximately 90% of head and neck cancers originate in the squamous cells—thin, flat cells that line the mucosal surfaces (mouth, nose, and throat) of the head and neck—and are therefore called squamous cell carcinomas. As shown in Figure 34, this group of cancers includes cancer of the oral cavities (cheeks, lips, gums, tongue, hard and soft palate, and mouth floor), salivary glands, paranasal sinuses and nasal cavity, pharynx, larynx (voice box), and lymph nodes. In total, there are more than 30 locations in the head and neck for cancer to develop (Sources: American Dental Association). Most squamous cell carcinomas are traditionally considered tobacco- and alcohol-exposure related. However, high risk alpha human papillomaviruses (HPV), mainly HPV type 16 (HPV16), have recently been recognized as causally related to a subset of oropharyngeal squamous cell carcinomas (Source: *PLoS One*, 13(2), 2018).

Cancer often begins in one area, such as the tongue, and spreads to the lymph nodes. This effect is known as tumor metastasis and is associated with cancer recurrence and decreased survival. Metastasis and cancer recurrence are significant clinical issues in head and neck cancers. The American Cancer Society estimates that 10% to 40% of patients whose oral cancer was considered "cured" will likely develop cancer of the oral cavity again (a local recurrence) or of a nearby organ, such as the larynx, esophagus (regional recurrence), or lung (distal recurrence). (Source: *Annals of Oncology*, Vol. 30 (5):744–756, 2019). The recurrence rate affects the diseases' 5-year survival. In the U.S., the 5-year relative survival rate for head and neck cancers is 65%. While this constitutes a 28% increase from the 1975-77 levels (53% 5-year survival rate), this improvement considerably lags the 40% increase in 5-year survival rate for overall cancer during the same period (Sources: American Cancer Society's *Cancer Facts and Figures 2020* and The Oral Cancer Foundation, and The Head and Neck Cancer Alliance).

Worldwide, head and neck cancer is expected to account for more than 650,000 occurrences and 330,000 deaths in 2020 (Source: the Head and Neck Cancer Alliance). In the U.S., head and neck cancers account for approximately 3% of all cancers, representing over 53,000 new cases and over 10,000 death each year, while Europe accounts for approximately 150,000 cases annually (Sources: American Cancer Society and *PLoS One*, 13(2), 2018). Figure 35 lists the estimated new cancer cases and deaths in the U.S. for several types of head and neck cancer during 2020.

Figure 35
HEAD AND NECK CANCER STATISTICS

	Estimated New Cases			Estimated Deaths		
	Both Sexes	Male	Female	Both Sexes	Male	Female
All Cancer Types	1,806,590	893,660	912,930	606,520	321,160	285,360
Oral Cavity and pharynx	53,260	38,380	14,880	10,750	7,760	2,990
Tongue	17,660	12,960	4,700	2,830	1,980	850
Mouth	14,320	8,430	5,890	2,660	1,690	970
Pharynx	17,950	14,630	3,320	3,640	2,820	820
Other Oral cavity	3,330	2,360	970	1,620	1,270	350

Source: American Cancer Society, Inc. (2020).

Specifically, the global market for head and neck cancer is expected to reach $4.5 billion by 2027, growing at CAGR of 17.3%, driven by rising epidemic of HPV-associated head and neck cancer, and the potential approval of novel immunotherapy options (Source: iHealthcareAnalyst, Inc.'s *Head and Neck Squamous Cell Carcinoma Market by Drug Class*, February 2020).

GeoVax's Approach

In July 2018, GeoVax began collaborating with Emory University on the development of a therapeutic vaccine for HPV infection, with a specific focus on head and neck cancer. The GeoVax/Emory collaboration will include testing of 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. In 2006, Dr. Ahmed discovered that the PD-1 pathway could also be exploited by many pathogens to repress normal T-cell function during chronic viral infection, leading to the development of numerous blockbuster anti-PD1 antibodies being used for treatment of various cancers and which hold promise as adjunctive therapy for several chronic infectious diseases. To increase the therapeutic efficacy of the Company's HPV vaccine, GeoVax intends to apply a combination strategy, which could include coadministration of anti-PD1 antibodies and/or other newly discovered immunotherapy drugs to improve a patient's own anticancer immune response. Furthermore, in November 2018, GeoVax announced a collaboration with Virometix, a company developing next-generation Synthetic Virus-Like Particle (SVLPTM)-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' synthetic HPV vaccine candidate. This collaboration complements the Company's collaboration with Emory University for HPV-related head and neck cancers. GeoVax believes that the combination of its MVA-vectored HPV vaccines and Virometix' SVLP-based HPV vaccine could bring a synergy that significantly increases the therapeutic potential over each platform used separately.

Investment Highlights

- GeoVax Labs, Inc. is a clinical-stage biotechnology company developing preventive and therapeutic 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 expresses non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (*in vivo*). VLPs mimic a natural infection, stimulating the immune system to recognize, prevent, and control the target infection through durable immune responses.

- The Company's platform results in highly immunogenic, long-lasting, and safe vaccines. Important attributes of GeoVax's vaccine platform include: the need for only a single dose with no adjuvant, durable immunity, and cost-effective manufacturing that is conducive to affordable scale-up. GeoVax's HIV vaccines have demonstrated outstanding safety in multiple human clinical trials.

- 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), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), Zika virus (ZIKV), and malaria. Furthermore, GeoVax is applying its MVA-VLP technology to cancer immunotherapy (immuno-oncology).

- The Company's vaccine development activities are financially supported by the U.S. Government in the form of research grants and clinical trial support, with the Company's HIV program having received >$50 million to date from the NIH. In addition, GeoVax has multiple license and research collaboration agreements to advance its product candidates. The Company's owned and in-licensed worldwide patent estate includes 56 granted or pending patent applications spread over 16 patent families.

HIV/AIDS Vaccine Program

- GeoVax's HIV vaccine technology was developed in collaboration with researchers at Emory University, the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC). The technology is exclusively licensed to GeoVax from Emory.

- The Company's most advanced program is a preventive vaccine (GOVX-B11) for the clade B subtype of HIV, the most common form of HIV in the Americas, Western and Central Europe, Australia, and Japan. GOVX-B11 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.

    - GeoVax began a follow-up human clinical trial (HVTN 132) testing the ability of "late boosts" (additional vaccinations given years after the original) to increase the antibody responses elicited by GOVX-B11. HVTN 132 is being conducted with support from the HVTN and funding from NIAID.

- The Company has partnered with American Gene Technologies International Inc. (AGT) (March 2017) and the University of California, San Francisco (UCSF) (November 2019) to develop a functional cure for HIV infection. On August 24, 2020, GeoVax announced the initiation of the UCSF Phase 1 clinical study testing the companies' combined technologies. The AGT trial has been cleared by the FDA and GeoVax expects its vaccine to be added to the trial in early 2021.

Hemorrhagic Fever (HF) Vaccine Program

- GeoVax's HF vaccine program is focused on developing a **tetravalent vaccine (TV)** designed to protect against all major HF viruses (Ebola, Sudan, Marburg, and Lassa) endemic in African countries. Each vaccine is also being developed as a **monovalent** vaccine. GeoVax's preclinical studies in rodents and non-human primates have demonstrated 100% single-dose protection in lethal challenge models for its EBOV, MARV, and LASV vaccines. Further development of this program is dependent upon additional funding support

Zika Virus (ZIKV) Vaccine Program

- GeoVax is focused on 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. Further development of this program is dependent upon additional funding and/or partnering support.

Malaria Vaccine Program

- 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) to develop a vaccine to prevent malaria infection and transmission by targeting antigens derived from multiple stages of the parasites' life cycle. The Company's vaccine constructs are currently being evaluated in small animal models.

Coronavirus Disease (COVID-19) Program

- GeoVax has constructed four novel candidate vaccines and plans to use preclinical studies to select one in preparation for advancement to manufacturing and initial human clinical trials. The Company's recent financing will allow it to aggressively pursue preclinical development activities as it awaits third-party funding for advanced development.

Cancer Immunotherapy Vaccine Program

- GeoVax's 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 (to reverse immune tumor tolerance); and select peptides.

    - The Company is collaborating with ViaMune, which has developed a fully synthetic MUC1 vaccine candidate (MTI), to assess each companies' vaccine platform separately (and in combination) with the goal of developing a tumor Mucin 1 (MUC1) vaccine that can produce a broad spectrum of anti-tumor antibody and T cell responses. Preclinical studies of the combined MTI and MVA-VLP-MUC1 vaccines conducted at the University of North Carolina at Charlotte have shown the combination of the Company's vaccine with MTI and ICI have significantly arrested tumor growth and shrank tumors in a mouse model for colorectal cancer. MUC1 protein is linked to a range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung.

    - In July 2018, GeoVax began collaborating with Emory University to develop 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 of GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV. Furthermore, in November 2018, GeoVax announced a collaboration with Virometix, a company developing next-generation Synthetic Virus-Like Particle (SVLP™)-based vaccines, to develop a therapeutic vaccine for HPV infection using GeoVax's MVA-vectored HPV vaccine candidates in combination with Virometix' synthetic HPV vaccine candidate.

Competition

The biotechnology and pharmaceutical industries are highly competitive with numerous companies, as well as public and private universities and research organizations, actively engaged in researching and developing products that may be considered competitive to those being developed by GeoVax. As GeoVax seeks to develop and commercialize its product candidates, it will face competition from existing or development-stage drug and immunotherapy approaches targeting the same diseases. In addition, GeoVax is likely to face competition from initiatives supported by private and government entities, including the National Institute of Allergy and Infectious Diseases (NIAID) (part of the U.S. National Institutes of Health [NIH]), the U.S. Military, the International Aids Vaccine Initiative (IAVI), the European Vaccine Initiative (EVI), and the South African AIDS Vaccine Initiative (SAAVI), among others. Specific to its technology, since the 1980s, MVA vaccines have been under development in academic as well as commercial settings, though GeoVax is uniquely focused on developing MVA vaccines expressing VLPs. Two companies similarly use MVA as a vaccine vector: Bavarian Nordic and Transgene. The Jenner Institute of Oxford University has an active MVA program in which MVA vaccines are being used primarily as heterologous boosts.

GeoVax is focused is developing preventive vaccines against infectious diseases, including the novel coronavirus (COVID-19), Human Immunodeficiency Virus (HIV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), malaria, and Zika. As well, the Company is focused on developing therapeutic vaccines within immunoncology to treat solid tumors and HPV-associated head and neck cancers. To the Company's knowledge, there are currently no U.S. Food and Drug Administration (FDA)-licensed and commercialized preventive HIV vaccines, Zika vaccines, or HF virus vaccines available in the world. As well, with the recent worldwide COVID-19 pandemic, there is a global push to develop a vaccine against this virus, having killed 1.1 million people to date worldwide as of October 21, 2020. GeoVax is aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, who are engaged in vaccine research and development within these areas, as outlined below. Many of these entities and their efforts have been mentioned throughout this report within their respective sections. Consequently, this list, as well as those companies/entities mentioned within the Core Story, is not intended to be an exhaustive collection of potential competitors to GeoVax; however, it is believed to represent the type of competition the Company may encounter as it seeks to further develop and commercialize its product candidates.

GeoVax is aware of a variety of established enterprises, including leading pharmaceutical companies, that are broadly engaged in vaccine/immunotherapy research and development. These include, among others, Janssen Pharmaceuticals, Sanofi-Aventis, GlaxoSmithKline, Merck, Pfizer, and MedImmune. There are additional development-stage biotechnology companies involved in different vaccine and immunotherapy technologies, including Aduro Biotech, Advaxis, BioNTech, Curevac, Dynavax, Juno, Moderna, and Novavax. If these companies are successful in developing their technologies, it could impact GeoVax's business as well as its future growth potential. The number of companies looking to develop products and therapies to treat unmet needs for these indications is likely to increase. Several of these competing products and therapies are based on scientific approaches that are similar to those being used at GeoVax, while others are based on completely different approaches. A large percentage of GeoVax's competitors, either alone or with strategic partners, have considerably greater financial, technical, and human resources and overall experience in discovering and developing product candidates, obtaining FDA and other regulatory approvals of products, and commercializing those products. Competitors' products may be more effective (or more effectively marketed and sold) than any drug GeoVax may bring to market and may render GeoVax's product candidates obsolete or non-competitive.

The Company expects to see strong and growing competition as new drugs enter the market and advanced technologies become available. GeoVax believes that any products it develops and commercializes will compete based on efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payers (among other things). GeoVax is aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, that are engaged in vaccine research and development within these specific areas. A number of companies are developing various types of therapeutic vaccines or other immunotherapy approaches to treat cancer, as described in the accompanying sections.

HIV (PREVENTIVE AND THERAPEUTIC)

There are numerous FDA-approved treatments for HIV—primarily antiretroviral therapies—marketed by large pharmaceutical companies; however, there is no approved therapies for the eradication of HIV. It is possible that major pharmaceutical companies that currently market antiretroviral therapies or other companies that are developing HIV product candidates could develop products to eradicate HIV. As well, with no vaccine available to prevent HIV infection or treat those who have it; scientists are working hard to develop one.

NIH is investing multiple approaches to prevent HIV, including a safe and effective preventive HIV vaccine. These research efforts include two late-stage, multinational vaccine clinical trials called Imbokodo and Mosaico. In 2017, NIAID and partners launched Imbokodo or HVTN 705/HPX2008, a Phase 2b proof-of-concept study evaluating the safety and efficacy of an experimental regimen based on a "mosaic" vaccine designed to induce immune responses against a wide variety of global HIV strains. Other NIH-supported research aims to deliver additional HIV prevention options that are safe, effective, and desirable to diverse populations and scalable worldwide to help end the global pandemic.

The following companies are currently actively engaged in vaccine research and development within the area of HIV, including Sanofi, GlaxoSmithKline, and Johnson & Johnson. Other HIV vaccines are in varying stages of research, testing and clinical trials, including those supported by the NIH Vaccine Research Center, the U.S. Military, The International AIDS Vaccine Initiative (IAVI), the European Vaccine Initiative, and the South African AIDS Vaccine Initiative. The ultimate development goal is for a safe and effective vaccine that protects individuals from acquiring HIV. Yet, even if a vaccine only protects certain people who get vaccinated, or if it provides less than total protection by reducing the risk of infection, it could still have a significant impact on the rates of transmission and aid in controlling the pandemic—specifically for those who are at high risk of getting HIV. A partially effective vaccine could decrease the number of people who get infected with HIV, helping reducing the number of individuals who can pass the virus to others.

MALARIA

There are currently no commercialized vaccines to prevent malaria infection. A first-generation infection-blocking malaria vaccine, RTS,S, is under regulatory review. It requires four doses and has been recommended by the WHO for pilot implementation studies. Since this vaccine is based on a single antigen and has modest efficacy (30% to 40%, depending on the subject's age), the WHO has defined a Road Map for developing and licensing both next generation of malaria vaccines. These vaccines are expected to contain multiple antigens intended to block both infection and transmission of malaria, with at least a 75% efficacy rate.

VIRAL HEMORRHAGIC FEVER (VHF) VIRUSES

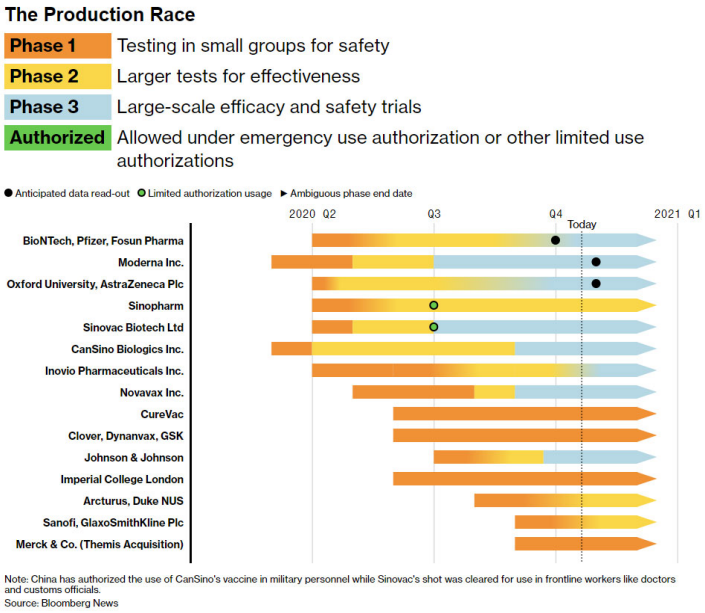
Viral hemorrhagic fevers (VHFs) are a group of illnesses caused by four families of viruses and includes Ebola, Sudan, Marburg, and Lassa fever. VHFs have common features where they affect many organs, they damage the blood vessels, and they affect the body's ability to regulate itself. Some VHFs cause mild disease, but some, like Ebola or Marburg, cause severe disease and death. While VHFs are found around the world, specific diseases are usually limited to areas that have animals who carry them. For instance, Lassa fever is limited to rural areas of West Africa where rats and mice carry the virus. There are no effective treatments for some of these viral infections, creating a concern about their use in bioterrorism.

In December 2019, the FDA approved the first vaccine (Ervebo) for prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older, developed by Merck. As well, ribavirin (Rebetol, Copegus) medical treatment has been effective in treating some individuals with Lassa fever, and treatment with convalescent-phase plasma has been used with success in a several patients (other experimental antiviral agents have also been tried in a few patients). The following companies are currently actively engaged in vaccine research and development within the area of VHF: NewLink Genetics and Merck, Johnson & Johnson, Novavax, Profectus Biosciences, Protein Sciences, Inovio, and GlaxoSmithKline.

COVID-19

The global push to develop and bring to market a COVID-19 vaccine is accelerating, with researchers reporting positive developments in early studies and countries signing agreements to sure up supplies. To date, more than 180 vaccines are under development globally (Source: Bloomberg), driven by the U.S. government's Operation Warp Speed program along with other fast-track initiatives, with 24 candidates having already reached human testing—with some gearing up for Phase 3 (Source: World Health Organization). Candidates from the University of Oxford with AstraZeneca Plc, Moderna Inc. and a partnership of Pfizer Inc. and BioNTech SE are among the forerunners. China's CanSino Biologics has received regulatory approval to start final-stage trials in Russia. The company is also planning a trial in Pakistan of 40,000 people. The shot has already received a special authorization to be used by China's military. Hospitals and research facilities worldwide are testing a variety of therapies on coronavirus-positive patients in seeking to find a potential treatment for these COVID-19 patients. Some of the medications and treatments being employed within the science community include Remdesivir, Dexamethasone, and Convalescent Plasma. Figure 36 provides an overview of a selection of the vaccines and treatments targeting COVID-19, with greater details available through the following link. https://www.bloomberg.com/features/2020-coronavirus-drug-vaccine-status/ (Source: Bloomberg.com).

Figure 36
COVID-19 DEVELOPMENT PROCESS



Source: Bloomberg Intelligence.

CANCER IMMUNOTHERAPY

Immunotherapy uses the natural power of a patient's immune system to fight illnesses, including cancer. In the past few decades, it has become an important part of therapy for a variety of cancer types, noting that not all immunotherapies work the same way. Certain of them boost the overall immune system, while others try to teach it to attack extremely specific types of cells found in tumors, noting that each immunotherapy has different benefits and risks—thus they are used differently depending on the case. Examples include CAR T-cell (short for chimeric antigen receptor T-cell therapy); T-cell receptor therapy (TCR), which is another type of ACT used to fight cancer; Tumor-infiltrating lymphocytes (TIL), which is an alternative type of ACT therapy; monoclonal antibodies; immune checkpoint inhibitors; cancer vaccines; and general immunotherapies, such as interleukins, interferons, colony stimulating factors, and others. A number of companies are developing various types of therapeutic vaccines or other immunotherapy approaches to treat cancer, including Advaxis, Immune Design, Oncothyreon, Bavarian Nordic, Roche Pharmaceuticals, Merck & Co, Bristol Myers Squibb, AstraZeneca plc, and Medimmune, LLC, among others.

Historical Financial Results

Figures 37, 38, and 39 (pages 61-63) provide a summary of GeoVax's most recent key financial statements for the three months ended June 30, 2020 (Note that share and per share information in the financial statements has not been restated for the Company's 1-for-20 reverse stock split effected September 25, 2020).

Of note, the Company offered 2,560,000 units at $5.00 per share on September 24, 2020. Each unit consisted of one share of common stock and one warrant; each warrant will be immediately exercisable at a price of $5.00 for a period of five years. This means there are another 2,560,000 shares that could go into the float if the warrants are exercised. At market close on September 24, 2020, the previously traded shares on the OTCQB marketplace, under the symbol GOVX, was reverse split at 1:20. The common stock and warrant have been approved and are now listed on the NASDAQ Capital Markets under the symbols "GOVX" and "GOVXW".

Figure 37
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Grant and collaboration revenue	$440,602	$209,941	$1,156,579	$574,173
Operating expenses:				
Research and development	461,421	451,227	1,270,357	1,006,945
General and administrative	427,292	412,650	929,637	922,714
Total operating expenses	888,713	863,877	2,199,994	1,929,659
Loss from operations	(448,111)	(653,936)	(1,043,415)	(1,355,486)
Other income (expense):				
Interest income	60	881	812	2,105
Interest expense	(7,153)	(1,093)	(8,295)	(2,221)
Total other income (expense)	(7,093)	(212)	(7,483)	(116)
Net loss	($455,204)	($654,148)	($1,050,898)	($1,355,602)
Basic and diluted:				
Net loss per common share	($0.03)	($1,994.35)	($0.11)	($4,706.95)
Weighted average shares outstanding	13,823,452	328	9,255,497	288

Source: GeoVax Labs, Inc.

Figure 38
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 710,682	$ 283,341
Grant funds and other receivables	187,163	68,603
Prepaid expenses and other current assets	40,470	95,320
Total current assets	938,315	447,264
Property and equipment, net (Note 5)	8,618	10,606
Deposits	11,010	11,010
Total assets	$ 957,943	$ 468,880
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	$ 91,416	$ 152,653
Accrued expenses (Note 6)	2,076,359	1,851,040
Current portion of notes payable	182,379	12,500
Convertible debentures	435,711	-
Total current liabilities	2,785,865	2,016,193
Note payable, net of current portion	21,699	27,243
Total liabilities	2,807,564	2,043,436
Commitments (Note 9)		
Stockholders' equity (deficiency):		
Preferred Stock, $.01 par value (Note 10):		
Authorized shares – 10,000,000		
Issued and outstanding shares – 400 and 2,486		
June 30, 2020 and December 31, 2019, respectively	376,095	1,932,433
Common stock, $.001 par value:		
Authorized shares – 600,000,000		
Issued and outstanding shares – 13,834,075 and 299,835 at		
June 30, 2020 and December 31, 2019, respectively	13,834	300
Additional paid-in capital	41,658,861	39,340,224
Accumulated deficit	(43,898,411)	(42,847,513)
Total stockholders' equity (deficiency)	(1,849,621)	(1,574,556)
Total liabilities and stockholders' equity (deficiency)	$ 957,943	$ 468,880

Source: GeoVax Labs, Inc.

Figure 39

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	($1,050,898)	($1,355,602)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,033	3,795
Stock-based compensation expense	18,000	258,396
Changes in assets and liabilities:		
Grant funds and other receivables	(118,560)	57,568
Prepaid expenses and other current assets	54,850	(30)
Accounts payable and accrued expenses	164,082	262,064
Total adjustments	125,405	581,793
Net cash used in operating activities	(925,493)	(773,809)
Cash flows from investing activities:		
Purchase of property and equipment	—	(4,272)
Net cash used in investing activities	—	(4,272)
Cash flows from financing activities:		
Net proceeds from sale of preferred stock	300,000	740,000
Net proceeds from issuance of note payable	170,200	—
Net proceeds from bridge financing	888,500	—
Principal repayment of note payable	(5,866)	(5,209)
Net cash provided by financing activities	1,352,834	734,791
Net increase (decrease) in cash and cash equivalents	427,341	(43,290)
Cash and cash equivalents at beginning of period	283,341	259,701
Cash and cash equivalents at end of period	$710,682	$216,411

Source: GeoVax Labs, Inc.

Recent Events

September 29, 2020—GeoVax Labs, Inc. 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. A total of 2,310,000 units were issued at a price to the public of $5.00 per unit consisting of one share of common stock and one five-year warrant to purchase one share of common stock at an exercise price of $5.00, and a total of 250,000 units were issued at a price to the public of $4.99 per unit consisting of one pre-funded warrant to purchase one share of common stock at an exercise price of $0.01 and one five-year warrant to purchase one share of common stock at an exercise price of $5.00. The common stock, pre-funded warrants and warrants were immediately separable.

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 will effectuate a reverse split of its issued and outstanding common stock at a ratio of 1-for-20. The reverse stock split is expected to be effective at 12:01 a.m., Eastern Time, on Friday, September 25, 2020. The share numbers and pricing information in this release are adjusted to reflect the impact of the reverse stock split.

September 15, 2020—Announced that its Chief Scientific Officer Emeritus, Harriet L. Robinson, PhD, is an invited speaker at the 20th annual World Vaccine Congress, September 28th to October 1st. Dr. Robinson will speak on September 28th 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 (NPJ) 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).

August 10, 2020—Announced financial results for the quarter ended June 30, 2020 and provided an update on its corporate developments.

June 29, 2020—Announced the closing, on June 26, 2020, of a private placement offering whereby the Company entered into a securities purchase agreement with an institutional investor. Pursuant to the Purchase Agreement, the Company issued the Investor convertible senior secured debentures in the aggregate principal amount of $1,200,000 (including a 12.5% original issue discount) and Warrants to purchase an aggregate of 2,400,000 shares of the Company's common stock. The Debentures accrue interest at a rate of 5% per annum and are initially convertible into shares of the Company's common stock at a conversion price of $0.50 per share, subject to adjustment. The Debentures mature one year from the date of issuance, are secured by substantially all of the Company's assets, and contain customary events of default.

June 29, 2020—Announced that its Chief Scientific Officer Emeritus, Harriet Robinson, PhD, will be an invited speaker during a webinar on the topic "*The Fight Against COVID-19: What We Know About Vaccines."* The webinar was held on July 1, 2020 and was sponsored by the Sheikh Hamdan Bin Rashid Al Maktoum Award for Medical Science. Registration for the webinar is available at www.dicms.ae/covid19/#/home. During the webinar, Dr. Robinson will speak on the "prospects of a SARS-COV-2 vaccine." Also speaking during the webinar will be Stanley Plotkin, MD, a world-renowned vaccine expert and member of GeoVax's Scientific Advisory Board. Dr. Plotkin will speak on the topic "vaccine for a difficult target."

June 10, 2020—Announced that its Chief Scientific Officer, Farshad Guirakhoo, PhD, will be a featured speaker at the National Foundation for Infectious Diseases Annual Conference on Vaccinology Research, being held virtually on June 18-19, 2020. Dr. Guirakhoo delivered a presentation entitled *Development of Potential Single-Dose Vaccine Against COVID-19 Using GV-MVA-VLP™ Vector Platform*, during which he discussed GeoVax's unique multi-antigens approach toward COVID-19 vaccine development, including vaccine design and preclinical testing results to date.

June 4, 2020—Announced that it has been approved to trade on the OTCQB Venture Market as of June 4, 2020. Investors can find current financial disclosure and Real-Time Level 2 quotes for the Company at www.otcmarkets.com.

May 6, 2020—Announced its financial results for the three months ended March 31, 2020 and provided an update on its corporate development progress. David Dodd, President & CEO, commented, "During the early months of 2020, GeoVax continued to make progress in various areas of product development and corporate business strategy, despite the limited capital resources which have constrained the Company's activities. Most notable was GeoVax's decision to use its technology and expertise to develop a vaccine against novel coronavirus (COVID-19)."

March 30, 2020—GeoVax Labs, Inc. commented on the passage of the Coronavirus Aid, Relief, and Economic Security Act (CARES ACT), which was signed into law by President Trump on March 27, 2020. Among the many provisions of this unprecedented $2 trillion economic stimulus bill, $27 billion of emergency funding is appropriated for the "Public Health and Social Services Emergency Fund" to prevent, prepare for, and respond to the current coronavirus pandemic, including the development of countermeasures and vaccines. These appropriations include not less than $3.5 billion for the Biomedical Advanced Research and Development Authority (BARDA) for manufacturing, production and purchase of vaccines, therapeutics and diagnostics.

March 25, 2020—Announced its financial results for the year ended December 31, 2019 and provided an update on its corporate development progress. David Dodd, President & CEO, commented, "During the past year and the early months of 2020, GeoVax made substantial progress in various areas of product development. This was combined with tough capital restructuring decisions that, while painful at the time, have now resulted in GeoVax being better positioned for future financing efforts in support of its programs and increasing shareholder value."

March 18, 2020—Provided an update on its development of a vaccine for prevention/control of novel coronavirus disease (COVID-19) caused by SARS-Cov-2 coronavirus. GeoVax is using its GV-MVA-VLPTM vaccine platform and expertise to design and construct vaccine candidates using genetic sequences from the virus responsible for the ongoing COVID-19 outbreak originating in Wuhan, China.

March 4, 2020 –Provided an update on its development of a vaccine for prevention/control of novel coronavirus disease (COVID-19) caused by SARS-Cov-2 coronavirus. The update was given by GeoVax's Chief Scientific Officer, Farshad Guirakhoo, PhD, during his presentation on emerging infectious diseases entitled "*Development of Single-Dose Vaccines for Emerging Infectious Diseases Using a Novel MVA Platform"* at the World Immunotherapy Congress in San Diego, California. GeoVax is using its GV-MVA-VLP™ vaccine platform and expertise to design and construct vaccine candidates using genetic sequences from the virus responsible for the ongoing COVID-19 outbreak originating in Wuhan, China.

February 6, 2020—Commented on the recent discontinuance of the HVTN 702 clinical trial. On February 3, 2020, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), announced that it has stopped the administration of vaccinations in its HVTN 702 clinical trial of an investigational HIV vaccine. Although there were no safety concerns, an independent data and safety monitoring board (DSMB) found during an interim review that the regimen did not prevent HIV infection. The HVTN 702 vaccine regimen consisted of two experimental vaccines supplied by Sanofi Pasteur and GSK. HVTN 702 was based on the only vaccine regimen ever to show protection from HIV—the regimen tested in the RV144 clinical trial in Thailand led by the U.S. Military HIV Research Program and the Thai Ministry of Health. For HVTN 702, the vaccine regimen was adapted to the HIV subtype Clade C most common in southern Africa, where the pandemic is most pervasive.

January 27, 2020—GeoVax Labs, Inc., together with BravoVax, a vaccine developer in Wuhan, China, announced the signing of a Letter of Intent to jointly develop a vaccine against the new coronavirus (known as 2019-nCoV). Under the collaboration, GeoVax will use its MVA-VLP vaccine platform and expertise to design and construct the vaccine candidate using genetic sequences from the ongoing coronavirus outbreak originating in Wuhan, China. BravoVax will provide further development, including testing and manufacturing support, as well as direct interactions with Chinese public health and regulatory authorities.

January 23, 2020—Announced it has implemented a 1-for-2000 reverse stock split of its common stock with a market effective date of January 24, 2020. For the 20-business day period beginning January 24, 2020, GeoVax's ticker symbol will be "GOVXD" to reflect the post-split price. Following, the ticker symbol will revert to "GOVX."

December 3, 2019—Announced that its Chief Scientific Officer, Farshad Guirakhoo, PhD, will be a featured speaker at the World Vaccine & Immunotherapy conference, being held December 2-5, 2019 in San Francisco, California. On Wednesday, December 4, Dr. Guirakhoo will deliver a presentation entitled, "*Development of Single-Dose Vaccines for Emerging and Re-Emerging Infectious Diseases, Preclinical Data for Ebola, Marburg, Lassa Fever and Zika as Examples*." During a second presentation on that day entitled, *"Utilizing a Live Modified Vaccinia Ankara Virus to Deliver Tumor Associated Antigen MUC1 on the Surface of Virus Like Particles for Prevention or Treatments of MUC1 Positive Tumors",* Dr. Guirakhoo will discuss the use of GeoVax's technology toward development of cancer immunotherapies.

December 2, 2019—Noted its observance of World AIDS Day 2019. World AIDS Day is a global initiative to raise awareness, fight prejudice, and improve education about HIV and AIDS.

November 14, 2019—Announced that its Chief Scientific Officer, Farshad Guirakhoo, PhD, was to be a featured speaker at the Vaccines Research and Development conference, being held November 18-20, 2019 in Boston, Massachusetts. Dr. Guirakhoo co-chaired a session on infectious diseases, during which he delivered a presentation entitled, *MVA as a Safe and Effective Platform for Delivery of Multi-Antigen Vaccine Candidates for Infectious Diseases and Cancer*. During the conference, Dr. Guirakhoo also served as a panelist for a session discussing the development of vaccines for the current Ebola crisis.

November 13, 2019—Announced its participation in a collaborative effort led by researchers at the University of California, San Francisco (UCSF), to develop a combinational therapy aimed at inducing remission in HIV-positive individuals. The studies will be conducted with funding from amfAR, The Foundation for AIDS Research.

October 24, 2019—Announced its participation in a planned clinical trial led by researchers at American Gene Technologies (AGT) (www.americangene.com), to develop a therapy aimed at eliminating HIV from infected people. On October 18, 2019, AGT announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for AGT's lead HIV program, AGT103-T, a lentiviral vector-based gene therapy. Upon clearance by the FDA, this IND will allow AGT to initiate a Phase 1 clinical trial that will investigate the safety of AGT103-T in humans, measure key biomarkers, and explore surrogate markers of efficacy. AGT expects to begin recruiting patients for the Phase 1 study in January. Pursuant to its collaboration agreement with AGT, GeoVax will provide its novel MVA-VLP HIV vaccine (MVA62B) for evaluation in an arm of the clinical trial in combination with AGT103-T.

October 15, 2019—Announced that it would be represented during presentations at the following upcoming European scientific conferences: Festival of Biologics / World Immunotherapy Congress, Basel, Switzerland, Oct. 15-17; International Society for Virology (ISV), 2019 Annual Congress, Ghent, Belgium, Oct. 27-29; and World Vaccine Congress-Europe, Barcelona, Spain, Oct. 29-31.

October 1, 2019—Published a shareholder letter from its President & CEO, David Dodd.

Risks and Disclosures

This Executive Informational Overview® (EIO) 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 EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in GeoVax's statements on Forms 10-K, 10-Q, and 8-K as well as other forms filed from time to time.

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

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

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

RISKS RELATED TO GEOVAX'S BUSINESS

GeoVax has a history of operating losses and expects losses to continue for the foreseeable future.

As a research and development-focused company, GeoVax has had no product revenue to date and revenues from the Company's government grants and other collaborations have not generated sufficient cash flows to cover operating expenses. Since inception, GeoVax has incurred operating losses each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with its operations. The Company incurred a net loss of $1,050,898 and $2,370,629 for the six months ended June 30, 2020 and the year ended December 31, 2019, respectively. GeoVax expects to incur additional operating losses and expect cumulative losses to increase as its research and development, preclinical, clinical, and manufacturing efforts expand. The Company's ability to generate revenue and achieve profitability depends on its ability to successfully complete the development of its product candidates, conduct preclinical tests and clinical trials, obtain the necessary regulatory approvals, and manufacture and market or otherwise commercialize its products. Unless the Company is able to successfully meet these challenges, it will not be profitable and may not remain in business.

The Company has received a going concern opinion from its auditors.

GeoVax has received a "going concern" opinion from its independent registered public accounting firm, reflecting substantial doubt about the Company's ability to continue as a going concern. Its consolidated financial statements contemplate that GeoVax will continue as a going concern and do not contain any adjustments that might result if it were unable to continue as a going concern. The Company's ability to continue as a going concern is dependent upon its ability to raise additional capital and implement its business plan. GeoVax believes the net proceeds from the most recent offering will be sufficient to fund its planned operations through early 2022. If the Company is unable to achieve or sustain profitability or to secure additional financing on acceptable terms, it may not be able to meet its obligations as they come due, raising substantial doubts as to its ability to continue as a going concern. Any such inability to continue as a going concern may result in the Company's stockholders losing their entire investment. There is no guarantee that GeoVax will become profitable or secure additional financing on acceptable terms.

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

To date, the Company has financed its operations principally through the sale of its equity securities and through government grants and clinical trial support. GeoVax will require substantial additional financing at various intervals for its operations, including clinical trials, operating expenses, intellectual property protection and enforcement, for pursuit of regulatory approvals, and for establishing or contracting out manufacturing, marketing, and sales functions. There is no assurance that such additional funding will be available on terms acceptable to the Company or at all.

If the Company is unable to secure the significant funding that is required to maintain and continue its operations at current levels, or at levels that may be required in the future, GeoVax may be required to delay clinical studies or clinical trials, curtail operations, or obtain funds through collaborative arrangements that may require it to relinquish rights to some of its products or potential markets. The costs of conducting all of the Company's human clinical trials to date for its preventive HIV vaccine have been borne by the HVTN, with funding by NIAID, and the Company expects NIAID support for additional clinical trials. GeoVax incurs costs associated with manufacturing the clinical vaccine supplies and other study support. The Company cannot predict the level of support it will receive from the HVTN or NIAID for any additional clinical trials of its HIV vaccines. GeoVax's current operations are also partially supported by a U.S. government grant awarded to the Company to support its Lassa Fever vaccine program. As of June 30, 2020, there was approximately $650,000 of unused grant funds remaining and available for use through September 2021. Of this amount, the Company anticipates that approximately $401,000 will be paid by GeoVax to unaffiliated third parties who are providing services called for by the grant.

The Company is pursuing additional support from the federal government for its vaccine programs; however, as it progresses to the later stages of its vaccine development activities, government financial support may be more difficult to obtain, or may not be available at all. Furthermore, there is some risk that actual funding for grants could be delayed, cut back, or eliminated due to government budget constraints. Therefore, it will be necessary for GeoVax to look to other sources of funding to finance its development activities. The Company expects that its current working capital, combined with proceeds from current government grants and the bridge financing, will be sufficient to support its planned level of operations into the fourth quarter of 2020. GeoVax believes the net proceeds from the most recent offering will be sufficient to fund its planned operations through early 2022. The Company will need to raise additional funds to significantly advance its vaccine development programs and to continue operations. In order to meet its operating cash flow needs, GeoVax plans to seek sources of non-dilutive capital through government grant programs and clinical trial support. The Company may also plan additional offerings of its equity securities, debt, or convertible debt instruments. Should the financing GeoVax requires to sustain its working capital needs be unavailable or prohibitively expensive when the Company requires it, the consequences could have a material adverse effect on its business, operating results, financial condition, and prospects.

Significant disruptions of information technology systems or breaches of information security systems could adversely affect GeoVax's business.

The Company relies upon a combination of information technology systems and traditional recordkeeping to operate its business. In the ordinary course of business, GeoVax collects, stores, and transmits confidential information (including, but not limited to, personal information and intellectual property). The Company has also outsourced elements of its operations to third parties, including elements of its information technology systems and, as a result, it manages a number of independent vendor relationships with third parties who may or could have access to confidential information.

GeoVax's information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, or data loss from inadvertent or intentional actions by its employees or vendors. The Company's information technology and information security systems and records are also potentially vulnerable to malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of expertise and motives (including, but not limited to, financial crime, industrial espionage, and market manipulation). While the Company has invested, and continues to invest, a portion of its limited funds into information technology and information security systems, there can be no assurance that its efforts will prevent security breaches, service interruptions, or data losses. Any security breaches, service interruptions, or data losses could adversely affect its business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business, and reputational harm to GeoVax or allow third parties to gain material, inside information that they may use to trade in the Company's securities.

GeoVax's business could be adversely affected by widespread public health epidemics, such as COVID-19, or other catastrophic events beyond its control.

In addition to the Company's reliance on its own employees and facilities, GeoVax depends on its collaborators, laboratories, and other facilities for the continued operation of its business. Despite any precautions the Company takes, public health epidemics, such as COVID-19, or other catastrophic events, such as natural disasters, terrorist attack, hurricanes, fire, floods, and ice and snowstorms, may result in interruptions in its business. In response to the COVID-19 pandemic, GeoVax has suspended all non-essential travel for its employees, is canceling or postponing in-person attendance at industry events, and limiting in-person work-related meetings. Currently, as a result of the work and travel restrictions related to the ongoing pandemic, several of its business activities are being conducted remotely, which might be less effective than in-person meetings or in-office work. Despite these precautions, the necessary work within GeoVax's laboratory and of its collaborators has continued without significant interruption.

Although the Company continues to monitor the situation and may adjust its current policies as more information and guidance becomes available, temporarily suspending travel and limitations on doing business in-person has and could continue to negatively impact GeoVax's business development efforts and create operational or other challenges, any of which could harm the Company's business, financial condition, and results of operations. In addition, the COVID-19 pandemic could disrupt the Company's operations due to absenteeism by infected or ill members of management or other employees because of its limited staffing. COVID-19 related illness could also impact members of GeoVax's Board of Directors, resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of the Company's affairs.

RISKS RELATED TO DEVELOPMENT AND COMMERCIALIZATION OF PRODUCT CANDIDATES AND DEPENDENCE ON THIRD PARTIES

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

To become profitable, the Company must generate revenue through sales of its products. However, GeoVax's products are in varying stages of development and testing. The Company's products have not been proven in human clinical trials and have not been approved by any government agency for sale. If it cannot successfully

develop and prove its products and processes, or if the Company does not develop other sources of revenue, it will not become profitable and at some point, GeoVax would discontinue operations.

GeoVax depends upon key personnel who may terminate their employment with it at any time. If the Company were to lose the services of any of these individuals, its business and operations may be adversely affected.

The success of the Company's business strategy will depend to a significant degree upon the continued services of key management, technical and scientific personnel, and its ability to attract and retain additional qualified personnel and managers. Competition for qualified personnel is intense among companies, academic institutions, and other organizations. The ability to attract and retain personnel is adversely affected by the Company's financial challenges. If GeoVax is unable to attract and retain key personnel and advisors, it may negatively affect its ability to successfully develop, test, commercialize, and market the Company's products and product candidates.

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

To manufacture and sell its products, GeoVax must comply with extensive domestic and international regulation. In order to sell its products in the U.S., approval from the U.S. Food and Drug Administration (the "FDA") is required. Satisfaction of regulatory requirements, including FDA requirements, typically takes many years, and if approval is obtained at all, it is dependent upon the type, complexity, and novelty of the product, and requires the expenditure of substantial resources. GeoVax cannot predict whether its products will be approved by the FDA. Even if they are approved, the Company cannot predict the time frame for approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to meet than FDA requirements. As with the FDA, GeoVax cannot predict if or when it may obtain these regulatory approvals. If the Company cannot demonstrate that its products can be used safely and successfully in a broad segment of the patient population on a long-term basis, its products would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

GeoVax faces intense competition and rapid technological change that could result in products that are superior to the products the Company will be commercializing or developing.

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

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

GeoVax is subject to the risks of failure inherent in the development of product candidates based on new medical technologies. These risks include the possibility that the products it creates will not be effective, that its product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals, and that its product candidates will be hard to manufacture on a large scale or will be uneconomical to market. Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long term follow-up data may reveal previously unidentified complications associated with GeoVax's products. The responses of potential physicians and others to information about complications could materially adversely affect the market acceptance of the Company's products, which in turn would materially harm its business.

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

The Company does not know whether planned pre-clinical and clinical trials will begin on time or whether it will complete any of its trials on schedule, if at all. Product development costs will increase if GeoVax has delays in testing or approvals or if the Company needs to perform more or larger clinical trials than planned. Significant delays may adversely affect its financial results and the commercial prospects for the Company's products and delay its ability to become profitable. GeoVax relies heavily on the HVTN, independent clinical investigators, vaccine manufacturers, and other third-party service providers for successful execution of its clinical trials, but does not control many aspects of their activities. The Company is responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires the Company to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. The Company's reliance on third parties that it does not control does not relieve it of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct its clinical trials in accordance with regulatory requirements or its stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of GeoVax's product candidates. There is also a risk of changes in clinical trial strategy and timelines due to the HVTN and NIAID altering their trial strategy.

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

None of the Company's vaccines are approved by the FDA for sale in the U.S. or by other regulatory authorities for sale in foreign countries. To exploit the commercial potential of GeoVax's technologies, the Company is conducting and planning to conduct additional pre-clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials could delay or preclude regulatory approval and restrict the Company's ability to commercialize its technology or products. Any such failure may severely harm GeoVax's business. In addition, any approvals the Company obtains may not cover all of the clinical indications for which approval is sought or may contain significant limitations in the form of narrow indications, warnings, precautions, or contraindications with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post-approval study requirements.

State pharmaceutical marketing compliance and reporting requirements may expose the Company to regulatory and legal action by state governments or other government authorities.

Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless GeoVax is in full compliance with these laws, the Company could face enforcement action, fines, and other penalties and could receive adverse publicity, all of which could harm its business.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact the Company's business in ways that it cannot currently predict, and may have a significant adverse effect on GeoVax's business and results of operations.

In the U.S. and foreign jurisdictions, there have been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect GeoVax's ability to profitably sell any product candidates for which it obtains marketing approval. Among policy makers and payors in the U.S. and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and/or expanding access.

In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act includes a number of provisions that are intended to lower healthcare costs, including provisions relating to prescription drug prices and government spending on medical products. Since its enactment, there have also been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the statute.

GeoVax continues to evaluate the effect that the Affordable Care Act and subsequent changes to the statute has on its business. It is uncertain the extent to which any such changes may impact the Company's business or financial condition. There has also been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products. There have been several Congressional inquiries and proposed bills, as well as state efforts, designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

In June 2017, the FDA issued a Drug Competition Action plan intended to lower prescription drug prices by encouraging competition from generic versions of existing products. In July 2018, the FDA issued a Biosimilar Action Plan, intended to similarly promote competition to prescription biologics from biosimilars. Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures. For example, in September 2017, the California State Assembly approved SB17, which requires pharmaceutical companies to notify health insurers and government health plans at least 60 days before any scheduled increases in the prices of their products if they exceed 16% over a two-year period, and further requiring pharmaceutical companies to explain the reasons for such increase. Effective in 2016, Vermont passed a law requiring certain manufacturers identified by the state to justify their price increases.

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

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

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

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

The Company does not have experience in manufacturing, selling, or marketing. To obtain the expertise necessary to successfully manufacture, market, and sell its products, GeoVax must develop its own commercial infrastructure and/or collaborative commercial arrangements and partnerships. The Company's ability to execute its current operating plan is dependent on numerous factors, including, the performance of third-party collaborators with whom GeoVax may contract.

The Company's products under development may not gain market acceptance.

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

- the efficacy and safety of the Company's products;
- the time and scope of regulatory approval;
- reimbursement coverage from insurance companies and others;
- the price and cost-effectiveness of the Company's products, especially as compared to any competitive products; and
- the ability to maintain patent protection.

GeoVax may be required to defend lawsuits or pay damages for product liability claims.

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

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

Market acceptance of products the Company develops, if approved, will depend on reimbursement policies and may be affected by, among other things, future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. GeoVax cannot be certain that reimbursement will be available for any products that it may develop. Also, the Company cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for its products. If reimbursement is not available or is available on a limited basis, GeoVax may not be able to successfully commercialize products that it develops.

RISKS RELATED TO GEOVAX'S INTELLECTUAL PROPERTY

GeoVax could lose its license rights to important intellectual property if the Company does not fulfill its contractual obligations to its licensors.

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

filing and maintenance expenses. Should GeoVax become bankrupt or otherwise unable to fulfill its contractual obligations, the Company's licensors could terminate its rights to critical technology that the Company relies upon.

If the Company is unable to finalize its license agreements with the NIH, it may not be able to continue its work.

GeoVax has agreed on the material terms for a non-exclusive commercial license to the NIH MVA backbone for its SARS CoV-2 vaccine with the NIAID of the NIH on behalf of the U.S., which includes the use of certain patents and patent applications arising from the Moss laboratory and the provided materials. The Company has also agreed on material terms for a non-exclusive research and development license to use the MVA backbone for its other vaccine candidates. The licenses have been approved by the appropriate committees within the NIH and are awaiting final signature. If the Company later decides to commercialize vaccine candidates that are under the research and development license, it will need to negotiate appropriate commercialization licenses. If unable to finalize these agreements on the decided-upon terms, GeoVax may have to accept less favorable terms, and it is possible that it will be unable to agree. In that case, the Company may be unable to continue its work.

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

GeoVax's success will depend, in part, on its ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use, and sale of new products have been subject to substantial patent rights litigation in the pharmaceutical industry. These lawsuits generally relate to the validity and infringement of patents or proprietary rights of third parties. Infringement litigation is prevalent with respect to generic versions of products for which the patent covering the brand name product is expiring, particularly since many companies that market generic products focus their development efforts on products with expiring patents.

Pharmaceutical companies, biotechnology companies, universities, research institutions, or other third parties may have filed patent applications or may have been granted patents that cover aspects of GeoVax's products or its licensors' products, product candidates, or other technologies. Future or existing patents issued to third parties may contain patent claims that conflict with those of the Company's products. GeoVax expects to be subject to infringement claims from time to time in the ordinary course of business, and third parties could assert infringement claims against GeoVax in the future with respect to its current products or with respect to products that the Company may develop or license.

Litigation or interference proceedings could force GeoVax to:

- stop or delay selling, manufacturing, or using products that incorporate, or are made using the challenged intellectual property;
- pay damages; or
- enter into licensing or royalty agreements that may not be available on acceptable terms, if at all.

Any litigation or interference proceedings, regardless of their outcome, would likely delay the regulatory approval process, be costly, and require significant time and attention of GeoVax's key management and technical personnel.

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

The Company will rely on trade secrets, unpatented proprietary know-how, continuing technological innovation and, in some cases, patent protection to preserve its competitive position. GeoVax's patents and licensed patent rights may be challenged, invalidated, infringed, or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to the Company.

GeoVax and its licensors may not be able to develop patentable products with acceptable patent protection. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to the Company. If patents containing competitive or conflicting claims are issued to third parties, GeoVax may be prevented from commercializing the products covered by such patents or may be required to obtain or develop alternate technology. In addition, other parties may duplicate, design around, or independently develop similar or alternative technologies. GeoVax may not be able to prevent third parties from infringing or using its intellectual property, and the parties from whom the Company may license intellectual property may not be able to prevent third parties from infringing or using the licensed intellectual property.

GeoVax generally attempts to control and limit access to, and the distribution of, its product documentation and other proprietary information. Despite efforts to protect this proprietary information, unauthorized parties may obtain and use information that the Company may regard as proprietary. Other parties may independently develop similar know-how or may even obtain access to these technologies. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the U.S., and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Neither the U.S. Patent and Trademark Office nor the courts have established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of GeoVax's proprietary rights.

RISKS RELATED TO THE COMPANY'S COMMON STOCK

Upon exercise of the Company's outstanding warrants, GeoVax will be obligated to issue a substantial number of additional shares of common stock, which will dilute the Company's present shareholders.

GeoVax is obligated to issue additional shares of its common stock in connection with its outstanding warrants. Currently outstanding warrants are exercisable for 182,626 shares (on an as-adjusted basis upon consummation of the most recent offering). The exercise of these warrants will cause the Company to issue additional shares of its common stock and will dilute the percentage ownership of Company shareholders.

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

The market price of the Company's common stock has been, and is expected to continue to be, highly volatile. Certain factors, including announcements of new developments by GeoVax or other companies, regulatory matters, new or existing medicines or procedures, concerns about the Company's financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of GeoVax's stock. In addition, potential dilutive effects of future sales of shares of common stock by the Company, and subsequent sales of common stock by the holders of its Convertible Debentures and other options and warrants, including the June 2020 Warrants, could have an adverse effect on the market price of GeoVax's shares. In addition, the securities markets from time to time experience significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of the Company's common stock.

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

The Company has a limited active public market for its common stock. A more active public market, allowing investors to buy and sell large quantities of its common stock, may never develop even though its shares are now listed on Nasdaq. Consequently, investors may not be able to liquidate their investments in the event of an emergency or for any other reason.

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

In order to meet the Company's operating cash flow needs, it may plan additional offerings of GeoVax's equity securities, debt, or convertible debt instruments. The sale of additional equity securities could result in significant additional dilution to Company stockholders. Certain securities, such as its outstanding Convertible Debentures or warrants, including the June 2020 Warrants, and the warrants being offered by this prospectus, and subsequent issuances, contain or may contain anti-dilution provisions, which could result in the issuance of additional shares at lower prices if the Company sells other shares below specified prices. The incurrence of indebtedness could result in debt service obligations and operating and financing covenants that would restrict Company operations. GeoVax cannot assure investors that financing will be available in amounts or on terms acceptable to it, if at all.

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

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

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

GeoVax is subject to reporting obligations under the U.S. securities laws. The SEC, as required by the Sarbanes-Oxley Act of 2002, adopted rules requiring every public company to include a management report on such company's internal controls over financial reporting in its annual report. Effective internal controls are necessary for the Company to produce reliable financial reports and are important to help prevent fraud. As a result, the Company's failure to achieve and maintain effective internal controls over financial reporting could result in the loss of investor confidence in the reliability of its financial statements, which in turn could negatively impact the trading price of GeoVax's stock.

Public company compliance may make it more difficult for the Company to attract and retain officers and directors.

The Sarbanes-Oxley Act, the Dodd-Frank Act, the JOBS Act, the FAST Act, and rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, GeoVax expects these rules and regulations, and amendments to them, to contribute to its compliance costs and to make certain activities more time consuming and costly. As a public company, GeoVax also expects that these rules and regulations may make it difficult and expensive for it to obtain director and officer liability insurance and may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be difficult for GeoVax to attract and retain qualified persons to serve on its board of directors or as executive officers.

The Company's Certificate of Incorporation and Bylaws may be amended by the affirmative vote of a majority of its stockholders.

Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended by the affirmative vote of the holders of a majority of the outstanding shares entitled to vote, and a majority of the outstanding shares of each class entitled to vote as a class, unless the articles require the vote of a larger percentage of shares. GeoVax's Certificate of Incorporation as amended, does not require the vote of a larger percentage of shares. As permitted under the Delaware General Corporation Law, Company Bylaws give its board of directors the power to adopt, amend, or repeal its Bylaws. GeoVax stockholders entitled to vote have concurrent power to adopt, amend, or repeal Company Bylaws.

Broker-dealers may be discouraged from effecting transactions in shares of the Company's common stock if GeoVax is considered to be a penny stock and thus subject to the penny stock rules.

The SEC has adopted a number of rules to regulate "penny stocks" that restrict transactions involving stock which is deemed to be penny stock. Such rules include Rules 3a51-1, 15g-1, 15g-2, 15g-3, 15g-4, 15g-5, 15g-6, 15g-7, and 15g-9 under the Exchange Act. These rules may have the effect of reducing the liquidity of penny stocks. "Penny stocks" generally are equity securities with a price of less than $5.00 per share (other than securities registered on certain national securities exchanges or quoted on Nasdaq if current price and volume information with respect to transactions in such securities is provided by the exchange or system).

GeoVax's securities have, in the past, constituted and may again in the future, if the Company is delisted from Nasdaq, constitute, "penny stock" within the meaning of the rules. The additional sales practice and disclosure requirements imposed upon U.S. broker-dealers may discourage broker-dealers from effecting transactions in shares of the Company's common stock, which could severely limit the market liquidity of such shares and impede their sale in the secondary market.

A U.S. broker-dealer selling penny stock to anyone other than an established customer or "accredited investor" (generally, an individual with net worth in excess of $1,000,000 [exclusive of personal residence] or an annual income exceeding $200,000, or $300,000 together with his or her spouse) must make a special suitability determination for the purchaser and must receive the purchaser's written consent to the transaction prior to sale, unless the broker-dealer or the transaction is otherwise exempt. In addition, the "penny stock" regulations require the U.S. broker-dealer to deliver, prior to any transaction involving a "penny stock", a disclosure schedule prepared in accordance with SEC standards relating to the "penny stock" market, unless the broker-dealer or the transaction is otherwise exempt. A U.S. broker-dealer is also required to disclose commissions payable to the U.S. broker-dealer and the registered representative and current quotations for the securities. Finally, a U.S. broker-dealer is required to submit monthly statements disclosing recent price information with respect to the "penny stock" held in a customer's account and information with respect to the limited market in "penny stocks."

Stockholders should be aware that, according to the SEC, the market for "penny stocks" has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) "boiler room" practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, resulting in investor losses.

GeoVax management is aware of the abuses that have occurred historically in the penny stock market. Although the Company does not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to its securities.

Glossary

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

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

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

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

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

Aviremic—Level of plasma viremia that is below the limit of detection measured by ultrasensitive bDNA assay (50 copies of HIV-1 RNA per ml of plasma).

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

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

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

COVID-19—Coronavirus (COVID-19) is an illness caused by a virus that can spread from person to person. The virus that causes COVID-19 is a new coronavirus that has spread throughout the world.

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

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

Endemic—(Of a disease or condition) regularly found among particular people or in a certain area.

Enveloped Viruses—A virus that has an outer wrapping or envelope. This envelope comes from the infected cell, or host, in a process called "budding off." During the budding process, newly formed virus particles become "enveloped" or wrapped in an outer coat that is made from a small piece of the cell's plasma membrane.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Medical Countermeasures (MCM)—FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease.

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

Modified Vaccinia Ankara (MVA)—The Modified Vaccinia Ankara (MVA) is an attenuated strain of vaccinia virus that was developed towards the end of the campaign for the eradication of smallpox. MVA is widely considered as the vaccinia virus strain of choice for clinical investigation because of its high safety profile, and holds great promise as a vaccine platform or delivery system. MVA can encode one or more foreign antigens and thus functions as a multivalent vaccine.

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

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

MUC1—Mucin 1, cell surface associated, also called polymorphic epithelial mucin or epithelial membrane antigen or EMA, is a mucin encoded by the MUC1 gene in humans. MUC1 is a glycoprotein with extensive O-linked glycosylation of its extracellular domain.

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

Parasitemia—The demonstrable presence of parasites in the blood.

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

Reassortant—Reassortment is the mixing of the genetic material of a species into new combinations in different individuals. Several different processes contribute to reassortment, including assortment of chromosomes, and chromosomal crossover.

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

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

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

Tumor Tolerance—A state of unresponsiveness of the immune system to cancer cells. A process by which growing tumors, which have mutated proteins and altered antigen expression, prevent elimination by the host immune system.

Vector—An agent (such as a plasmid or virus) that contains or carries modified genetic material (such as recombinant DNA) and can be used to introduce exogenous genes into the genome of an organism. A live vector vaccine is a vaccine that uses a chemically weakened or inactive virus to transport pieces of the pathogen in order to stimulate an immune response.

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

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

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