

Company Description

GeoVax Labs, Inc. (“GeoVax” or “the Company”) is a clinical-stage biotechnology company developing preventive and therapeutic human vaccines and immunotherapies 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 need for a broadly-effective 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

- On March 23, 2021, GeoVax reported year-end financial results and provided a Company update. For the year, ended December 31, 2020, GeoVax reported a net loss of \$3.0 million versus \$2.4 million for the year ended December 31, 2019.
- GeoVax completed a public offering of its common stock (GOVX) and publicly traded warrants (GOVXW) in September 2020, with net proceeds of \$11.2 million. As of December 31, 2020, the Company’s cash balance was \$9.9 million versus \$283,341 at the end of 2019. During the first quarter of 2021, GeoVax further supplemented its cash resources with net proceeds of \$9.4 million from a follow-on offering of its common stock, and \$3.2 million from the exercise of outstanding warrants. The Company expects to report total cash balances in excess of \$20 million at the end of the first quarter of 2021.
- With the recent funding, GeoVax is well-positioned to advance several of its development efforts, focused on its COVID-19 vaccine and cancer immunotherapy programs, and expects several data announcements during the first half of this year.
- The Company is developing a SARS-CoV-2 (COVID-19) vaccine that is based on its GV-MVA-VLP™ technology, which enables the insertion of multiple antigen fragments, potentially allowing for broad-spectrum virus prevention. In contrast to certain competitor vaccines that only target the COVID-19 spike protein, GeoVax’s vaccines are designed to provoke a response to multiple COVID-19 antigens—potentially translating into these vaccines being less susceptible to viral mutations. The Company’s vaccines are intended to be used as either a primary vaccine or to boost other COVID-19 vaccines as part of vaccination strategies to provide immunity to a range of SARS-CoV-2 variants.
- GeoVax’s cancer immunotherapy program, which is built on the idea of combining a tumor-associated antigen vaccine with a potent anti-tumor agent, such as an Immune Checkpoint Inhibitor (ICI), seeks to achieve regression of tumor growth and development. Initial animal studies, based upon the Company’s MUC1 vaccine/ICI combination, have been encouraging.
- The Company maintains a solid patent position, with over 70 granted or pending patent applications spread over 20 patent families that are either wholly owned, co-owned, and in-licensed.



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GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (03/29/2021)	\$4.50
52-week Range	\$2.56 – 8.71
Shares Outstanding	6.3 million
Market Capitalization	\$28.5 million
Avg. 10-day Volume	1.829 million
EPS (Year ended 12/31/20)	(\$2.14)
Employees	9

YEAR END 2020 FINANCIAL RESULTS

On March 23, 2021, GeoVax reported a net loss for the year ended December 31, 2020 of \$3.0 million versus \$2.4 million for the year ended December 31, 2019. The Company reported grant and collaboration revenue of \$1.8 million for 2020 versus \$1.2 million in 2019, largely relating to GeoVax's grant from the U.S. Department of Defense (DoD) for the Lassa Fever vaccine as well as the collaboration with Leidos, Inc. for GeoVax's malaria vaccine program. As of December 31, 2020, there were \$165,500 of approved funds remaining and available for use related to the Company's grant from the DoD. In January 2021, NIAID awarded a \$299,927 SBIR grant to the Company in support of its COVID-19 vaccine program, which is earmarked to support the ongoing design, construction, and preclinical testing of the vaccine candidates in preparation for human clinical trials.

Research and development (R&D) expenses were \$2.4 million in 2020 versus \$1.9 million in 2019. General and administrative (G&A) expenses were \$2.2 million for 2020 versus \$1.6 million in 2019. Variations in R&D expenses are largely due to the timing of expenses stemming from the DoD grant. Other income (expense) was (\$141,253) for 2020 versus \$1,864 in 2019, with 2020 including \$138,851 of interest expense and amortized debt discount related to convertible debentures that were retired during the year.

GeoVax reported cash balances of \$9.9 million at December 31, 2020 versus \$283,341 at December 31, 2019. The increase in cash balances were due to the sale of convertible preferred stock in January 2020 for proceeds of \$300,000, the issuance of a note payable in April 2020 for proceeds of \$170,200, the sale of convertible debentures in June 2020 for net proceeds of \$888,500, and net proceeds of approximately \$11.2 million from the September 2020 offering. In connection with the September offering, approximately \$1.2 million of convertible debentures and accrued interest were converted into the Company's equity securities. Additionally, \$1.5 million of accumulated amounts owed to the Company's current and former executive officers and directors were converted to equity under terms substantially the same as those offered to the public. During the first quarter of 2021, the Company further supplemented its cash resources with net proceeds of \$9.4 million from a follow-on offering of its common stock, and \$3.2 million from the exercise of outstanding warrants.

RECENT TIMELINE OF EVENTS

- **March 23, 2021**—Reported 2020 year-end financial results and provided a corporate update.
- **March 17, 2021**—Announced that the Company will present at the Benzinga Biotech Small Cap Conference to be held March 24-25, 2021. On Wednesday, March 24, GeoVax's Chief Scientific Officer, Mark Newman, PhD, will participate in a panel discussion entitled, Cancer Immunotherapies: Fighting Cancer with the Power of the Immune System.
- **March 15, 2021**—Announced plans to report 2020 financial results on Tuesday, March 23, 2021 after the market closes.
- **March 10, 2021**—Announced that the Company has been invited to present at Maxim Group's Inaugural Emerging Growth Virtual Conference to be held March 17-18. During this virtual conference, GeoVax's Chairman and CEO, David Dodd, will present an overview of GeoVax's immunotherapy and vaccine research and development efforts, focusing on the Company's COVID-19 and cancer immunotherapy programs. GeoVax's Chief Scientific Officer, Mark Newman, PhD, will also participate in a panel discussion on recent developments in cancer vaccines and immuno-oncology.
- **March 4, 2021**—Announced the filing of two additional patent applications important to the Company's key focus on vaccines against SARS-CoV-2 (COVID-19) and cancer immunotherapies. The Company has filed an International Patent Application under the Patent Cooperation Treaty to protect its proprietary COVID-19 vaccines based on its platform modified vaccinia Ankara (MVA) viral vector technology. Unlike certain competitor vaccines that target only the COVID-19 spike protein, GeoVax's vaccines are designed to provoke a response to multiple COVID-19 antigens, which are differentiated from competitive vaccines in that they may be less susceptible to viral mutations in the spike protein region that have emerged as problematic in multiple regions of the world. The Company's vaccines are intended to be used as a primary vaccine or to boost COVID-

19 vaccines from other companies as part of vaccination strategies to provide immunity to a range of SARS-CoV-2 variants. GeoVax also filed a U.S. patent application as part of its immunotherapy program, which covers updates in its innovative MVA viral vector technology to amplify an immune response to a cancer antigen in a patient via vaccination. Cancer vaccination is the subject of growing interest as a means to boost the body's innate defense to cancer.

- **March 3, 2021**—Announced that Chairman, President, and CEO David Dodd will present at the H.C. Wainwright Global Life Sciences Conference taking place March 9-10, 2021. The presentation will be available for on-demand listening beginning at 7:00 AM ET on Tuesday, March 9, 2021 and will be available for 90 days.
- **March 1, 2021**—Announced that Chairman & CEO, David Dodd and CFO, Mark Reynolds will present at Tribe Public's Webinar Presentation and Q&A Event titled "Advancing a Unique Broad-based Vaccine Approach to Fighting COVID-19, Ebola & Beyond". The Event is scheduled to begin at 8:30 am Pacific/11:30 am Eastern on Wednesday, March 3, 2021.
- **February 11, 2021**—Announced the closing of its bought deal offering of 1,644,000 shares of its common stock, which included 204,000 shares sold pursuant to the full exercise of the underwriter's option to purchase additional shares, at a price to the public of \$6.25, less underwriting discounts and commissions. The gross proceeds from the offering were approximately \$10.3 million, before deducting underwriting discounts and commissions and estimated offering expenses. Maxim Group LLC acted as the sole book-running manager for the offering.
- **February 8, 2021**—Announced that it has entered into an underwriting agreement with Maxim Group LLC, under which the underwriter has agreed to purchase, on a firm commitment basis, 1,440,000 shares of common stock of the Company, at a price to the public of \$6.25 per share, less underwriting discounts and commissions. The gross proceeds from the offering are expected to be approximately \$9.0 million, before deducting underwriting discounts and commissions and estimated offering expenses. GeoVax has granted the underwriters a 45-day option to purchase up to an additional 204,000 shares of common stock to cover over-allotments, if any. The offering is expected to close on February 11, 2021, subject to customary closing conditions. Maxim Group LLC is acting as sole book-running manager for the offering.
- **January 11, 2021**—Announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has awarded the Company a Small Business Innovative Research (SBIR) grant in support of its development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The Phase 1 grant, titled, "Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19," will support the ongoing design, construction and preclinical testing of GeoVax's vaccine candidates in preparation for human clinical trials. The efficacy testing will be performed in collaboration with the University of Texas Medical Branch (UTMB).

RECENT COMPANY DEVELOPMENTS

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

GeoVax's COVID-19 Vaccine Development Program

GeoVax's SARS-CoV-2 (COVID-19) vaccine is based on its GV-MVA-VLP™ technology, enabling insertion of multiple antigen fragments, potentially allowing for broad-spectrum virus prevention. In contrast to certain competitor vaccines that only target the COVID-19 spike protein, GeoVax's vaccines are designed to provoke a response to multiple COVID-19 antigens—potentially translating into these vaccines being less susceptible to viral mutations. GeoVax's vaccines are intended to be used as either a primary vaccine or to boost other COVID-19 vaccines as part of vaccination strategies to provide immunity to a range of SARS-CoV-2 variants.

On January 11, 2021, GeoVax Labs, Inc. announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), had awarded the Company a Small Business Innovative Research (SBIR) grant in support of its development of a vaccine against SARS-CoV-2. The Phase 1 grant, titled, "Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19," will support the ongoing design, construction, and preclinical testing of GeoVax's vaccine candidates in preparation for human clinical trials. The efficacy testing will be performed in collaboration with the University of Texas Medical Branch (UTMB).

Additionally, October 26, 2020, the Company announced the signing of a Patent and Biological Materials License Agreement with the NIAID in support of GeoVax's development of a vaccine against SARS-CoV-2. The Patent License Agreement to GeoVax includes access to NIAID's patent rights in the stabilized SPIKE protein, which is the protein that SARS-CoV-2 uses to enter human tissue.

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

Despite their being vaccines that have entered various stages of clinical testing (using different approaches and vector platforms than GeoVax), there is increasing evidence that alternative vaccine approaches, including those from various cohort populations will be necessary to successfully address COVID-19 and various coronaviruses. GeoVax expects to be ready to move into the clinic with its candidate during 2022. This timing, however, will depend on what the Company reports with its animal results, which could come in the latter part of first quarter or into early part of second quarter.

Global COVID-19 Vaccine Update

Pfizer, Moderna, & Johnson & Johnson Approved in U.S.

With over 545,000 deaths caused by the coronavirus in the past 12 months, the need for a vaccine is greater than ever. To date, the vaccines developed by Pfizer, Moderna, and Johnson & Johnson have been approved and are being distributed for public use. The Pfizer and Moderna vaccines are made using messenger RNA, or mRNA, a technology that delivers a bit of genetic code to cells—effectively a recipe to make the surface protein (known as spike) on the SARS-2 virus. The proteins made with the mRNA instructions activate the immune system, teaching it to see the spike protein as foreign and develop antibodies and other immunity weapons with which to fight it. The Johnson & Johnson (J&J) vaccine uses a different approach to instruct human cells to make the SARS-2 spike protein, which then triggers an immune response—known as a viral vectored vaccine. A harmless adenovirus (from a large

family of viruses), this vaccine has been engineered to carry the genetic code for the SARS-2 spike protein. Once the adenovirus enters cells, they use that code to make spike proteins. J&J employs this same approach to make an Ebola vaccine that has been authorized for use by the European Medicines Agency.

Immuno-Oncology Program

GeoVax's cancer immunotherapy program is built on the idea of combining a tumor-associated antigen vaccine with a potent anti-tumor agent, such as an Immune Checkpoint Inhibitor (ICI), with the objective of achieving regression of tumor growth and development. Initial animal studies, which were based upon the Company's MUC1 vaccine/ICI combination, have been encouraging. In February 2021, GeoVax filed a U.S. patent application, covering updates to its MVA viral vector technology to amplify an immune response to a cancer antigen via vaccination, which could strengthen the Company's intellectual property position within this space. Following GeoVax's most recent fund-raising activities, immuno-oncology is a key focus area, with the Company now engaged with multiple collaborators. GeoVax has stated that it expects to provide further details on its progress and plans to advance to human clinical testing in the near future.

Hemorrhagic Fever Vaccine Programs

- **Lassa Fever**—GeoVax's Lassa Fever (LASV) vaccine program continues to progress with grant funding from the U.S. Department of Defense. The project award supports generation of immunogenicity and efficacy data for its vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparing for human clinical trials. This work is in collaboration with U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation. GeoVax expects to announce results from this work during the first half of 2021.
- **Sudan ebolavirus (SUDV) and Marburg virus (MARV)**—In August 2020, GeoVax announced a multi-party collaboration for the development of its 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 is utilizing the suite of preclinical services from NIAID. Under the collaboration, GeoVax's SUDV and MARV vaccine candidates are being tested for immunogenicity and efficacy in the benchmark nonhuman primate model. This work builds upon earlier studies in rodents and nonhuman primates for the Company's Ebola virus (EBOV) vaccine candidate that demonstrated 100% protection against a lethal dose of EBOV upon a single immunization. The Company expects to announce results during the first half of 2021.
- **Malaria Vaccine**—The Company continues to collaborate separately with Leidos, Inc. and the Burnet Institute to develop a malaria vaccine candidates using its GV-MVA-VLPTM vaccine platform. The collaboration with Leidos has been funded by a grant to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). Several vaccine candidates have recently entered initial animal testing with results expected during the first half of 2021.

HIV Vaccine Programs

- **HIV Preventive Vaccine**—NIAID is funding a clinical trial that includes GeoVax's HIV preventive vaccine (GOVX-B11) through the HIV Vaccine Trials Network (HVTN). The next trial (HVTN 132) has been delayed due to COVID-19, but the Company expects to begin in late 2021. HVTN 132 will further evaluate the safety and immunogenicity of adding "protein boost" components to the GOVX-B11 vaccination regimen.

- **HIV Immunotherapy**—GeoVax is part of two separate efforts to develop a combination therapy to induce remission in HIV-positive individuals (a “functional cure”). In August 2020, a consortium led by researchers at the University of California, San Francisco (UCSF), began enrolling patients in a Phase 1 human clinical trial using the Company’s vaccine as part of a combination therapy intended to induce remission in HIV-positive individuals. In September 2020, American Gene Technologies International, Inc. (AGT) began enrolling patients in a Phase 1 clinical trial evaluating its gene therapy technology in this area. GeoVax expects its vaccine to be added to an arm of the AGT trial during 2021.

Licenses and Intellectual Property

In October 2020, GeoVax signed a license agreement with NIAID allowing the Company to use the materials and patent rights owned by agencies of the United States Department of Health and Human Services (HHS) in combination with its proprietary technology for the creation of a preventive vaccine that primes and/or boosts the immune system against COVID-19. The agreement provides GeoVax with nonexclusive rights to develop, manufacture, and commercialize its Company’s COVID-19 vaccine.

In November 2020, the Company signed another license agreement with NIAID in support of its non-clinical development of preventive and/or therapeutic vaccines against numerous pathogens, including Ebola-Zaire, Ebola-Sudan, Lassa virus, Marburg virus, Zika virus, and malaria. The agreement also extends to GeoVax’s research and development efforts in certain oncology areas.

In February 2021, the Company filed international and U.S. patent applications in its key focus areas of SARS-CoV-2 (COVID-19) and cancer immunotherapy. Following these filings, GeoVax’s wholly owned, co-owned, and in-licensed intellectual property portfolio now stands at over 70 granted or pending patent applications spread over 20 patent families.

Capital Resources

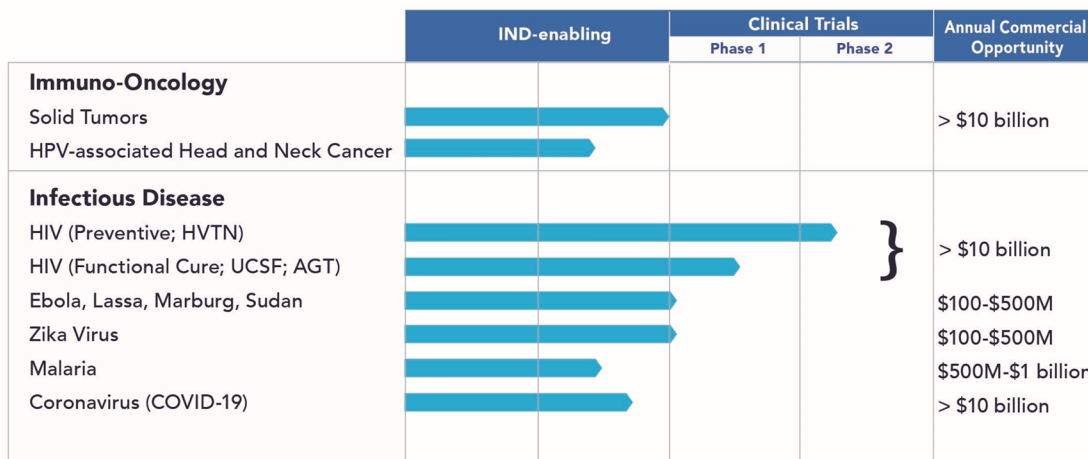
In September 2020, GeoVax completed a public offering of its common stock (GOVX) and publicly traded warrants (GOVXW), with net proceeds of \$11.2 million. At December 31, 2020, the Company’s cash balance was \$9.9 million versus \$283,341 at the end of 2019. During the first quarter of 2021, GeoVax further supplemented its cash resources with net proceeds of \$9.4 million from a follow-on offering of its common stock, and \$3.2 million from the exercise of outstanding warrants. The Company expects to report total cash balances in excess of \$20 million at the end of the first quarter of 2021.

Company Background

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

The Company’s development efforts are focused on preventive vaccines within the following areas (shown in Figure 1): human immunodeficiency virus (HIV), hemorrhagic fever (HF) viruses (Lassa Fever, Sudan ebolavirus (SUDV), Marburg virus (MARV), and Malaria Vaccine), and Zika virus (ZIKV). GeoVax is capitalizing on the safety and efficacy of its technology platform to address the urgent need for a COVID-19 vaccine—currently a high-priority program for the Company. Moreover, the Company is applying its MVA-VLP technology to cancer immunotherapy and plans to accelerate this program with proceeds from its recent financing. Greater Company details on GeoVax’s development efforts can be found in the base report, Executive Informational Overview (<https://bit.ly/3ljlBC0>).

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.

As well, on February 11, 2021, GeoVax announced the closing of a bought deal offering of 1,644,000 shares of its common stock, which included 204,000 shares sold pursuant to the full exercise of the underwriter’s option to purchase additional shares, at a price to the public of \$6.25, less underwriting discounts and commissions. The gross proceeds from the offering were approximately \$10.3 million, before deducting underwriting discounts and commissions and estimated offering expenses. Following this transaction, GeoVax’s cash balances now stands at approximately \$20 million, positioning the Company to support accelerated development of its COVID-19 vaccine development candidates, advance its cancer immunotherapy program as well as other infectious disease vaccines.

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.

American Gene Technologies Collaboration

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

Collaboration with UCSF

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

Hemorrhagic Fever (HF) Vaccine Programs

Ebola (EBOV), Sudan (SUDV), and Marburg viruses (MARV) are the most virulent species of the Filoviridae family, causing up to a 90% fatality rate in humans, and are epizootic in Central and West Africa (28 outbreaks since 1976). Lassa fever virus (LASV) also causes severe and often fatal hemorrhagic illnesses in an overlapping region to that of Ebola, but is endemic, with an annual rate of >300,000 infections and leading to 5,000-10,000 deaths.

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

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.

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.

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 March 2021, more than 125 million cases have been reported, resulting in nearly 2.75 million deaths. The U.S. is currently considered one of the epicenters of the disease, with roughly 30 million cases and 545,000 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, (with Pfizer, Moderna, and Johnson & Johnson's COVID-19 vaccines currently having been approved and being distributed), the GV-MVA-VLP™ platform offers unique advantages, including safety and breadth of responses. This makes the Company's platform ideal for immunization of those most vulnerable, including the immunocompromised and comorbid. GeoVax's recently completed financing will allow it to aggressively pursue preclinical evaluation of its vaccine candidates while continuing negotiations in support of clinical development.

Cancer Immunotherapy Vaccine Program

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

Solid Tumors

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

Patent Portfolio

In February 2021, GeoVax filed international and U.S. patent applications in its key focus areas of SARS-CoV-2 (COVID-19) and cancer immunotherapy. Following these filings, the Company's wholly owned, co-owned, and licensed intellectual property portfolio now stands at over 70 granted or pending patent applications spread over 20 patent families.



Corporate Background

The Company's primary business is conducted by its wholly-owned subsidiary, GeoVax, Inc., which was incorporated under the laws of Georgia in June 2001. The predecessor to its parent company, GeoVax Labs, Inc. was originally incorporated in June 1988 under the laws of Illinois as Dauphin Technology, Inc. In September 2006, Dauphin completed a merger with GeoVax, Inc. As a result of the merger, GeoVax, Inc. became a wholly-owned subsidiary of Dauphin, and Dauphin changed its name to GeoVax Labs, Inc. In June 2008, the Company was reincorporated under the laws of Delaware.

Risks and Disclosures

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

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

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

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



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