

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 (antibody) and cellular (T-cells) 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 August 11, 2021, GeoVax reported second quarter 2021 financial results and provided a Company update. For the three months ended June 30, 2021, GeoVax reported a net loss of \$1,314,033 (\$0.21 per share) versus a net loss of \$455,204 (\$0.66 per share) for the same period in 2020. For the six months ended June 30, 2021, the Company reported a net loss of \$2,876,811 (\$0.49 per share) versus a net loss of \$1,050,898 (\$2.27 per share) in 2020.
- Regarding the Company’s COVID-19 vaccine efforts, GeoVax’s vaccine is based on its proprietary GV-MVA-VLP™ technology, enabling insertion of multiple antigen fragments and potentially allowing for broad-spectrum virus prevention. Unique from other vaccines that target only the COVID-19 spike protein, GeoVax’s vaccines are designed to provoke a response to multiple COVID-19 antigens, which could translate into it being less susceptible to viral mutations. The Company’s vaccines are intended to be used as either a primary vaccine or a booster to other COVID-19 vaccines as part of vaccination strategies to provide immunity to a range of coronavirus variants.
- Small animal studies are continuing with results, to date, supporting GeoVax’s approach of using MVA as a vector for the design and production of “next-generation” COVID-19 vaccines encoding multiple proteins. Details of these studies will be presented on August 19, 2021 during the European Society of Medicine (ESMED) General Assembly.
- In addition to COVID-19, the Company expects several data announcements from its development programs in the coming weeks and months, particularly within the areas Lassa Fever virus, Sudan/Marburg virus, and immuno-oncology.
- GeoVax continues to strengthen its intellectual property portfolio, with over 70 granted or pending patent applications across 20 patent families. 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, and in July 2021, announced the issuance of a U.S. patent covering its Hepatitis B vaccine.
- As of June 30, 2021, GeoVax’s reported cash balance was \$19.5 million versus \$9.9 million at December 31, 2020. Adding to the increase in cash balances were net proceeds of \$9.4 million from the sale of 1,644,000 shares of common stock, and \$3.2 million from the exercise of warrants to purchase 690,034 shares of common stock.



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GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (08/16/2021)	\$4.03
52-week Range	\$2.56 - 8.71
Shares Outstanding	6.3 million
Market Capitalization	\$25.4 million
Avg. 10-day Volume	439,762
EPS (Year ended 06/30/21)	(\$0.21)
Employees	11

SECOND QUARTER 2021 FINANCIAL RESULTS

For the three months ended June 30, 2021, GeoVax reported a net loss of \$1,314,033 (\$0.21 per share) versus a net loss of \$455,204 (\$0.66 per share) for the same period in 2020. For the six months ended June 30, 2021, the Company's reported a net loss of \$2,876,811 (\$0.49 per share) versus a net loss of \$1,050,898 (\$2.27 per share) in 2020.

Grant and collaboration revenues were \$79,708 and \$190,125 for the three- and six-month periods of 2021, respectively, versus \$440,602 and \$1,156,579 in the comparable periods of 2020. The 2021 period reflects amounts related to the Company's grant from NIH supporting its COVID-19 vaccine program, while the 2020 period reflects amounts related to GeoVax's grant from the U.S. Department of Defense (DoD) for its Lassa Fever vaccine along with its collaboration with Leidos, Inc. for its malaria vaccine program. As of June 30, 2021, \$275,302 of approved funds remain and are available for use connected to the COVID-19 and Lassa Fever grants.

Research and development (R&D) expenses were \$832,835 and \$1,435,618 for the three-month and six-month periods of 2021, respectively, versus \$461,421 and \$1,270,357 for the comparable periods of 2020, with increases largely due to the Company's COVID-19 vaccine program, manufacturing process development, and a greater level of activity, partially offset by the timing and amount of external expenditures due to the Company's government grants. General and administrative (G&A) expenses were \$733,499 and \$1,805,209 for the three-month and six-month periods of 2021, respectively, versus \$427,292 and \$929,637 for the comparable periods of 2020. G&A increases were primarily attributable to higher Delaware franchise taxes; legal, accounting and patent costs; insurance costs; consulting fees; Nasdaq listing fees; investor relations costs; and personnel costs.

Other income (expense) was \$172,593 and \$173,891 for the three-month and six-month periods of 2021, respectively, versus (\$7,093) and (\$7,483) for the comparable periods of 2020. The 2021 periods include a \$172,056 gain on extinguishment of debt, reflecting forgiveness of the Company's loan pursuant to the Paycheck Protection Program (PPP).

As of June 30, 2021, GeoVax reported cash balances of \$19.5 million versus \$9.9 million as of December 31, 2020. Supporting the increase in cash balances were net proceeds of \$9.4 million from the sale of 1,644,000 shares of common stock, and \$3.2 million from the exercise of warrants to purchase 690,034 shares of common stock.

RECENT TIMELINE OF EVENTS

- **August 12, 2021**—Announced that the Company will be presenting at the SNN Network Summer Virtual Event 2021 on Wednesday, August 18, 2021 at 12:30 PM EST. David Dodd, Chairman and CEO, will be hosting the presentation and answering questions from investors.
- **August 11, 2021**—Announced financial results for the quarter ended June 30, 2021.
- **August 4, 2021**—Announced that the Company will report second quarter 2021 financial results on Wednesday, August 11, 2021 after the market closes.
- **July 22, 2021**—Announced the presentation of data from a study of its preventive vaccine against Sudan Ebolavirus (SUDV). The presentation titled "A single immunization of guinea pigs with a modified vaccinia Ankara virus producing Sudan virus-like particles protects from Sudan virus lethal challenge," was delivered by Dr. Delphine Malherbe of the Bukreyev Lab, Department of Pathology, University of Texas Medical Branch, Galveston, Texas, during the Annual Meeting of the American Society for Virology, held virtually July 19-23.
- **July 7, 2021**—Announced that the U.S. Patent and Trademark Office has issued Patent No. 11,052,148, entitled "Composition and Methods of Generating an Immune Response to Hepatitis B Virus."
- **June 10, 2021**—Announced that it will be participating in the Alliance Global Partners' Virtual Healthcare Symposium being held on Thursday, June 17, 2021.

- **June 7, 2021**—Announced that GeoVax has been selected to deliver a company presentation at 2021 BIO Digital, the premier biotech event. BIO Digital is scheduled June 10-11 and June 14-18, 2021.
- **May 11, 2021**—Announced that David Dodd, Chairman & CEO, will be attending the Q2 Virtual Investor Summit.
- **May 6, 2021**—Reported 2021 first quarter financial results and provided corporate update.
- **May 6, 2021**—Announced that the Company is to present to investors at the Benzinga Global Small Cap Conference on May 13, 2021.
- **April 1, 2021**—Announced that the U.S. Patent and Trademark Office (USPTO) has issued a Notice of Allowance for Patent Application No. 16/305,305 entitled “Composition and Methods of Generating an Immune Response to Hepatitis B Virus.” The work supporting the patent application was performed through a collaboration between GeoVax and Georgia State University and the patent is jointly owned by the Company and the Georgia State University Research Foundation (GSURF).
- **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.
- **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.
- **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.
- **March 3, 2021**—Announced that David Dodd will present at the H.C. Wainwright Global Life Sciences Conference taking place March 9-10, 2021.
- **March 1, 2021**—Announced that 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”.
- **February 11, 2021**—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.
- **February 8, 2021**—Announced that the Company 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.
- **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 UTMB.

RECENT COMPANY DEVELOPMENTS

With the funding from its recent offering and subsequent financings, GeoVax is well-positioned to advance several candidates within its development program, including its COVID-19 vaccine as well as its cancer immunotherapy programs, noting that included in this development portfolio are six indications that qualify for the FDA Priority Voucher Program. The additional capital has further enabled the Company to make infrastructure and personnel investments along with funding commitments to support of other programs. GeoVax is additionally focused on manufacturing process development for its MVA-produced vaccines, concentrating on cost-effective, large-scale production for clinical and commercial distribution. GeoVax further 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 efforts are further detailed in the accompanying section.

GeoVax's COVID-19 Vaccine Development Program

GeoVax's SARS-CoV-2 (COVID-19) vaccine is based on its GV-MVA-VLP™ technology, which enables insertion of multiple antigen fragments, possibly permitting broad-spectrum virus prevention. Unique from other vaccines that target only 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 coronavirus variants. GeoVax believes a significant opportunity exists for a pan-coronavirus vaccine with the qualities the GV-MVA-VLP technology can offer.

In January 2021, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), awarded GeoVax a Small Business Innovative Research (SBIR) grant to develop a COVID-19 vaccine. The Phase 1 grant, titled "Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19," supports 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 continues to perform small animal studies, with results to date supporting the Company's approach of using MVA as a vector for the design and production of "next-generation" vaccines encoding multiple proteins. Specifics of the studies are expected to be presented on August 19, 2021 during the European Society of Medicine (ESMED) General Assembly. Based on these results, GeoVax recently submitted an application to NIAID for additional support for advanced testing.

Despite there 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 the Company's animal results, which are expected in the second quarter.

Global COVID-19 Vaccine Update

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

With over 621,000 U.S. deaths caused by the coronavirus to date, the need for a vaccine is greater than ever. 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 (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 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. Johnson & Johnson 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. Immuno-oncology is an important focus area for the Company, and GeoVax is engaging with multiple collaborators. 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 into 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. Technical issues associated with the manufacturing process, combined with the limited availability of nonhuman primates, have resulted in delays to this program, though the work is advancing and results are now expected to be available in late 2021 or early 2022.
- **Sudan ebolavirus (SUDV) and Marburg virus (MARV)**—In July 2021, GeoVax announced results of preclinical efficacy studies of its Sudan ebolavirus (SUDV) vaccine candidate (MVA-VLP-SUDV). Immunogenicity and efficacy of MVA-VLP-SUDV were tested in a guinea pig lethal challenge model, in which a single intramuscular dose of the GeoVax vaccine protected 100% of animals challenged with a lethal dose of SUDV. A comparison between prime and prime-boost vaccinations of guinea pigs showed that both regimens elicited SUDV-specific binding and neutralizing antibody responses, and that the second immunization enhanced these responses. Challenge of vaccinated animals with guinea pig-adapted SUDV demonstrated complete protection against death and disease by the prime and the prime-boost regimens. This is the first report that a replication-deficient MVA vector may confer full protection against SUDV after a single dose. This work was conducted in collaboration with researchers at the University of Texas Medical Branch (UTMB).

Separately, GeoVax is also leading a multi-party collaboration for the development of its (SUDV) and Marburg virus (MARV) vaccine candidates. The collaboration, between GeoVax, researchers at UTMB, and Battelle Memorial Institute, utilizes the suite of preclinical services from NIAID. Under the partnership, 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, which showed 100% protection against a lethal dose of EBOV following a single immunization. The Company expects to announce additional results during the second half of 2021.

- Of recently news, on August 10, 2021, health authorities in Guinea confirmed one death from Marburg virus, a highly infectious hemorrhagic fever similar to Ebola. This makes the first time that the deadly disease has been identified in West Africa. There have been 12 major Marburg outbreaks since 1967, mostly in southern and eastern Africa.

- **Malaria Vaccine**—GeoVax continues to collaborate separately with Leidos, Inc. and the Burnet Institute in Australia to develop a malaria vaccine candidates using its GV-MVA-VLP™ vaccine platform. The collaboration with Leidos has been funded by a grant to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). The Company continues to evaluate advancing this program into formal product development since a Malaria vaccine is not currently a product development initiative.

HIV Vaccine Programs

- **HIV Preventive Vaccine**—NIAID has funded multiple clinical trials of GeoVax’s HIV preventive vaccine (GOVX-B11) through the HIV Vaccine Trials Network (HVTN). The next planned trial (HVTN 132) is designed to further evaluate the safety and immunogenicity of adding “protein boost” components to the GOVX-B11 vaccination regimen. The start of HVTN 132 has been delayed due to COVID-19, with the Company awaiting further information from NIAID and HVTN on when the trial may commence.
- **HIV Immunotherapy**—GeoVax is also part of 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 GeoVax’s vaccine as part of a combination therapy intended to induce remission in HIV-positive individuals. Similar to HVTN 132, this trial has been affected by the pandemic. As such, the Company awaits further information regarding the status of patient enrollment and trial results. Its prior collaboration with American Gene Technologies International, Inc. (AGT) was recently discontinued due to AGT’s remodeling of their clinical trial plans, though GeoVax remains open to additional collaborations.

Licenses and Intellectual Property

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, and in July 2021 announced the issuance of a U.S. patent covering the Company’s Hepatitis B vaccine. 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.

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 within the following areas (summarized 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. 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
PIPELINE FOCUSED ON NEAR-TERM VALUE DRIVERS

		Status	Funding	PRV Candidate (priority review voucher)
Coronavirus (COVID-19)	GEO-CM02	IND-Enabling	Internal & Non-dilutive	
Immuno-Oncology				
Solid Tumors		IND-Enabling	Internal	
HPV-associated Head and Neck Cancer		IND-Enabling	Internal	
Infectious Disease				
HIV (Preventive; HVTN)	GOVX-B11	Phase 2A	Non-dilutive	
HIV (Functional Cure; UCSF)	GOVX-B01	Phase 1	Non-dilutive	
Lassa Fever	GEO-LM01	IND-Enabling	Non-dilutive	✓
Ebola, Marburg, Sudan	GEO-EM01	IND-Enabling	Non-dilutive	✓ ✓ ✓
Zika Virus	GEO-ZM02	IND-Enabling	Internal	✓
Malaria	GEO-MM01	Exploratory	Primarily non-dilutive	✓

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.

Following the Company’s recent financings, GeoVax’s cash balances now stands at approximately \$19.5 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.

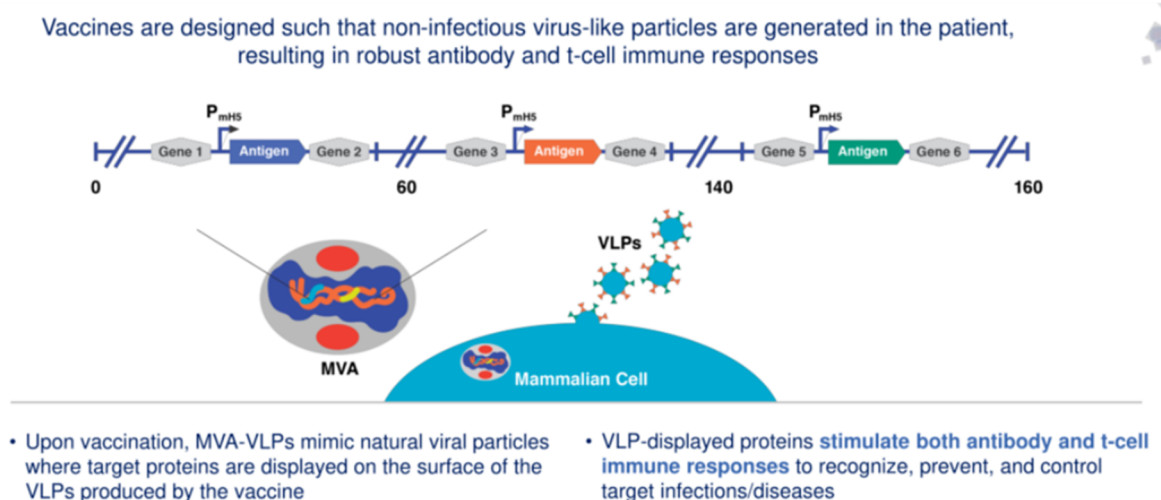
MVA-VLP TECHNOLOGY PLATFORM

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. Figure 2 provides a graphical depiction GeoVax’s GV-MVA-VLP™ vaccine technology.

Figure 2
GV-MVA-VLP™ VACCINE TECHNOLOGY



Source: GeoVax Labs, Inc.

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, enabling the body’s immune system to recognize the authentic virus more readily. In addition, GeoVax’s MVA-VLP platform has unique advantages, as summarized on page 9.

- *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.

Coronavirus (COVID-19) Vaccine Program

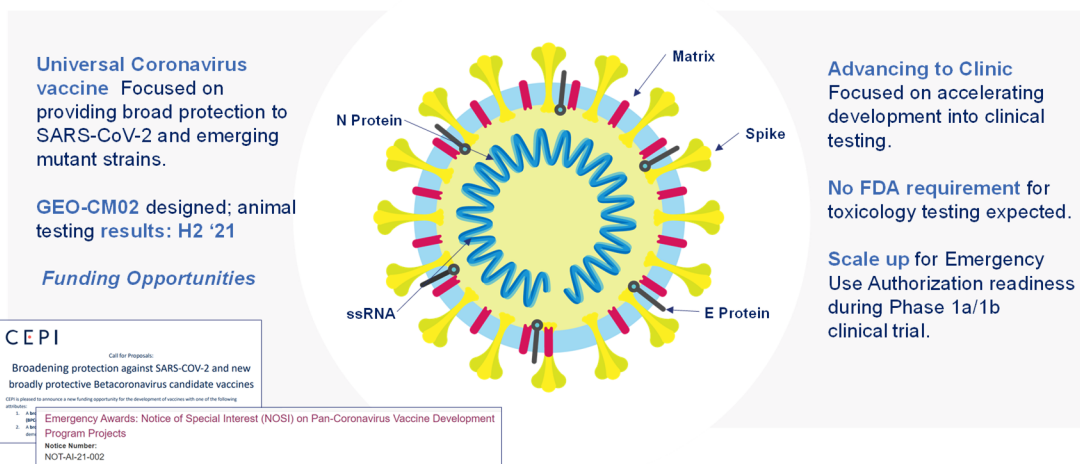
In January 2020, GeoVax announced initiation efforts to develop a vaccine against Coronavirus Disease 2019 (COVID-19) caused by the SARS-CoV-2 coronavirus. COVID-19 is an infectious disease first identified in Wuhan, China in December 2019, and has resulted in an ongoing worldwide pandemic. As of August 2021, more than 207 million cases have been reported, resulting in nearly 4.3 million deaths. The U.S. is currently considered one of the epicenters of the disease, with roughly 37 million cases and 621,000 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.

Its technology is 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. Figure 3 (page 10) summarizes key elements of the Company's COVID-19 vaccine technology.

The experimental COVID-19 vaccine, using the Company's MVA-VLP technology, encodes the S protein, which is the basis for all the first-generation products in use today and the targeted neutralizing antibodies. This is used in combination with the membrane (M protein) and the envelop (E protein). The M and E proteins provide the structural components required for the VLP formation in the body. The also serve as additional targets for the cellular immune responses. This design represents a first critical step towards the COVID vaccines that could induce broad, specific immune responses that are not significantly impacted by the variants that are arising as the S protein evolves within a population. GeoVax is working with this approach to attempt to circumvent the evolution of COVID-19, rather than to chase the new variants with modifier vaccines, as is commonly done today with flu vaccines.

GeoVax is currently involved in animal testing with three experimental vaccines, including in transgenic mice and hamsters (and all include infectious challenged).The product design that proves to induce the most protected immune response will be the basis for the initial clinical development. Additional designs are expected to include the incorporation of other coronavirus structural proteins and non-structural proteins based on data that is being generated within a population and immune responses from the current pandemic. The goal is to expand the induction of immune responses beyond the S protein, which is the basis for GeoVax's efforts and to develop a universal coronavirus vaccine.

Figure 3
UNIVERSAL SARS-COV-X VACCINE PROGRAM



Astuti & Ysrathi, Diabetes Metab Syndr. 2020 Apr 18

Source: GeoVax Labs, Inc.

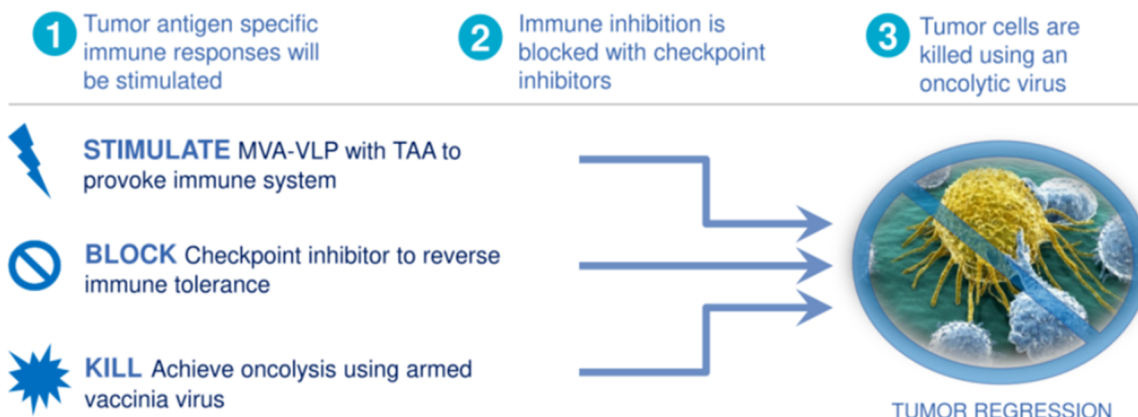
GeoVax is in discussions with the Biomedical Advanced Research and Development Authority (BARDA) and other entities to support and accelerate its COVID-19 vaccine development efforts. While other COVID-19 vaccine candidates are in later stages of development, (with Pfizer, Moderna, and Johnson & Johnson’s COVID-19 vaccines having been approved and being distributed), 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 (Figure 4). The Company believes that its MVA-VLP vector platform is well-suited for inducing immune responses in select tumor associated antigens (TAA). The VLPs are produced within the body of the vaccinated individual and are

Figure 4
IMMUNOTHERAPY TECHNOLOGY

Triple-threat Approach:

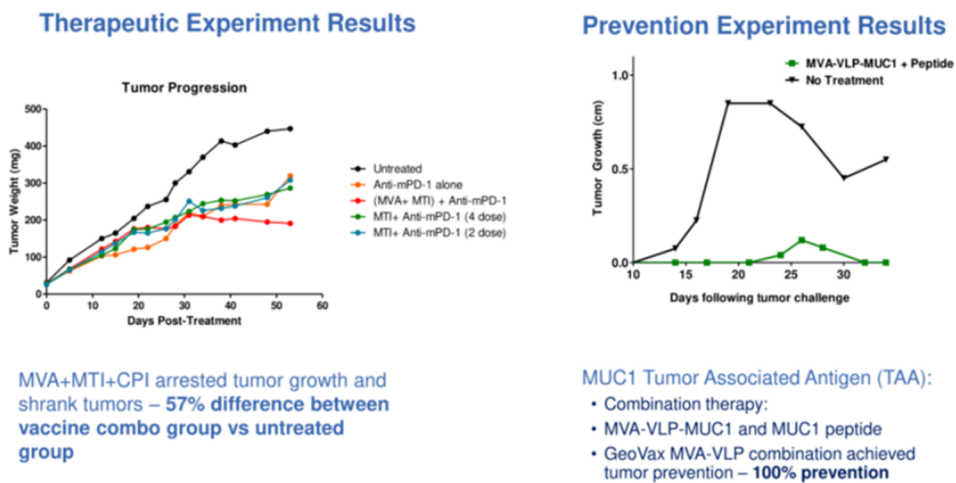


Source: GeoVax Labs, Inc.

composed of a structural protein from a virus but also a tumor associated antigen. These present the immune system with concentrated forms of the TAA to increase potency of the vaccine and to induce both antibody and T-cell cellular immune response. GeoVax seeks to combine a vaccine with a potential antitumor agent, such as a checkpoint inhibitors, thus resulting in immune responses that contribute to the regression of existing tumors and/or prevent the development and expansion of metastatic lesions.

The initial focus is on the MUC1 TAA's, which is a well-studied target for both antibody and cellular immunity (noting that there are multiple associated antigens, which the Company intends to investigate with this approach). As shown in Figure 5, GeoVax constructed a MUC1 MVA-VLP vaccine and has tested it in combination with two different experimental peptide vaccines and a checkpoint inhibitor in transgenic mouse models, which allow for the evaluation of the vaccine's effect against humanized tumors in a humanized mouse. In the treatment model, shown using the MVA-MT1 peptide, the combination induced responses showed a 57% decrease in tumor growth when the animals were immunized with both the MVA MUC1 and the tumor associated peptide (compared to the control animal). The combination was superior to either the peptide alone or the tumor checkpoint inhibitor alone. In a prevention model, designed as a post treatment recurrence setting in cancer treatment, the GeoVax VLP MUC1 induced immune responses that provided almost 100% protection against tumors reoccurring. These results have encouraged the Company to move quickly to initiate clinical development programs.

Figure 5
IMMUNONCOLOGY RESULTS



Source: GeoVax Labs, Inc.

From an investment perspective, the Company sees these efforts as a key component for strengthening the valuation 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 and intends to use a portion of the proceeds from its recent financing to accelerate development of its immuno-oncology program.

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.

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 functional cure collaborative effort led by the University of California, San Francisco (UCSF), with funding from amfAR, The Foundation for AIDS Research.

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 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 potential 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.

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, 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 in-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.

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