

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 recently significantly expanded its clinical stage portfolio through the in-licensing of two Phase 2 products/programs within SARS-CoV-2 and Head & Neck Cancer immunotherapy. 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, which 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. In addition to the GV-MVA-VLP™ technology, the recent license of the SARS-CoV-2 vaccine (GEO/COH04S1) provides the Company a complementary technology, sMVA (synthetic MVA), and the license of Gedeptin® adds the GDEPT (Gene Directed Enzyme Prodrug Therapy) technology to the GeoVax technology platform portfolio. GeoVax is capitalizing on these technologies and its vaccine/immunotherapy design expertise to address the need for a broadly effective COVID-19 vaccine. The Company is also developing vaccines against Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa Fever), and malaria, while also applying its MVA-VLP™ technology to cancer immunotherapy (immuno-oncology).

Key Points

- On March 9, 2022, GeoVax announced financial results from the fiscal year ended December 31, 2021 and provided a corporate update. For the year ended December 31, 2021, GeoVax reported a net loss of \$18.6 million versus \$3.0 million for the year ended December 31, 2020.
- During the quarter, GeoVax announced the initiation of vaccine dosing in the Phase 2 portion of its Phase 1/2 clinical trial of COH04S1, a multi-antigenic SARS-CoV-2 investigational vaccine, targeting both the spike (S) and nucleocapsid (N) proteins, to evaluate its use as a universal booster to current FDA-approved vaccines. COH04S1 is uniquely different from the many vaccines that have been developed because it targets both the spike and nucleocapsid proteins, in contrast to the current U.S. FDA-approved COVID-19 vaccines, which only target the spike protein.
- By inducing immune responses to both the S and N antigens, the COH04S1 vaccine may offer greater protection against the significant sequence variation observed with the S antigen, particularly with the newly identified Omicron VOC. The COH04S1 vaccine’s MVA backbone may also be more effective at inducing SARS-CoV-2 cellular immunity, since MVA strongly induces T cell responses, even in immunocompromised individuals.
- Patient enrollment continues for a Phase 1/2 trial of Gedeptin® therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options. In January 2022, GeoVax announced the engagement of CATO SMS to manage the clinical trial.
- GeoVax continues to strengthen its intellectual property portfolio, with over 70 granted or pending patent applications across 20 patent families.
- At December 31, 2021, GeoVax’s cash balance was \$11.4 million. During the first quarter of 2022, the Company further supplemented its cash resources with net proceeds of \$9.4 million from a private placement of its common stock and warrants.



GeoVax Labs, Inc.

1900 Lake Park Drive, Suite 380
 Smyrna, GA 30080
 Phone (678) 384-7220
 Fax (678) 384-7281
www.geovax.com

GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (03/15/2022)	\$1.41
52-week Range	\$1.35 – 7.50
Shares Outstanding	7.1 million
Market Capitalization	\$10 million
Avg. 10-day Volume	109,285
EPS (Year ended 12/31/21)	(\$3.04)
Employees	11

YEAR END 2021 FINANCIAL RESULTS

On March 9, 2022, GeoVax announced financial results from the fiscal year ended December 31, 2021 and provided a corporate update. The Company reported a net loss for the year ended December 31, 2021 of \$18.6 million versus \$3.0 million for the year ended December 31, 2020.

Grant and collaboration revenues were \$0.4 million for 2021 versus \$1.8 million in 2020. These amounts primarily relate to grants from NIAID for the Company's COVID-19 vaccine program and from the U.S. Department of Defense (DoD) for its Lassa Fever vaccine program. As of December 31, 2021, there were \$81,526 of approved funds remaining and available for use related to GeoVax's grant from the DoD.

Research and development (R&D) expenses were \$15.6 million in 2021 versus \$2.4 million in 2020. Contributing to the year-over-year increase in R&D expense were upfront payments and clinical trial expense reimbursements made pursuant to GeoVax's in-license agreements with City of Hope and PNP Therapeutics, expenditures associated with the Company's pan coronavirus vaccine program, manufacturing process development costs, and a generally higher level of activity.

General and administrative (G&A) expenses were \$3.6 million for 2021 versus \$2.2 million in 2020, with the increase primarily due to higher Delaware franchise taxes; stock-based compensation expense; legal, accounting, and patent costs; insurance costs; consulting fees; and investor relations costs.

Other income (expense) was \$175,506 in 2021 versus \$(141,253) in 2020. The 2021 amount includes a gain of \$172,056 recorded upon the extinguishment of the Company's PPP loan principal and accrued interest. The 2020 amount includes \$138,851 of interest expense and amortized debt discount related to convertible debentures that were retired during 2020.

At December 31, 2021, GeoVax reported cash balances of \$11.4 million versus \$9.9 million at December 31, 2020. During the first quarter of 2022, the Company further supplemented its cash resources with net proceeds of \$9.4 million from a private placement of its common stock and warrants (see January 20, 2022 press release).

RECENT DEVELOPMENTS

- **March 14, 2022**—GeoVax Labs, Inc. announced the engagement of CATO SMS to manage GeoVax’s two ongoing Phase 2 clinical trials of its vaccine candidate, GEO-CM04S1, against SARS-CoV-2.
- **March 10, 2022**—A COVID-19 investigational vaccine, developed by City of Hope scientists and now licensed to GeoVax Labs Inc., produced a robust neutralizing antibody and T cell (an immune cell) response against SARS-CoV-2 with no significant side effects in a Phase 1 clinical trial led by John Zaia, M.D., Aaron D. Miller and Edith Miller Chair for Gene Therapy, according to a study published today in *The Lancet Microbe*.
- **March 9, 2022**—GeoVax Labs announced its financial results for the year ended December 31, 2021 and provided an update on product development programs. Management hosted a live conference call and webcast at 4:30 p.m. Eastern Standard Time on Wednesday, March 9 to discuss financial results and provide a general business update.
- **March 7, 2022**—Announced recent key staff appointments and changes. Jeffrey Welch has been appointed to serve as Head, Process Development and Manufacturing Operations (consultant). Erica Raiden has been appointed to serve as Director, Clinical Operations. The Company also announced that Mark J. Newman, PhD, Chief Scientific Officer, is now serving in a full-time capacity, having previously worked on a part-time basis.
- **February 22, 2022**—Announced that its Chairman and CEO, David Dodd, has been selected as a 2022 Georgia Titan 100. The Titan 100 program recognizes Georgia’s Top 100 CEO’s & C-level executives. They represent the state’s most accomplished business leaders in their respective industry demonstrating exceptional leadership, vision, and passion
- **February 8, 2022**—Announced that its Chairman and CEO, David Dodd, will present a company overview at the 2022 BIO CEO & Investor Digital Conference taking place February 14-17, 2022.
- **January 20, 2022**—Announced the closing of its previously announced private placement for the issuance and sale of 707,484 shares of common stock, 2,360,000 pre-funded warrants to purchase common stock, and accompanying warrants to purchase an aggregate of up to 3,067,484 shares of common stock. Each share of common stock (or pre-funded warrant in lieu thereof) is being sold together with an accompanying warrant at a combined effective purchase price of \$3.26. The warrants are exercisable immediately at an exercise price of \$3.26 per share and will expire five years from the date of issuance.
- **January 14, 2022**—Announced that it has entered into a securities purchase agreement with a single institutional investor to raise approximately \$10.0 million through the private placement of 707,484 shares of common stock, 2,360,000 pre-funded warrants to purchase common stock and accompanying warrants to purchase an aggregate of up to 3,067,484 shares of common stock. Each share of common stock (or pre-funded warrant in lieu thereof) is being sold together with an accompanying warrant at a combined effective purchase price of \$3.26. The warrants will be exercisable immediately at an exercise price of \$3.26 per share and will expire five years from the date of issuance.
- **January 13, 2022**—Announced the engagement of CATO SMS to manage GeoVax’s ongoing Phase 1/2 trial, evaluating the safety and efficacy of repeat cycles of Gedeptin[®] therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC). CATO SMS is a global provider of clinical research solutions, including strategic consulting, full-service clinical trial operations, biometrics, and clinical pharmacology. With more than 30 years of experience focusing on the needs of small and emerging biopharmaceutical companies, CATO SMS effectively designs and executes studies—from strategy to approval—in complex indications and modalities across a variety of therapeutic areas with a proven center of excellence in oncology. CATO SMS’ regulatory, therapeutic and operational expertise enables the company to meet goals and exceed expectations

- **January 11, 2022**—Announced the appointment of Kelly T. McKee, Jr., M.D., M.P.H., to serve as the Company’s Chief Medical Officer (CMO). Dr. McKee brings over 30 years of experience in research and development, with specific expertise in vaccines, emerging diseases, biodefense, and respiratory viral infections.
- **January 5, 2022**—Announced that its Chairman and CEO, David Dodd, will present at the H.C. Wainwright Bioconnect 2022 Virtual Conference taking place January 10-13, 2022. The Company also scheduled investor meetings with its senior management team during the Biotech Showcase virtual conference being held January 17-19, 2022.
- **January 4, 2022**—Issued an update letter from Chairman and CEO, David Dodd, to the Company’s shareholders and other interested parties.
- **December 15, 2021**—Announced the initiation of vaccine dosing in the Phase 2 portion of its Phase 1/2 clinical trial of COH04S1, a multi-antigenic SARS-CoV-2 investigational vaccine, designed to target both the spike (S) and nucleocapsid (N) proteins, to evaluate its use as a universal booster to current FDA-approved vaccines. The clinical trial, titled “Phase 1/2 Dose Escalation Study to Evaluate the Safety and Biologically Effective Dose of COH04S1, a Synthetic MVA-based SARS-CoV-2 Vaccine, Administered as One or Two Injections or as a Booster to Healthy Adult Volunteers” is being conducted at City of Hope, a world-renowned cancer research and treatment organization near Los Angeles.
- **December 14, 2021**—Announced that the U.S. Patent and Trademark Office issued a Notice of Allowance for Patent Application No. 16/648,693 titled “Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria.” In general, the claims to be granted in the patent cover GeoVax’s modified vaccinia Ankara (MVA) vector expressing certain antigens from the malaria parasite.
- **December 3, 2021**—Presented data from ongoing studies of its investigational vaccines against hemorrhagic fevers (Sudan, Ebola, and Marburg) at the recent World Vaccine & Immunotherapy Congress, held November 30-December 2 in San Diego, California. The presentation, titled “Design and Evaluation of Vaccines Against Hemorrhagic Fevers using the MVA-VLP Platform”, was delivered by Mary Hauser, PhD, GeoVax Senior Scientist.
- **December 1, 2021**—Announced that its Chief Scientific Officer, Mark J. Newman, Ph.D., participated in an expert panel discussion on design approaches to produce a universal SARS-CoV-2 vaccine during the World Vaccine & Immunotherapy Congress, being held November 30-December 2 in San Diego, California. Dr. Newman also presented data from ongoing studies of GEO-CM02, GeoVax’s investigational pan coronavirus vaccine.
- **November 17, 2021**—Presented data from ongoing studies of its preventive vaccine against COVID-19. The presentation titled, “Addressing Evolving SARS-CoV-2 Variants through a Universal Coronavirus Vaccine,” was delivered virtually by Mark J. Newman, Ph.D., GeoVax’s Chief Scientific Officer, during the Vaccine World Asia Congress & Global COVID-19 Vaccine Manufacturing & Supply Chain Summit, being held November 17-18.
- **November 16, 2021**—Announced that the U.S. Patent and Trademark Office has issued a Notice of Allowance for Patent Application No. 16/068,527 entitled “Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen.” In general, the claims to be granted in the patent cover GeoVax’s vector platform for expressing tumor associated antigens in virus-like particles (VLPs) from a Modified Vaccinia Ankara (MVA) viral vector and encompass GeoVax’s Mucin 1 (MUC1) tumor-associated antigen immunotherapy candidate.

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 areas as summarized in Figure 1.

Figure 1
GEOVAX PIPELINE FOCUSED ON NEAR-TERM VALUE DRIVERS

	Product Candidate	Status
Coronavirus		
COVID-19 (Immunocompromised)	GEO-CM04S1	Phase 2
COVID-19 (Booster to mRNA)	GEO-CM04S1	Phase 2
Pan Coronavirus	GEO-CM02	IND-Enabling
Cancer Immunotherapy		
Solid Tumors (Advanced Head & Neck Cancer)*	Gedepin®	Phase 1/2
Solid Tumors (MUC1)	MVA-VLP-MUC1	IND-Enabling
Infectious Disease		
Ebola, Marburg, Sudan**	GEO-EM01	IND-Enabling
Zika Virus**	GEO-ZM02	IND-Enabling
Lassa Fever**	GEO-LM01	Exploratory
Malaria**	GEO-MM02	Exploratory

*: Orphan Drug status granted; **: Indication within FDA Priority Review Voucher program

Source: GeoVax Labs, Inc.

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>). 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.

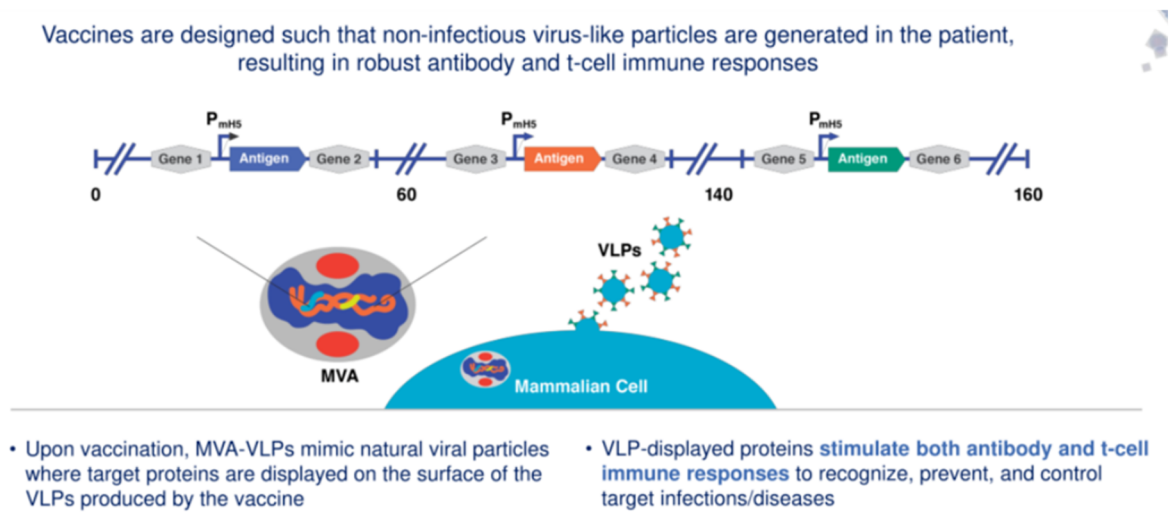
Following the Company’s recent financings, GeoVax’s cash balance now stands at approximately \$11.4 million, positioning the Company to support accelerated development of its COVID-19 vaccine development candidates, advance its cancer immunotherapy program, as well as other infectious disease vaccines.

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. 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, summarized as follows:

- *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.

MVA-VLP-MUC1

Using GeoVax's GV-MVA-VLP™ vaccine platform, the Company is developing a cancer immunotherapy based on the abnormal, aberrantly glycosylated forms of the cell surface-associated MUC1 protein that is expressed on a wide range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung, with the goal of raising therapeutic anti-tumor antibodies and T cell responses in cancer patients. GeoVax's cancer immunotherapy program is based on the concept of combining a tumor-associated antigen vaccine with a potent anti-tumor agent, such as an Immune Checkpoint Inhibitor ("ICI"), with the goal of achieving regression of tumor growth and development.

The initial animal studies of the Company's MVA-VLP-MUC1 vaccine and ICI combination have been encouraging, showing that a combination of the MVA-VLP-MUC1 vaccine candidate with a MUC1 synthetic peptide was capable of breaking tolerance to human MUC1 in transgenic mice and inducing immune responses with efficacy against challenge in a lymphoma tumor model. The studies also demonstrated a significant reduction of the tumor burden in a mouse model for colorectal cancer. GeoVax plans to further these animal studies in collaboration to define the optimal course and schedule of vaccination to define a protocol that can be evaluated in a Phase 1 clinical trial.

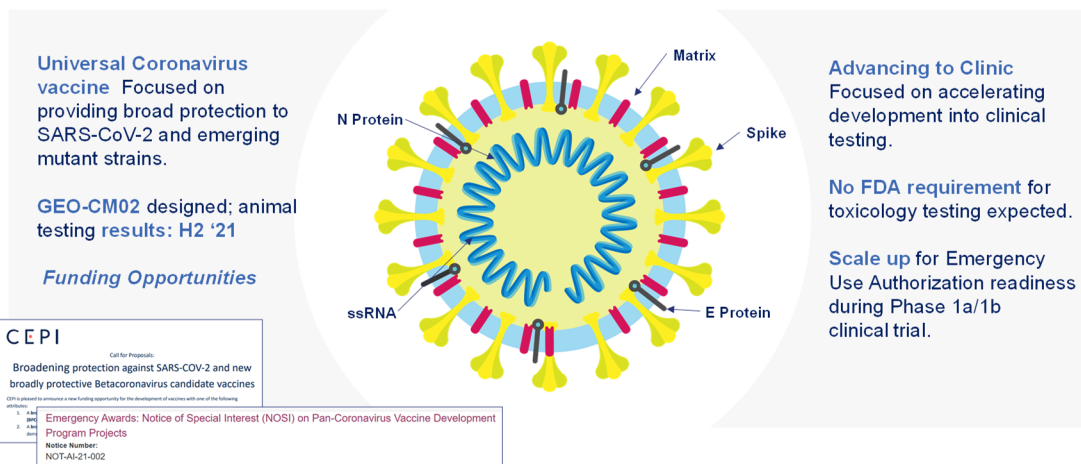
During the quarter, GeoVax announced that the U.S. Patent and Trademark Office had issued a Notice of Allowance for Patent Application No. 16/068,527 entitled "Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen." In general, the claims to be granted in the patent cover GeoVax's vector platform for expressing tumor associated antigens in virus-like particles (VLPs) from a Modified Vaccinia Ankara (MVA) viral vector and encompass GeoVax's Mucin 1 (MUC1) tumor-associated antigen immunotherapy candidate.

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. As of March 2022, more than 452 million cases have been reported worldwide, resulting in over 6 million deaths. The U.S. is still considered one of the epicenters of the disease, with roughly 79 million cases and 963,000 deaths so far. 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 8) 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.

Figure 3
UNIVERSAL SARS-COV-X VACCINE PROGRAM



[Astuti & Ysrafil, Diabetes Metab Syndr](#) 2020 Apr 18

Source: GeoVax Labs, Inc.

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.

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 breadth of responses. This makes the Company’s platform ideal for immunization of those most vulnerable, including the immunocompromised and comorbid.

Two Phase 2 Clinical Trials Underway for SARS-CoV-2

GEO-CM04S1 for Immunocompromised Patients. GEO-CM04S1 is being studied in an ongoing Phase 2 clinical trial (NCT04977024) to evaluate its safety and immunogenicity compared to the Pfizer/BioNTech mRNA-based vaccine, in patients who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant, or chimeric antigen receptor (CAR) T cell therapy. GEO-CM04S1 is the only COVID-19 vaccine that includes both SARS-CoV-2 spike and nucleocapsid proteins to advance to a Phase 2 trial in cancer patients. Such vaccines tend to produce an immune response quickly (in less than 14 days) with only mild side effects. The trial is also the first to compare an investigational multi-antigenic COVID-19 vaccine to the current FDA-approved mRNA vaccine from Pfizer/BioNTech in people who are immunocompromised. Such patients have often shown a weak antibody response after receiving currently available COVID-19 vaccines.

GEO-CM04S1 as a Booster Vaccine. In December 2021, patient enrollment began for the Phase 2 portion of a Phase 1/2 trial (NCT04639466) of GEO-CM04S1, evaluating its use as a universal booster vaccine to current FDA-approved two-shot mRNA vaccines from Pfizer/BioNTech and Moderna. The completed Phase 1 portion of the trial was designed as a dose-escalation safety study in healthy individuals who had not been previously infected with SARS-CoV-2. The ongoing Phase 2 booster study includes healthy individuals who were previously fully vaccinated with either the Pfizer/BioNTech or Moderna vaccine. The dose-escalation study is designed to specifically evaluate the safety profile and immunogenicity of GEO-CM04S1 as a booster. The immunological responses measured throughout the study will include the level of SARS-CoV-2 neutralizing antibodies against SARS-CoV-2 variants of concern (VOC), including the newly identified Omicron VOC, as well as specific T-cell responses.

On March 14, 2022, GeoVax announced the engagement of CATO SMS to manage GeoVax's two ongoing Phase 2 clinical trials of its vaccine candidate, GEO-CM04S1, against SARS-CoV-2. CATO SMS is a global provider of clinical research solutions, including strategic consulting, full-service clinical trial operations, biometrics, and clinical pharmacology. With more than 30 years of experience focusing on the needs of small and emerging biopharmaceutical companies, CATO SMS effectively designs and executes studies (from strategy to approval) in complex indications and modalities across a variety of therapeutic areas with a proven center of excellence in oncology.

IND-Enabling Activities Progressing for Pan Coronavirus Vaccine

GEO-CM02 as a Pan-Coronavirus Vaccine. First-generation SARS-CoV-2 vaccines were designed to encode the spike (S) protein of the SARS-CoV-2 virus with the goal of inducing high levels of neutralizing antibodies. However, potential limitations of narrowly focusing on the spike (S) protein are becoming evident with emerging variants capable of partially escaping neutralization by vaccine induced antibodies. Consequently, the effectiveness of these vaccines against new SARS-CoV-2 variants and future coronavirus spillover events remains an enormous concern.

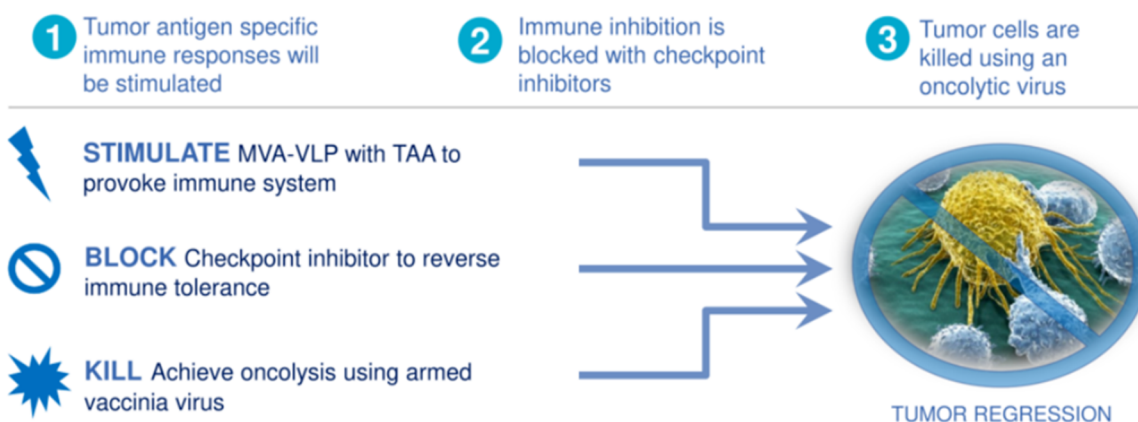
GeoVax's vaccine candidate (GEO-CM02) encodes the spike (S) protein as the neutralizing antibody target as well as the membrane (M) and envelope (E) proteins as T-cell targets and to support in vivo virus-like particle formation to augment potency. This strategy may provide the basis for generating a single dose universal coronavirus vaccine. Unique compared to other vaccines approved or under development, the GeoVax vaccine candidate is therefore specifically designed to provide a broader and more durable level of protective immunity against SARS-CoV-2, which may protect against emerging variants while avoiding the potential side effects that can limit vaccine utility and acceptance. In small animal studies, the Company measured functional immune responses after a single dose that mediated protection from infection and pathogenesis, including protection against the more virulent Beta variant. Additional studies are planned for 2022 to prepare for IND filing and subsequent human clinical trials.

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 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.

Figure 4
IMMUNOTHERAPY TECHNOLOGY

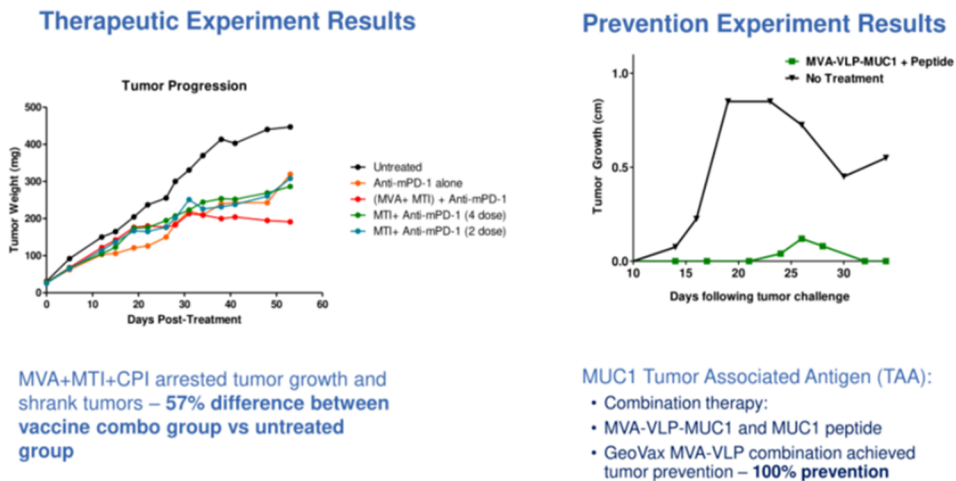
Triple-threat Approach:



Source: GeoVax Labs, Inc.

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 (page 11), 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.

Phase 2 Clinical Trial Underway for Advanced Head and Neck Cancer

Gedepin®. Gedepin is a novel, patented product/technology for the treatment of solid tumors through a gene therapy strategy known as Gene-Directed Enzyme Prodrug Therapy (GDEPT). In September 2021, GeoVax entered into an assignment and license agreement with PNP Therapeutics, Inc. (“PNP”), granting GeoVax exclusive rights to develop and commercialize Gedepin. The Gedepin technology was developed with funding support from the National Cancer Institute (NCI), part of the NIH. GeoVax’s license to Gedepin includes the rights to expand the use of Gedepin to all human diseases and/or conditions including, but not limited to, other cancers.

In GDEPT, a vector is used to selectively transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a very toxic antitumor compound, in situ. A cycle of Gedepin therapy consists of three intra-tumoral injections of Gedepin over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days. A Phase 1 dose ranging study, evaluating the safety of a single cycle of Gedepin therapy, found the therapy to be well tolerated, with evidence of a reduction in tumor size in patients with solid tumors.

A Phase 1/2 trial (NCT03754933), evaluating the safety and efficacy of repeat cycles of Gedepin therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options, is currently enrolling at Stanford University in collaboration with Emory University. The trial design involves repeat administration using Gedepin followed by systemic fludarabine, to gain additional information prior to expansion towards a larger patient trial.

The initial stage of the study is being funded by the FDA under its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedepin orphan drug status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities. In January 2022, GeoVax engaged CATO SMS, a global provider of clinical research solutions, to manage the ongoing Phase 1/2 trial and to assist with the expansion of clinical sites and acceleration of patient enrollment and evaluation.

Hemorrhagic Fever (HF) Vaccine Programs (Ebola, Sudan, Marburg and Lassa)

GeoVax's initial preclinical studies in rodents and nonhuman primates for its MVA-VLP-EBOV vaccine candidate have shown 100% protection against a lethal dose of EBOV upon a single immunization. Recent studies in lethal challenge guinea pig models demonstrated that GeoVax vaccines MVA-VLP-SUDV and MVA-VLP-MARV conferred 100% protection from death. These vaccines were subsequently evaluated in a rigorous cynomolgus macaque infectious challenge model. Vaccination protected nonhuman primates from viremia, weight loss and death following challenge with a dose of Sudan or Marburg virus that is lethal in nonvaccinated animals.

Evaluation of immune responses following vaccination demonstrated presence of both neutralizing antibodies and functional T cells, indicating a breadth of responses that combine for optimal protection. Similarly, the initial preclinical studies in rodents for GeoVax's LASV vaccine candidate have shown 100% single-dose protection against a lethal dose of LASV challenge composed of multiple strains delivered directly into the brain. The nonhuman primate studies are ongoing in collaboration with NIAID and the U.S. Army and clinical development programs will be defined based on efficacy data and global priorities as potentially dangerous outbreaks occur.

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 (34 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.

Malaria Vaccine Program

GeoVax has collaborated with the Burnet Institute, a leading infectious diseases research institute in Australia, for the development of a vaccine to prevent malaria infection. The project included the design, construction, and characterization of multiple malaria vaccine candidates using GeoVax's GV-MVA-VLP™ vaccine platform combined with malaria *Plasmodium falciparum* and *Plasmodium vivax* sequences identified by the Burnet Institute. The Company also collaborated separately with Leidos, Inc. with work funded by a grant to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). This program has recently been inactive as GeoVax has prioritized other development programs. However, pending additional funding support via federal grants or other sources, the Company may further pursue this area.

During the quarter, GeoVax announced that the U.S. Patent and Trademark Office issued a Notice of Allowance for Patent Application No. 16/648,693 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." In general, the claims to be granted in the patent cover GeoVax's modified vaccinia Ankara (MVA) vector expressing certain antigens from the malaria parasite

Worldwide, malaria causes 229 million infections and 409,000 deaths every year (mostly in children living in sub-Saharan Africa). 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.

ZIKA Virus (ZIKV) Vaccine Program

To address the unmet need for a vaccine against Zika virus, GeoVax is developing novel vaccine candidates constructed using its GV-MVA-VLP™ platform. MVA has an outstanding safety record, which is particularly important given the need to include women of child-bearing age and newborns among those being vaccinated. The Company's Zika vaccine is designed around the NS1 gene product to eliminate the risk of Antibody Dependent Enhancement (ADE), which is a serious side effect observed when a vaccinated individual does not have a fully protective immune

response which causes a more virulent reaction if infected. GeoVax's initial preclinical studies in rodents using its GEO-ZM02 vaccine candidate demonstrated 100% single-dose protection against a lethal dose of ZIKV delivered directly into the brain. In rhesus macaques, vaccination with GEO-ZM02 induced immune responses that effectively controlled the virus replication despite the fact the vaccine is not designed to induce ZIKV neutralizing antibodies. Further development of the Company's Zika vaccine will be dependent upon partnering support.

HIV Program (being discontinued but available for out-license or partnering)

Due to the Company's corporate refocusing of development efforts in prioritizing its SARS-CoV-2 and cancer immunotherapy programs, and a lack of continuing government support for its HIV vaccine development efforts, GeoVax recently decided to discontinue active development of these programs. The Company's technology and intellectual property will remain available for out-license or partnering, but GeoVax will no longer devote any corporate resources to the programs.

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

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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