

March 4, 2024

Company Description

GeoVax Labs, Inc. ("GeoVax" or "the Company") is a clinical-stage biotechnology company developing novel therapies and vaccines for cancers and many of the world's most threatening infectious diseases. The Company's lead program in oncology is a novel oncolytic solid tumor gene-directed therapy, Gedeptin®, currently in a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. GeoVax's lead infectious disease candidate, GEO-CM04S1, is a next-generation COVID-19 vaccine targeting high-risk immunocompromised patient populations. GEO-CM04S1 is being evaluated in three Phase 2 clinical trials: (1) as a primary COVID-19 vaccine for immunocompromised patients versus mRNA vaccines; (2) as a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines; and (3) most recently, as a more robust, durable booster versus mRNA vaccines in patients with chronic lymphocytic leukemia (CLL). GeoVax has a leadership team who has driven significant value creation across multiple life science companies over the past several decades.

Key Points

- On February 29, 2024, GeoVax announced financial results for the year ended December 31, 2023, and provided a corporate update. Net loss for the year ended December 31, 2023, was \$26.0 million (\$14.29/share) versus \$14.0 million (\$12.39/share) for the year ended December 31, 2022.
- GeoVax completed enrollment for its Phase 2 clinical trial during 2023 investigating GEO-CM04S1 as a universal booster for mRNA COVID vaccines. Concurrently, the Company expanded its Phase 2 trial to encompass multiple sites targeting immunocompromised/stem cell transplant patients, aiming to assess GEO-CM04S1 as a primary vaccine, directly comparing its efficacy to mRNA vaccines. Additionally, GeoVax initiated a third Phase 2 trial focusing on evaluating GEO-CM04S1 among immunocompromised/chronic lymphocytic leukemia (CLL) patients. This trial seeks to assess the vaccine's efficacy as a booster for patients initially vaccinated with an mRNA vaccine in direct comparison to mRNA vaccination.
- During 2023, the Company completed patient enrollment for the Phase 1/2 clinical trial of Gedeptin among advanced head and neck cancer patients with results demonstrating safety and consistent reduction in treated tumors. The data presented at the AACR-AHNS Head and Neck Cancer Conference emphasized the safety and feasibility of Gedeptin therapy, providing insights into its potential as a treatment option for patients with limited therapeutic alternatives. The initial Phase 1/2 trial aims to guide future studies, potentially expanding the application of Gedeptin in other solid tumor areas and in combination with immune checkpoint inhibitors. The Company expects to report additional results from the Gedeptin Phase 1/2 clinical trial during the first half of 2024, with plans for an expanded Phase 2 clinical trial.
- Relative to its MVA vaccine against Mpox and smallpox, GeoVax expects to report its regulatory path and plans related to advancing this product towards registration. Furthermore, the Company anticipates providing further updates related to its advanced MVA manufacturing process to enable GeoVax to effectively produce and distribute MVA-based vaccines in response to real-time market needs worldwide.
- GeoVax continues to announce actions which strengthened its global intellectual property position, with the Company now holding over 115 granted or pending patent applications spread over twenty-four patent families.
- As of December 31, 2023, the Company's reported cash balance was \$6.5 million versus \$27.6 on December 31, 2022.



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GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (03/01/2024)	\$2.54
52-week Range	\$2.04 – 11.85
Shares Outstanding	2.2 million
Market Capitalization	\$5.6 million
Avg. Volume	38,385
EPS (Yr. ended 12/31/2023)	(\$14.29)
Employees	19

FOURTH QUARTER AND YEAR END 2023 FINANCIAL RESULTS

On February 29, 2023, GeoVax Labs, Inc. announced its financial results for the year ended December 31, 2023, and provided a corporate update. Net loss for the year ended December 31, 2023, was \$26.0 million (\$14.29/share) versus \$14.0 million (\$12.39/share) for the year ended December 31, 2022.

Research and development expenses were \$20.7 million for 2023 versus \$9.1 million in 2022, with the increase primarily due to the costs of conducting clinical trials for GEO-CM04S1 and Gedeptin; costs of manufacturing materials for use in the Company's clinical trials; technology license fees; personnel costs; costs of preclinical research activities; as well as higher travel costs.

General and administrative expenses were \$6.0 million for 2023 versus \$5.0 million in 2022, with the increase primarily attributable to higher personnel costs, investor relations consulting costs, legal fees, patent costs, and travel expenses.

Interest income was \$776,000 in 2023 versus \$7,000 in 2022, reflecting increasing interest rates available through the Company's Money Market accounts.

On December 31, 2023, GeoVax's reported cash balances were \$6.5 million versus \$27.6 million on December 31, 2022. The change in the cash loss is reflective of \$25 million used in operating activities, partially offset by \$4.1 million in net proceeds from the exercise of warrants this past December.

Throughout 2023, the Company continued to advance its ongoing clinical programs for its clinical-safe products GEO-CM04S1, which is its next-generation COVID-19 vaccine, and for Gedeptin, in development as a therapy against advanced head and neck cancer, further outlined in the accompanying sections. GeoVax seeks to develop innovative cancer therapies and infectious disease vaccines that address critically important unmet medical needs and is pursuing initial indications that support expedited registration pathways. The Company anticipates worldwide development, commercialization, and distribution via business partnerships and collaborations.

GEO-CM04S1

GeoVax's CM04S1, GeoVax's next generation COVID-19 vaccine, is unique from the current authorized COVID-19 vaccines in targeting both the antibody and cellular arms of the immune system—specifically focused on providing more robust and durable protection versus current vaccines. This is important in addressing high-risk populations of immune-compromised individuals, specifically those for whom the current vaccines and monoclonal antibody therapies are inadequate, including those with various blood cancers, renal disease, sickle cell anemia, HIV positive, autoimmune diseases such as lupus, and those on immune-depressive therapy. Overall, patient groups with ablated immune systems who are unable to respond adequately to approved mRNA vaccines are at an elevated risk. There are approximately fifteen million immune-compromised individuals in the U.S. and a 240 plus million worldwide.

GEO-CM04S1 is based on GeoVax's MVA viral vector platform, which supports the presentation of multiple vaccine antigens to the immune system in a single dose. GEO-CM04S1 encodes for both the spike (S) and nucleocapsid (N) antigens of SARS-CoV-2 and is to induce both antibody and T cell responses to those parts of the virus less likely to mutate over time. The more broadly functional engagement of the immune system is to protect against severe disease caused by continually emerging variants of COVID-19. Vaccines of this format should not require frequent and repeated modification or updating.

During 2023, GeoVax achieved the following milestones for GEO-CM04S1.

- **Successfully completed enrollment for the Phase 2 clinical trial evaluating GEO-CM04S1 as a potential universal booster for individuals previously immunized with Pfizer or Moderna vaccines.** Data unveiled during this period revealed promising findings, suggesting GEO-CM04S1's potential as a versatile COVID-19 vaccine capable of granting immunity against a spectrum of strains, encompassing the Wuhan, Delta, and Omicron variants. The trial comprises sixty-three healthy adults who received mRNA vaccines as their primary immunization. Notably, no serious adverse events were reported, alongside significant enhancements in neutralizing antibody levels and cellular immune responses targeting multiple SARS-CoV-2 variants. The final outcomes of this trial are anticipated in the fourth quarter of 2024.
- **A Phase 2 booster trial was initiated,** focusing on immunocompromised chronic lymphocytic leukemia (CLL) patients who often exhibit diminished immune responses to mRNA vaccines due to their medical circumstances. This investigator-led trial aims to recruit eighty participants and directly contrast GEO-CM04S1 with the Pfizer/BioNTech Bivalent vaccine. An interim analysis is projected to unveil results in the first half of 2024.
- **Data from the Phase 2 trial of GEO-CM04S1 in immunocompromised/stem cell transplant patients** were presented at the World Vaccine Congress (further described in the accompanying section) and published in the peer-reviewed journal, *Vaccines*. The findings displayed strong immunogenicity, indicating the vaccine's capacity to elicit both antibody and T cell responses crucial for providing protection, especially in immunocompromised individuals. The article emphasized GEO-CM04S1's unique ability to offer protective immunity against the ancestral Wuhan strain, the Delta variant, and the highly virulent Omicron XBB.1.5 variant. This study has expanded into a multi-site trial, with further results expected throughout 2024.
- **During second quarter 2023, the White House announced Project NextGen,** a \$5 billion initiative to follow on from Operation Warp Speed, seeking COVID-19 vaccines with enhanced breadth of protection against variants and improved durability, being particularly interested in novel vaccine candidates already in clinical trials. GeoVax believes that CM04S1 is a key example of the desired next generation COVID-19 vaccine, with the potential for an expedited regulatory path due to the Company's focus on high-risk populations unserved by the current COVID-19 vaccines and monoclonal antibody therapies. GeoVax is currently in active discussions related to formal participation in the Project NextGen initiative.

GeoVax COVID-19 Vaccine Clinical Data Presented at World Vaccine Congress

In November 2023, the Company announced the presentation of data from the active development program for GEO-CM04S1, including Phase 2 clinical trial data. The data include some of which was recently published in the journal *Vaccines* and can be accessed here: [GEO-CM04S1 Publication \(Vaccines | Free Full-Text | Stimulation of Potent Humoral and Cellular Immunity via Synthetic Dual-Antigen MVA-Based COVID-19 Vaccine COH04S1 in Cancer Patients Post Hematopoietic Cell Transplantation and Cellular Therapy \(mdpi.com\)\)](#).

The presentation, titled "COVID-19 Vaccines for Immunocompromised Patients," was delivered by Don Diamond, PhD, Professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope Comprehensive Cancer Center. In his presentation, Dr. Diamond described the immune response analyses conducted on the open-label portion of the Phase 2 trial, indicating that GEO-CM04S1 is highly immunogenic in these immunocompromised patients, inducing potent humoral (antibody) and cellular (T cell) responses, including neutralizing antibodies against SARS-CoV-2 ancestral virus and variants of concern and the highly immune-evasive Omicron XBB 1.5 variant.

The Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT04977024) is evaluating the safety and immunogenicity of GEO-CM04S1, compared to either the Pfizer/BioNTech or Moderna 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. These patients have significantly compromised immune system function as the result of their treatment and are at exceptionally elevated risk for COVID. They must be re-vaccinated and will benefit from the types of immune responses induced by the GEO-CM04S1 vaccine, both the antibodies and T cells.

Gedepin®

Gedepin is based on a novel patented technology for the treatment of solid tumors through a gene therapy strategy known as Gene-Directed Enzyme Prodrug Therapy (GDEPT). In GDEPT, a vector is used to selectively transduce tumor cells with a non-human gene, which expresses an enzyme that can convert a non-toxic prodrug into a highly toxic anti-tumor compound in situ. Gedepin is tumor agnostic, providing the opportunity to address a variety of solid tumors, either cancerous or benign. GeoVax holds worldwide rights for all indications of this technology. In the U.S., there are 67,000 new cases of head and neck cancers with approximately 15,000 deaths annually. Worldwide, there are approximately 900,000 new cases of head and neck cancers annually, and roughly 400,000 deaths.

GeoVax's initial targeted patient population for the application of Gedepin represents those who are end stage care, as these patients represent a critical unmet medical need with many unable to swallow food and having great difficulties being able to speak. Most have exhausted existing therapies and standards of care and are receiving palliative care. GeoVax seeks to provide an improved end-stage quality of life by reducing and/or eliminating various targeted tumors. Current protocol entails up to five treatment cycles, each consisting of three intratumoral injections of Gedepin over two days, followed by infusion of a prodrug, fludarabine phosphate, once daily for three days. The Phase 1 dose ranging study demonstrated that treating a tumor with a single cycle of Gedepin followed by fludarabine infusions was well-tolerated with evidence of a reduction in tumor size in patients with solid tumors. Due to results from that study, the FDA is funding the current trial under the Orphan Drug Clinical Trials Program.

- ***During 2023, the Company completed patient enrollment for the Phase 1/2 clinical trial of Gedepin among advanced head and neck cancer patients with results demonstrating safety and consistent reduction in treated tumors.*** The data presented at the AACR-AHNS Head and Neck Cancer Conference emphasized the safety and feasibility of Gedepin therapy, providing insights into its potential as a treatment option for patients with limited therapeutic alternatives. The initial Phase 1/2 trial aims to guide future studies, potentially expanding the application of Gedepin in other solid tumor areas and in combination with immune checkpoint inhibitors. The Company expects to report additional results from the Gedepin Phase 1/2 clinical trial during the first half of 2024, with plans for an expanded Phase 2 clinical trial.
- ***On January 4, 2024, GeoVax announced the closure of patient enrollment for the Phase 1/2 clinical study evaluating Gedepin in patients suffering from advanced head and neck cancer.*** Completion of this trial is a significant milestone in the Company's Gedepin clinical development program. Allowing time for the maximum number of cycles of Gedepin therapy and patient follow-up, GeoVax expects to complete the study by the third quarter 2024. In the meantime, the Company is in active discussions with advisors on protocol development in support of a follow-on Phase 2 or Phase 2/3 trial among patients with advanced head and neck cancer in whom current therapeutic options are suboptimal. The intent is to discuss this follow-on protocol with the FDA, in conjunction with a complete review of the results of the current trial, to ensure alignment with the regulator's expectations.
- The Company believes that the successful completion of the current trial, in conjunction with earlier findings from the completed Phase 1 first-in-human trial and preclinical investigations, provide a sound rationale for proceeding with further Gedepin investigations. During 2024, the Company expects to announce plans relative to an expanded Phase 2 study among advanced head and cancer patients, following discussions with regulatory authorities. In addition, GeoVax expects to outline plans for further Gedepin clinical development, both in additional monotherapy and in combination-therapy (e.g., Gedepin + immune-checkpoint inhibitor) indications.

Gedepin and GEO-CM04S1 provide the potential to achieve leadership within their respective categories as they represent areas where larger competitors are not adequately addressing these patients (likely due to the relatively small size of these opportunities, which is the case for advanced head and neck cancer), or because current technologies do not adequately address specific patient populations.

Advanced Vaccine Manufacturing Process

Considerable progress has been made at enhancing the Company's MVA manufacturing capabilities, with a particular emphasis on implementing an innovative production method to bolster MVA-based vaccines and immunotherapies. The comprehensive license agreement with ProBioGen, utilizing the cutting-edge AGE1.CR.PIX® suspension cell line, greatly amplifies GeoVax's capacity to produce MVA-based vaccines and immunotherapies on an unprecedented scale. Additionally, the partnership with Advanced Bioscience Laboratories, Inc. (ABL) ensures compliance with cGMP production standards, facilitating GeoVax's transition towards global commercialization. These advancements underscore GeoVax's commitment to improving vaccine accessibility through efficient and scalable manufacturing processes. The Company's objective is to successfully develop and distribute its products worldwide, leveraging strategic partnerships and collaborative efforts.

Modified Vaccinia Ankara (MVA) For Immunization Against Monkeypox (Mpox) And Smallpox

GeoVax is further developing GEO-MVA, a vaccine that targets both Mpox and smallpox. The Company's goal is to establish itself as the leading supplier of an MVA-based vaccine in the U.S., offering protection against Mpox and smallpox. By doing so, GeoVax aims to address the global demand for these vaccines, particularly in low and middle-income countries that have historically faced challenges in accessing essential vaccines.

MVA is used and stockpiled in the U.S. Strategic National Stockpile for immunization against the MPox and smallpox viruses. GeoVax had previously demonstrated that an experimental HIV vaccine, using NIH-MVA as the vaccine vector, protected non-human primates challenged with a lethal dose of the MPox virus. Further, in August 2022, City of Hope, which originally developed GEO-CM04S1, published results demonstrating that both their proprietary sMVA (synthetic MVA) and GEO-CM04S1 elicited robust orthopoxvirus-specific binding and neutralizing antibody responses. The authors concluded that GEO-CM04S1 and sMVA represent unique vaccine candidates to control the unforeseen global MPox outbreak.

GeoVax secured rights from the National Institutes of Health (NIH) covering preclinical, clinical, and commercial uses of the NIH-MVA against MPox or smallpox viruses. The Company is evaluating development and regulatory pathways towards expanding the public health options available to reduce and manage the risk of MPox worldwide with the intent to be the first U.S.-based supplier of a MVA-vaccine against MPox and smallpox.

GEO-MVA is intended to disrupt the existing monopoly within this category, which could provide a leadership position as the first U.S.-based supplier for such a vaccine. GeoVax holds worldwide rights for its products and is highly focused and engaged in discussions to ensure worldwide access and commercialization.

Intellectual Property Developments

GeoVax recently announced multiple actions by global patent offices, strengthening the Company's intellectual property assets and securing multiple patents covering a range of vaccine candidates. The expanded rights under the NIH COVID-19 license to include Mpox and smallpox further diversify GeoVax's vaccine portfolio, potentially offering broader protection against infectious diseases. As well, the issuance of patents for Ebola, Marburg, Malaria, and HIV vaccines underscores the Company's innovative approach to vaccine development and its dedication to advancing global health initiatives. As of February 2024, the following actions were taken by global patent offices, further strengthening the Company's intellectual property assets:

- The Japanese Patent Office issued a Decision of Grant notifying GeoVax of the allowance of the Company's Patent Application No. 2022-153352 titled "Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen." The allowed claims are directed to recombinant MVA viral vectors comprising specific MUC-1 nucleic sequences used in GeoVax's MUC-1 tumor-associated antigen immunotherapy program. Pharmaceutical compositions for inducing immune responses, preventing or reducing neoplasm growth, or treating cancer are also covered by the granted claims.

- The U.S. Patent and Trademark Office issued Patent No. 11,896,657 to GeoVax, pursuant to the Company's patent application No. 17/584,231 titled "Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Marburg Virus Glycoprotein (GP) and Matrix Protein (VP40)." The allowed claims cover GeoVax's vector platform for expressing Marburg virus antigens in virus-like particles (VLPs) utilizing an MVA viral vector.
- The U.S. Patent and Trademark Office issued Patent No. 11,897,919 pursuant to the Company's patent application No. 17/409,574 titled "Multivalent HIV Vaccine Boost Compositions and Methods of Use." The allowed claims cover a priming vaccination with a DNA vector encoding multiple HIV antigens in virus-like particles (VLPs), followed by a boost vaccination with GeoVax's vector platform for expressing HIV-1 antigens in VLPs utilizing an MVA viral vector.
- On January 3, 2024, GeoVax announced that the U.S. Patent and Trademark Office has issued Patent No. 11,857,611 to GeoVax, pursuant to the Company's patent application No. 17/726,254 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." The claims granted by the patent cover compositions comprising GeoVax's modified vaccinia Ankara (MVA) vector expressing Plasmodium antigens and methods of inducing an immune response to malaria utilizing the compositions. The compositions and methods covered in the claims are useful both prophylactically and therapeutically and may be used to prevent and/or treat malaria.

POTENTIAL NEAR TERM MILESTONES

For 2024, the Company is focused on accelerating efforts in support of the Gedeptin and CM04S1 Phase 2 clinical programs, as well as advancing its MVA vaccine specific to Mpox and smallpox and to make further progress on its advanced MVA manufacturing system. Furthermore, GeoVax expects to continue to participate in various oncology conferences, some of which to present Gedeptin clinical data and others to conduct partnering discussions.

In 2024, the Company expects to report results from its CM04S1 Phase 2 programs, including results from the Healthy Volunteer Booster trial, complete enrollment and results from the Immunocompromised DLL trial, and conduct additional side initiations of further results from its Immunocompromised Stem Cell Transplant trial.

For Gedeptin in 2024, GeoVax expects to report results from the current trial and its plans for the expanded Phase 2 trial. The Company further expects to report plans regarding the next steps related to evaluating Gedeptin as combination therapy used in conjunction with immune checkpoint inhibitors.

Regarding GEO-MVA against Mpox and smallpox, GeoVax anticipates reporting its regulatory path and plans related to advancing that product towards registration. The Company expects to continue to provide updates related to its advanced MVA manufacturing process targeted to enable GeoVax to effectively produce and distribute MVA-based vaccines in response to real-time market needs.

RECENT COMPANY DEVELOPMENTS

- **February 29, 2024**—GeoVax Labs, Inc. announced its financial results and key operational accomplishments for the year ended December 31, 2023.
- **February 22, 2024**—Announced that the Company will report 2023 financial results on Thursday, February 29, 2024, after the close of U.S. markets. Following the release, management will host a live conference call and webcast, including Q&A, at 4:30 p.m. ET to provide a corporate update and discuss financial results.
- **February 19, 2024**—Announced that its Chairman and CEO, David Dodd, will present at the 2024 BIO CEO & Investor Conference, taking place in-person in New York, NY on February 26-27, 2024.
- **February 13, 2024**—Announced multiple actions by global patent offices, strengthening the Company's intellectual property assets, outlined on pages 5-6.
- **February 6, 2024**—Announced positive initial safety and immune response findings from its Phase 2 clinical trial at one month following administration of its COVID-19 vaccine, GEO-CM04S1. The trial, evaluating GEO-CM04S1 as a heterologous booster in sixty-three healthy adults who had previously received the Pfizer or Moderna mRNA vaccine (ClinicalTrials.gov Identifier: NCT04639466), was fully enrolled at the end of September 2023.
- **January 29, 2024**—Announced that the Company's Board of Directors has approved a reverse stock split of its issued and outstanding shares of common stock, par value \$0.001 per share at a ratio of 1-for-15. The Company is effecting the reverse split to regain compliance with the \$1.00 minimum bid price required for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). The reverse stock split was approved by GeoVax's stockholders at a meeting held January 16, 2024. The reverse stock split became effective on January 30, 2024, and the Common began trading on the split-adjusted basis on the Nasdaq Stock Exchange at the market open on January 31, 2024.
- **January 8, 2024**—Announced the appointment of J. Marc Pipas, M.D., to serve as the Company's Executive Medical Director, Oncology. Dr. Pipas has extensive clinical, research, and leadership expertise in oncology, built on a long and successful academic career at Dartmouth-Hitchcock Medical Center/Norris Cotton Cancer Center, an NCI Comprehensive Cancer Center.
- **January 4, 2024**—Announced the closure of patient enrollment for the Phase 1/2 clinical study evaluating Gedeptin in patients suffering from advanced head and neck cancer. Completion of this trial will be a significant milestone in the Company's Gedeptin clinical development program. Allowing time for the maximum number of cycles of Gedeptin therapy and patient follow-up, GeoVax expects to complete the study by the third quarter of this year. In the interim, the Company is in active discussions with advisors on protocol development in support of a follow-on Phase 2 or Phase 2/3 trial among patients with advanced head and neck cancer in whom current therapeutic options are suboptimal. The intent is to discuss this follow-on protocol with the FDA, in conjunction with a complete review of the results of the current trial, to ensure alignment with the regulator's expectations.
- **January 3, 2024**—Announced that the U.S. Patent and Trademark Office has issued Patent No. 11,857,611 to GeoVax, pursuant to the Company's patent application No. 17/726,254 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." The claims granted by the patent cover compositions comprising GeoVax's MVA vector expressing Plasmodium antigens and methods of inducing an immune response to malaria utilizing the compositions. The compositions and methods covered in the claims are useful both prophylactically and therapeutically and may be used to prevent and/or treat malaria.
- **December 27, 2023**—Announced that David Dodd, Chief Executive Officer, will present at the Biotech Showcase coinciding with the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco, January 8-11, 2024. Additionally, senior management of GeoVax will be available for one-on-one meetings during the week with potential partners, collaborators, and investors.

- **December 19, 2023**—Announced that the Company has amended a previously executed Patent and Biological Materials License Agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), in support of GeoVax’s development of a vaccine against SARS-CoV-2 (COVID-19). The amendment expands GeoVax’s commercial license to include Mpox and smallpox as additional indications. The License Agreement, as amended, allows GeoVax to use these materials and patent rights owned by agencies of the United States Department of Health and Human Services (HHS) in combination with the Company’s proprietary technology for the creation of preventive Modified Vaccinia Ankara Virus-Virus Like Particle (MVA-VLP) vaccines that prime and/or boost the immune system against SARS-CoV-2 (the virus that causes COVID-19) as well as Mpox and/or smallpox. Financial terms of the License Agreement were not disclosed.
- **November 30, 2023**—Announced the presentation of data from recent preclinical studies of its vaccine candidates against Marburg virus and Sudan virus. The data were presented during the World Vaccine Congress, West Coast conference, being held in Santa Clara, CA from November 27-30, 2023. The presentation, titled “Design and evaluation of vaccines against hemorrhagic fevers using the MVA-VLP platform,” was delivered by Jason Comer, Ph.D., Associate Professor, Department of Microbiology and Immunology, University of Texas Medical Branch at Galveston (UTMB).
- **November 29, 2023**—Announced that GeoVax’s senior management will participate in two upcoming investor events: NobleCon19, December 3-5, 2023, Boca Raton, FL; and Emerging Growth Conference, December 6-7, 2023, Virtual.
- **November 28, 2023**—Announced the presentation of data from the active development program for its next-generation COVID-19 vaccine (GEO-CM04S1), including Phase 2 clinical trial data. The data include some of which was recently published in the journal *Vaccines*. The data were presented during the World Vaccine Congress, West Coast conference, being held in Santa Clara, CA from November 27-30, 2023. The presentation, titled “COVID-19 Vaccines for Immunocompromised Patients,” was delivered by Don Diamond, PhD, Professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope Comprehensive Cancer Center.
- **November 14, 2023**—Announced the presentation of preclinical vaccine efficacy data for GEO-CM02, a multi-antigen investigational SARS-CoV-2 vaccine. The data were presented during the Vaccines Summit 2023 conference, being held in Boston, MA on November 13-15, 2023. The presentation, titled “MVA-vectored multi-antigen COVID-19 vaccines induce protective immunity against SARS-CoV-2 variants spanning Alpha to Omicron in preclinical animal models,” was delivered by Mukesh Kumar, PhD, Associate Professor, Department of Biology, Georgia State University.

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, both clinical stage as well as preclinical stage, are focused within the areas summarized in Figure 1.

Figure 1
GEOVAX PIPELINE: CLINICAL DEVELOPMENT PROGRAMS

Product	Indication	Trial	Status
GEO-CM04S1	Covid-19	Primary Vaccine For Immunocompromised Blood Cancer Patients (NCT04977024)	Phase 2
		Booster Vaccine vs mRNA For Chronic Lymphocytic Leukemia Patients (NCT05672355)	Phase 2
		Booster Vaccine vs mRNA Among Healthy Volunteers (NCT04639466)	Fully Enrolled
Gedeptin®	Advanced Head & Neck Cancer	Effect on Targeted Tumors (NCT03754933)	Fully Enrolled

GEOVAX PIPELINE: PRECLINICAL DEVELOPMENT PROGRAMS

Product	Target	Completion Testing Status
GEO-MVA-MUC1	Solid Tumor Cancers	Mice
GEO-EM01 - Z	Vaccine for Ebola Zaire	Non-Human Primate
GEO-EM01 - S	Vaccine for Ebola Sudan	Non-Human Primate
GEO-MM01	Vaccine for Marburg	Non-Human Primate
GEO-ZM02	Vaccine for Zika Flavivirus	Mice

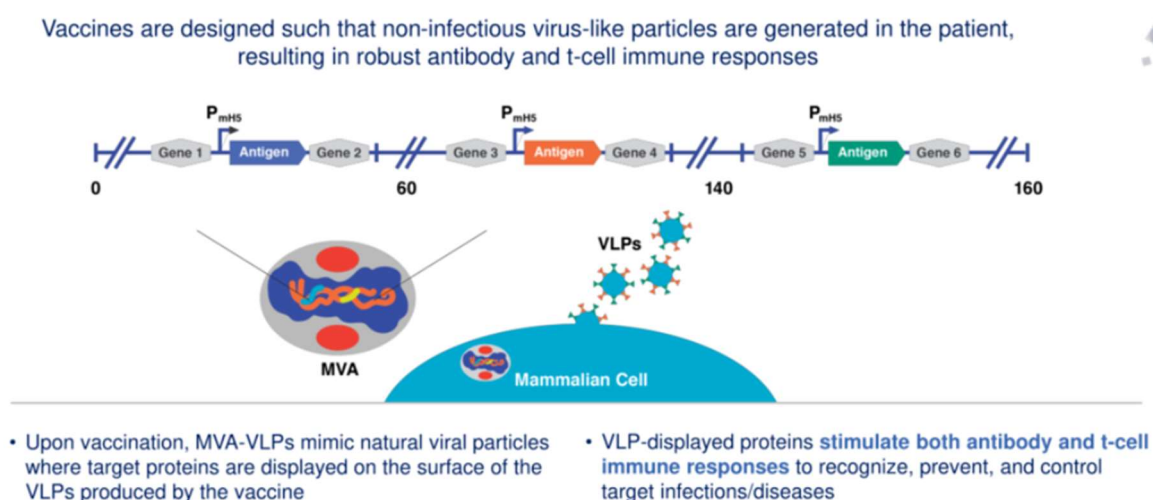
Source: GeoVax Labs, Inc.

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 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 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. GeoVax's technology drives the production of VLPs in the body of the person being vaccinated (*in vivo*), thus 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 GeoVax's HIV vaccines has 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 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 select 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 for Solid Tumor Cancers

The Company uses its GV-MVA-VLP vaccine platform to express abnormal, aberrantly glycosylated forms of the cell surface-associated MUC1 protein that is associated with 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.

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 2024, more than 774 million cases have been reported worldwide, resulting in over seven million deaths. In the U.S. there has been 111 million cases and 1.2 million 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 12) summarizes key elements of the Company's COVID-19 vaccine technology.

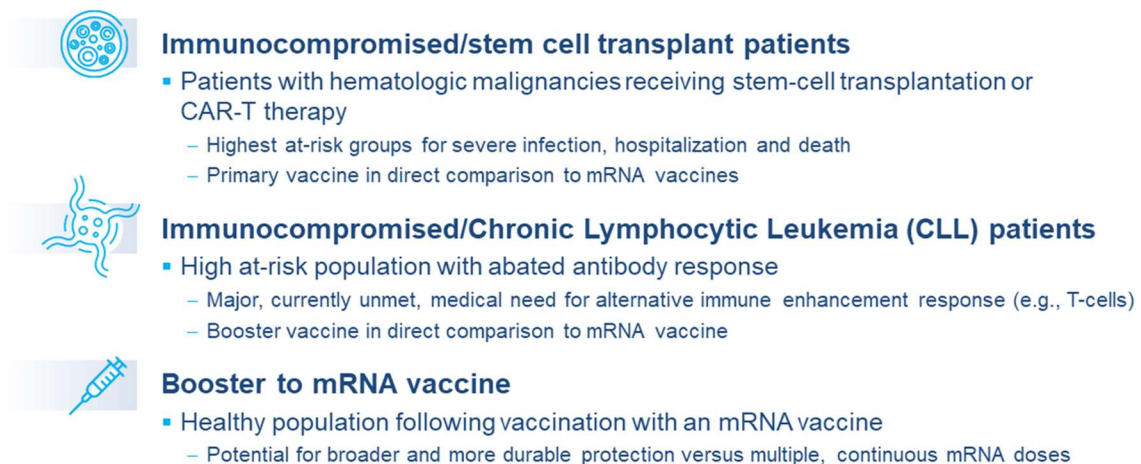
The experimental COVID-19 vaccine, using the Company's MVA-VLP technology, encodes the S protein, which is the basis for all the first-generation products in use today and the targeted neutralizing antibodies. This is used in combination with the membrane (M protein) and the envelop (E protein). The M and E proteins provide the structural components required for the VLP formation in the body. They 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.

GEO-CM04S1

GEO-CM04S1, the Company's next-generation COVID-19 vaccine, aims to provide a more practical public health friendly COVID-19 vaccine solution than with currently approved vaccines. It expects to do this by stimulating a robust and durable immune response across multiple virus variants because of targeting both the antibody and cellular arms of the immune system and using a proven safe and efficient replication-deficient vaccine delivery pathway. This is critically important in addressing the high-risk populations of immune compromised individuals for whom the current vaccines in monoclonal antibody therapies are inadequate. The immune profile generated following receipt of GEO-CM04S1 also positions it well for more widespread use as a heterologous booster to current mRNA vaccines, providing a more robust durable functional response against emerging variants, potentially without the need for the continuous vaccine reconfiguration that appears necessary with the mRNA vaccines.

As summarized in Figure 3, there are currently three Phase 2 clinical trials underway with GEO-CM04S1, two of which address the high-risk populations of immunocompromised patients; the other Phase 2 trial is evaluating GeoVax's vaccine as a booster following prior receipt of an mRNA vaccine. The Company expects to demonstrate that its COVID-19 vaccine addresses the current unmet needs among the millions of immunocompromised patients while also demonstrating it as a more robust, durable universal booster for the current authorized vaccines.

Figure 3
GEO-CM04S1: PHASE 2 CLINICAL TRIALS



Source: GeoVax Labs, Inc.

In September 2023, the Company completed enrollment in its Phase 2 trial assessing CM04S1 as the booster for the mRNA vaccines. This trial involves sixty-three healthy adults who had previously received the Pfizer or Moderna mRNA vaccine. The immunological responses measured throughout the study include both neutralizing antibodies against SARS-CoV-2 variants and specific T cell responses. In February 2024, the Company reported positive interim data from this trial, indicating no serious adverse events and statistically significant increases in neutralizing antibodies against multiple SARS-CoV-2 variants ranging from the original Wuhan strain through Delta in the highly virulent Omicron SBB 1.5, as well as demonstrating robust cellular immune responses. Additional testing against the current variant of concern, the JN 1 variant is currently underway. Results from this trial are anticipated during the fourth quarter 2024, reflecting the 12-month monitoring of these patients.

Worldwide, there are an estimated 240 million plus individuals, including those with various blood cancers, renal disease, autoimmune diseases such as lupus, which includes transplant patients and others with disease or therapy-induced immunosuppression. Many of these patients are limited in their ability to respond adequately to the approved mRNA vaccine, placing them at significantly increased risk of severe COVID-19 infection hospitalization and potential death. It was reported in February's edition of *JAMA* that the number of immunocompromised adults in the U.S. has been updated, indicating a population of twenty-three million versus the previous estimate of fifteen million.

During 2023, initial data from stem cell transplant trial was presented at several international conferences, including the World Vaccine Congress in Washington, D.C. In addition, results were published in the peer-reviewed journal *Vaccines*. These findings demonstrated robust immunogenicity, illustrating the vaccine ability to strongly induce both antibody and T-cell responses essential for confirming protection, particularly in immunocompromised individuals. The *Vaccines* article also highlighted the unique feature of CM04S1, providing protective immune levels from the ancestral Wuhan strain through the Omicron XBB1.5 variant. Initial patient enrollments into this trial occurred at the City of Hope Medical Center in California.

Following the initiation of patient enrollment in the immunocompromised CLL in August 2023, this investigator-initiated trials continue to recruit and enroll patients more recently expanding to additional City of Hope locations. The trial is designed to evaluate CM04S1 among approximately 80 CLL patients directly comparing with the Pfizer-BioNTech mRNA vaccine. Typically, these patients are unable to generate adequate levels of protective antibodies following mRNA vaccination due to their underlying hematologic malignancy, placing them at extreme risk of developing clinically severe COVID-19. Consequently, many of these patients remain homebound more than three years since the pandemic began. Results from an interim analysis of the ongoing trial are anticipated during the first half 2024. Relative developing CM04S1 immunocompromised patients, GeoVax believes that an opportunity exists for an expedited regulatory path due to the Company's focus on such high-risk unserved populations.

In addition to the patients initially enrolled from City of Hope, there are now four additional sites actively recruiting patients in the Phase 2 trial. The four expansion sites include the Fred Hutchinson Cancer Center in Seattle, University of Massachusetts Medical Center in Worcester, Mass, Wake Forest Baptist Medical Center in Winston-Salem North Carolina, and Eastern Carolina Medical Center in Benson, North Carolina. While currently focused on optimizing patient enrollment from these sites, GeoVax has seen considerable interest, both domestically and internationally and participating in this clinical study.

Project NextGen

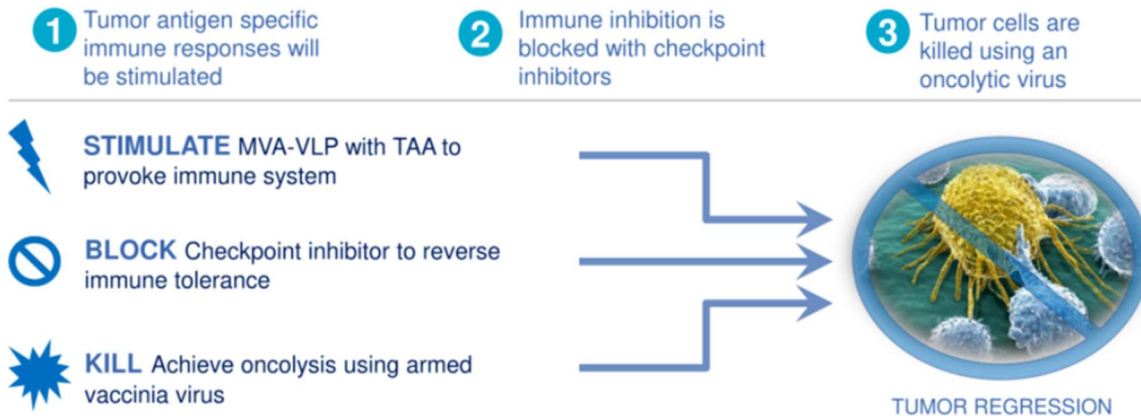
In April 2023, the White House announced a \$5 billion initiative to follow on from operation Warp Speed, seeking COVID-19 vaccines with enhanced breadth of protection against variants and improved durability, particularly in novel vaccine candidates already in clinical trials. GeoVax continues to be in active discussions related to formal participation in this program. Of the \$5 billion set aside for funding, there remains over \$3 billion still to be awarded. The Company anticipates partnering and collaborating on additional clinical and research efforts in support of worldwide commercialization and distribution of CM04S1.

Cancer Immunotherapy Vaccine Program

GeoVax is additionally developing the next generation of immunotherapies to address unmet medical needs in cancer (Figure 4, page 14). 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 as well as 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

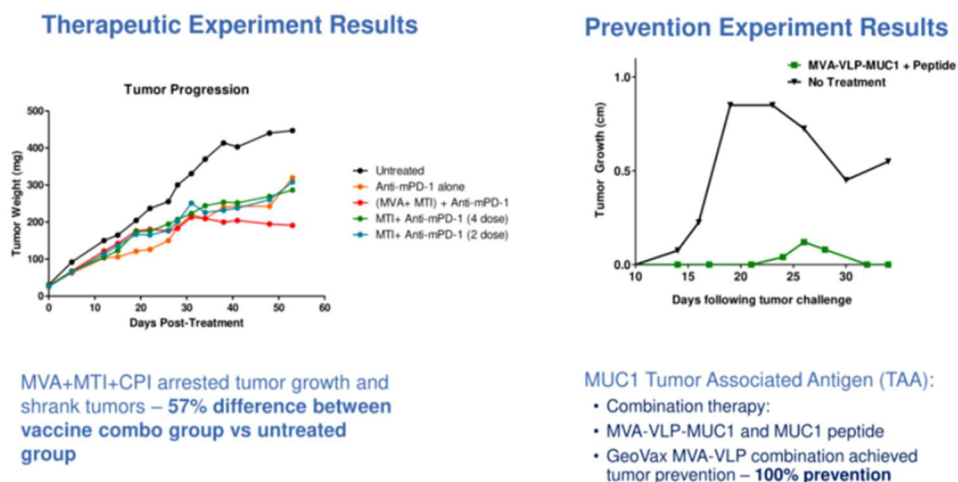
Triple-threat Approach:



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, GeoVax has 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 that 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 provided almost 100% protection against tumors recurring.

Figure 5
IMMUNONCOLOGY RESULTS



Source: GeoVax Labs, Inc.

Gedepitin

In 2023, GeoVax announced the closure of enrollment for its Phase 1/2 trial of Gedepitin among advanced head and neck cancer patients. This initial targeted patient population represents those who are in end-stage care—the 15,000 U.S. and 400,000 worldwide of patients, which represents a critical unmet medical need. Many of these patients are unable to swallow food and have difficulty speaking, and they typically have exhausted existing therapies and standard of care and are receiving palliative care. GeoVax seeks to provide an improved end-stage quality of life in these patients by shrinking and/or eliminating various targeted tumors and to provide clinical evidence supporting advancement of this therapy in earlier-stage disease. This trial was funded by the FDA under the Orphan Drugs clinical trials program, with initial clinical data results presented at the AACR AHNS Conference in Montreal in July 2023. That presentation noted that administration of Gedepitin was shown to be safe and feasible reflecting stabilization and/or reduction in size of treated tumors. Results from this trial are expected during the first half 2024, followed by discussing the Company's plans for further evaluation in patients with advanced head and neck cancer.

The Company seeks to also consider Gedepitin therapy for earlier-stage head and neck squamous cell carcinoma (HNSCC) with less tumor burden, including a role like neoadjuvant or cytoreductive radiotherapy in combination with checkpoint blockade inhibition. GeoVax further anticipates discussions with the FDA during 2024 related to an expedited path to registration. The vast array of unmet medical needs within oncology represents significant opportunities for GeoVax to advance novel approaches, addressing various cancer patient needs worldwide.

The Company refers to Gedepitin as tumor-agnostic, as its mechanism of action enables the ability to address a variety of solid tumors, both cancerous and benign. The Company holds worldwide rights for all indications of this technology and participates in various oncology and partnering conferences.

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

During the quarter, GeoVax announced the presentation of data from recent preclinical studies of its vaccine candidates against Marburg virus and Sudan virus. The data were presented during the World Vaccine Congress, West Coast conference, being held in Santa Clara, CA from November 27-30, 2023. The presentation, titled "Design and evaluation of vaccines against hemorrhagic fevers using the MVA-VLP platform," was delivered by Jason Comer, Ph.D., Associate Professor, Department of Microbiology and Immunology, University of Texas Medical Branch at Galveston (UTMB).

The Company reported that it was highly encouraged by the results of its MARV vaccine candidate studies. It is also important to note that, by virtue of the MVA vector utilized in the design of this vaccine, it also provides the potential to protect against Mpox ("Monkeypox"), which is critically important in many regions of the world where MARV and other Ebola outbreaks occur.

In this presentation, Dr. Comer discussed UTMB's services for regulated, nonclinical studies, and presented information about the Filoviridae family of viruses which include, among others, Ebola virus (EBOV), Sudan virus (SUDV) and Marburg virus (MARV). Of particular interest, immunization with GeoVax's MARV vaccine candidate (MVA-VLP-MARV) conferred 80% survival in cynomolgus macaques following a challenge with a lethal dose of MARV. Vaccination protected nonhuman primates from viremia, weight loss, and death. Evaluation of immune responses following vaccination demonstrated the presence of both neutralizing antibodies and functional T cells, indicating a breadth of responses that combine for optimal protection.

The work conducted by UTMB built upon earlier studies demonstrating that guinea pigs vaccinated with MVA-VLP-MARV were 100% protected against death and disease caused by the Angola strain of MARV. The vaccine induced immune responses were characterized by MARV-specific binding and neutralizing antibodies as well as other effector functions like antibody-dependent phagocytosis. The Angola strain is the most virulent strain of MARV characterized by a fatality rate of up to 90% in humans.

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.

GeoVax is committed to supporting the successful advancement of vaccines against lethal hemorrhagic fever viruses such as Marburg virus, as the Company recognizes the critically important medical and biodefense need, reflected by the inclusion of Marburg virus in the FDA Priority Review Voucher program.

Modified Vaccinia Ankara (MVA) and Mpox

The vaccine used and stockpiled for immunization against Mpox is MVA, which is also the vaccine vector utilized in numerous GeoVax vaccines targeting COVID-19, Hemorrhagic fever viruses (e.g., Sudan ebolavirus and Zaire ebolavirus), HIV, Zika, and the GeoVax MVA-VLP-MUC1 cancer immunotherapy. Evaluation is currently underway related to GEO-CM04S1 in preventing Mpox. It is anticipated that the results will demonstrate successful protection, validating that GEO-CM04S1 is protective against both COVID-19 and Mpox. GeoVax also anticipates validating its hemorrhagic fever virus vaccines as protective against Mpox, potentially providing unique vaccines preventing both hemorrhagic fever virus and Mpox virus in a single vaccine. MVA (against Mpox and smallpox) is intended to disrupt an existing global monopoly in that key area, providing GeoVax a leadership position as the first U.S.-based supplier of such a vaccine.

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 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. Worldwide, as of 2022, malaria causes 249 million infections and 608,000 deaths annually (mostly in children living in sub-Saharan Africa).

Despite decades of vaccine research, vaccine candidates have failed to induce substantial protection (e.g., >50%). Most of these vaccines are based on individual proteins that induce immune responses targeting only one stage of the malaria parasite's life cycle. GeoVax's MVA-VLP malaria vaccine candidates incorporate antigens derived from multiple stages of the parasite's life cycle and are designed to induce an immune response with durable functional antibodies and CD4+ and CD8+ T cell responses—all features of an ideal vaccine-induced immune response.

In January 2024, GeoVax announced that the U.S. Patent and Trademark Office has issued Patent No. 11,857,611 to GeoVax, pursuant to the Company's patent application No. 17/726,254 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." The claims granted by the patent cover compositions comprising GeoVax's modified vaccinia Ankara (MVA) vector expressing Plasmodium antigens and methods of inducing an immune response to malaria utilizing the compositions. The compositions and methods covered in the claims are useful both prophylactically and therapeutically and may be used to prevent and/or treat malaria.

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 infectious disease and cancer immunotherapy programs, and a lack of continuing government support for its HIV vaccine development efforts, GeoVax has discontinued 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. While not currently under active development, the Company's HIV program forms an important part of the dataset underpinning all of GeoVax's MVA-based development programs. The patent protection associated with this vaccine is an important part of this technology platform.

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 115 granted or pending patent applications spread over twenty-four 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, CRA has 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 their 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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