Company Description

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing next-generation vaccines and immunotherapies for serious infectious diseases and solid tumor cancers. Its lead candidate, GEO-CM04S1, is a multi-antigen COVID-19 vaccine designed to provide broader, longer-lasting protection—especially for immunocompromised individuals. Currently in three Phase 2 trials, GEO-CM04S1 is being studied in healthy adults, Chronic Lymphocytic Leukemia (CLL) patients, and those undergoing stem cell transplant or CAR-T therapy. Although the BARDA-funded Phase 2b trial under Project NextGen ended due to external shifts, GeoVax continues to advance the program, driven by strong interim data and unmet global need. In oncology, GeoVax is advancing Gedeptin®, a gene-directed therapy for solid tumors, into a planned Phase 2 trial for recurrent head and neck cancer, alongside preclinical studies in other tumor types. GEO-MVA, the Company's Mpox and smallpox vaccine candidate, is expected to enter clinical trials in late 2025, addressing global biosecurity risks and vaccine access gaps. Backed by global rights, a robust intellectual property (IP) portfolio, and scalable manufacturing capabilities, GeoVax is supported by an experienced management team with proven success in product development and commercialization.

Key Points

- On May 1, GeoVax announced its Q1 2025 results, reporting a net loss of $5.4 million for the quarter ended March 31, 2025, compared to a $5.9 million loss in the same period of 2024.
- In April 2025, BARDA issued a stop-work order on GeoVax's planned Phase 2b trial under Project NextGen due to shifting priorities. The award, granted in June 2024, was intended to evaluate GEO-CM04S1 in 10,000 participants. While the program was discontinued, the award affirmed external confidence in GEO-CM04S1's promise as a next-generation COVID-19 booster, particularly for immunocompromised individuals. Notably, GEO-CM04S1 was the only dual-antigen COVID-19 vaccine selected under the initiative—highlighting its distinct positioning and public health relevance. It should also be noted that the BARDA termination has no impact on GeoVax's ongoing clinical trials of GEO-CM04S1, primarily addressing immunocompromised patient populations.
- In oncology, GeoVax is preparing a Phase 2 trial of Gedeptin® for recurrent head and neck cancer, in combination with an immune checkpoint inhibitor, with planning and clinical material production underway.
- GeoVax is also advancing GEO-MVA, its Mpox and smallpox vaccine candidate, with clinical trials expected to begin in late 2025. Developed in response to rising health threats, including WHO's Mpox emergency declaration, GEO-MVA is designed to enhance global pandemic preparedness and provide a U.S.-sourced alternative amid limited international supply. The Company is also investing in domestic manufacturing to support rapid response and strengthen national biosecurity.
- GeoVax is leveraging AI to optimize clinical development, streamline manufacturing, and improve regulatory and supply chain efficiency. These tools are being used to enhance protocol design, accelerate trial analytics, and optimize manufacturing forecasting.
- GeoVax holds more than 130 granted or pending patents across 23 families, providing broad protection for its pipeline and platform technologies.
- As of March 31, 2025, the Company reported cash balances of $7.4 million, up from $5.5 million as of December 31, 2024.

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GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (05/07/2025)	$0.93
52-week Range	$0.73-11.18
Shares Outstanding	15.49 mm
Market Capitalization	$14.40 mm
Avg. Volume	541,367
EPS (Yr ended 03/31/2025)	($0.45)
Employees	19

See page 14 for applicable disclosures.

FIRST QUARTER 2025 FINANCIAL RESULTS

GeoVax reported a net loss of $5.4 million or ($0.45) per share for the year quarter March 31, 2025, compared with a net loss of $5.9 million or ($2.47) per share for three months ended March 31, 2024.

For the three months ended March 31, 2025, the Company reported $1.6 million in government contract revenue related to the BARDA/RRPV Project NextGen award, compared to no revenue during the same period in 2024.

Research and development expenses totaled $5.4 million for the three months ended March 31, 2025, up from $4.4 million in the same period of 2024. The increase was primarily driven by costs related to the BARDA/RRPV Project NextGen award, as well as the Gedeptin and GEO-MVA programs.

General and administrative expenses were $1.7 million for the three months ending March 31, 2025, compared to $1.5 million in the same period of 2024. The increase was mainly attributable to higher costs for investor relations consulting and stock-based compensation.

As of March 31, 2025, GeoVax reported cash balances of $7.4 million, up from $5.5 million as of December 31, 2024. Noteworthy is that in March 2025, GeoVax entered a securities purchase agreement with a healthcare-focused institutional investor, raising funds through a registered direct offering of common stock and accompanying warrants.

The Company remains committed to advancing innovative cancer therapies and infectious disease vaccines, with a focus on addressing critical unmet medical needs and prioritizing initial indications that offer accelerated regulatory approval pathways.

RECENT BUSINESS ACCOMPLISHMENTS

GEO-CM04S1: Next-Generation COVID-19 Vaccine Program

GeoVax's GEO-CM04S1 vaccine candidate continues to show promise as both a primary and booster COVID-19 vaccine, particularly for immunocompromised individuals. GEO-CM04S1 is a multi-antigen COVID-19 vaccine based on the synthetic MVA platform, expressing both S and N antigens for potentially broader and more durable immune protection than current mRNA vaccines. Several key developments are expected in 2025:

- ***Healthy Adult Booster Trial***. Enrollment has been completed, with a data readout anticipated in Q2 2025.

- ***Chronic Lymphocytic Leukemia (CLL) Study.*** Enrollment is ongoing in this Phase 2 trial evaluating GEO-CM04S1 as a booster in immunocompromised patients. Interim results supported continuation of the GEO-CM04S1 arm, while the Data Safety Review Board recommended early termination of the mRNA comparator arm.

- ***Stem Cell Transplant/CAR-T Study.*** Enrollment and evaluation continue in this trial for hematological patients receiving stem cell transplants or CAR-T therapy, comparing GEO-CM04S1 to mRNA-based vaccines.

In April 2025, a peer-reviewed article published in *Vaccines (MDPI)* titled "Preclinical Evaluation of a Multi-Antigen SARS-CoV-2 Vaccine Candidate GEO-CM02" highlighted the advantages of GeoVax's multi-antigen approach and further validated the design of GEO-CM04S1. The publication supports the need for next-generation vaccines that deliver broader, longer-lasting protection. GEO-CM04S1 targets a substantial global market opportunity estimated at over $30 billion.

Additionally, at the April World Vaccine Congress, GeoVax presented strong clinical data on GEO-CM04S1, showing robust antibody and T cell responses in both healthy and immunocompromised patients. In a Phase 2 trial, it outperformed Pfizer's Comirnaty® in CLL patients, prompting the DSMB to halt the Pfizer arm. The vaccine was well tolerated and highlights the promise of GeoVax's dual-antigen approach for underserved populations.

Gedeptin®: Gene-Directed Oncolytic Therapy for Solid Tumors

GeoVax is preparing to advance its Gedeptin® oncology program into a Phase 2 clinical trial for first recurrent head and neck (H&N) cancer, in combination with an immune checkpoint inhibitor. Gedeptin has been granted Orphan Drug designation for the treatment of advanced head and neck cancer, highlighting its potential in addressing critical unmet medical needs. Beyond head and neck cancer, the technology also shows promise for treating other solid tumors, including triple-negative breast cancer, melanoma, and soft tissue sarcoma. The global market potential for Gedeptin in head and neck cancer alone is estimated to exceed $15 billion.

At the April 2025 AACR Annual Meeting, GeoVax presented positive clinical data on Gedeptin® for advanced head and neck cancer. The study showed stable disease in several heavily pretreated patients, with a median survival of 7.0 months and no dose-limiting toxicities. Building on these results, GeoVax plans a Phase 2 trial combining Gedeptin with Keytruda® to enhance immune response and treatment efficacy.

GEO-MVA: Mpox and Smallpox Vaccine Platform

GeoVax plans to begin clinical trials in 2025 for GEO-MVA, its Mpox and smallpox vaccine candidate, aimed at enhancing global vaccine equity and strengthening biosecurity. The Company has successfully manufactured cGMP clinical material and is finalizing vialing in preparation for clinical evaluation in the second half of 2025. GEO-MVA offers a U.S.-developed alternative to foreign-sourced vaccines, addressing growing concerns around global supply constraints and emerging biosecurity threats. The global market opportunity for GEO-MVA is estimated to exceed $10 billion.

Vaccine Manufacturing Process Development

GeoVax is progressing the development of a continuous cell line manufacturing process for its MVA-based vaccines, enabling scalable and cost-efficient production. This approach supports the potential for localized manufacturing in low- and middle-income countries, helping to close critical gaps in vaccine self-sufficiency and strengthen global supply chain resilience.

Corporate and Intellectual Property Developments

GeoVax announced plans to establish a strategic presence in the United Kingdom to support manufacturing partnerships, foster collaborations with European service providers and academic institutions, explore technology licensing opportunities, and leverage regional scientific expertise.

The Company also continued to strengthen its intellectual property portfolio, with multiple advancements across global patent offices. As of year-end, GeoVax holds over 130 granted or pending patents spanning 23 distinct patent families, underscoring its commitment to innovation and long-term value creation.

Additionally, on April 21, 2025, Dr. Senthil Ranganathan joined the Company as Vice President of Technical Development & CMC Operations, marking a key step forward in advancing GeoVax's product authorization and commercialization efforts.

GeoVax anticipates significant revenue potential from its cancer and infectious disease portfolio, with upcoming clinical milestones and partnership opportunities expected to add to shareholder value.

RECENT COMPANY DEVELOPMENTS

May 1, 2025—Announced its financial results and key operational accomplishments for the quarter ended March 31, 2025.

April 29, 2025—Announced the presentation of new clinical data on its gene-directed enzyme prodrug therapy, Gedeptin®, at the American Association for Cancer Research (AACR) Annual Meeting 2025, being held April 25-30 in Chicago, IL.

April 24, 2025—Recapped the successful presentation of new clinical data on its multi-antigen SARS-CoV-2 vaccine candidate, GEO-CM04S1, delivered at the 25th Annual World Vaccine Congress in Washington, D.C.

April 23, 2025—Announced that it will report first quarter 2025 financial results on Thursday, May 1, 2025, 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.

April 22, 2025—Announced the appointment of Senthil Ranganathan, Ph.D. as Vice President, Technical Development and CMC Operations. Dr. Ranganathan brings over 20 years of experience in biologics development to commercialization across vaccines, cell and gene therapies, monoclonal antibodies, and viral vector products.

April 16, 2025—Announced the publication of a peer-reviewed study in *Vaccines (MDPI)* showcasing strong preclinical data for its multi-antigen COVID-19 vaccine candidate, GEO-CM02. The study, led by Dr. Mukesh Kumar of Georgia State University, demonstrated that GEO-CM02, based on the MVA platform, offers broader and more durable protection against SARS-CoV-2 variants than traditional spike-only vaccines. These findings support GeoVax's lead clinical candidate, GEO-CM04S1, now in Phase 2 trials targeting immunocompromised patients.

April 16, 2025—Addressed the termination of its Project NextGen (PNG) award by the Biomedical Advanced Research and Development Authority (BARDA), effective April 11, 2025. The Company also provided a comprehensive business update across its core programs, including the next-generation COVID-19 vaccine (GEO-CM04S1), cancer immunotherapy (Gedeptin®), Mpox/smallpox vaccine (GEO-MVA), and advanced MVA manufacturing process.

On April 15, 2025—Announced its participation in the World Vaccine Congress held from April 22–24, 2025, in Washington, DC. On April 24, at 10:25 a.m. EDT in Room 207A, Dr. Don J. Diamond, Director of the Division of Vaccine Research at City of Hope Comprehensive Cancer Center, presented Phase 2b study results comparing GeoVax's multi-antigen vaccine candidate, GEO-CM04S1, to an approved COVID-19 vaccine.

April 9, 2025—Announced that the U.S. Patent and Trademark Office (USPTO) has issued a Notice of Allowance for Patent Application No. 18/394,555 titled "*Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Marburg Virus Glycoprotein (GP) and Matrix Protein (VP40).*" The allowed claims generally cover prevention of Marburg virus infection utilizing GeoVax's proprietary MVA-based Marburg vaccine.

April 1, 2025—GeoVax recently had the opportunity to participate in a webinar, "MPOX 2025: Navigating the Global Public Health Emergency", sponsored by Vista Partners/Tribe Public. In the Tribe Public webinar (available on YouTube), GeoVax's CEO, David Dodd, outlined the urgent global threat posed by a new, deadlier strain of Mpox, now declared a Public Health Emergency of International Concern by the WHO. GeoVax is advancing its GEO-MVA vaccine, built on its proven MVA platform, which also inherently protects against smallpox. With clinical-grade doses manufactured and vialing underway, the Company is targeting emergency use authorization and broader global access, especially in Africa where vaccine demand far exceeds supply.

POTENTIAL NEAR TEM MILESTONES

GEO-CM04S1 (Next-Generation COVID-19 Vaccine)

- ***BARDA Project NextGen Phase 2b Trial.*** In April 2025, GeoVax received a stop-work order from BARDA, leading to the termination of the Project NextGen Phase 2b trial for GEO-CM04S1. Despite this setback, GeoVax remains committed to advancing GEO-CM04S1, focusing on its potential to provide robust immune responses, especially in immunocompromised populations.

- ***Healthy Adult Booster Trial.*** Enrollment is complete, with data readouts expected in the first half of 2025.

- ***CLL Patient Study.*** Enrollment is ongoing in the Phase 2 study evaluating GEO-CM04S1 as a COVID-19 booster vaccine for immunocompromised patients. Interim data led to the continuation of the GEO-CM04S1 arm, while the mRNA arm was terminated based on recommendations from the Data Safety Review Board.

- ***Scientific Presentations.*** GeoVax plans to present results from its COVID-19 vaccine program at several major conferences in 2025, including the European Hematology Association and the International Workshop on Chronic Lymphocytic Leukemia.

GEO-MVA (Mpox and Smallpox Vaccine Candidate)

- ***Clinical Trial Initiation.*** GeoVax anticipates initiating clinical trials for GEO-MVA in the second half of 2025, enrolling approximately 400 participants across Europe and Sub-Saharan Africa. The Company has successfully produced cGMP clinical product and is completing vaccine vialing to support the clinical evaluation.

- ***Global Engagement.*** GeoVax is actively engaged with WHO, Africa CDC, and UNICEF to explore emergency use and equitable access pathways for GEO-MVA.

Gedeptin® (Oncology Program)

- ***Phase 2 Oncology Trial.*** GeoVax plans to initiate a Phase 2 trial of Gedeptin® in mid-to-late 2025, evaluating it in combination with an immune checkpoint inhibitor for recurrent head and neck cancer.

- ***Scientific Presentations.*** New data from the Gedeptin® program were presented at the American Association for Cancer Research (AACR) conference in April 2025.

Manufacturing and Strategic Partnerships

- ***Advanced MVA Process.*** GeoVax is implementing its advanced MVA manufacturing platform designed for scalable, decentralized, and cost-effective vaccine production, including localized manufacturing for low- and middle-income countries.

- **Strategic Presence in the UK:** The Company announced plans to establish a strategic presence in the United Kingdom to advance manufacturing partnerships, European collaborations with service providers and academic partners, technology licensing opportunities, and scientific expertise.

Despite the termination of the BARDA Project NextGen award, GeoVax anticipates a milestone-rich 2025 across its portfolio, continuing to engage with government and industry partners, pursuing clinical trial completions, and driving innovation through expanded AI integration to optimize development, trial operations, and manufacturing efficiency.

The Company is also actively engaging with global health organizations—including WHO, Africa CDC, and UNICEF—to explore international access and emergency use pathways for GEO-MVA, supporting pandemic preparedness in regions with limited vaccine supply.

Company Background

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human cancer therapies and vaccines for infectious diseases, with a focus on high-impact indications and unmet medical needs. The Company's programs leverage two key proprietary platforms: its Modified Vaccinia Ankara (MVA) vector vaccine technology and its patented Gedeptin® gene-directed enzyme prodrug therapy for solid tumors. The MVA platform enables delivery of multiple vaccine antigens using a replication-defective live vector that expresses virus-like particles (VLPs) in vivo. These VLPs mimic natural infection, triggering robust and durable immune responses by engaging both the humoral and cellular arms of the immune system.

GeoVax's infectious disease portfolio includes clinical-stage candidates such as GEO-CM04S1, a next-generation, multi-antigen COVID-19 vaccine currently in multiple Phase 2 trials, and GEO-MVA, an Mpox/smallpox vaccine preparing for clinical evaluation in 2025. In oncology, the Company is advancing Gedeptin® into a planned Phase 2 trial for recurrent head and neck cancer in combination with an immune checkpoint inhibitor, with preclinical studies underway to expand into additional solid tumors. GeoVax holds worldwide rights to its platforms and product candidates and is supported by a growing IP portfolio and scalable manufacturing capabilities. The Company's development efforts are summarized in Figure 1 (page 7).

Figure 1

GEOVAX PIPELINE: CLINICAL DEVELOPMENT PROGRAMS

Product	Indication	Trial	Status
GEO-CM04S1	COVID-19	Primary Vaccine for: Immunocompromised/Stem Cell Transplant Patients (NCT04977024)	Phase 2 Currently Enrolling
		Booster Vaccine for: Immunocompromised/Chronic Lymphocytic Leukemia Patients (NCT05672355)	Phase 2 Currently Enrolling
		Booster Vaccine for: Healthy Adult Patients (NCT04639466)	Phase 2 Enrollment Closed
Gedeptin®	Advanced Head & Neck Cancer	Effect on Targeted Tumors (NCT03754933)	Phase 1/2 Enrollment Closed
Gedeptin®	Squamous Cell Head & Neck Cancer	First Reoccurrence Therapy in Combination with Immune Checkpoint	Phase 2 Trial Design in Process

GEOVAX PIPELINE: PRECLINICAL DEVELOPMENT PROGRAMS

Product	Target	Completion Testing Status
GEO-MVA-MUC1	Solid Tumor Cancers	Humanized Mouse Model
GEO-CM02	Vaccine for Pan-Coronavirus	Humanized Mouse Model
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	Mouse Model
GEO-MVA	Vaccine for Mpox & Smallpox	Regulatory Strategy and Manufacturing Scale-Up

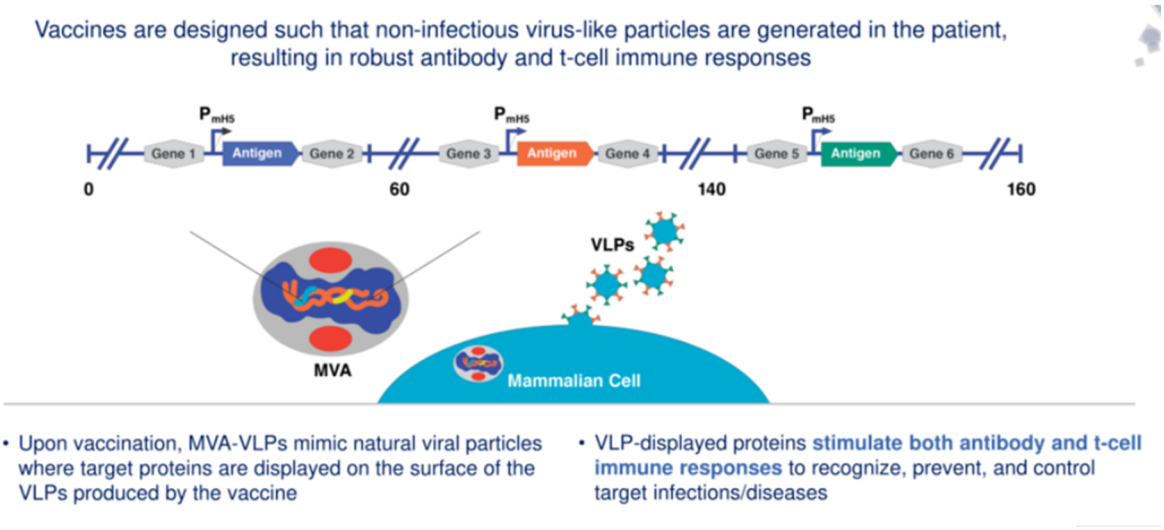
Source: GeoVax Labs, Inc.

MVA/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 virus-like particles (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 MVA/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 May 2024, more than 775 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.

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 candidate, 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.

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 2024's edition of *JAMA* that the number of immunocompromised adults in the U.S. has been updated, indicating a population of 23 million versus the previous estimate of 15 million.

Project NextGen Termination and Continued Commitment to GEO-CM04S1

In April 2025, GeoVax Labs received a Stop Work Order from the U.S. Department of Health and Human Services (HHS), effectively terminating its Project NextGen contract with the Biomedical Advanced Research and Development Authority (BARDA). The contract, awarded in June 2024, had provided $24.3 million to support a 10,000-participant Phase 2b trial of GEO-CM04S1, GeoVax's multi-antigen COVID-19 vaccine candidate. The termination, effective April 11, was issued "for the convenience of the government," with no indication of concerns regarding the vaccine's safety or efficacy.

GeoVax expressed surprise at the decision, noting that the majority of the funding was allocated to an external clinical research organization, and the financial impact on the Company is estimated at less than $750,000 annually. Despite the contract termination, GeoVax remains committed to advancing GEO-CM04S1, particularly for immunocompromised populations. Ongoing Phase 2 trials continue to evaluate the vaccine's potential as both a primary and booster immunization, with data readouts anticipated later in 2025 .

Notably, GEO-CM04S1 remains the only dual-antigen COVID-19 vaccine candidate to have received funding under BARDA's Project NextGen initiative, highlighting its unique scientific positioning and public health relevance despite the program's early closure.

Scientific Presentations in 2025

GeoVax is actively advancing its scientific visibility through key conference presentations in 2025. Data from its COVID-19 vaccine program, particularly the multi-antigen candidate GEO-CM04S1, are being presented at major meetings including the World Vaccine Congress, European Hematology Association, International Workshop on Chronic Lymphocytic Leukemia, and the American Association of Immunologists.

Interim results from ongoing Phase 2 trials in patients with chronic lymphocytic leukemia (CLL) and stem cell transplant or CAR-T therapy recipients are anticipated throughout the year. The CLL study at City of Hope is nearing full enrollment, while early data from the stem cell transplant cohort are expected in 2026, further supporting GEO-CM04S1's potential in immunocompromised populations.

Cancer Immunotherapy Vaccine Program

GeoVax is additionally developing the next generation of immunotherapies to address unmet medical needs in cancer. The Company believes that its MVA-VLP vector platform is well-suited for 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, resulting in immune responses that contribute to the regression of existing tumors and/or prevent the development and expansion of metastatic lesions.

The initial focus is on the MUC1 TAA's, which is a well-studied target for both antibody and cellular immunity (noting that there are multiple associated antigens, which the Company intends to investigate with this approach). GeoVax has constructed a MUC1 MVA-VLP vaccine and has evaluated 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 showing 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.

Gedeptin®

The Company has recently completed its review of Gedeptin® clinical results and announced plans to advance Gedeptin® into an expanded Phase 2 clinical trial for patients with first-recurrence head and neck cancer. The primary goal of this trial is to establish the efficacy of neoadjuvant Gedeptin® therapy combined with an immune checkpoint inhibitor in treating squamous cell head and neck cancer. The Company has begun necessary planning activities, including protocol development, manufacturing, and CRO selection, with trial activation anticipated in the first half of 2025. The Company anticipates funding the expanded Phase 2 trial through a combination of internal funding, potential partnering, and potential non-diluted funding resources.

In 2023, GeoVax announced the closure of enrollment for its Phase 1/2 trial of Gedeptin® 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 providing 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 Gedeptin® 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 Gedeptin® 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 Gedeptin® 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.

<u>Update</u>

Building on promising Phase 1/2 data, GeoVax is preparing to initiate a Phase 2 clinical trial of Gedeptin® for recurrent head and neck squamous cell carcinoma in combination with an immune checkpoint inhibitor. As of May 2025, trial planning is well underway, with initiation targeted for mid-to-late 2025. The Company is actively exploring non-dilutive funding opportunities and strategic partnerships to support trial execution.

At the 2025 American Association for Cancer Research (AACR) Annual Meeting, GeoVax presented new clinical data on Gedeptin®. The Phase 1/2 study, led by Dr. J. Marc Pipas, involved patients with advanced head and neck cancer who had undergone multiple prior treatments. Results showed that several patients achieved stable disease, with both median progression-free survival and overall survival at 7.0 months. The therapy was well tolerated, with no dose-limiting toxicities and only minor side effects like injection site pain. Based on these encouraging results, GeoVax is preparing a Phase 2 trial to evaluate Gedeptin® in combination with pembrolizumab (Keytruda®) as a neoadjuvant therapy, aiming to enhance immune response in recurrent head and neck cancer. This data further reinforces the therapeutic potential of its gene-directed prodrug platform in hard-to-treat solid tumors

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

GeoVax is advancing a suite of preclinical vaccine candidates targeting the world's deadliest hemorrhagic fever viruses—Marburg (MARV), Sudan (SUDV), Ebola (EBOV), and Lassa fever virus (LASV)—using its proprietary MVA-VLP vaccine platform. These diseases, primarily affecting Central and West Africa, cause high fatality rates and remain urgent global health and biodefense threats.

At the World Vaccine Congress West Coast in November 2023, preclinical data on GeoVax's MARV and SUDV vaccines were presented by Dr. Jason Comer of the University of Texas Medical Branch (UTMB). In a nonhuman primate challenge model, GeoVax's MARV candidate (MVA-VLP-MARV) achieved 80% survival following a lethal viral dose, preventing viremia, weight loss, and death. These results were supported by earlier studies in guinea pigs showing 100% protection against the highly virulent Angola strain of MARV.

Immunization with GeoVax's hemorrhagic fever vaccines induced broad immune responses, including neutralizing antibodies and functional T cells, critical for durable protection. Importantly, due to the shared MVA vector backbone, these candidates may also offer cross-protection against Mpox (Monkeypox)—a growing concern in regions where filovirus outbreaks occur.

Additional studies demonstrated that MVA-VLP-EBOV conferred 100% protection in nonhuman primates against a single high-dose Ebola virus challenge. GeoVax's SUDV and LASV vaccines have shown similar protection in animal models, with LASV candidates demonstrating 100% single-dose protection in rodents using a multi-strain, intracranial challenge. Nonhuman primate studies for LASV are ongoing in collaboration with NIAID and the U.S. Army, and further development plans will align with emerging global priorities and outbreak risks.

GeoVax's hemorrhagic fever vaccine portfolio targets diseases with high fatality rates—up to 90% for Marburg, Sudan, and Ebola viruses, and up to 10,000 deaths annually from Lassa fever. The Company is committed to advancing these programs in support of public health preparedness and biodefense needs, including pursuing eligibility for the FDA Priority Review Voucher (PRV) program, which applies to vaccines for pathogens like Marburg virus.

Malaria Vaccine Program

GeoVax has previously collaborated with the Burnet Institute, a leading infectious disease research center in Australia, to develop a vaccine targeting malaria infection using its proprietary GV-MVA-VLP™ platform. The program involved designing and characterizing multiple vaccine candidates incorporating antigens from both *Plasmodium falciparum* and *Plasmodium vivax*, based on sequences identified by the Burnet Institute. In a separate effort, GeoVax partnered with Leidos, Inc., under a grant from the U.S. Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP).

While this program is currently inactive, GeoVax continues to view malaria as a critical global health challenge and may resume development pending new funding through government grants or strategic partnerships. As of 2022, malaria remains a major threat worldwide, causing an estimated 249 million infections and over 600,000 deaths annually, primarily among children in sub-Saharan Africa. Unlike most traditional malaria vaccine approaches that target a single protein or life cycle stage, GeoVax's MVA-VLP malaria vaccine candidates are designed to deliver multi-stage antigens, aiming to stimulate broad and durable immune responses—including both CD4+ and CD8+ T cell activity—a profile consistent with an ideal malaria vaccine.

ZIKA Virus (ZIKV) Vaccine Program

GeoVax is developing novel Zika virus vaccine candidates using its proprietary GV-MVA-VLP™ platform, aimed at addressing the ongoing unmet medical need for a safe and effective vaccine. The use of the MVA vector, known for its strong safety profile, is especially relevant for protecting women of childbearing age and newborns, who are most vulnerable to Zika-related complications.

GeoVax's lead candidate, GEO-ZM02, is uniquely designed around the NS1 gene product to avoid the risk of antibody-dependent enhancement (ADE)—a potentially severe immune reaction seen with some other flavivirus vaccines. In preclinical studies, rodents demonstrated 100% single-dose protection against a lethal intracranial challenge, while rhesus macaques showed strong immune control of viral replication, despite the vaccine's design intentionally avoiding the induction of neutralizing antibodies. While the scientific proof of concept is strong, further development of the Zika vaccine program is currently on hold pending external funding or strategic partnership support. GeoVax continues to monitor global health priorities and remains prepared to advance this candidate should public health or funding landscapes shift.

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

GeoVax has established a broad network of collaborations with leading government agencies, academic institutions, and industry partners to support the development of its vaccine and immunotherapy programs. Current and recent collaborators include the National Institute of Allergy and Infectious Diseases (NIAID/NIH), the HIV Vaccine Trials Network (HVTN), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Defense (DoD), U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the U.S. Naval Research Laboratory (USNRL), and the Geneva Foundation.

Academic and research collaborations include 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, University of California, San Francisco (UCSF), and the Burnet Institute in Australia. GeoVax has also partnered with industry organizations such as Leidos, Inc. and ViaMune, Inc., among others. These partnerships have been instrumental in advancing the Company's pipeline and securing non-dilutive funding through competitive government and foundation grants.

Patent Portfolio

As of March 2025, GeoVax holds more than 130 granted or pending patents across 23 patent families. This robust intellectual property portfolio supports its vaccine and immunotherapy pipeline.

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.

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