Company Description

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing next-generation vaccines and immunotherapies for serious infectious diseases and solid tumors. Its lead infectious disease 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, patients with Chronic Lymphocytic Leukemia (CLL), and individuals undergoing stem cell transplant or CAR-T therapy. In oncology, GeoVax is preparing a new Phase 2 trial of Gedeptin® as a neoadjuvant therapy for head and neck squamous cell carcinoma, in combination with pembrolizumab and fludarabine. Additional preclinical studies are ongoing in other tumor types. The Company's Mpox and smallpox vaccine candidate, GEO-MVA, is expected to enter clinical trials in late 2025, following favorable guidance from the European Medicines Agency supporting a streamlined development path. Backed by global rights, a growing intellectual property portfolio, and scalable manufacturing capabilities—including a transition to cell-based platforms—GeoVax is led by an experienced management team focused on advancing high-impact vaccines and immunotherapies to address urgent and underserved medical needs.

Key Points

- On July 28, 2025, GeoVax reported a net loss of $5.4 million ($0.35 per share) for Q2 2025, compared to a net loss of $5.1 million ($1.99 per share) in Q2 2024.
- Key pipeline programs advanced during the quarter, including favorable European Medicines Agency (EMA) guidance for GEO-MVA and strong immune response data from GEO-CM04S1 in immunocompromised patients, particularly those with Chronic Lymphocytic Leukemia (CLL).
- GEO-MVA is now positioned for centralized EU approval and global procurement access. As the only U.S.-based MVA vaccine developer for Mpox/smallpox, GeoVax is targeting a $10 billion+ market amid rising demand and transitioning to scalable, cell-based manufacturing.
- Preparations are underway for a Phase 2 trial of Gedeptin® in head and neck cancer, reinforcing GeoVax's focus on immunotherapies for underserved oncology indications.
- During the quarter, Dr. Senthil Ranganathan joined as VP of Technical Development and CMC Operations, bringing 20+ years of biologics and manufacturing expertise across vaccines, viral vectors, and cell and gene therapies.
- GeoVax further strengthened its IP portfolio with a new U.S. patent covering its malaria vaccine platform and a Notice of Allowance for claims related to Gedeptin® combined with radiation therapy. The Company now holds over 135 patents across 23 families, supporting its multi-antigenic approach to infectious disease and cancer.
- GeoVax ended Q2 with $3.1 million in cash and completed a public offering in July 2025, raising $5.6 million in net proceeds to support operations and near-term growth.

GeoVax
Vaccines Serving Humanity

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

GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (07/29/2025)	$0.75
52-week Range	$0.43-11.18
Shares Outstanding	25.3 mm
Market Capitalization	$18.9 mm
Avg. Volume	1,549,198
EPS (Qtr. ended 06/30/2025)	($0.35)
Employees	19

See page 15 for applicable disclosures.

SECOND QUARTER 2025 FINANCIAL RESULTS

GeoVax reported a net loss of $5.4 million, or $0.35 per share, for the second quarter ended June 30, 2025, compared to a net loss of $5.1 million, or $1.99 per share, for the same period in 2024. For the first half of 2025, the net loss totaled $10.7 million, or $0.79 per share, slightly improved from a net loss of $10.9 million, or $4.68 per share, in the first half of 2024.

Revenue for the second quarter of 2025 was $852,282, with year-to-date revenue totaling $2.5 million—a significant increase from $300,677 for both the second quarter and first half of 2024. These revenues were primarily driven by the Company's BARDA/RRPV Project NextGen contract. GeoVax disclosed that BARDA has elected to terminate the contract during Q2 2025.

R&D expenses rose to $4.7 million for the quarter and $10.1 million year-to-date, compared to $4.3 million and $8.7 million, respectively, in 2024. The increase was largely due to project-specific costs tied to the BARDA/RRPV program and development of the GEO-MVA vaccine, partially offset by reduced spending on GEO-CM04S1 clinical trials and related manufacturing expenses.

G&A expenses for Q2 2025 were $1.5 million, and $3.2 million for the first half, up from $1.1 million and $2.5 million in the respective 2024 periods. The increase was mainly attributed to higher investor relations costs and stock-based compensation.

As of June 30, 2025, GeoVax held $3.1 million in cash, down from $5.5 million at year-end 2024. In July 2025, the Company completed a public offering of common stock and warrants, raising approximately $5.6 million in net proceeds to strengthen its balance sheet.

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

In a July 30 press release, GeoVax renewed its call for urgent U.S. investment in domestic vaccine manufacturing and biodefense, citing the global spread of virulent Mpox strains, immune-evasive COVID-19 variants, and bipartisan momentum for reducing foreign dependency. The Company highlighted its GEO-MVA (Mpox/smallpox) and GEO-CM04S1 (COVID-19) candidates—both supported by favorable regulatory guidance and clinical data—as front-line solutions for pandemic preparedness. GeoVax also emphasized its advanced MVA platform and readiness to deliver U.S.-based, scalable production. Echoing recent government statements and proposed legislation, GeoVax called for immediate action to modernize the national stockpile and diversify countermeasure platforms before the next public health crisis emerges.

GEO-MVA: Mpox and Smallpox Vaccine Platform

GeoVax is advancing its GEO-MVA vaccine candidate for the prevention of Mpox and smallpox, with clinical trials expected to begin in the second half of 2025. The Company has successfully manufactured cGMP clinical material and is completing vialing in preparation for the upcoming evaluation. Designed as a U.S.-developed alternative to foreign-sourced vaccines, GEO-MVA addresses critical global concerns around supply constraints, emerging biosecurity threats, and the need for greater vaccine equity.

In support of its regulatory pathway, GeoVax recently received favorable Scientific Advice from the European Medicines Agency (EMA), which endorsed the Company's clinical and nonclinical development strategy. This feedback provides regulatory clarity and supports a streamlined route to potential approval, eliminating multiple development steps typically required for vaccines. Notably, the EMA confirmed that a single successful Phase 3 immuno-bridging trial could meet the criteria for market authorization across all 27 EU member states. GeoVax anticipates initiating this pivotal trial in the second half of 2026. The global market opportunity for GEO-MVA could exceed $10 billion.

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

GeoVax continued to advance its GEO-CM04S1 vaccine program in the second quarter of 2025, highlighted by multiple presentations of compelling clinical and preclinical data. At the European Hematology Association (EHA) 2025 Conference, the Company presented positive immune response results from its ongoing Phase 2 trial in patients with chronic lymphocytic leukemia (CLL). GEO-CM04S1 demonstrated significantly enhanced T cell responses—specifically IFN-γ secretion and activation-induced markers (AIM+)—compared to a matched cohort receiving an authorized mRNA vaccine. While both vaccines generated humoral immune responses, only GEO-CM04S1 produced statistically significant nucleocapsid (N)-specific IgG and T cell responses. Notably, the mRNA vaccine failed to meet its predefined primary immunogenicity endpoint, and as a result, further enrollment in the study is now limited to the GEO-CM04S1 arm. Both vaccines were well tolerated, with no grade ≥3 adverse events reported.

Additional data from a Keystone Symposia study underscored the preclinical strength of GEO-CM04S1. In a K18-hACE2 mouse model, the vaccine provided full protection against both the original SARS-CoV-2 B.1 strain and the Omicron XBB.1.5 subvariant, preventing clinical disease, lung injury, and inflammation. At the 2025 Annual Meeting of the American Association of Immunology (AAI), researchers presented new findings from a Phase 2 study of GEO-CM04S1 in blood cancer patients who had received hematopoietic cell transplants or CAR-T therapy. Conducted at City of Hope Medical Center, the study showed that the vaccine—licensed by GeoVax from the COH04S1 program—was highly immunogenic in this high-risk population. The presentation also included data from healthy adults and non-human primates, demonstrating the vaccine's ability to induce orthopox-specific and Mpox cross-reactive immune responses, highlighting the platform's potential dual-protective applications.

Further validation of the vaccine's performance came at the 25th Annual World Vaccine Congress in April 2025, where Dr. Don J. Diamond presented results from multiple Phase 1 and 2 trials. GEO-CM04S1 showed strong immunogenicity in both healthy and immunocompromised patients, including CLL and stem cell transplant recipients, and outperformed a leading mRNA vaccine in key immunological endpoints. Collectively, these data reinforce the value of GeoVax's dual-antigen approach and the vaccine's potential to meet critical global needs.

GEO-CM04S1 continues to attract attention as a next-generation COVID-19 vaccine with potential applications beyond the current pandemic. The vaccine addresses a significant global unmet need, with an estimated market opportunity exceeding $30 billion.

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.

At the American Association for Cancer Research (AACR) Annual Meeting in April 2025, GeoVax presented encouraging clinical data on Gedeptin. The presentation, titled *"Viral-Vectored, Gene-Directed Prodrug Therapy (Gedeptin) in Needle-Accessible Solid Tumors,"* was delivered by Dr. J. Marc Pipas, Executive Medical Director of Oncology, during the Phase 2 Clinical Trials 1 Poster Session on April 29. The session drew strong interest from both researchers and clinicians, highlighting growing recognition of Gedeptin's potential as a novel therapeutic option. The corresponding abstract was also published in *Cancer Research*, the journal of the AACR.

The ongoing clinical study evaluated Gedeptin in patients with advanced, needle-accessible solid tumors. The trial design allowed for up to five treatment cycles per patient, with each cycle consisting of an intratumoral injection of Gedeptin followed by an intravenous dose of fludarabine. The study enrolled eight heavily pretreated patients, with a median of four prior systemic therapies. Diagnoses included squamous cell carcinoma, nasopharyngeal carcinoma, and lymphoepithelial carcinoma.

Despite the challenging patient population, several individuals achieved stable disease, and the study reported a median progression-free survival (PFS) and overall survival (OS) of 7.0 months. No dose-limiting toxicities were observed, and treatment-related adverse events were minimal—limited primarily to injection site pain. Serious adverse events occurred in five patients but were largely attributed to underlying disease rather than the treatment itself. Gedeptin continues to show promise as a safe, targeted therapy with potential applicability across a range of solid tumors. The market opportunity for Gedeptin is estimated to exceed $15 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 continued to expand its intellectual property portfolio and strengthen its leadership during the quarter. The U.S. Patent and Trademark Office issued U.S. Patent No. 12,329,808, titled *"Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria,"* covering a novel vaccine construct for malaria prevention. The Company also received a Notice of Allowance for patent application 17/502,101, which includes claims for the combination of Gedeptin with radiation therapy—further reinforcing GeoVax's position in oncology. During the quarter, Dr. Senthil Ranganathan joined as VP of Technical Development and CMC Operations, bringing 20+ years of biologics and manufacturing expertise across vaccines, viral vectors, and cell and gene therapies. GeoVax also further continues to integrate artificial intelligence across its clinical development, trial management, and manufacturing workflows—aimed at reducing timelines, improving decision-making, and optimizing resource allocation.

RECENT COMPANY DEVELOPMENTS

July 30, 2025—GeoVax renewed its call for decisive U.S. action on pandemic preparedness and biodefense. With escalating outbreak risks, public health system strain, and growing bipartisan consensus for domestic solutions, GeoVax underscored the urgent need to modernize the nation's countermeasure infrastructure and end foreign vaccine dependency.

July 29, 2025—Announced an accelerated development strategy for its GEO-MVA Mpox vaccine in response to a global surge in cases, renewed WHO emergency status, and favorable regulatory guidance from the EMA. The Company aims to meet urgent global demand amid supply constraints and rising virulence of Mpox strains.

July 28, 2025—Reported second quarter 2025 financial results, highlighting increased revenue from BARDA contracts, ongoing R&D investments, and a recent $5.6 million capital raise to support operations and clinical programs.

July 28, 2025—Initiated a preclinical study with the University of Queensland to evaluate GEO-MVA delivered via Vaxxas' needle-free HD-MAP platform. The study aims to assess immune response, delivery efficiency, and thermostability for enhanced vaccine distribution.

July 24, 2025—Announced a shift in its Gedeptin® clinical strategy to target head and neck cancer in a neoadjuvant setting with pembrolizumab, following strong data from the KEYNOTE-689 trial. A new Phase 2 trial is planned to begin in 2026.

July 22, 2025—Announced it would release Q2 2025 financial results on July 28, followed by a webcast and conference call with management.

July 21, 2025—Detailed the EMA's support for a single Phase 3 immuno-bridging trial to approve GEO-MVA across the EU. The Company highlighted key benefits including faster timelines, reduced risk, and strong market potential.

July 16, 2025—Reinforced the urgency of Mpox vaccine development as new outbreaks emerge globally. The Company is accelerating regulatory engagement following EMA support for an expedited path to market for GEO-MVA.

July 14, 2025—Announced its participation in the Emerging Growth Conference on July 16, offering shareholders and investors direct access to management and a live Q&A session.

July 3, 2025—Emphasized the need for advanced COVID-19 vaccines like GEO-CM04S1 as the highly transmissible Nimbus (NB.1.8.1) variant spreads globally, reinforcing the importance of broad, durable protection for at-risk populations.

July 2, 2025—Highlighted the growing strategic importance of its GEO-MVA Mpox/smallpox vaccine amid rising global health threats and regulatory momentum from the EMA.

July 1, 2025—Raised approximately $6 million through a public offering of stock and warrants. Proceeds will support working capital and general operations.

June 25, 2025—The U.S. Patent Office issued a new patent covering GeoVax's malaria vaccine platform. The Company now holds over 135 patents across 23 families, supporting its multi-antigenic approach to infectious disease and cancer.

June 24, 2025—Welcomed FDA approval of pembrolizumab for head and neck cancer, aligning with its planned Gedeptin® Phase 2 trial that combines Gedeptin and checkpoint inhibition in a neoadjuvant setting.

June 17, 2025—At the EHA Congress, new Phase 2 data showed GEO-CM04S1 elicited stronger cellular immune responses than an mRNA vaccine in CLL patients, a group known for poor vaccine responsiveness.

June 16, 2025—Received Scientific Advice from the EMA confirming that GEO-MVA may proceed directly to a Phase 3 immuno-bridging trial, eliminating earlier-stage studies and accelerating time to market.

June 12, 2025—Announced its attendance at the BIO 2025 International Convention, highlighting its pipeline and pursuing strategic partnerships and manufacturing expansion.

June 11, 2025—Responded to the WHO's latest Mpox emergency declaration, noting the spread of the Clade 1 strain and reinforcing the need for its GEO-MVA vaccine.

June 10, 2025—Previewed clinical data to be presented at the EHA 2025 Hybrid Congress, showing promising results for GEO-CM04S1 in immunocompromised patients, particularly those with CLL.

June 9, 2025—At Keystone Symposia, GeoVax presented preclinical data showing its multi-antigen COVID-19 vaccine candidates protect against multiple SARS-CoV-2 variants, including Omicron subvariant XBB.1.5.

June 4, 2025—Previewed its upcoming poster presentations at Keystone Symposia, focusing on cross-variant protection of its multi-antigen COVID-19 vaccines.

May 29, 2025—Supported new bipartisan legislation to boost U.S. pharmaceutical manufacturing, aligning with the Company's mission to strengthen domestic vaccine production and supply chain resilience.

May 27, 2025—Endorsed updated FDA vaccine guidance that shifts focus toward high-risk individuals. The Company noted GEO-CM04S1 is well-suited to meet these targeted needs.

May 21, 2025—Supported the launch of the EQUIP-A-Pharma initiative, a public-private partnership aimed at modernizing pharmaceutical manufacturing through AI and innovation.

May 20, 2025—Responded to anticipated HHS changes in COVID-19 vaccine policy, which would prioritize high-risk populations—an area aligned with the design of GEO-CM04S1.

May 8, 2025—At IMMUNOLOGY2025™, GeoVax presented data showing that GEO-CM04S1 elicits immune responses in CAR-T and stem cell transplant patients, with potential cross-protection against Mpox.

May 7, 2025—Received a Notice of Allowance for a patent supporting the combination of Gedeptin with radiation therapy, strengthening its oncology IP portfolio.

May 6, 2025—Voiced support for President Trump's Executive Order aimed at revitalizing U.S.-based pharmaceutical manufacturing and reducing reliance on foreign supply chains.

POTENTIAL NEAR TEM MILESTONES

GEO-MVA (Mpox and Smallpox Vaccine Candidate)

- ***Clinical Trial Initiation.*** GeoVax anticipates initiating clinical trials for GEO-MVA in late 2025, supported by EMA guidance allowing a single Phase 3 immuno-bridging trial. Clinical material is complete and vialing is underway.

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

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

- ***Phase 2b Trial.*** 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 and data readout is expected imminently.

- ***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.

Gedeptin® (Oncology Program)

- ***Phase 2 Oncology Trial.*** GeoVax plans to initiate a neoadjuvant Phase 2 trial of Gedeptin® in combination with pembrolizumab and fludarabine for resectable head and neck cancer, with trial launch expected in 2026.

- ***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.

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.

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 are built on two 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—mimicking natural infection to stimulate both humoral and cellular immune responses.

GeoVax's infectious disease pipeline includes GEO-CM04S1, a multi-antigen COVID-19 vaccine currently in multiple Phase 2 trials targeting immunocompromised populations, and GEO-MVA, a Mpox/smallpox vaccine preparing for clinical evaluation in late 2025 under a streamlined regulatory path approved by the European Medicines Agency (EMA). In oncology, the Company is advancing Gedeptin® toward a planned Phase 2 trial in 2026 as a neoadjuvant therapy for head and neck cancer in combination with an immune checkpoint inhibitor, with additional preclinical efforts underway across other tumor types. GeoVax holds worldwide rights to its platforms and product candidates and is supported by a growing IP portfolio and scalable manufacturing infrastructure, including a transition to cell-based production systems. The Company's development efforts are summarized in Figure 1 (page 9).

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.

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.

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.

COVID-19 Vaccine Program

In January 2020, GeoVax announced initiation efforts to develop a vaccine against COVID-19. 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 (spike) protein, which served as the main target in first-generation COVID-19 vaccines. 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 is designed to stimulate 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.

Recent Updates

GEO-CM04S1 continues to show strong promise, particularly for immunocompromised patients. At the 2025 European Hematology Association (EHA) Conference, the vaccine demonstrated significantly stronger T cell responses and broader immune activation in CLL patients compared to a matched cohort receiving an approved mRNA vaccine. As a result, enrollment in the ongoing study has shifted exclusively to the GEO-CM04S1 arm.

Additional data presented at the Keystone Symposia and AAI 2025 highlighted GEO-CM04S1's protective efficacy in preclinical models against both the original B.1 strain and the Omicron XBB.1.5 subvariant, as well as cross-reactive immune responses to Mpox. Clinical results shared at the World Vaccine Congress further supported its potential as a broadly protective COVID-19 vaccine, especially in high-risk populations, with a global market opportunity estimated at over $30 billion.

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 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.

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.

Recent Updates

GeoVax presented encouraging clinical data on Gedeptin® at the 2025 AACR Annual Meeting, highlighting its potential as a gene-directed prodrug therapy for solid tumors. The Phase 2 study, which included patients with various advanced cancers who had undergone multiple prior treatments, showed disease stabilization in several participants, with both median progression-free and overall survival reaching seven months. The therapy was well tolerated, with minimal treatment-related side effects and no dose-limiting toxicities.

Presented by Dr. J. Marc Pipas, the findings drew strong interest from the oncology community and were published in the journal *Cancer Research*. With its ability to deliver targeted intratumoral treatment and an estimated market potential of $15 billion, Gedeptin offers a promising new approach for treating hard-to-manage solid tumors.
Ask ChatGPT

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.

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.

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 mid-2025, GeoVax's patent portfolio includes over 135 granted or pending patent applications across 23 patent families, offering broad protection for its vaccine and immunotherapy platforms

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 Company 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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