

Company Description

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing multi-antigen vaccines for infectious diseases and gene-directed therapies for solid tumors. Its lead program, GEO-CM04S1, is an MVA-based COVID-19 vaccine designed to provide broader, more durable protection, particularly for immunocompromised patients who remain underserved by current mRNA vaccines. GEO-CM04S1 is in multiple Phase 2 trials as a primary vaccine in immunocompromised patients (including those with hematologic malignancies or post-transplant status) and as a booster in both patients with chronic lymphocytic leukemia (CLL) and healthy adults previously vaccinated with mRNA vaccines. In oncology, the Company's lead asset is Gedeptin®, a gene-directed enzyme prodrug therapy that has completed a multicenter Phase 1/2 trial in advanced head and neck cancers, with a Phase 2 neoadjuvant trial (AdPNP-203) in preparation that will evaluate intra-tumoral Gedeptin with intravenous fludarabine and neoadjuvant pembrolizumab, alongside expanded preclinical work in additional solid tumors. GeoVax is also advancing GEO-MVA, a Mpox and smallpox vaccine candidate that, based on favorable European Medicines Agency advice, is expected to move directly into a single Phase 3 immunobridging trial. Supported by worldwide rights, a growing intellectual property portfolio, and scalable manufacturing plans, including a shift from egg-based to modern cell line platforms, GeoVax is led by an experienced management team focused on high-impact vaccines and immunotherapies for urgent, underserved medical needs.

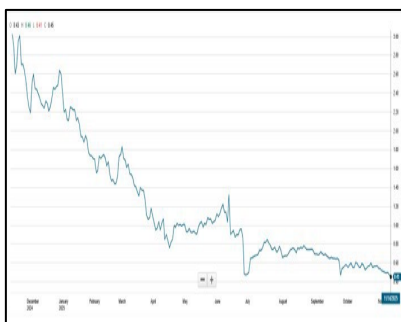
Key Points

- On November 13, 2025, GeoVax reported a Q3 2025 net loss of \$6.3 million (\$0.31 per share) versus \$5.8 million (\$0.91 per share) in Q3 2024. The Company ended the quarter with \$5.0 million in cash.
- Phase 2 trials of GEO-CM04S1 in immunocompromised and CLL patients continue to show strong T-cell and antibody responses, no serious vaccine-related adverse events, and achievement of the CLL trial's primary immunogenicity endpoint.
- GEO-MVA advanced along an EMA-endorsed pathway in which a single Phase 3 immunobridging trial is expected to support centralized EU marketing authorization, with WHO's reaffirmation of Mpox as a global emergency and reinforcing the need for additional MVA-based vaccine supply.
- Gedeptin® is being advanced into AdPNP-203, a Phase 2 neoadjuvant trial in resectable head and neck squamous cell carcinoma (Gedeptin + fludarabine + neoadjuvant pembrolizumab), with preclinical work expanding into triple-negative breast and cutaneous malignancies.
- GeoVax reinforced its role as a U.S.-based "Made-in-America" MVA vaccine developer, highlighting continuous avian cell-line manufacturing, alignment with U.S. biodefense and onshoring priorities, and active engagement with U.S. and global health agencies.
- The Company's IP portfolio includes a June 2025 U.S. patent on a novel MVA-based malaria vaccine construct and more than 135 patents across 23 families supporting its multi-antigen infectious disease and oncology platforms.



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GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (11/13/2025)	\$0.46
52-week Range	\$0.42 - 3.15
Shares Outstanding	29.7 mm
Market Capitalization	\$13.6 mm
Avg. Volume	833,840
EPS (Qtr. ended 09/30/2025)	(\$0.31)
Employees	19

THIRD QUARTER 2025 FINANCIAL RESULTS

Net Loss. For the three-month period ended September 30, 2025, net loss was \$6,318,914, (\$0.31) per share, compared with \$5,815,468, or (\$0.91) per share, for the same period in 2024. For the nine-month period ended September 30, 2025, the Company reported a net loss of \$17,046,348, or (\$0.97) per share, versus \$16,729,642, or (\$4.52) per share, for the corresponding period in 2024.

Revenue. During the three-month and nine-month periods ended September 30, 2025, the Company recorded \$0 and \$2,489,145, respectively, in government contract revenues related to the BARDA/RRPV Project NextGen award, compared with \$2,789,484 and \$3,090,161 for the comparable periods in 2024. In April 2025, GeoVax received notice that BARDA had elected to terminate the contract for the convenience of the government.

R&D Expenses. Research and development expenses were \$5,043,504 and \$15,127,090 for the three-month and nine-month periods ended September 30, 2025, respectively, compared with \$7,402,884 and \$16,105,480 for the same periods in 2024. The overall decrease was primarily attributable to discontinued costs associated with the termination of the BARDA/RRPV Contract, as well as reduced costs for the GEO-CM04S1 clinical trials and manufacturing costs related to the GEO-CM04S1 and Gedeptin programs. These reductions were partially offset by higher personnel and consulting expenses and increased manufacturing costs related to the GEO-MVA development program.

G&A Expenses. General and administrative (G&A) expenses totaled \$1,329,711 and \$4,559,346 for the three-month and nine-month periods ended September 30, 2025, respectively, compared with \$1,241,176 and \$3,784,559 for the comparable periods in 2024. The increase was primarily driven by higher personnel costs, investor relations consulting and other programmatic expenses, and stock-based compensation expense.

Cash Position. GeoVax reported cash balances of \$5,008,997 as of September 30, 2025, compared with \$5,506,941 as of December 31, 2024.

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

During the third quarter of 2025, GeoVax continued to advance its multi-antigen vaccine and oncology portfolio, with particular emphasis on accelerating GEO-MVA in response to the ongoing global Mpox emergency, strengthening the clinical profile of GEO-CM04S1 in immunocompromised patients, and positioning Gedeptin® for Phase 2 evaluation in first-line head and neck cancer while expanding into additional solid tumor indications. The Company also highlighted its role as a U.S.-based MVA vaccine developer aligned with domestic biodefense and onshoring priorities, and continued active engagement with global health agencies and prospective partners.

GEO-MVA: Mpox and Smallpox Vaccine Platform

GeoVax is advancing GEO-MVA as a next-generation Mpox/smallpox vaccine in the context of the World Health Organization's reaffirmation of Mpox as a global public health emergency and the continued spread of Clade I outbreaks across Africa, Europe, and the U.S. Favorable Scientific Advice from the European Medicines Agency (EMA) supports an expedited development path that bypasses separate Phase 1 and Phase 2 studies and allows GeoVax to proceed directly to a single Phase 3 immunobridging trial that could support centralized approval across EU member states.

The Company has completed cGMP manufacture of clinical GEO-MVA material and has initiated fill/finish activities, with vaccine supply expected to be available for clinical evaluation in early 2026. In parallel, GeoVax is working with Oxford Biomedica as its CDMO partner for near-term production on a chicken embryo fibroblast (CEF) platform, while planning to expand supply and ultimately transition to continuous cell-line manufacturing to support global demand.

A new collaboration with the University of Queensland and UniQuest will evaluate needle-free administration using Vaxxas Inc.'s high-density microarray patch (HD-MAP) platform, with the goal of improving thermostability, enabling self-administration, and reducing dose requirements in settings where cold-chain and healthcare infrastructure are limited.

GeoVax continues to position GEO-MVA as a U.S.-developed alternative to foreign-sourced MVA vaccines and remains in active dialogue with stakeholders such as the White House, Congressional offices, HHS, WHO, CEPI, Africa CDC, and UNICEF regarding stockpile needs, emergency-use strategies, and long-term preparedness.

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

GEO-CM04S1, GeoVax's multi-antigen COVID-19 vaccine, continued to generate strong clinical data in immunocompromised populations. At the iwCLL 2025 Workshop and the 6th ESCMID Conference on Vaccines, investigators reported robust T-cell and cross-variant antibody responses in CLL and hematologic cancer patients, with no serious adverse events attributed to GEO-CM04S1. The ongoing CLL Phase 2 trial achieved its primary immunogenicity endpoint, leading to discontinuation of the comparator mRNA arm, and sustained cellular responses across multiple time points support the potential for more durable protection in high-risk patients.

On the corporate update call, management emphasized that GEO-CM04S1 is being developed for an estimated 40+ million immunocompromised adults in the U.S. and approximately 400 million globally who remain inadequately protected by first-generation, single-antigen vaccines. Recent Infectious Disease Society of America (IDSA) guidance on vaccination in immunocompromised patients is viewed as broadly supportive of this strategy, and presentations at global meetings, including the World Vaccine Congress Europe, have driven increased partnering discussions. GeoVax is also advancing a next-generation GEO-CM04S1 construct incorporating an Omicron KP.2 Spike sequence for enhanced coverage of emerging variants, with clinical evaluation targeted for 2026.

Gedepin®: Gene-Directed Oncolytic Therapy for Solid Tumors

GeoVax is preparing a Phase 2 trial (AdPNP-203) of Gedepin® in combination with pembrolizumab and fludarabine in first-line, resectable head and neck squamous cell carcinoma (HNSCC), with initiation targeted for the second half of 2026. The study design has been updated in light of the KEYNOTE-689 Phase 3 results, which reinforced the value of perioperative checkpoint inhibition in HNSCC; AdPNP-203 is now focused on a neoadjuvant regimen intended to improve pathological response rates in patients undergoing surgery with curative intent.

Manufacturing of Gedepin clinical supply is underway and remains the primary gating factor for Phase 2 initiation, while clinical operations and regulatory planning continue in parallel. Earlier Phase 1/2 data, presented at the 2025 AACR Annual Meeting, showed disease control and a favorable safety profile in heavily pretreated patients with needle-accessible solid tumors, and a peer-reviewed publication of these results is expected in JCO Oncology Advances.

Beyond head and neck cancer, GeoVax and collaborators at Emory University's Winship Cancer Institute are expanding preclinical studies of Gedepin into triple-negative breast cancer and cutaneous malignancies, with additional work planned in other solid tumors and potential combinations with multiple checkpoint inhibitors. Management continues to view Gedepin as a key long-term oncology asset with potential applicability across several high-value solid tumor markets.

Vaccine Manufacturing Process Development

In parallel with product-specific progress, GeoVax is progressing an advanced MVA manufacturing process designed to enable continuous, suspension-based production of MVA vaccines using modern avian cell lines, which GeoVax describes as a potential game-changer for scalability and cost of goods. While GEO-MVA's near-term clinical material is being produced on the CEF platform with Oxford Biomedica, the longer-term objective is to migrate to this continuous process, which would support higher-throughput production, regional manufacturing hubs, and improved access in low- and middle-income countries.

This manufacturing strategy aligns with U.S. federal initiatives to onshore critical biomanufacturing capacity and reduce dependency on foreign vaccine suppliers, and it is a recurring theme in GeoVax's discussions with agencies such as ASPR, BARDA, CEPI, WHO, Africa CDC, and UNICEF.

Corporate and Intellectual Property Developments

During the quarter, GeoVax underscored how its U.S.-based MVA platform and infectious disease portfolio fit within the broader national agenda around pandemic preparedness, "Made in America" manufacturing, and biosecurity. The Company's continuous cell-line manufacturing vision and domestic production footprint are intended to support U.S. stockpile modernization as well as global health equity.

GeoVax also sponsored the Dr. David Satcher Global Health Equity Summit to highlight its commitment to equitable vaccine innovation, and it continues to emphasize the long clinical track record and safety profile of MVA-based vaccines in immunocompromised and other special populations. The Company's intellectual property estate remains a core strategic asset, including a U.S. patent issued in June 2025 covering a novel MVA-based malaria vaccine construct and a Notice of Allowance for claims covering Gedeptin in combination with radiation therapy, alongside a broad portfolio of patents supporting its multi-antigen vaccine and oncology platforms.

RECENT COMPANY DEVELOPMENTS

November 13, 2025—GeoVax Labs, Inc. reported a Q3 2025 net loss of \$6.3 million (\$0.31 per share) and ended the quarter with \$5.0 million in cash. During the quarter, the Company advanced its GEO-MVA Mpox/smallpox vaccine under an expedited, EMA-aligned pathway amid the ongoing global Mpox emergency, progressed GEO-CM04S1 with strong Phase 2 data in immunocompromised and CLL patients, and moved Gedeptin® toward a Phase 2 trial in first-line, resectable head and neck cancer while expanding into additional solid tumor models. Management highlighted GeoVax's U.S.-based MVA platform, evolving continuous cell-line manufacturing strategy, and engagement with global health agencies as aligned with U.S. priorities in pandemic preparedness and onshoring.

November 10, 2025—Marked World Immunization Day by highlighting its role in closing the “trust gap” around vaccines through transparent, science-driven development of diversified, multi-antigen vaccines such as GEO-CM04S1 for COVID-19 and GEO-MVA for Mpox/smallpox. The Company also emphasized its focus on protecting immunocompromised patients and advancing U.S.-based continuous cell line manufacturing to expand supply, cut costs, and support domestic and global health security.

November 4, 2025—GeoVax Labs, Inc. announced that it will report its financial results for the quarter ended September 30, 2025, after the close of U.S. markets on Thursday, November 13, 2025. Following the release, management will host a live conference call and audio webcast at 4:30 p.m. ET to review results and provide a business update.

November 3, 2025—GeoVax announced that the Company will relocate both its lab and corporate HQ in Q4 2025 to support growth and commercialization plans. The R&D team is moving to Science Square/Portal Innovations in midtown Atlanta, while the new headquarters will be at 1955 Lake Park Drive in Smyrna, Georgia. Leadership says the moves deepen ties to Georgia's bio-ecosystem and positions the Company for late-stage development, highlighting the advancing GEO-MVA program and multiple oncology and infectious-disease trials.

October 30, 2025—GeoVax is urging swift U.S. action after BIO CEO John Crowley warned biotech leadership could slip to China. The Company calls for diversifying beyond mRNA, onshoring manufacturing, protecting NIH funding, modernizing FDA pathways, expanding incentives, and pairing China guardrails with domestic investment—highlighting GEO-MVA (Mpox/smallpox) and CM04S1 (COVID-19 for immunocompromised) as near-term solutions.

October 29, 2025—GeoVax says new IDSA guidance highlights the need for better COVID-19 vaccines for immunocompromised patients and aligns with its Phase 2 data for GEO-CM04S1. Interim results show strong T-cell responses to Spike and Nucleocapsid, cross-variant activity, and a favorable safety profile, with no vaccine-related serious adverse events. In high-risk groups like post-transplant and hematologic cancer patients, breakthrough cases were mild to moderate. The Company positions CM04S1 as a multi-antigen, MVA-based option designed to provide broader, more durable protection than current mRNA boosters.

October 28, 2025—GeoVax welcomes new Infectious Diseases Society of America (IDSA) guidance prioritizing COVID-19 vaccination for immunocompromised people, noting current vaccines offer only moderate, short-lived protection. The Company positions its MVA-based, multi-antigen vaccine GEO-CM04S1 as designed for this gap, aiming to drive both antibody and durable T-cell responses. Ongoing Phase 2 studies in CLL and transplant patients show durable immunity, cross-variant activity, and good tolerability; in the CLL trial, the mRNA arm was halted for not meeting a continuation endpoint while CM04S1 advanced. GeoVax says CM04S1 could better serve the ~40 million immunocompromised Americans.

October 20, 2025—GeoVax warns that locally transmitted Clade 1 Mpox cases in Los Angeles highlight a fragile U.S. vaccine supply that currently depends on a single foreign MVA manufacturer. The Company promotes GEO-MVA as a second-source solution, noting the EMA has endorsed a direct path to a Phase 3 immuno-bridging trial. In parallel, GeoVax is building U.S.-based continuous cell-line (AGE1) manufacturing to enable rapid, high-volume production. The plan aligns with recent federal initiatives to onshore medical manufacturing (White House EO, HHS/ASPR-DARPA programs, bipartisan legislation, and NSCEB recommendations).

October 16, 2025—GeoVax’s interim Phase 2 data show its MVA-based, multi-antigen COVID-19 vaccine GEO-CM04S1 triggers strong T-cell responses to Spike and Nucleocapsid that exceed mRNA boosters, with a favorable safety profile in post-transplant/CAR-T patients (mostly mild-to-moderate reactions, no vaccine-related serious events; breakthrough cases were mild). The vaccine targets broader, more durable protection for immunocompromised people and is being tested as a primary vaccine, a CLL booster, and a durable booster for previously mRNA-vaccinated adults.

October 13, 2025—GeoVax announced that its leaders will attend World Vaccine Congress Europe and BIO-Europe Fall to advance partnerships with NGOs and academic groups. Priorities include second-source Mpox/smallpox supply (GEO-MVA), the CM04S1 COVID-19 vaccine for immunocompromised patients, Gedeptin® in oncology, and broader MVA platform/tech-transfer deals—aimed at accelerating development, manufacturing readiness, and regional access.

October 9, 2025—GeoVax announced that it will present data on its multi-antigen COVID-19 vaccine GEO-CM04S1 at World Vaccine Congress Europe (Oct 13-16, Amsterdam). CSO Mark Newman will speak on vaccine design for immunocompromised patients, and CMO Kelly McKee will present interim safety/reactogenicity results in adults with hematologic malignancies receiving cellular therapies. The Company aims to highlight CM04S1’s safety profile and relevance for vulnerable populations.

October 7, 2025—GeoVax announced that CEO David Dodd will attend the invite-only ROTH Healthcare Opportunities Conference on October 9, 2025, at the Yale Club in NYC for 1-on-1 and small-group investor meetings. Discussions will center on the pipeline: GEO-MVA (Mpox/smallpox vaccine with favorable EMA guidance), GEO-CM04S1 (multi-antigen COVID-19 vaccine in three Phase 2 trials), and Gedeptin® (gene-directed therapy moving toward a Phase 2 head and neck cancer study).

October 1, 2025—GeoVax is sponsoring the 3rd Dr. David Satcher Global Health Equity Summit at Morehouse School of Medicine on October 2, 2025, underscoring its commitment to equitable vaccine access. The event features leaders including U.S. Global AIDS Coordinator Dr. John Nkengasong and sessions on vaccine access, pandemic preparedness, and community-driven equity. GeoVax’s Mary Hauser, PhD, will attend to discuss the Company’s MVA-based vaccines aimed at immunocompromised and underserved populations.

September 30, 2025—GeoVax entered a registered direct offering with healthcare-focused institutional investors for ~\$2.5M, selling 3,968,256 shares (or equivalents) plus warrants for up to 11,904,768 shares at a combined \$0.63 per share/warrant. Warrants carry a \$0.63 exercise price, become exercisable upon shareholder approval, and expire five years after that approval. Closing was expected Sept 30, 2025; proceeds support R&D, manufacturing, clinical studies, and working capital. Roth Capital Partners served as sole placement agent.

September 29, 2025—GeoVax voiced support for the new “America First Global Health Strategy,” saying its programs align with the plan’s focus on U.S. innovation, onshore manufacturing, and global partnerships. The Company highlighted GEO-MVA (Mpox/smallpox) and GEO-CM04S1 (multi-antigen COVID-19) plus its continuous cell-line manufacturing (AGE1) as tools for faster, more resilient pandemic response. Favorable EMA advice for GEO-MVA and a second-source U.S. supply position are framed as advancing national security and global health access.

September 24, 2025—GeoVax is widening development of Gedeptin® beyond head and neck cancer, testing it with checkpoint inhibitors in preclinical models for additional solid tumors. A Phase 2 trial in resectable head & neck squamous cell carcinoma is planned for 2H26, adding intratumoral Gedeptin plus fludarabine to neoadjuvant pembrolizumab, with MPR and event-free survival endpoints. The plan leverages KEYNOTE-689 momentum and Gedeptin’s tumor-debulking, immune-priming mechanism (Orphan Drug Designation for oral/pharyngeal cancers).

September 22, 2025—GeoVax reaffirmed its science-based approach to vaccine safety, noting VAERS flags signals but doesn’t prove causality. It highlighted GEO-CM04S1, an MVA-based, multi-antigen COVID-19 vaccine in Phase 2 for immunocompromised patients, with favorable safety to date and ongoing rigorous monitoring and regulator collaboration.

September 18, 2025—GeoVax will present at the Emerging Growth Conference on September 25, 2025, with CEO David Dodd discussing interim clinical results for its multi-antigen COVID-19 vaccine GEO-CM04S1. Phase 2 data in CLL met the immune-response primary endpoint while the mRNA comparator did not, leading the DSMB to continue enrollment only in the CM04S1 arm. Additional interim data in immunocompromised blood-cancer and post-transplant patients showed robust, durable T-cell and cross-variant antibody responses with no serious adverse events, reinforcing CM04S1's differentiation versus standard-of-care vaccines.

September 15, 2025—GeoVax reported positive interim Phase 2 results in CLL: GEO-CM04S1 met the trial's primary immune-response endpoint while the mRNA comparator did not, prompting the DSMB to continue enrollment only in the CM04S1 arm. Both vaccines were well tolerated with no ≥Grade 3 adverse events. The Company positions CM04S1's multi-antigen, MVA platform (Spike + Nucleocapsid) as a potential solution for immunocompromised patients underserved by current vaccines.

September 12, 2025—GeoVax reported interim Phase 2 data at ESCMID showing its multi-antigen COVID-19 vaccine GEO-CM04S1 produced strong, durable T-cell and cross-variant antibody responses in immunocompromised patients, with no vaccine-related serious adverse events. In a CLL trial, CM04S1 met the primary endpoint while the mRNA comparator did not, leading enrollment to continue only in the CM04S1 arm. An updated construct with the Omicron KP.2 spike is slated for clinical testing in 2026.

September 8, 2025—GeoVax will present new GEO-CM04S1 clinical data in immunocompromised patients at two September meetings: ESCMID (Sept 10-13, Lisbon) and iwCLL (Sept 12-15, Krakow). Posters will highlight cross-variant antibody activity and robust cellular (T-cell) responses, including Phase 2 results in CLL showing improved cellular immunity versus an mRNA vaccine.

September 3, 2025—GeoVax will present at the H.C. Wainwright Global Investment Conference (Sept 8-10, NYC) and host investor meetings, with a webcast on Sept 8 at 7:00 a.m. ET. CEO David Dodd will update on GEO-MVA (Mpox/smallpox), GEO-CM04S1 (multi-antigen COVID-19, three Phase 2 trials), Gedeptin® (headed to Phase 2 in head & neck cancer), and the Company's U.S.-based continuous cell-line manufacturing.

August 20, 2025—GeoVax received a USPTO Notice of Allowance for a patent covering MVA-based, multi-antigen COVID-19 vaccine constructs that encode Spike, Membrane, and Envelope to form virus-like particles and drive both antibody and T-cell responses. The claims span ancestral and variant mutations, strengthening IP behind programs like CM01/CM02 and complementing Phase 2 candidate GEO-CM04S1. The Company says this broadens its next-generation COVID-19 vaccine portfolio beyond single-antigen approaches.

August 18, 2025—GeoVax will present at the Emerging Growth Conference on August 20, 2025 (3:40-3:50 p.m. ET). CEO David Dodd will update progress and milestones for GEO-MVA. GeoVax will also highlight its MVA platform and U.S.-based continuous cell-line manufacturing for supply diversification and pandemic readiness. A live Q&A and replay will be available.

August 7, 2025—GeoVax backs HHS's rollback of BARDA-funded mRNA projects and urges a pivot to multi-antigen vaccines, spotlighting its MVA-based GEO-CM04S1 as broader and more durable. It cites Phase 2 data (including CLL) where CM04S1 outperformed an mRNA comparator, emphasizes MVA's safety and U.S. manufacturing plans, and invites federal collaboration to advance CM04S1 and GEO-MVA for preparedness.

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.

POTENTIAL NEAR-TERM MILESTONES

GEO-MVA (Mpox and Smallpox Vaccine Candidate)

- *Clinical readiness and trial initiation.* Complete fill/finish of the cGMP clinical batch and have GEO-MVA vaccine available for clinical evaluation in early 2026, with the goal of moving directly into a single Phase 3 immunobridging trial under EMA-endorsed expedited guidance.
- *Regulatory and stakeholder engagement.* Continue EMA and other regulatory interactions while expanding discussions with U.S. and global health stakeholders (including WHO, Africa CDC, CEPI, UNICEF and others) regarding stockpile needs, emergency-use strategies, and long-term procurement.
- *Needle-free delivery collaboration.* Generate initial data from the University of Queensland/UniQuest collaboration evaluating Vaxxas' HD-MAP patch for needle-free, thermostable, and dose-sparing delivery of GEO-MVA.

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

- *Ongoing Phase 2 readouts.* Provide additional interim and longer-term data from Phase 2 studies in hematologic cancer and CLL patients, including durability of T-cell and cross-variant antibody responses and outcomes following discontinuation of the comparator mRNA arm after the CLL trial met its primary immunogenicity endpoint.
- *Healthy adult booster trial.* Report data from the healthy-adult booster study, with results expected in the fourth quarter of 2025 as highlighted in the investor presentation.
- *Next-generation construct.* Advance a KP.2-based GEO-CM04S1 construct toward a planned 2026 clinical trial to enhance coverage of emerging Omicron-family variants.
- *Scientific and partnering visibility.* Continue presenting clinical data at major meetings (e.g., ESCMID, iwCLL, World Vaccine Congress) and using these venues to support ongoing partnering and collaboration discussions.

Gedepin® (Oncology Program)

- *Phase 2 trial activation.* Complete manufacturing of clinical supply and finalize regulatory and operational preparations for AdPNP-203, a Phase 2 neoadjuvant trial of Gedepin plus pembrolizumab and fludarabine in first-line, resectable head and neck squamous cell carcinoma, with trial initiation targeted for the second half of 2026.
- *Data dissemination and pipeline expansion.* Publish the completed Phase 1/2 data set in JCO Oncology Advances and generate additional preclinical data in triple-negative breast and cutaneous malignancies through collaborations with Emory's Winship Cancer Institute, supporting future solid-tumor expansion and checkpoint-inhibitor combinations.

Manufacturing and Strategic Partnerships

- *Advanced MVA process development.* Advance the transformative continuous avian cell-line MVA manufacturing process for both GEO-CM04S1 and GEO-MVA, targeting higher throughput, lower cost of goods, and compatibility with regional manufacturing hubs and stockpile programs.
- *CDMO and collaboration strategy.* Work with Oxford Biomedica and potential additional manufacturing partners to expand GEO-MVA supply on the CEF platform for near-term clinical and stakeholder needs, while pursuing broader strategic and funding collaborations aligned with U.S. onshoring and global pandemic-preparedness initiatives.

GeoVax Positioned to Benefit from Evolving Federal Vaccine Priorities

During the Q3 2025 call, GeoVax emphasized that U.S. federal agencies are increasingly focused on diversifying beyond first-generation, single-antigen mRNA vaccines and strengthening domestic manufacturing capacity—an approach that aligns directly with the Company’s multi-antigen MVA platform. Management noted that ASPR, BARDA, Congressional offices, and global health organizations continue to highlight the need for vaccines that deliver broader and more durable immune protection, particularly for immunocompromised patients and for pathogens prone to rapid viral evolution such as Mpox and SARS-CoV-2. GeoVax’s dual-antigen COVID-19 vaccine, GEO-CM04S1, and its MVA-based Mpox/smallpox vaccine, GEO-MVA, fit squarely within this emerging framework.

GEO-CM04S1 expresses both the spike and nucleocapsid antigens, generating robust T-cell and cross-variant antibody responses across multiple Phase 1 and Phase 2 studies. In the ongoing Phase 2 CLL trial, interim analysis showed that GEO-CM04S1 achieved its primary immunogenicity endpoint while the comparator mRNA vaccine arm was discontinued, reinforcing the vaccine’s potential to address the needs of more than 40 million immunocompromised individuals in the U.S. The MVA backbone has a long clinical and safety history, including extensive use in immunocompromised populations—a key differentiator as public health agencies reevaluate the limitations of narrow-target vaccines.

Management further highlighted that federal priorities now include:

- expanding U.S.-based manufacturing,
- diversifying the national stockpile with non-mRNA platforms, and
- supporting technologies capable of rapid deployment in both domestic and global settings.

GeoVax’s MVA infrastructure, its ongoing development of a next-generation continuous cell-line MVA manufacturing process, and its U.S. footprint position the Company to engage more deeply with government agencies as biodefense and pandemic-preparedness initiatives advance. The Company also continues active outreach with BARDA, ASPR, the State Department, WHO, CEPI, Africa CDC, and UNICEF regarding stockpile modernization, Mpox response, and equitable global access.

Capitalizing on Momentum in Multi-Antigen Vaccines

Investor interest in GeoVax’s differentiated approach has increased in recent months, with management reporting more inbound engagement following multiple scientific presentations and growing recognition of the limitations of first-generation mRNA vaccines in high-risk populations. Despite being one of the smallest companies still developing a COVID-19 vaccine, GeoVax believes it is well positioned for the next phase of vaccine innovation, particularly as public health agencies, clinicians, and investors shift their attention toward multi-antigen, durable, broadly protective platforms. Management reiterated the Company’s confidence in its clinical trajectory and its ability to serve both domestic and global needs as federal priorities continue to evolve.

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 underserved 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 in multiple Phase 2 trials in immunocompromised populations, including patients with chronic lymphocytic leukemia (CLL), where interim data have shown achievement of the primary immunogenicity endpoint and superiority versus a comparator mRNA vaccine. Additional studies include a healthy adult booster trial, with data expected in late 2025, and a next-generation GEO-CM04S1 construct incorporating an Omicron KP.2 Spike sequence planned for clinical evaluation in 2026. GEO-MVA, the Company's Mpox/smallpox vaccine, is advancing under EMA-endorsed guidance that supports a direct path into a single Phase 3 immunobridging trial; a cGMP clinical batch has been manufactured and fill/finish is underway to support early 2026 clinical evaluation and stakeholder discussions. In oncology, GeoVax is advancing Gedeptin® toward a planned Phase 2 neoadjuvant trial (AdPNP-203) in first-line, resectable head and neck squamous cell carcinoma in combination with pembrolizumab and fludarabine, with initiation targeted for the second half of 2026, alongside preclinical expansion into additional solid tumors. GeoVax holds worldwide rights to its platforms and product candidates and is supported by a broad, growing intellectual property portfolio and an evolving manufacturing infrastructure, including development of an advanced, continuous avian cell-line MVA production process. The Company's development programs are summarized in Figure 1 (page 11).

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
Gedepin®	Advanced Head & Neck Cancer	Effect on Targeted Tumors (NCT03754933)	Phase 1/2 Enrollment Closed
Gedepin®	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 have traditionally been created from weakened or killed forms of a virus. Newer vaccines use recombinant DNA technology to produce antigens from specific portions of a pathogen's genetic sequence. Among the most successful of these approaches are non-infectious virus-like particles (VLPs), which are used in licensed vaccines such as the hepatitis B vaccines Recombivax® (Merck) and Engerix® (GSK), and the human papillomavirus vaccines Cervarix® (GSK) and Gardasil® (Merck).

GeoVax's MVA-VLP vector vaccine platform combines the safety of a replication-defective Modified Vaccinia Ankara (MVA) live vector with the immunogenicity of VLPs and the durability of immune responses induced by vaccinia vectors. VLPs train the immune system to recognize and neutralize the authentic virus and to identify and destroy infected cells, helping to control infection and reduce disease severity. One of the key challenges for VLP-based vaccines is ensuring that the VLPs resemble the authentic virus closely enough to elicit the appropriate immune responses. GeoVax's technology drives the production of VLPs in vivo, within the vaccinated individual, which more closely mimics natural infection and supports strong humoral and cellular immune responses.

Multiple studies have shown that VLPs for enveloped viruses such as HIV, Ebola, Sudan, Marburg, and Lassa fever, produced using the MVA-VLP platform, are structurally very similar to authentic virus particles because they include viral protein antigens and a lipid envelope derived from the vaccinated individual's cells. In contrast, VLPs made ex vivo may lack an envelope or use an envelope derived from cultured cells. GeoVax believes that in-vivo VLP production offers important advantages by generating particles that more closely resemble the authentic virus and are therefore more readily recognized by the immune system.

MVA-VLP-MUC1 AND CANCER IMMUNOTHERAPY VACCINE PROGRAM

GeoVax uses its MVA/MVA-VLP vaccine platform to express abnormal, aberrantly glycosylated forms of the cell surface-associated MUC1 protein, which is associated with a wide range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung cancer. The goal is to generate therapeutic anti-tumor antibodies and T-cell responses in cancer patients.

The Company's cancer immunotherapy strategy is based on combining a tumor-associated antigen (TAA) vaccine with a potent anti-tumor modality, such as an immune checkpoint inhibitor (ICI), to drive regression of established tumors and reduce the likelihood of metastatic spread or recurrence. GeoVax has constructed an MUC1 MVA-VLP vaccine and evaluated it in transgenic mouse models in combination with peptide vaccines and checkpoint blockade. In treatment models, the combination of MVA-MUC1 plus tumor-associated peptide reduced tumor growth compared with controls and outperformed either component alone. In prevention/recurrence models, MVA-VLP-MUC1 induced immune responses that provided near-complete protection against tumor recurrence. These data support continued advancement of MVA-VLP-based immunotherapies targeting MUC1 and other TAAs, alone and in combination with checkpoint inhibitors.

COVID-19 VACCINE PROGRAM

GeoVax initiated development of COVID-19 vaccines in early 2020 using its MVA-VLP platform, with the goal of generating broad, durable immunity that engages both neutralizing antibodies and functional T-cell responses and potentially offers protection across multiple SARS-CoV-2 variants. The platform is designed to favor Th1-biased cellular responses, which are associated with lower risk of vaccine-associated immunopathology and better viral clearance.

Early candidates encoded multiple structural proteins (including Spike, membrane, and envelope) to support in-vivo VLP formation and broaden immune recognition. Building on this foundation, GeoVax's lead COVID-19 program is now GEO-CM04S1, a next-generation, dual-antigen MVA-based vaccine that expresses both Spike (S) and nucleocapsid (N) antigens to enhance breadth and durability of protection, particularly in immunocompromised populations.

GEO-CM04S1

GEO-CM04S1 is GeoVax's lead COVID-19 vaccine candidate and is designed to provide a practical, public-health-oriented solution for high-risk, immunocompromised individuals who respond poorly to first-generation vaccines. By expressing both S and N antigens on an MVA backbone with an extensive safety history, GEO-CM04S1 is intended to generate robust and durable humoral and cellular immune responses across evolving SARS-CoV-2 variants and to serve as a heterologous booster to mRNA vaccines.

Globally, hundreds of millions of people are considered immunocompromised due to underlying conditions (such as hematologic malignancies, solid tumors, renal disease, or autoimmune disorders) or therapies (including transplants and B-cell-depleting agents). Management estimates that more than 40 million adults in the U.S. and roughly 400 million worldwide fall into high-risk immunocompromised categories, many of whom mount suboptimal responses to currently approved vaccines and remain at increased risk of severe COVID-19.

Recent Updates

Phase 2 studies of GEO-CM04S1 in immunocompromised patients, including those with chronic lymphocytic leukemia (CLL) and other hematologic cancers, continue to generate encouraging data. Interim results from the CLL trial showed that GEO-CM04S1 achieved its primary immunogenicity endpoint and produced robust T-cell and cross-variant antibody responses, while the comparator mRNA vaccine failed to meet its predefined immune response threshold and its arm was discontinued. No serious adverse events have been attributed to GEO-CM04S1 in these studies, reinforcing the favorable safety profile of the MVA platform.

Data presented at multiple international meetings have highlighted the differentiated immunologic profile of GEO-CM04S1, including strong cellular responses, breadth across variants, and promising durability signals in immunocompromised cohorts. Management is positioning GEO-CM04S1 specifically for the large and underserved immunocompromised population, initially in the U.S. and then globally. In parallel, GeoVax is advancing a next-generation GEO-CM04S1 construct incorporating an Omicron KP.2 Spike sequence, with clinical evaluation planned for 2026, to further enhance coverage of contemporary and emerging variants.

GEDEPTIN®

Gedepin® is GeoVax's lead oncology asset, a gene-directed enzyme prodrug therapy (GDEPT) designed to selectively convert a systemically administered, relatively non-toxic prodrug into a cytotoxic agent within the tumor microenvironment. The therapy is administered via intratumoral injection of a viral vector encoding the enzyme, followed by intravenous administration of the corresponding prodrug, with the goal of achieving high local concentrations of chemotherapeutic activity while minimizing systemic toxicity. Gedepin has received Orphan Drug designation for the treatment of head and neck cancer.

An earlier multicenter Phase 1/2 trial evaluated Gedepin in patients with advanced, needle-accessible solid tumors who had received multiple prior lines of therapy. The study allowed up to five treatment cycles per patient and included diagnoses such as head and neck squamous cell carcinoma, nasopharyngeal carcinoma, and lymphoepithelial carcinoma. The regimen was generally well tolerated, with no dose-limiting toxicities and primarily low-grade, local adverse events such as injection-site discomfort. Several patients achieved stable disease, and median progression-free and overall survival were approximately seven months in this heavily pretreated population. These data were presented at the 2025 AACR Annual Meeting and are being further documented in peer-reviewed publications.

Building on these findings and emerging data supporting perioperative checkpoint inhibition in head and neck cancer, GeoVax is planning AdPNP-203, a Phase 2 neoadjuvant trial evaluating Gedepin in combination with intravenous fludarabine and pembrolizumab in first-line, resectable head and neck squamous cell carcinoma (HNSCC). Trial initiation is targeted for the second half of 2026, subject to completion of clinical-grade manufacturing and regulatory preparations. Parallel preclinical work with collaborators at Emory University's Winship Cancer Institute is expanding the Gedepin platform into additional solid tumors, including triple-negative breast and cutaneous malignancies.

GeoVax views Gedeptin as a tumor-agnostic platform with the potential to address multiple solid tumor indications and is exploring opportunities to combine Gedeptin with different checkpoint inhibitors and other modalities to enhance anti-tumor immune responses.

HEMORRHAGIC FEVER (HF) VACCINE PROGRAMS

(Ebola, Sudan, Marburg, and Lassa)

GeoVax is advancing a suite of preclinical vaccine candidates targeting high-consequence hemorrhagic fever viruses, including Marburg (MARV), Sudan (SUDV), Ebola (EBOV), and Lassa fever virus (LASV), using its MVA-VLP platform. These pathogens, which primarily affect Central and West Africa, cause high fatality rates and remain priorities for global health security and biodefense.

In animal models, GeoVax's hemorrhagic fever vaccines have induced broad immune responses that include neutralizing antibodies and functional T cells, both of which are important for durable protection. Additional studies have shown that MVA-VLP-EBOV can confer 100% protection in non-human primates against a lethal Ebola virus challenge. GeoVax's SUDV and LASV vaccine candidates have also demonstrated protection in preclinical models, with LASV constructs providing 100% single-dose protection in rodents using a multi-strain intracranial challenge. Non-human primate studies for LASV are ongoing in collaboration with NIAID and the U.S. Army, and future development will be guided by emerging outbreak patterns, funding, and prioritization by global health agencies. GeoVax intends to position these programs for potential eligibility under the FDA Priority Review Voucher (PRV) framework for certain high-priority pathogens.

MALARIA VACCINE PROGRAM

GeoVax has previously collaborated with the Burnet Institute in Australia to develop malaria vaccine candidates using its GV-MVA-VLP™ platform, incorporating antigens from *Plasmodium falciparum* and *Plasmodium vivax*. In a separate effort, the Company partnered with Leidos, Inc. under a USAID-funded Malaria Vaccine Development Program. While active development is currently on hold, GeoVax continues to view malaria as a critical global health challenge. A recently issued U.S. patent covering a novel MVA-based malaria vaccine construct strengthens the Company's intellectual property position in this area, and the program may be re-initiated if suitable non-dilutive funding or strategic partnerships become available.

ZIKA VIRUS (ZIKV) VACCINE PROGRAM

GeoVax is developing Zika virus vaccine candidates using its GV-MVA-VLP™ platform, targeting the ongoing unmet need for a safe and effective Zika vaccine, particularly for women of childbearing age and newborns. The lead candidate, GEO-ZM02, is designed around the NS1 gene product to avoid antibody-dependent enhancement (ADE), a concern with some flavivirus vaccines.

In preclinical studies, rodents vaccinated with GEO-ZM02 demonstrated 100% protection against a lethal intracranial Zika challenge after a single dose, while rhesus macaques showed strong control of viral replication despite the vaccine's intentional avoidance of neutralizing antibody induction. Although these results provide strong proof of concept, further clinical development is currently on hold pending external funding or partnerships. GeoVax continues to monitor the Zika landscape and remains prepared to advance GEO-ZM02 should public health needs and funding priorities shift.

HIV PROGRAM (DISCONTINUED; AVAILABLE FOR OUT-LICENSE / PARTNERING)

GeoVax has discontinued active development of its HIV vaccine programs following a strategic decision to prioritize its infectious disease and oncology pipelines and in light of reduced external funding for HIV vaccine development. The underlying HIV technology and intellectual property remain available for out-licensing or partnering and continue to support the broader MVA-based platform, providing important safety, manufacturing, and immunogenicity data that inform current programs.

PARTNERSHIPS

GeoVax has established a broad network of collaborations with government agencies, academic institutions, and industry partners to advance its vaccine and immunotherapy programs and to secure non-dilutive funding where possible. U.S. government collaborators have included 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 Department of Defense (DoD), the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and the U.S. Naval Research Laboratory (USNRL), among others.

Academic and research partnerships have included Emory University, the University of Pittsburgh, Georgia State University Research Foundation, the University of Texas Medical Branch (UTMB), the Institute of Human Virology at the University of Maryland, The Scripps Research Institute, the University of California, San Francisco (UCSF), the Burnet Institute, and, more recently, the University of Queensland and UniQuest in connection with Vaxxas' HD-MAP technology. Industry collaborations have included Leidos, Inc., ViaMune, Inc., Oxford Biomedica, and others. These partnerships have been instrumental in advancing GeoVax's pipeline and supporting access to specialized expertise, facilities, and grant-based funding.

PATENT PORTFOLIO

As of mid-2025, GeoVax's patent portfolio comprises more than 135 granted and pending patents across 23 patent families, providing broad protection for its vaccine and immunotherapy platforms. Recent additions include a U.S. patent covering an MVA-based malaria vaccine construct and a Notice of Allowance for claims covering the use of Gedeptin in combination with radiation therapy. The portfolio encompasses core MVA-VLP technologies, product-specific claims for GEO-CM04S1, GEO-MVA, and Gedeptin, and various applications in infectious diseases and oncology.

CORPORATE BACKGROUND

GeoVax's primary operations are conducted through its wholly owned subsidiary, GeoVax, Inc., 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., after which GeoVax, Inc. became a wholly owned subsidiary 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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