Company Description

GeoVax Labs, Inc. is a clinical-stage biotechnology company advancing next-generation vaccines and immunotherapies for some of the world's most serious infectious diseases and solid tumor cancers. The Company's lead infectious disease candidate, GEO-CM04S1, is a novel COVID-19 vaccine designed to offer broader and more durable protection. GEO-CM04S1 is currently being evaluated in three Phase 2 clinical trials and is the focus of a BARDA-funded Phase 2b trial involving 10,000 participants, comparing its efficacy to an approved COVID-19 vaccine. The ongoing studies target immunocompromised individuals, such as those with hematologic cancers, patients with chronic lymphocytic leukemia (CLL), and healthy individuals previously vaccinated with mRNA-based vaccines. In oncology, GeoVax's lead program is Gedeptin®, a gene-directed oncolytic therapy for solid tumors. Following a successful multicenter Phase 1/2 trial in advanced head and neck cancers, the Company is planning a follow-on Phase 2 trial evaluating Gedeptin® in combination with an immune checkpoint inhibitor in patients with first recurrent disease. In addition, GEO-MVA is advancing to a definitive clinical evaluation with the goal of becoming the first U.S.-provided vaccine against Mpox and smallpox. GeoVax holds worldwide rights to its product candidates and underlying technologies, supported by a strong intellectual property portfolio. The Company is led by a proven management team with decades of experience creating value across the life sciences sector.

Key Points

- On March 27, GeoVax announced year end 2024 financial results and provided a corporate update. The Company reported a 2025 net loss of $25.0 million, slightly improved from 2023's $26.0 million net loss, driven by $4.0 million in BARDA-related revenue and increased R&D spending on GEO-CM04S1, with general and administrative expenses declining year-over-year.
- GeoVax was awarded nearly $400 million in June 2024 through BARDA's Project NextGen to support a 10,000-patient Phase 2b trial of GEO-CM04S1, marking a major validation of its COVID-19 vaccine program. Managed by Allucent, the trial is expected to evaluate the efficacy of GEO-CM04S1 versus an approved COVID-19 vaccine.
- The Company presented compelling data showing GEO-CM04S1's ability to generate strong immune responses and protection against COVID-19, including in individuals previously vaccinated with mRNA vaccines—highlighting its potential as a next-generation booster.
- In oncology, GeoVax has plans for a Phase 2 trial of Gedeptin® for first recurrent head and neck cancer in combination with an immune checkpoint inhibitor. Planning with leading academic oncology centers is underway, while clinical trial material is being produced.
- In response to emerging health threats, including WHO's Mpox emergency declaration, GeoVax is advancing GEO-MVA, its vaccine candidate targeting Mpox and smallpox, enhancing its pandemic preparedness portfolio. The Company is investing in domestic manufacturing capabilities for its MVA-based vaccines, aiming to strengthen U.S. national security and support rapid response to infectious disease outbreaks.
- GeoVax continues to strengthen its global intellectual property position, with over 130 granted or pending patent applications spread over twenty-three patent families.
- As of December 31, 2024, the Company reported cash balances of $5.5 million versus $6.5 million as of December 31, 2023.

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GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (04/02/2025)	$1.08
52-week Range	$1.03-11.18
Shares Outstanding	13.84 mm
Market Capitalization	$15.36 mm
Avg. Volume	640,000
EPS (Yr ended 12/31/2024)	($4.82)
Employees	19

See page 16 for applicable disclosures.

YEAR END 2024 FINANCIAL RESULTS

GeoVax reported a net loss of $25.0 million for the year ended December 31, 2024, compared to a net loss of $26.0 million for the prior year.

The Company recognized $4.0 million in government contract revenues associated with the BARDA/RRPV Project NextGen award during 2024. No revenues were reported in 2023.

R&D expenses increased to $23.7 million in 2024 from $20.7 million in 2023, primarily due to manufacturing costs for clinical trial materials related to GEO-CM04S1 and other expenses associated with the BARDA Project NextGen contract.

G&A expenses decreased to $5.4 million in 2024 from $6.0 million in 2023, mainly due to reductions in stock-based compensation, consulting fees, patent-related costs, and franchise taxes.

As of December 31, 2024, GeoVax held cash balances totaling $5.5 million, down from $6.5 million at the end of 2023.

Noteworthy is that in March 2025, GeoVax entered a securities purchase agreement with a healthcare-focused institutional investor, raising funds through a registered direct offering of common stock and accompanying warrants.

The Company remains dedicated to developing innovative cancer therapies and vaccines for infectious diseases, addressing critical unmet medical needs. It aims to prioritize initial indications that support faster regulatory approval pathways.

RECENT BUSINESS ACCOMPLISHMENTS

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

GeoVax continues to advance multiple Phase 2 clinical trials for GEO-CM04S1, its dual-antigen, next-generation COVID-19 vaccine, targeting both general and immunocompromised populations. GEO-CM04S1 is designed to address substantial unmet medical needs, particularly among vulnerable populations, and targets a global market opportunity estimated to exceed $30 billion. Recent highlights on this program are summarized below.

- ***BARDA Project NextGen Phase 2b Trial.*** Preparations are underway for a pivotal, randomized, double-blinded Phase 2b trial supported by BARDA under Project NextGen. The 10,000-participant study will compare the efficacy, safety, and immunogenicity of GEO-CM04S1 to an FDA-approved mRNA COVID-19 vaccine. Target sites have been confirmed and trial initiation activities are in progress. BARDA awarded GeoVax nearly $400 million to support the Phase 2b trial of GEO-CM04S1. Allucent, GeoVax's contact research organization (CRO), was appointed to oversee trial implementation.

- ***Chronic Lymphocytic Leukemia (CLL) Trial.*** The study evaluated two vaccine doses administered three months apart, with patients randomized 1:1 to receive either GEO-CM04S1 or an mRNA control. An interim data review by the independent Data Safety Monitoring Board (DSMB) for the ongoing Phase 2 CLL trial concluded that the mRNA control arm did not meet the predetermined primary endpoint. However, the DSMB recommended continued enrollment in the experimental arm using GEO-CM04S1.

- ***Immunocompromised/Stem Cell Transplant Trial.*** The Company is expanding clinical trial sites for its ongoing Phase 2 study evaluating GEO-CM04S1 as a primary vaccine in immunocompromised patients undergoing stem cell transplantation—a population for whom current COVID-19 vaccines may be inadequate.

- ***Healthy Adult Booster Trial.*** Enrollment has been completed in a Phase 2 trial evaluating GEO-CM04S1 as a booster in healthy adults previously vaccinated with COVID-19 vaccines. This study examines safety and immune response at two dose levels, with data expected in the first half of 2025.

Gedeptin®: Gene-Directed Oncolytic Therapy for Solid Tumors

GeoVax is advancing Gedeptin®, its novel gene-directed oncolytic therapy, into a Phase 2 clinical trial for patients with first recurrent head and neck (H&N) cancer. This next-stage study follows encouraging data from previously completed Phase 1 (single-cycle) and Phase 1/2 (multi-cycle) trials in patients with advanced head and neck tumors.

The upcoming Phase 2 trial is expected to evaluate neoadjuvant Gedeptin® in combination with an FDA-approved immune checkpoint inhibitor (ICI). The study is to enroll approximately 36 patients, with pathologic response rate as the primary endpoint. Additional endpoints will assess overall treatment outcomes and durability of response. Planning is currently underway in collaboration with leading academic oncology centers, and production of clinical trial material is in progress.

Gedeptin® holds Orphan Drug Designation from the U.S. FDA for the treatment of anatomically accessible oral and pharyngeal cancers, offering strategic regulatory and market advantages. In addition to head and neck cancers, Gedeptin®'s platform has the potential to address other solid tumors, including triple-negative breast cancer, soft tissue sarcoma, and melanoma.

With a global market opportunity estimated at over $15 billion, Gedeptin® represents a significant therapeutic advancement for difficult-to-treat cancers with high unmet medical need.

Mpox and Smallpox Vaccine Platform (GEO-MVA)

GeoVax is preparing to initiate clinical evaluations of GEO-MVA, its vaccine candidate targeting Mpox and Smallpox, with trials expected to begin in late 2025. Developed on the Company's proven Modified Vaccinia Ankara (MVA) platform, GEO-MVA is designed to offer broad, durable protection and address urgent global health needs, particularly among underserved populations, including those in regions such as Africa.

In 2024, GeoVax successfully manufactured a clinical-grade batch of GEO-MVA under current Good Manufacturing Practice (cGMP) standards. The Company's proprietary advanced MVA manufacturing process supports scalable, flexible, and cost-effective vaccine production—helping reduce dependence on foreign suppliers and strengthening domestic biodefense capabilities.

GeoVax is actively engaging with government agencies, NGOs, and private-sector partners to expand access and drive adoption of GEO-MVA globally. Recommended by WHO and the CDC, MVA is recognized for its safety and effectiveness across diverse patient populations, including pregnant women, children, and the immunocompromised. MVA is also stockpiled in the U.S. Strategic National Stockpile for immunization against potential bioterrorism threats involving the smallpox virus.

With an estimated market opportunity exceeding $10 billion, GEO-MVA represents a critical solution in global preparedness against orthopoxvirus threats. GeoVax believes that its vaccine is well positioned to disrupt the global smallpox and Mpox vaccine supply chain, aiming to become the first U.S.-based supplier—enhancing national biosecurity.

Corporate and Intellectual Property Developments

In 2024, GeoVax announced plans to establish a strategic presence in the United Kingdom, aimed at supporting the expansion of manufacturing partnerships, fostering collaborations with European service providers and academic institutions, and exploring technology licensing opportunities and access to regional scientific expertise.

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

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

RECENT COMPANY DEVELOPMENTS

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

March 27, 2025—Announced its financial results and key operational accomplishments for the year ended December 31, 2024, as further detailed within this Update.

March 24, 2025—Announced that the Company has entered into a securities purchase agreement with a healthcare-focused institutional investor for a registered direct offering of 3,435,115 shares of common stock (or equivalents) and accompanying warrants at $1.31 per share. The warrants, also priced at $1.31, will become exercisable upon shareholder approval and will expire five years thereafter.

March 17, 2025—Announced that it will report 2024 financial results on Thursday, March 27, 2025, after the close of U.S. markets. Following the release, management hosted a live conference call and webcast, including Q&A, at 4:30 p.m. ET to provide a corporate update and discuss financial results.

March 12, 2025—Announced that it is expanding into Europe, starting with the UK, to advance its vaccine and immunotherapy pipeline. The Company has established key collaborations, including appointing Professor Teresa Lambe to its Scientific Advisory Board and partnering with Oxford Biomedica, ProBioGen AG, and UK academic institutions. This strategic move strengthens GeoVax's global manufacturing capabilities and supports the development of its infectious disease vaccines and lead immuno-oncology candidate, Gedeptin®, currently in clinical trials.

March 11, 2025—Announced that David Dodd was to present at the 37th Annual Roth Conference, taking place in Dana Point, CA on March 16-18, 2025. Mr. Dodd's presentation was in the form of a fireside chat moderated by Roth Managing Director, Senior Research Analyst Jonathan Aschoff, PhD.

March 4, 2025—Announced that David Dodd presented at Tribe Public's CEO Presentation and Q&A Webinar titled "MPOX 2025: Navigating the Global Public Health Emergency" on March 6, 2025, at 8:30 AM Pacific Time (11:30 AM Eastern Time). The webinar addressed the ongoing Mpox crisis, particularly the more transmissible and severe Clade 1b variant, which has led to over 60,000 suspected cases and 1,300 deaths in the Democratic Republic of the Congo in 2024. The virus's spread to countries including the U.S., Canada, and Europe underscores the urgency for effective vaccines. GeoVax's Mpox vaccine candidate, GEO-MVA, is advancing to clinical evaluation, anticipated in the second half of 2025. Registration for the webinar is open, and participants can submit questions in advance or during the event.

March 3, 2025—Emphasized the strategic importance of its MVA vaccine platform in bolstering U.S. biodefense capabilities. Aligning with recommendations from the "Bolstering U.S. Biodefense: Recommendations For The New Administration" report, GeoVax is developing MVA-based vaccines, including GEO-MVA for Mpox and smallpox, and transitioning to a next-generation manufacturing platform utilizing a continuous avian cell line.

February 27, 2025—Responded to the World Health Organization's (WHO) third declaration of Mpox as a Public Health Emergency of International Concern by advancing its GEO-MVA vaccine candidate to bolster global supply options. The WHO's declaration underscores the persistent and escalating nature of the Mpox outbreak, with nearly 128,000 confirmed cases across 130 countries since 2022. The Democratic Republic of the Congo has been particularly affected, reporting over 60,000 cases and 1,300 deaths in 2024. GeoVax aims to address vaccine supply challenges, including severe shortages and reliance on a single non-U.S. manufacturer, by developing GEO-MVA with expanded manufacturing capacity at lower costs and U.S.-based production to enhance biosecurity. The Company has strategic partnerships to support production scale-up and is working closely with regulatory agencies to expedite approvals and ensure equitable vaccine distribution.

February 24, 2025—Emphasized the importance of MVA-based vaccines in enhancing public health preparedness, complementing existing mRNA vaccines. The Company's candidate, GEO-CM04S1, expresses both Spike (S) and Nucleocapsid (N) antigens, aiming to elicit a broader immune response, particularly benefiting immunocompromised individuals. This approach seeks to provide enhanced durability and protection against emerging variants, addressing the need for diversified vaccine strategies.

February 19, 2025—The recent detection of a fourth Clade 1 Mpox case in New York highlights the critical need for a diversified vaccine supply chain. GeoVax is advancing its GEO-MVA vaccine to bolster U.S. and global preparedness. Clade 1 Mpox, with a fatality rate between 3% and 10%, has been reported in several U.S. states, including California, Georgia, New Hampshire, and New York. The current dependence on a single non-U.S. manufacturer for the preferred MVA-based Mpox vaccine poses risks, such as supply chain instability, limited production capacity, and high costs, hindering effective outbreak response. GeoVax's GEO-MVA aims to address these challenges by offering scalable production, cost-effective manufacturing, and enhanced accessibility, thereby strengthening the global fight against Mpox.

February 18, 2025—Reaffirmed its dedication to advancing vaccine innovation, transparency, and public health. GeoVax aligns its initiatives with national priorities by focusing on diversified vaccine platforms, such as its MVA platform, which aims to provide durable immunity across various infectious diseases.

February 17, 2025—Announced that it has been invited to present at the next Emerging Growth Conference being held February 18-19, 2025. This live, interactive online event will give existing shareholders and the investment community the opportunity to interact with the Company's Chairman and CEO, David Dodd, in real time.

February 11, 2025—Congratulated Dr. Valerie Montgomery Rice, President and CEO of Morehouse School of Medicine, on receiving the 2025 Healthcare Champions Lifetime Achievement Award from the Atlanta Business Chronicle. This prestigious honor recognizes Dr. Montgomery Rice's dedication to advancing health equity, particularly among underserved and minority populations globally. Since joining GeoVax as a Special Advisor in December 2022, her expertise has significantly contributed to the company's mission of addressing health disparities through innovative medical solutions.

February 5, 2025—Outlined its strategic milestones for 2025, focusing on advancing its vaccine and immunotherapy programs. The Company plans to complete trials for its next-generation COVID-19 vaccine, GEO-CM04S1, particularly among immunocompromised patients, and initiate a BARDA-funded Phase 2b trial involving 10,000 participants. GeoVax also aims to commence clinical evaluations for GEO-MVA, a vaccine targeting Mpox and Smallpox, with potential deployment in underserved regions. Additionally, the oncology program featuring Gedeptin® is set to enter a Phase 2 trial for recurrent head and neck cancer. GeoVax is integrating artificial intelligence into its research processes to enhance efficiency and innovation.

February 4, 2025—Announced that David Dodd was to present GeoVax's 2025 strategic vision and milestones at the 2025 BIO CEO & Investor Conference, taking place in-person in New York, NY on February 10-12, 2025.

February 3, 2025—Announced its support for President Trump's Stargate Initiative by integrating Artificial Intelligence (AI) into its vaccine and immunotherapy development processes. This integration aims to accelerate research, optimize operations, and enhance biosecurity. AI applications include predicting pathogen mutations for durable vaccines, optimizing cancer immunotherapies, refining patient targeting, and improving manufacturing scalability. CEO David Dodd emphasized that this alignment positions GeoVax to contribute to U.S. leadership in healthcare innovation.

January 29, 2025—Announced its commitment to enhancing America's biosecurity by developing GEO-MVA, a vaccine targeting both smallpox and Mpox. The 2022 Mpox pandemic exposed vulnerabilities in the U.S. vaccine supply, notably the reliance on a single foreign manufacturer. GEO-MVA, built on the MVA platform, has completed current Good Manufacturing Practice (cGMP) production, with clinical evaluations slated for this year. This initiative aligns with bipartisan efforts to bolster domestic biomanufacturing and reduce dependence on foreign vaccine suppliers. David Dodd emphasized the goal of establishing GEO-MVA as the first U.S.-based Mpox vaccine source, reinforcing national preparedness against health threats.

January 27, 2025—Announced it has developed an advanced manufacturing process for its MVA-based vaccines, utilizing a continuous avian suspension cell line licensed from ProBioGen AG. This innovation eliminates the need for pathogen-free eggs, streamlining production, reducing costs, and enhancing scalability. The process is compatible with standard manufacturing equipment, facilitating local vaccine production, particularly in middle- and low-income regions, thereby improving global vaccine accessibility.

January 15, 2025—Announced plans to initiate a Phase 2 clinical trial evaluating Gedeptin, its gene-directed enzyme prodrug therapy, in combination with an approved immune checkpoint inhibitor for patients with first-recurrence head and neck cancer scheduled for curative resection. This decision follows promising data from earlier trials and Gedeptin®'s Orphan Drug Designation by the U.S. FDA, highlighting its potential to address unmet medical needs in solid tumor treatments.

January 13, 2025—Made significant progress in 2024 with its next-generation COVID-19 vaccine, GEO-CM04S1, achieving key milestones. The Company secured a Project NextGen award from BARDA to support a 10,000-participant Phase 2b trial. An interim review of its Phase 2 study in chronic lymphocytic leukemia (CLL) patients led to the discontinuation of the mRNA control arm, as it failed to meet immune response criteria, while GEO-CM04S1 continued enrollment. Additionally, GeoVax completed enrollment for a booster vaccine trial in healthy adults. These advancements reinforce the vaccine's potential, particularly for immunocompromised individuals.

January 8, 2025—Announced that Company has been invited to present at the next Emerging Growth Conference being held January 15-16, 2025. This live, interactive online event will allow existing shareholders and the investment community to interact with the Company's Chairman and CEO, David Dodd, in real-time.

January 6, 2025—Announced that David Dodd was to review 2024 progress in a presentation at the Biotech Showcase coinciding with the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, January 13-16, 2025.

December 9, 2024—Announced that the U.S. Patent and Trademark Office has issued a Notice of Allowance for Patent Application No. 17/876,682 to GeoVax, titled "Vaccinia Viral Vectors Encoding Chimeric Virus Like Particles." The allowed claims add to GeoVax's intellectual property protection related to its vector platform for expressing a tumor associated antigen (TAA) in virus-like particles (VLPs) from a recombinant Modified Vaccinia Ankara (MVA) viral vector, further demonstrating the GeoVax technical expertise.

November 26, 2024—Announced that David Dodd was to present at NobleCon20 - the Noble Capital Markets Twentieth Annual Emerging Growth Equity Conference taking place December 2-5, 2024 in Boca Raton, FL.

November 19, 2024—Announced the completion of an interim data review by the Data Safety Monitoring Board (DSMB) for the ongoing Phase 2 clinical trial of GEO-CM04S1, GeoVax's dual-antigen next-generation COVID-19 vaccine, as a booster vaccine for patients with chronic lymphocytic leukemia (CLL).

POTENTIAL NEAR TEM MILESTONES

GEO-CM04S1

- *Phase 2b Trial Launch.* GeoVax plans to initiate its BARDA-funded Phase 2b clinical trial of GEO-CM04S1, its next-generation COVID-19 vaccine, in the fourth quarter of 2025 or early 2026.

- *Booster Trial Data Readout.* The Company anticipates data readouts from its Phase 2 booster trial in healthy adults during the first half of 2025.

- *CLL Trial Progress.* Interim data from the CLL trial is expected to be presented at scientific conferences by year-end 2025.

- *Immunocompromised Patient Trials.* GeoVax is expanding trial sites to support ongoing studies in immunocompromised populations.

- *Scientific Visibility.* Results from the Company's COVID-19 vaccine program will be presented at several major conferences in 2025.

GEO-MVA

- *Clinical Trial Initiation.* GeoVax expects to begin clinical evaluation of GEO-MVA, its Mpox and Smallpox vaccine candidate, by late 2025, enrolling approximately 400 participants across Europe and Sub-Saharan Africa.

- *Global Engagement.* The Company is actively engaged with WHO, Africa CDC, and UNICEF to explore emergency use and equitable access pathways.

- *U.S. Supply Leadership.* GeoVax aims to become the first U.S.-based supplier of a Mpox vaccine, helping to reduce dependence on foreign manufacturers.

Gedeptin®

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

- *Upcoming Scientific Presentation.* New data from the Gedeptin® program will be presented at the American Association for Cancer Research (AACR) conference.

- *Preclinical Expansion.* Animal validation studies are planned to explore Gedeptin®'s potential use in other solid tumors.

Manufacturing

- *Advanced MVA Process.* GeoVax is implementing its advanced MVA manufacturing platform designed for scalable, decentralized, and cost-effective vaccine production.

Strategic Partnerships

- *Commercial Expansion.* The Company continues to pursue strategic partnerships and licensing opportunities to support global development and commercialization of its pipeline.

Company Background

GeoVax Labs, Inc. is a clinical-stage biotechnology company focused on developing human cancer therapies and infectious disease vaccines. Its technology, targeting infectious diseases and cancer, employs the Company's proprietary MVA vector vaccine technology platform and the patented Gedeptin® gene-therapy technology. The vaccine vector technology utilizes a MVA vector, a large virus capable of carrying several vaccine antigens. MVA is a replication-defective live vector that expresses non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (*in vivo*). VLPs mimic a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection through durable immune responses. The Company's development efforts, both clinical stage as well as preclinical stage, are focused within the areas summarized in Figure 1 (page 9).

Figure 1

GEOVAX PIPELINE: CLINICAL DEVELOPMENT PROGRAMS

Product	Indication	Trial	Status
GEO-CM04S1	COVID-19	BARDA Project NextGen - 10,000 Patient Clinical Study to Evaluate GEO-CM04S1 COVID-19 Vaccine	Phase 2b In Process to Initiate
		Primary Vaccine for: Immunocompromised/Stem Cell Transplant Patients (NCT04977024)	Phase 2 Currently Enrolling
		Booster Vaccine for: Immunocompromised/Chronic Lymphocytic Leukemia Patients (NCT05672355)	Phase 2 Currently Enrolling
		Booster Vaccine for: Healthy Adult Patients (NCT04639466)	Phase 2 Enrollment Closed
Gedeptin®	Advanced Head & Neck Cancer	Effect on Targeted Tumors (NCT03754933)	Phase 1/2 Enrollment Closed
Gedeptin®	Squamous Cell Head & Neck Cancer	First Reoccurrence Therapy in Combination with Immune Checkpoint	Phase 2 Trial Design in Process

GEOVAX PIPELINE: PRECLINICAL DEVELOPMENT PROGRAMS

Product	Target	Completion Testing Status
GEO-MVA-MUC1	Solid Tumor Cancers	Humanized Mouse Model
GEO-CM02	Vaccine for Pan-Coronavirus	Humanized Mouse Model
GEO-EM01 - Z	Vaccine for Ebola Zaire	Non-Human Primate
GEO-EM01 - S	Vaccine for Ebola Sudan	Non-Human Primate
GEO-MM01	Vaccine for Marburg	Non-Human Primate
GEO-ZM02	Vaccine for Zika	Mouse Model
GEO-MVA	Vaccine for Mpox & Smallpox	Regulatory Strategy and Manufacturing Scale-Up

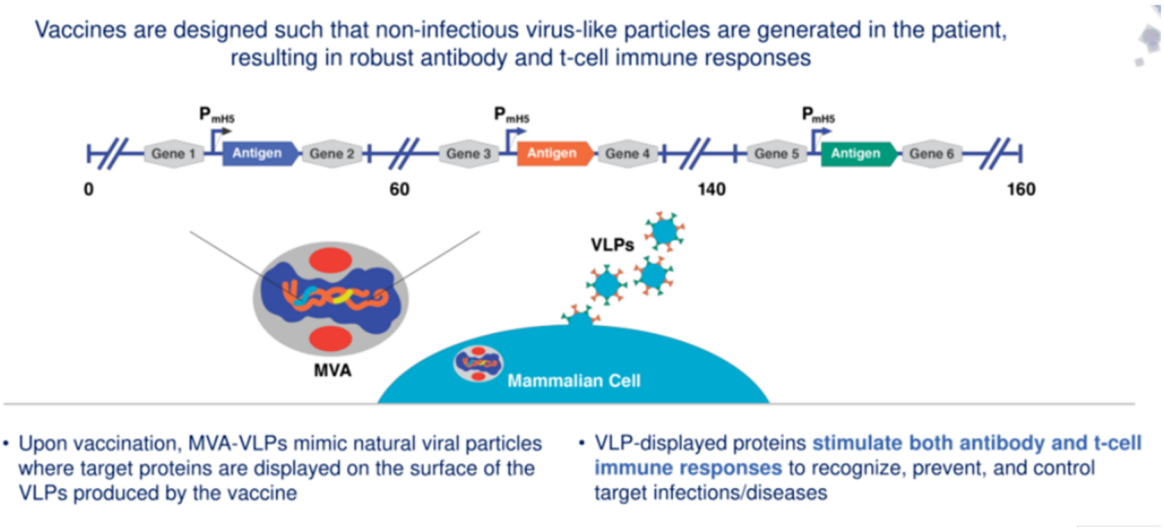
Source: GeoVax Labs, Inc.

MVA/MVA-VLP TECHNOLOGY PLATFORM

Vaccines are most often made of agents (antigens) that resemble disease-causing microorganisms and are traditionally created from weakened or killed forms of the virus. Newer vaccines use recombinant DNA technology to produce vaccine antigens from specific portions of the DNA sequence of the target pathogen. The most successful of these purified antigens have been non-infectious virus-like particles (VLPs) used in vaccines, such as the hepatitis B vaccines (Merck's Recombivax® and GlaxoSmithKline's [GSK's] Engerix®) and human papillomavirus vaccine (GSKs Cervarix® and Merck's Gardasil®).

GeoVax's MVA-VLP vector vaccine technology platform combines the safety of a replication-defective live vector with the immunogenicity of VLPs and the durability of immune responses induced by vaccinia vectors. VLPs train the body's immune system to identify and attack the authentic virus should it appear, and to recognize and kill infected cells to control infection and decrease the length and severity of disease. Among the most challenging aspects of VLP-based vaccines is to design the vaccines in such a way that the VLPs are recognized by the immune system the same way it would an authentic virus. GeoVax's technology drives the production of VLPs in the body of the person being vaccinated (*in vivo)*, thus more closely mimicking a viral infection and inducing the appropriate types of immune responses. Figure 2 provides a graphical depiction GeoVax's GV-MVA-VLP™ vaccine technology.

Figure 2
GV-MVA-VLP™ VACCINE TECHNOLOGY



Source: GeoVax Labs, Inc.

Multiple studies have demonstrated the VLPs for enveloped viruses, such as HIV, Ebola, Sudan, Marburg, or Lassa fever, produced using the MVA-VLP platform are identical in appearance to the authentic virus because they include viral protein antigens and the viral envelope, consisting of membranes from the vaccinated individual's cells. In contrast, VLPs produced externally have no envelope or an envelope derived from the cultured cells used to produce them. Based on its efforts to date, GeoVax believes its technology provides unique advantages by producing VLPs that more closely resemble the authentic virus, enabling the body's immune system to recognize the authentic virus more readily. In addition, GeoVax's MVA-VLP platform has unique advantages, summarized as follows:

- *Safety.* Clinical testing of GeoVax's HIV vaccines has documented an optimal safety profile. This is consistent with the safety profile for MVA used as a smallpox vaccine and documented in more than 120,000 subjects throughout Europe.

- *Durability.* The Company's vaccine technology promotes durable and long-lasting immune responses.

- *Limited pre-existing immunity to vector.* Following the eradication of smallpox in 1980, smallpox vaccinations ended, which left individuals born after 1980 (except for select populations, such as vaccinated laboratory workers, first responders, etc.) unvaccinated and without pre-existing immunity.

- *No need for adjuvants*. MVA stimulates strong innate immune responses without the use of adjuvants.

- *Thermal stability.* MVA is stable in both liquid and lyophilized formats (> 6 years of storage).

- *Genetic stability and manufacturability*. MVA is genetically stable when properly engineered and can be reliably manufactured using the most modern technologies that support scalability, consistency, and efficiency.

MVA-VLP-MUC1 for Solid Tumor Cancers

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

Coronavirus (COVID-19) Vaccine Program

In January 2020, GeoVax announced initiation efforts to develop a vaccine against Coronavirus Disease 2019 (COVID-19) caused by the SARS-CoV-2 coronavirus. As of May 2024, more than 775 million cases have been reported worldwide, resulting in over seven million deaths. In the U.S. there has been 111 million cases and 1.2 million deaths so far. GeoVax has constructed novel candidate vaccines against SARS-CoV-2 based on the MVA-VLP platform. Its technology is designed to: (1) induce both neutralizing antibodies and cellular immune response; (2) induce a Th1 based cellular immune response to prevent immunopathology; (3) potentially cross-protect against other coronaviruses; and (4) induce full protection after a single dose in less than two weeks.

The experimental COVID-19 vaccine, using the Company's MVA-VLP technology, encodes the S protein, which is the basis for all the first-generation products in use today and the targeted neutralizing antibodies. This is used in combination with the membrane (M protein) and the envelop (E protein). The M and E proteins provide the structural components required for the VLP formation in the body. They also serve as additional targets for the cellular immune responses. This design represents a first critical step towards the COVID vaccines that could induce broad, specific immune responses that are not significantly impacted by the variants that are arising as the S protein evolves within a population. GeoVax is working with this approach to attempt to circumvent the evolution of COVID-19, rather than to chase the new variants with modifier vaccines, as is commonly done today with flu vaccines.

GEO-CM04S1

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

Worldwide, there are an estimated 240 million plus individuals, including those with various blood cancers, renal disease, autoimmune diseases such as lupus, which includes transplant patients and others with disease or therapy-induced immunosuppression. Many of these patients are limited in their ability to respond adequately to the approved mRNA vaccine, placing them at significantly increased risk of severe COVID-19 infection hospitalization and potential death. It was reported in February 2024's edition of *JAMA* that the number of immunocompromised adults in the U.S. has been updated, indicating a population of 23 million versus the previous estimate of 15 million.

Project NextGen Update

On June 18, 2024, GeoVax was awarded a contract under HHS's Project NextGen to evaluate GEO-CM04S1 in a 10,000-participant Phase 2b trial against an FDA-approved mRNA vaccine. The BARDA-supported award includes up to $45 million for GeoVax and $343 million via its CRO partner Allucent. As of March 2025, trial initiation is expected in Q4 2025 or early 2026, with eighty of the approximate100 trial sites having been confirmed.

The Company is implementing a next-generation MVA manufacturing process using its AGE1 Master Cell Bank to enable scalable, cost-effective, decentralized production for both pandemic preparedness and global vaccine access.

Scientific Presentations in 2025

GeoVax plans to present data from its COVID-19 vaccine trials at several conferences including the World Vaccine Congress, European Hematology Association, International Workshop on Chronic Lymphocytic Leukemia, and the American Association of Immunologists.

Interim data from ongoing Phase 2 trials in chronic lymphocytic leukemia (CLL) and stem cell transplant patients are expected to be presented in 2025. The CLL trial, being conducted at City of Hope, is progressing toward full enrollment, while the stem cell transplant trial is expected to generate early data in 2026.

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

In 2023, GeoVax announced the closure of enrollment for its Phase 1/2 trial of Gedeptin® among advanced head and neck cancer patients. This initial targeted patient population represents those who are in end-stage care—the 15,000 U.S. and 400,000 worldwide of patients, which represents a critical unmet medical need. Many of these patients are unable to swallow food and have difficulty speaking, and they typically have exhausted existing therapies and standard of care and are receiving palliative care.

GeoVax seeks to provide an improved end-stage quality of life in these patients by shrinking and/or eliminating various targeted tumors and providing clinical evidence supporting advancement of this therapy in earlier-stage disease. This trial was funded by the FDA under the Orphan Drugs clinical trials program, with initial clinical data results presented at the AACR AHNS Conference in Montreal in July 2023. That presentation noted that administration of Gedeptin® was shown to be safe and feasible reflecting stabilization and/or reduction in size of treated tumors. Results from this trial are expected during the first half 2024, followed by discussing the Company's plans for further evaluation in patients with advanced head and neck cancer.

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

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

Update

Following encouraging Phase 1/2 data, GeoVax is advancing Gedeptin® into a Phase 2 trial for recurrent head and neck squamous cell carcinoma, combined with an immune checkpoint inhibitor. As of March 2025, trial initiation is expected in mid-to-late 2025. The Company is considering various funding options including partnerships and non-dilutive sources.

New clinical findings from the Gedeptin® program are expected to be presented at the 2025 American Association for Cancer Research (AACR) conference.

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

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

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

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

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

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

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

Ebola, Sudan, and Marburg viruses are the most virulent species of the Filoviridae family, causing up to a 90% fatality rate in humans, and are epizootic in Central and West Africa (34 outbreaks since 1976). Lassa fever virus (LASV) also causes severe and often fatal hemorrhagic illnesses in an overlapping region to Ebola, but is endemic, with an annual rate of more than 300,000 infections and leading to 5,000-10,000 deaths.

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

Malaria Vaccine Program

GeoVax has collaborated with the Burnet Institute, a leading infectious diseases research institute in Australia, for the development of a vaccine to prevent malaria infection. The project included the design, construction, and characterization of multiple malaria vaccine candidates using GeoVax's GV-MVA-VLP™ vaccine platform combined with malaria Plasmodium falciparum and Plasmodium vivax sequences identified by the Burnet Institute. The Company also collaborated separately with Leidos, Inc. with work funded by a grant to Leidos from the U.S. Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). This program has been inactive as GeoVax has prioritized other development programs. However, pending additional funding support via federal grants or other sources, the Company may further pursue this area. Worldwide, as of 2022, malaria causes 249 million infections and 608,000 deaths annually (mostly in children living in sub-Saharan Africa).

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

ZIKA Virus (ZIKV) Vaccine Program

To address the unmet need for a vaccine against Zika virus, GeoVax is developing novel vaccine candidates constructed using its GV-MVA-VLP platform. MVA has an outstanding safety record, which is particularly important given the need to include women of child-bearing age and newborns among those being vaccinated. The Company's Zika vaccine is designed around the NS1 gene product to eliminate the risk of Antibody Dependent Enhancement (ADE), which is a serious side effect observed when a vaccinated individual does not have a fully protective immune response, which causes a more virulent reaction if infected. GeoVax's initial preclinical studies in rodents using its GEO-ZM02 vaccine candidate demonstrated 100% single-dose protection against a lethal dose of ZIKV delivered directly into the brain. In rhesus macaques, vaccination with GEO-ZM02 induced immune responses that effectively controlled the virus replication despite the fact the vaccine is not designed to induce ZIKV neutralizing antibodies. Further development of the Company's Zika vaccine will be dependent upon partnering support.

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

Due to the Company's corporate refocusing of development efforts in prioritizing its infectious disease and cancer immunotherapy programs, and a lack of continuing government support for its HIV vaccine development efforts, GeoVax has discontinued active development of these programs. The Company's technology and intellectual property will remain available for out-license or partnering but GeoVax will no longer devote any corporate resources to the programs. While not currently under active development, the Company's HIV program forms an important part of the dataset underpinning all of GeoVax's MVA-based development programs. The patent protection associated with this vaccine is an important part of this technology platform.

Partnerships

Through its development efforts, the Company has achieved significant partnerships. Current and recent collaborators and partners include the NIAID/NIH, the HVTN, the CDC, U.S. Department of Defense (DoD), U.S. Army Research Institute of Infectious Disease (USAMRIID), U.S. Naval Research Laboratory (USNRL), Emory University, University of Pittsburgh, Georgia State University Research Foundation (GSURF), University of Texas Medical Branch (UTMB), the Institute of Human Virology (IHV) at the University of Maryland, the Scripps Research Institute (Scripps), Burnet Institute in Australia, the Geneva Foundation, ViaMune, Inc., Leidos, Inc., and UCSF, among others.

Patent Portfolio

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

Corporate Background

The Company's primary business is conducted by its wholly owned subsidiary, GeoVax, Inc., which was incorporated under the laws of Georgia in June 2001. The predecessor to its parent company, GeoVax Labs, Inc. was originally incorporated in June 1988 under the laws of Illinois as Dauphin Technology, Inc. In September 2006, Dauphin completed a merger with GeoVax, Inc. As a result of the merger, GeoVax, Inc. became a wholly owned subsidiary of Dauphin, and Dauphin changed its name to GeoVax Labs, Inc. In June 2008, the Company was reincorporated under the laws of Delaware.

Risks and Disclosures

This Company Update has been prepared by GeoVax Labs, Inc. ("GeoVax" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this Update relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in GeoVax's statements on Forms 10-K, 10-Q, and 8-K as well as other forms filed from time to time.

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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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