

Company Description

GeoVax Labs, Inc. is a clinical-stage biotechnology company focused on developing innovative vaccines for some of the world's most serious infectious diseases and therapies for solid tumor cancers. The Company's flagship program, GEO-CM04S1, is a next-generation COVID-19 vaccine. GeoVax recently secured a BARDA-funded contract to conduct a 10,000-participant Phase 2b clinical trial to assess the efficacy of GEO-CM04S1 compared to an approved COVID-19 vaccine. Additionally, GEO-CM04S1 is currently being tested in three Phase 2 clinical trials: (1) as a primary vaccine for immunocompromised patients, including those with hematologic cancers who may not benefit sufficiently from existing COVID-19 vaccines, (2) as a booster for patients with chronic lymphocytic leukemia (CLL), and (3) as a more robust, durable COVID-19 booster for healthy individuals who have previously received mRNA vaccines. In the oncology field, GeoVax's lead program is the evaluation of Gedeptin®, a novel oncolytic gene-directed therapy for solid tumors, which recently completed a multicenter Phase 1/2 trial targeting advanced head and neck cancers; plans are underway for a follow-on Phase 2 trial in first recurrent head and neck cancer evaluating Gedeptin in combination with an immune checkpoint inhibitor. GeoVax additionally has a solid intellectual property portfolio, holding global rights to its technologies and product candidates. The Company's leadership team has a proven track record of creating significant value across multiple life science companies over the past few decades.

Key Points

- On November 12, GeoVax announced third quarter 2024 financial results and provided a corporate update. Net loss for the three-month period ended September 30, 2024, was \$5.8 million or \$0.91 per share versus \$8.4 million or \$4.75 per share, for the comparable period in 2023.
- GeoVax's \$400 million contract from BARDA is to support a 10,000-participant Phase 2b trial for its GEO-CM04S1 COVID-19 vaccine. The trial, managed by Allucent, will evaluate the efficacy of GEO-CM04S1 versus an approved COVID-19 vaccine.
- On November 19, GeoVax announced that a DSMB interim review of its Phase 2 trial as a COVID-19 booster vaccine for patients with chronic lymphocytic leukemia (CLL) supported continued enrollment in the GEO-CM04S1 arm. While the mRNA control arm did not meet the primary endpoint, GEO-CM04S1 shows promise as a COVID-19 booster for CLL patients, delivering robust T-cell and antibody responses for durable immunity in immunocompromised groups.
- GeoVax has announced plans for a Phase 2 trial of Gedeptin for first recurrent head and neck cancer in combination with an immune checkpoint inhibitor. The trial is anticipated to begin in mid-2025.
- The development of the GEO-MVA vaccine, targeting Mpox and smallpox, continues with successful cGMP production milestones. The vaccine aims to become the first U.S.-based supplier in a market supported by WHO and CDC recommendations, addressing critical global supply needs.
- The Company continues to strengthen its global intellectual property position, with over 120 granted or pending patent applications spread over twenty-four patent families.
- GeoVax's collaborations with WHO, BARDA, and other stakeholders are expected to continue to drive global distribution, anticipating revenue growth from its cancer and infectious disease portfolio through clinical milestones and partnerships.
- As of September 30, 2024, GeoVax reported cash balances of \$8.5 million, up from \$6.5 million as of December 31, 2023.



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

GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (11/22/2024)	\$2.68
52-week Range	\$1.09-11.18
Shares Outstanding	9.44 million
Market Capitalization	\$24.6 million
Avg. Volume	2.1 million
EPS (Qtr. ended 09/30/2024)	(\$0.91)
Employees	19

THIRD QUARTER 2024 FINANCIAL RESULTS

On November 12, 2024, GeoVax announced third quarter 2024 financial results and provided a corporate update. For the three-month period ending September 30, 2024, GeoVax reported a net loss of \$5.8 million, or \$0.91 per share versus \$8.4 million, or \$4.75 per share, for the same period in 2023. Over the nine months ending September 30, 2024, the net loss totaled \$16.7 million, or \$4.52 per share versus \$18.4 million, or \$10.42 per share, for the comparable period in 2023.

The Company generated \$2.8 million in government contract revenue for the three-month period and \$3.1 million for the nine-month period ending September 30, 2024. These revenues stemmed from the BARDA/RRPV Project NextGen award, with no comparable revenue reported in 2023.

Research and development (R&D) expenses reached \$7.4 million for the three-month period and \$16.1 million for the nine-month period ending September 30, 2024, up from \$6.9 million and \$14.5 million, respectively, in 2023. The increase is primarily due to the costs of manufacturing materials for clinical trials of GEO-CM04S1 and expenses related to the BARDA Contract.

General and administrative (G&A) expenses were \$1.2 million for the three-month period and \$3.8 million for the nine-month period ending September 30, 2024, compared to \$1.7 million and \$4.6 million for the same periods in 2023. The decrease reflects lower expenses in stock-based compensation, consulting, legal and patent, and franchise tax costs.

As of September 30, 2024, GeoVax held cash balances totaling \$8.6 million, an increase from \$6.5 million reported on December 31, 2023.

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

BARDA Project NextGen and Partnership with Allucent

- *BARDA Partnership.* BARDA awarded GeoVax nearly \$400 million to support the Phase 2b trial of GEO-CM04S1, a 10,000-participant study comparing the efficacy, safety, and immunogenicity of GEO-CM04S1 to an FDA-approved mRNA COVID-19 vaccine. Allucent, GeoVax's CRO, was appointed to oversee trial implementation.
- *Trial Goals.* The Phase 2b trial aims to validate GEO-CM04S1's efficacy, durability, and immune response. GeoVax is positioning its vaccine as a more robust option for immunocompromised individuals, addressing the limitations of first-generation vaccines.
- *Manufacturing and Site Preparation.* All trial sites are confirmed, and manufacturing of clinical materials is underway, with enrollment expected in October 2025.

GEO-CM04S1 Program and R&D Focus

- *Phase 2 Trials.* GEO-CM04S1 is in Phase 2 for immunocompromised patients and as a booster in healthy adults. Based on the interim analysis of immune responses from the Chronic Lymphocytic Leukemia (CLL) study patients enrolled to date, the Data Safety Monitoring Board (DSMB) determined that, while the mRNA control arm of the study failed to meet the predetermined primary endpoint, the study should continue enrollment of the experimental arm utilizing GeoVax's Next-Generation GEO-CM04S1 vaccine. The outcome of this review appears to support the Company's view of GEO-CM04S1 as a potentially superior COVID-19 vaccine booster within the CLL patient population. Patient enrollment continues for the healthy adult booster trial.

- *Vaccine Strengths.* Leveraging the Modified Vaccinia Ankara (MVA) platform, the vaccine shows potential for broader, durable immune protection, especially for immunocompromised patients. Its dual efficacy against Mpox and COVID-19 is advantageous for regions facing both diseases. The Company's aim with GEO-CM04S1 is to provide a more practical public health-friendly COVID-19 vaccine than that offered from the first-generation approved vaccine.

Gedeptin® Clinical Development

- *Phase 2 Expansion.* GeoVax has launched a Phase 2 trial of Gedeptin in combination with a checkpoint inhibitor for recurrent head and neck squamous cell carcinoma. Gedeptin's safety and tumor-reduction profile support its development for broader cancer applications.
- *Trial Structure.* The trial will follow a single-cycle treatment with Gedeptin and pembrolizumab, followed by a surgical response assessment, targeting pathologic response as the primary endpoint.

Mpox and Smallpox Vaccine Platform

- *GEO-MVA Vaccine Candidate.* Development continues for GEO-MVA, intended to protect against Mpox and Smallpox. A cGMP Master Seed Virus has been successfully produced and released by OXB, with a cGMP clinical batch currently in production, expected to be completed by Q4.
- *Market Position.* 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. WHO's ongoing warnings about Mpox reinforce the demand for this vaccine platform.
- *MVA Vaccine.* 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.

Corporate Updates and Strategic Outlook

- *GeoVax Scientific Advisory Board.* During the quarter, Dr. Teresa Lambe, PhD, OBE, FMedSci, a professor of Vaccinology and Immunology at the Oxford Vaccine Group within the University of Oxford, was appointed to the Company's Scientific Advisory Board.
- *Partnership Environment.* GeoVax is in active discussions with potential partners and stakeholders, including international organizations like WHO and BARDA, aim to support worldwide distribution and commercialization.
- *Market Opportunities.* 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

November 19, 2024—GeoVax 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).

November 12, 2024—Announced financial results for the third quarter ended September 30, 2024, and provided a business update.

November 5, 2024—Announced that it will report third quarter 2024 financial results on Tuesday, November 12, 2024, after the close of U.S. markets. Following the release, management will host a live conference call and webcast, including Q&A, at 4:30 p.m. ET to provide a corporate update and discuss financial results.

October 2, 2024—Announced that its Chairman & CEO, David Dodd, will participate in a panel discussion on innovative therapies for solid tumors at the 3rd Annual ROTH Healthcare Opportunities Conference taking place on October 9, 2024 in New York, NY. Senior GeoVax management will also host one-on-one meetings with registered attendees.

September 3, 2024—Announced that its Chairman and CEO, David Dodd, will present at two upcoming investor events: H.C. Wainwright 26th Annual Global Investment Conference and Emerging Growth Conference.

August 28, 2024—Announced that it has entered into a definitive securities purchase agreement with a certain institutional investor for the purchase and sale of 975,610 shares of the Company’s common stock (or common stock equivalents) at a price of \$5.125 per share in a registered direct offering priced at-the-market under Nasdaq rules.

August 21, 2024—Announced that David Dodd, CEO of GeoVax Labs, will present at Tribe Public’s Webinar Presentation and Q&A Event titled “Now Is Not the Time to Monkey(pox) Around.” The Event is scheduled to begin at 8:00am PT / 11:00am ET on Friday, August 23, 2024. To register to join the complimentary event, please visit the Tribe Public LLC website at MonkeyPox.TribePublic.com.

August 20, 2024—Announced that it has entered into a definitive securities purchase agreement with a certain institutional investor for the purchase and sale of 1,700,000 shares of the Company’s common stock (or common stock equivalents) at a price of \$5.00 per share in a registered direct offering priced above-the-market under Nasdaq rules.

August 15, 2024—Announced that it has been invited to present at the next Emerging Growth Conference being held August 21-22, 2024. 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.

August 8, 2024—Announced the appointment of Teresa Lambe, PhD, OBE, FMedSci to its Scientific Advisory Board.

August 6, 2024—Announced financial results for the second quarter ended June 30, 2024 and provided a business update.

July 31, 2024—Announced the next steps for the clinical development of its Gedeptin cancer therapy, following a clinical advisory committee review. The review evaluated the safety and efficacy of Gedeptin from the recently completed Phase 1b/2a trial and the earlier Phase 1 trial. The Phase 1b/2a trial focused on patients with advanced head and neck squamous cell carcinoma (HNSCC) and showed that Gedeptin had acceptable safety and efficacy, justifying further development.

July 30, 2024—Announced that GeoVax will report second quarter 2024 financial results on Tuesday, August 6, 2024, after the close of U.S. markets. Following the release, management will host a live conference call and webcast, including Q&A, at 4:30 p.m. ET to provide a corporate update and discuss financial results.

POTENTIAL NEAR TERM MILESTONES

- The Company plans to accelerate its Phase 2 clinical programs for Gedeptin and CM04S1, while advancing its MVA vaccine for Mpox and smallpox, along with further developing its MVA manufacturing system. GeoVax also intends to participate in oncology conferences, showcasing Gedeptin clinical data and exploring partnership opportunities.
- The Company expects to report results from its CM04S1 Phase 2 programs, including results from the Healthy Volunteer Booster trial, complete enrollment and report initial data results from the Immunocompromised CLL trial, and conduct additional site initiations of further results from its Immunocompromised Stem Cell Transplant trial.
- GeoVax is advancing its MVA manufacturing process, with the initiation of the AGE.1 master cell bank preparation. These activities mark significant progress in the Company's goal of developing innovative cancer therapies and vaccines for infectious diseases, focusing on unmet medical needs and expedited registration pathways. GeoVax also plans to establish partnerships for global development and distribution.
- In July 2024, the Company announced plans to begin a Phase 2 trial of Gedeptin in combination with an immune checkpoint inhibitor for recurrent head and neck cancer patients. GeoVax further expects to report plans regarding the next steps related to evaluating Gedeptin as combination therapy used in conjunction with immune checkpoint inhibitors (ICIs).
- The GEO-MVA vaccine, targeting Mpox and smallpox, is progressing with cGMP production milestones achieved. It aims to be the first U.S.-based supplier in a market endorsed by WHO and CDC recommendations, addressing urgent global supply demands.
- GeoVax further expects to progress its GEO-CM04S1 and GEO-MVA cell-line manufacturing.

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 Modified Vaccinia Ankara (MVA) vector, a large virus capable of carrying several vaccine antigens. MVA is a replication-defective live vector that expresses non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (*in vivo*). VLPs mimic a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection through durable immune responses. The Company's development efforts, both clinical stage as well as preclinical stage, are focused within the areas summarized in Figure 1 (page 7).

Figure 1
GEOVAX PIPELINE: CLINICAL DEVELOPMENT PROGRAMS

Product	Indication	Trial	Status
GEO-CM04SI	COVID-19	BARDA Project NextGen - 10,000 Patient Clinical Study to Evaluate GEO-CM04SI 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

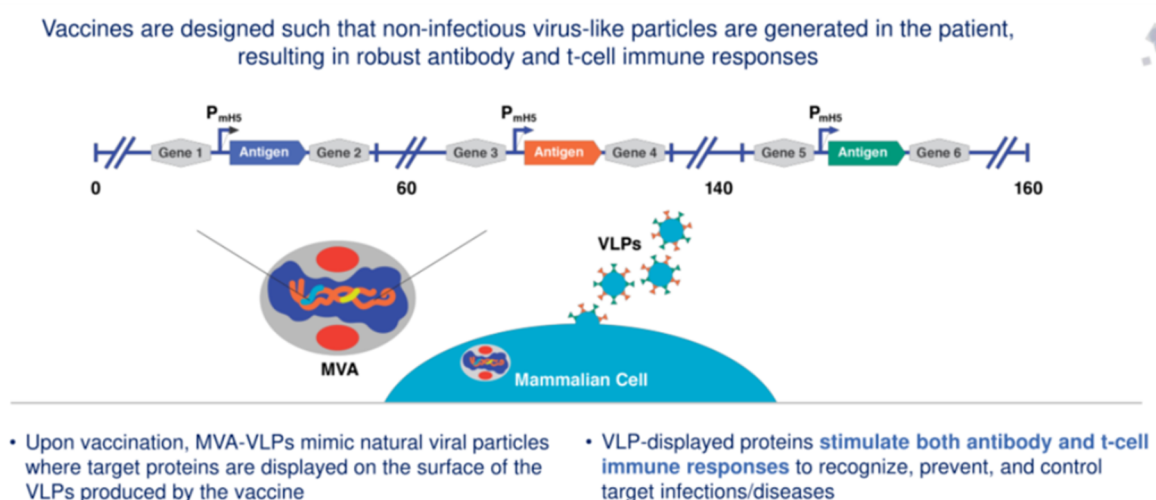
Source: GeoVax Labs, Inc.

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

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

Figure 3
GEO-CM04S1: PHASE 2 CLINICAL TRIALS

- 
- Immunocompromised/stem cell transplant patients**
 - Patients with hematologic malignancies receiving stem-cell transplantation or CAR-T therapy
 - Highest at-risk groups for severe infection, hospitalization and death
 - Primary vaccine in direct comparison to mRNA vaccines
- 
- Immunocompromised/Chronic Lymphocytic Leukemia (CLL) patients**
 - High at-risk population with abated antibody response
 - Major, currently unmet, medical need for alternative immune enhancement response (e.g., T-cells)
 - Booster vaccine in direct comparison to mRNA vaccine
- 
- Booster to mRNA vaccine**
 - Healthy population following vaccination with an mRNA vaccine
 - Potential for broader and more durable protection versus multiple, continuous mRNA doses

Source: GeoVax Labs, Inc.

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 announced it had received an award from the Rapid Response Partnership Vehicle (RRPV), funded by BARDA, to advance its next-generation COVID-19 vaccine, GEO-CM04S1, in a Phase 2b clinical trial. GeoVax will conduct a 10,000-participant study comparing GEO-CM04S1 with an FDA-approved mRNA vaccine, fully funded by BARDA. This vaccine selection represents 1 of only 6 vaccines awarded under Project NextGen.

The award includes \$24.3 million, potentially increasing to \$45 million, for manufacturing and regulatory support, and \$343 million from Project NextGen for trial execution. In total, the value of the award exceeds \$360 million with the potential to increase to over \$380 million. GeoVax believes that its vaccine holds tremendous potential to address limitations of current vaccines, particularly for immunocompromised individuals. The project is funded by HHS's Project NextGen initiative.

There are five vaccines that have been provided Project NextGen awards, each one that is going to conduct 10,000 patient trials, with an estimate of 100 sites in each trial. Of the 100 sites, there are currently eighty confirmed sites that have already been identified and signed on, with others that have not yet completed the confirmation process. The Company expects enrollment to take approximately six months and to be followed for approximately one year.

GeoVax is paired with Allucent as its CRO for the Project NextGen trial, with Allucent being the existing CRO supporting the Company's ongoing CM04S1 and recently completed Gedepin clinical trials.

GEO-CM04S1 Improved Immune Response vs mRNA Vaccine

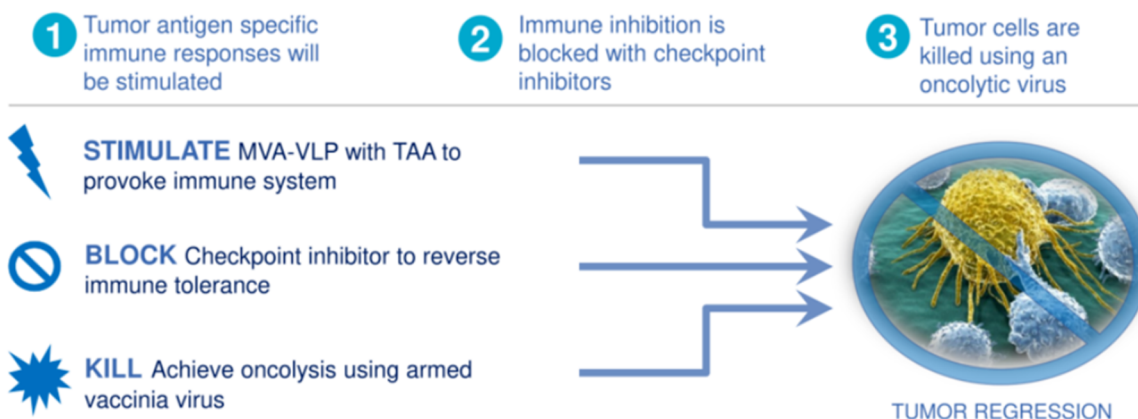
On November 19, 2024, GeoVax announced an interim review of its Phase 2 trial for GEO-CM04S1 for chronic lymphocytic leukemia (CLL) patients. While the mRNA control vaccine missed the primary endpoint, the DSMB recommended continuing enrollment for GEO-CM04S1, which uses a modified vaccinia virus platform to boost T cell and antibody responses. The trial supports GeoVax’s aim to deliver superior immunity for immune-compromised and healthy populations, with a BARDA-funded Phase 2b study set to follow.

Cancer Immunotherapy Vaccine Program

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

Figure 4
IMMUNOTHERAPY TECHNOLOGY

Triple-threat Approach:

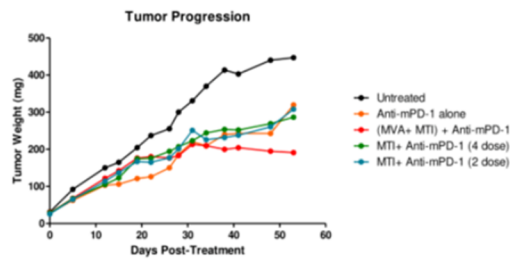


Source: GeoVax Labs, Inc.

The initial focus is on the MUC1 TAA’s, which is a well-studied target for both antibody and cellular immunity (noting that there are multiple associated antigens, which the Company intends to investigate with this approach). As shown in Figure 5 (page 12), 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.

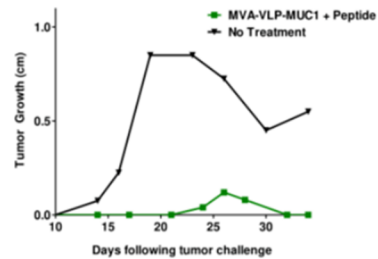
Figure 5
IMMUNONCOLOGY RESULTS

Therapeutic Experiment Results



MVA+MTI+CPI arrested tumor growth and shrank tumors – 57% difference between vaccine combo group vs untreated group

Prevention Experiment Results



MUC1 Tumor Associated Antigen (TAA):

- Combination therapy:
- MVA-VLP-MUC1 and MUC1 peptide
- GeoVax MVA-VLP combination achieved tumor prevention – 100% prevention

Source: GeoVax Labs, Inc.

Gedepitin

During the quarterly, the Company completed review of Gedepitin clinical results. Additionally, GeoVax recently announced its decision to advance Gedepitin 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 Gedepitin 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 Gedepitin among advanced head and neck cancer patients. This initial targeted patient population represents those who are in end-stage care—the 15,000 U.S. and 400,000 worldwide of patients, which represents a critical unmet medical need. Many of these patients are unable to swallow food and have difficulty speaking, and they typically have exhausted existing therapies and standard of care and are receiving palliative care.

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

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

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

Update

In the third quarter, GeoVax announced plans to initiate a Phase 2 trial of Gedeptin in combination with an immune checkpoint inhibitor for patients with locally recurrent head and neck squamous cell carcinomas after primary therapy, who are candidates for resection with curative intent. Clinical evaluation of Gedeptin has shown an acceptable safety profile and promising tumor stabilization or reduction, supporting the decision to advance its development in this expanded Phase 2 trial.

The primary goal of this trial is to demonstrate a pathological response using neoadjuvant Gedeptin therapy combined with an immune checkpoint inhibitor in previously treated patients with recurrent squamous cell head and neck cancer, who are candidates for surgery with curative intent. GeoVax believes Gedeptin's mechanism of action can address a range of solid tumors, both cancerous and benign. Holding worldwide rights to this technology, the Company is engaging in various oncology and partnering conferences.

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

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

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

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

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

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

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

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

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

Modified Vaccinia Ankara (MVA) and Mpx

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

In August, the WHO classified Mpx as a public health emergency of international concern, underscoring the serious medical threat posed by this highly virulent virus. GeoVax is strategically advancing GEO-MVA, its vaccine targeting both Mpx and smallpox, with the goal of challenging the current global monopoly in this critical area. The Company is confident that its efforts will position GeoVax as the first U.S.-based supplier of this essential vaccine.

Update

Regarding GEO-MVA, the vaccine candidate for Mpx and smallpox, GeoVax has made significant progress this past quarter, moving from the cGMP production of a master seed virus to establishing the working seed virus. Production of the first cGMP clinical substance batch is now underway, with release expected by year-end. This may also provide GeoVax our initial step into revenue generation due to significant governmental interest in U.S.-based supply chains versus overdependence on non-U.S. suppliers.

Malaria Vaccine Program

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

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

ZIKA Virus (ZIKV) Vaccine Program

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

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

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

Partnerships

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

Patent Portfolio

The Company's wholly owned, co-owned, and in-licensed intellectual property portfolio now stands at over 115 granted or pending patent applications spread over twenty-four patent families.

Corporate Background

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

Risks and Disclosures

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

The content of this report with respect to GeoVax has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. GeoVax is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by GeoVax or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of forty-eight thousand dollars for its services in creating the base report and for quarterly updates.

Investors should carefully consider the risks and information about GeoVax’s business. Investors should not interpret the order in which considerations are presented in their SEC filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in GeoVax’s SEC filings are not the only risks that the Company faces. Additional risks and uncertainties not presently known to GeoVax or that it currently believes to be immaterial may also adversely affect the Company’s business. If any of such risks and uncertainties develops into an actual event, GeoVax’s business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company’s shares could decline.

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