Company Description

GeoVax Labs, Inc. ("GeoVax" or "the Company") is a clinical-stage biotechnology company developing novel therapies and vaccines for cancers and many of the world's most threatening infectious diseases. The Company's lead program in oncology is a novel oncolytic solid tumor gene-directed therapy, Gedeptin®, currently in a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. GeoVax's lead infectious disease candidate, GEO-CM04S1, is a next-generation COVID-19 vaccine targeting high-risk immunocompromised patient populations. GEO-CM04S1 is being evaluated in three Phase 2 clinical trials: (1) as a primary COVID-19 vaccine for immunocompromised patients versus mRNA vaccines; (2) as a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines; and (3) most recently, as a more robust, durable booster versus mRNA vaccines in patients with chronic lymphocytic leukemia (CLL). GeoVax has a leadership team who has driven significant value creation across multiple life science companies over the past several decades.

Key Points

- On May 14, 2024, GeoVax announced first quarter 2024 financial results and provided a corporate update. Net loss for the three months ended March 31, 2024, was $5,580,132, or $2.47 per share versus $4,037,916, or $2.30 per share, for the three months ended March 31, 2023.
- During the quarter, the Company announced a significant milestone with the release of the first lot of GEO-CM04S1, the Company's next-generation COVID-19 vaccine, produced using a validated chicken embryonic fibroblast (CEF) based production system. This marks the successful transfer and scale-up of manufacturing from the research-focused Center for Biomedicine & Genetics at City of Hope to the experienced Contract Development and Manufacturing Organization (CDMO) ABL Europe, a subsidiary of Oxford Biomedica, the Company's Current Good Manufacturing Practice (CGMP) manufacturing partner.
- The Company completed patient enrollment for Phase 1/2 trial evaluating Gedeptin® in advanced head and neck cancer and anticipates trial completion by third quarter, engaging in protocol discussions for follow-up Phase 2/3 trial targeting advanced head and neck cancer patients with limited treatment options. Additionally, GeoVax expects to disclose its plans for evaluating Gedeptin as combination therapy alongside immune checkpoint inhibitors.
- Regarding its MVA vaccine for Mpox and Smallpox, GeoVax expects to outline its regulatory strategy and advancement plans toward registration. Updates are expected for the Company's advanced MVA manufacturing process, designed to facilitate the timely production and distribution of GeoVax's MVA-based vaccines to meet market demands effectively.
- GeoVax continues to announce actions which strengthen its global intellectual property position, with the Company now holding over 115 granted or pending patent applications spread over twenty-four patent families.
- GeoVax reported cash balances of $768,859 at March 31, 2024 versus $6,452,589 at December 31, 2023. The Company is currently undergoing advanced discussions with Biomedical Advanced Research and Development Authority (BARDA) related to Project NextGen, which could be a significant fundraising catalyst for the Company should this come to be.

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GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (05/14/2024)	$1.70
52-week Range	$1.38 – 11.85
Shares Outstanding	2.3 million
Market Capitalization	$3.8 million
Avg. Volume	35,721
EPS (Yr. ended 03/31/2024)	($2.47)
Employees	19

See page 15 for applicable disclosures.

FIRST QUARTER 2024 FINANCIAL RESULTS

On May 14, 2024, GeoVax Labs, Inc. announced first quarter 2024 financial results and provided a corporate update. Net loss for the three months ended March 31, 2024 was $5,580,132, or $2.47 per share versus $4,037,916, or $2.30 per share for the three months ended March 31, 2023.

Research and development expenses were $4,425,728 for the three months ended March 31, 2024 versus $2,819,189 for the comparable period in 2023, with the increase/decrease primarily due to costs of manufacturing materials for use in the Company's clinical trials and other related costs, personnel costs, and costs of preclinical research activities.

General and administrative expenses were $1,457,353 for the three months ended March 31, 2024 versus $1,451,425 for the three months ended March 31, 2023.

GeoVax reported cash balances of $768,859 at March 31, 2024 versus $6,452,589 at December 31, 2023.

The Company continues to work towards creating groundbreaking cancer treatments and vaccines for infectious diseases, targeting urgent medical gaps. It plans to focus on initial indications conducive to accelerated registration processes. GeoVax also expects to form strategic partnerships and collaborations to aid in global development, commercialization, and distribution efforts.

While no grant revenues or government contracts were made during the first quarter as had been reported in the prior years, GeoVax is undergoing advanced discussions with BARDA related to Project NextGen, which could be a significant fundraising catalyst for the Company should this come to be.

First Quarter Business Achievements

GEO-CM04S1

GeoVax's CM04S1, GeoVax's next generation COVID-19 vaccine, is unique from the current authorized COVID-19 vaccines in targeting both the antibody and cellular arms of the immune system—specifically focused on providing more robust and durable protection versus current vaccines. This is important in addressing high-risk populations of immune-compromised individuals, specifically those for whom the current vaccines and monoclonal antibody therapies are inadequate, including those with various blood cancers, renal disease, sickle cell anemia, HIV positive, autoimmune diseases such as lupus, and those on immune-depressive therapy. Overall, patient groups with ablated immune systems who are unable to respond adequately to approved mRNA vaccines are at an elevated risk.

GEO-CM04S1 is based on GeoVax's MVA viral vector platform, which supports the presentation of multiple vaccine antigens to the immune system in a single dose. GEO-CM04S1 encodes for both the spike (S) and nucleocapsid (N) antigens of SARS-CoV-2 and is to induce both antibody and T cell responses to those parts of the virus less likely to mutate over time. The more broadly functional engagement of the immune system is to protect against severe disease caused by continually emerging variants of COVID-19. Vaccines of this format should not require frequent and repeated modification or updating.

In April 2024, GeoVax presented data on GEO-CM04S1 at the 24th Annual World Vaccine Congress. The presentation, titled "*Vaccine Induction of Broadly-Specific Antibody and T Cell Responses to Combat SARS-CoV-2 Variation*," focused on results describing the unique immune system driven mechanisms that contribute to the broad efficacy of GEO-CM04S1. Data presented were created in collaboration with scientists at Georgia State University using the human ACE2 transgenic mice, one of the "gold standard" small animal models used for studying COVID vaccines. The presentation highlighted that vaccine induced immunity protects against infections, serious disease symptoms and death against the original Wuhan variant as well as the Omicron XBB.1.5 variant (which is the basis of the currently approved mRNA booster vaccines).

During the quarter, the Company also released positive initial safety and immune response findings from Phase 2 clinical trial at one month following administration of GEO-CM04S1. The trial, evaluating GEO-CM04S1 as a heterologous booster in 63 healthy adults who had previously received the Pfizer or Moderna mRNA vaccine (ClinicalTrials.gov Identifier: NCT04639466), was fully enrolled at the end of September 2023, and was designed to evaluate the safety and immunogenicity of two GEO-CM04S1 dose levels. The trial remains blinded to dose of vaccine received, with study subjects being followed for a total of one year.

To date, no serious adverse events have been reported and adverse events were in line with other routine vaccinations. The immunological responses measured throughout the study period include both neutralizing antibodies against SARS-CoV-2 variants and specific T-cell responses. Consolidated data from all subjects evaluated one-month post-vaccination, documented statistically significant increases in neutralizing antibody responses against multiple SARS-CoV-2 variants, ranging from the original Wuhan strain through Delta and Omicron XBB 1.5; further testing against the JN.1 variant is underway. Final results from this heterologous booster trial are expected in the fourth quarter, following the year-long monitoring of participants.

In the U.S., roughly 20 to 25 million adults are considered immune-compromised, while globally, this figure exceeds 250 million. This demographic comprises individuals with diverse conditions such as blood cancers, renal disease, lupus, transplant recipients, and others undergoing immunosuppressive therapies. Many of these individuals exhibit limited responsiveness to approved mRNA vaccines, heightening their susceptibility to severe COVID-19 outcomes, including hospitalization and mortality. Extensive medical literature underscores the urgent necessity for a next-generation vaccine tailored to this vital medical need.

GeoVax is seeking to participate in BARDA's Project NextGen, a $5 billion endeavor, succeeding Operation Warp Speed, which aims to expedite the clinical advancement of COVID-19 vaccines with broader protection against variants and increased longevity. The Company's focus lies particularly on novel vaccine candidates already undergoing clinical trials. CM04S1 stands as a prime illustration of the sought-after next-generation COVID-19 vaccine. Negotiations for CM04S1's inclusion in Project NextGen are ongoing.

Gedeptin®

Gedeptin is based on a novel patented technology for the treatment of solid tumors through a gene therapy strategy known as Gene-Directed Enzyme Prodrug Therapy (GDEPT). In GDEPT, a vector is used to selectively transduce tumor cells with a non-human gene, which expresses an enzyme that can convert a non-toxic prodrug into a highly toxic anti-tumor compound in situ. Gedeptin is tumor agnostic, providing the opportunity to address a variety of solid tumors, either cancerous or benign. GeoVax holds worldwide rights for all indications of this technology. In the U.S., there are 67,000 new cases of head and neck cancers with approximately 15,000 deaths annually. Worldwide, there are approximately 900,000 new cases of head and neck cancers annually, and roughly 400,000 deaths.

GeoVax's initial targeted patient population for the application of Gedeptin represents those who are end stage care, as these patients represent a critical unmet medical need with many unable to swallow food and having great difficulties being able to speak. Most have exhausted existing therapies and standards of care and are receiving palliative care. GeoVax seeks to provide an improved end-stage quality of life by reducing and/or eliminating various targeted tumors. Current protocol entails up to five treatment cycles, each consisting of three intratumoral injections of Gedeptin over two days, followed by infusion of a prodrug, fludarabine phosphate, once daily for three days. The Phase 1 dose ranging study demonstrated that treating a tumor with a single cycle of Gedeptin followed by fludarabine infusions was well-tolerated with evidence of a reduction in tumor size in patients with solid tumors. Due to results from that study, the FDA is funding the current trial under the Orphan Drug Clinical Trials Program.

In January 20234, GeoVax announced the closure of patient enrollment for the Phase 1/2 clinical study evaluating Gedeptin® in patients suffering from advanced head and neck cancer. Completion of this trial will be a significant milestone in the Gedeptin clinical development program. Allowing time for the maximum number of cycles of Gedeptin therapy and patient follow-up, GeoVax expects to complete the study by the third quarter of this year. In the interim, active discussions are taking place with advisors on protocol development in support of a follow-on Phase 2 or Phase 2/3 trial among patients with advanced head and neck cancer in whom current therapeutic options are suboptimal.

Funded by the FDA's Orphan Drugs Clinical Trials Program, GeoVax expects to release final trial results in the first half of 2024. Subsequently, it expects to discuss plans to further evaluate Gedeptin in head and neck cancer patients, potentially as a neoadjuvant or cytoreductive radiotherapy in combination with checkpoint blockade medications. Gedeptin's tumor-agnostic nature enables its application across various solid tumors, both malignant and benign.

With worldwide rights to all indications of this technology, GeoVax is actively engaged in oncology and partnering conferences to present Gedeptin clinical data and explore collaboration opportunities. Its recent meeting with oncology advisors reviewed current clinical results and potential opportunities for Gedeptin, including monotherapy indications and combination therapy with immune checkpoint inhibitors. The Company is optimistic about its discussions with the FDA regarding an expedited path to registration.

Vaccine Manufacturing Process Development

GeoVax reached a significant milestone in its manufacturing process development for Phase 3 and commercial production. This advancement signifies a critical move towards implementing a validated chicken embryonic fibroblast (CEF) based production system for the company's MVA-based vaccines. The release of the first lot of GEO-CM04S1 (the next-generation COVID-19 vaccine) manufactured with a commercial manufacturing platform marks the successful completion of the transfer and scale-up of manufacturing from the research-focused Center for Biomedicine & Genetics at City of Hope to Oxford Biomedica, the Company's cGMP (current Good Manufacturing Procedures) manufacturing partner.

Intellectual Property Developments

The Company's intellectual property assets were further strengthened through multiple actions undertaken by global patent offices, described below.

- The Japanese Patent Office issued a Decision of Grant notifying GeoVax of the allowance of the Company's Patent Application No. 2022-153352 titled "Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen." The allowed claims are directed to recombinant MVA viral vectors comprising specific MUC-1 nucleic sequences used in GeoVax's MUC-1 tumor-associated antigen immunotherapy program. Pharmaceutical compositions for inducing immune responses, preventing or reducing neoplasm growth, or treating cancer are also covered by the granted claims.

- The U.S. Patent and Trademark Office issued Patent No. 11,896,657 to GeoVax, pursuant to the Company's patent application No. 17/584,231 titled "Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Marburg Virus Glycoprotein (GP) and Matrix Protein (VP40)." The allowed claims generally cover GeoVax's vector platform for expressing Marburg virus antigens in virus-like particles (VLPs) utilizing an MVA viral vector.

- The U.S. Patent and Trademark Office issued Patent No. 11,897,919 pursuant to the Company's patent application No. 17/409,574 titled "Multivalent HIV Vaccine Boost Compositions and Methods of Use." The allowed claims generally cover a priming vaccination with a DNA vector encoding multiple HIV antigens in virus-like particles (VLPs), followed by a boost vaccination with GeoVax's vector platform for expressing HIV-1 antigens in VLPs utilizing an MVA viral vector.

- The U.S. Patent and Trademark Office issued Patent No. 11,857,611 to GeoVax, pursuant to the Company's patent application No. 17/726,254 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." The claims granted by the patent generally cover compositions comprising GeoVax's modified vaccinia Ankara (MVA) vector expressing Plasmodium antigens and methods of inducing an immune response to malaria utilizing the compositions. The compositions and methods covered in the claims are useful both prophylactically and therapeutically and may be used to prevent and/or treat malaria.

RECENT COMPANY DEVELOPMENTS

May 7, 2024—GeoVax Labs, Inc. announced that it was to report first quarter 2024 financial results on Tuesday, May 14, 2024, 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.

April 4, 2024—Announced that its Chief Scientific Officer, Mark Newman, PhD, presented data on GEO-CM04S1, the Company's next-generation Covid-19 vaccine candidate, during the 24th Annual World Vaccine Congress in Washington, DC.

March 28, 2024—Announced that its Chief Scientific Officer, Mark Newman, PhD, was to present data on GEO-CM04S1, the Company's next-generation Covid-19 vaccine candidate, during the upcoming 24th Annual World Vaccine Congress taking place in Washington, DC on April 1-4, 2024.

March 12, 2024—Announced that its Chairman and CEO, David Dodd, was to present at the 36th Annual Roth Conference, taking place in Dana Point, CA on March 17-19, 2024.

March 6, 2024—Announced a significant milestone toward implementation of a validated chicken embryonic fibroblast (CEF) based production system for the Company's MVA-based vaccines, with the release of its first lot of GEO-CM04S1 (next-generation Covid-19 vaccine) produced with a commercial manufacturing platform. This milestone marks the successful completion of the transfer and scale-up of manufacturing from the research-focused Center for Biomedicine & Genetics at City of Hope (Duarte, CA) to the experienced CDMO ABL Europe (a subsidiary of Oxford Biomedica), the Company's cGMP (current Good Manufacturing Procedures) manufacturing partner.

February 29, 2024—Announced its financial results and key operational accomplishments for the year ended December 31, 2023.

POTENTIAL NEAR TEM MILESTONES

For 2024, the Company is focused on accelerating efforts in support of the Gedeptin and CM04S1 Phase 2 clinical programs, as well as advancing its MVA vaccine specific to Mpox and smallpox and to make further progress on its advanced MVA manufacturing system. Furthermore, GeoVax expects to continue to participate in various oncology conferences, some of which to present Gedeptin clinical data and others to conduct partnering discussions.

In 2024, the Company expects to report results from its CM04S1 Phase 2 programs, including results from the Healthy Volunteer Booster trial, complete enrollment and results from the Immunocompromised CLL trial, and conduct additional side initiations of further results from its Immunocompromised Stem Cell Transplant trial.

For Gedeptin in 2024, GeoVax expects to report results from the current trial and its plans for the expanded Phase 2 trial. The Company further expects to report plans regarding the next steps related to evaluating Gedeptin as combination therapy used in conjunction with immune checkpoint inhibitors (ICIs).

Regarding GEO-MVA against Mpox and smallpox, GeoVax anticipates reporting its regulatory path and plans related to advancing that product towards registration. The Company expects to continue to provide updates related to its advanced MVA manufacturing process targeted to enable GeoVax to effectively produce and distribute MVA-based vaccines in response to real-time market needs.

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 vaccines—both preventive and therapeutic. Its technology, targeting infectious diseases and cancer, employs the Company's proprietary GV-MVA-VLP™ vector vaccine technology platform. This GV-MVA-VLP™ vector vaccine 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.

Figure 1

GEOVAX PIPELINE: CLINICAL DEVELOPMENT PROGRAMS

Product	Indication	Trial	Status
GEO-CM04S1	Covid-19	Primary Vaccine For Immunocompromised Blood Cancer Patients (NCT04977024)	Phase 2
		Booster Vaccine vs mRNA For Chronic Lymphocytic Leukemia Patients (NCT05672355)	Phase 2
		Booster Vaccine vs mRNA Among Healthy Volunteers (NCT04639466)	Fully Enrolled
Gedeptin®	Advanced Head & Neck Cancer	Effect on Targeted Tumors (NCT03754933)	Fully Enrolled

GEOVAX PIPELINE: PRECLINICAL DEVELOPMENT PROGRAMS

Product	Target	Completion Testing Status
GEO-MVA-MUC1	Solid Tumor Cancers	Mice
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 Flavivirus	Mice

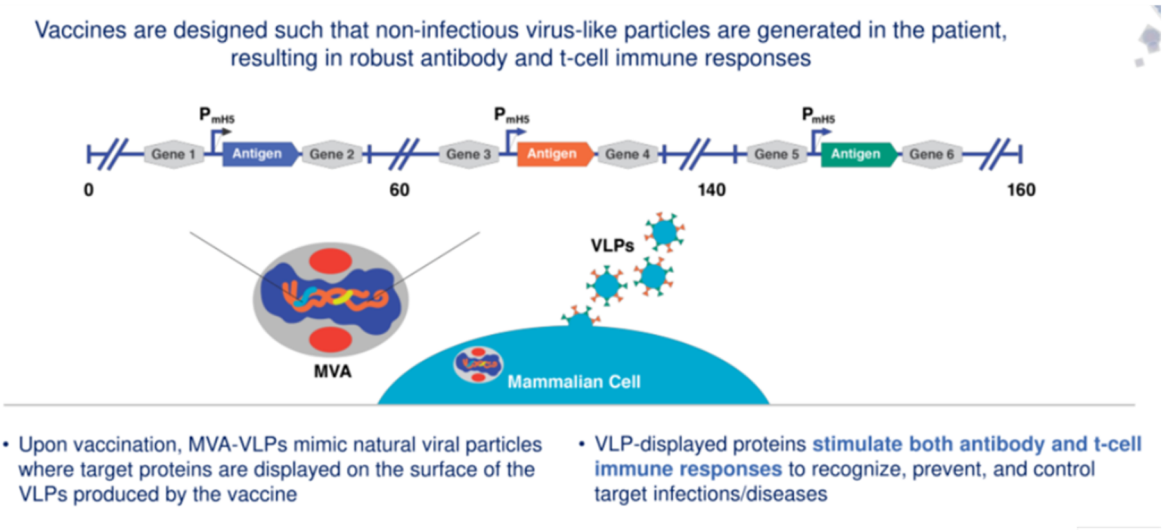
Source: GeoVax Labs, Inc.

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 GV-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 March 2024, more than 774 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.

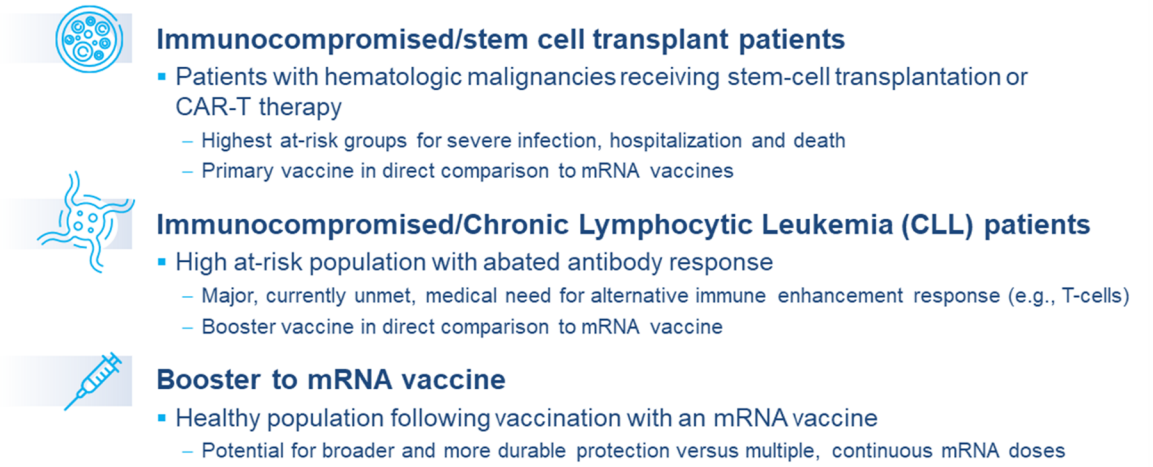
The experimental COVID-19 vaccine, using the Company's MVA-VLP technology, encodes the S protein, which is the basis for all the first-generation products in use today and the targeted neutralizing antibodies. This is used in combination with the membrane (M protein) and the envelop (E protein). The 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 a 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-CMS04S1: PHASE 2 CLINICAL TRIALS



Source: GeoVax Labs, Inc.

In September 2023, the Company completed enrollment in its Phase 2 trial assessing CM04S1 as the booster for the mRNA vaccines. This trial involves 63 healthy adults who had previously received the Pfizer or Moderna mRNA vaccine. The immunological responses measured throughout the study include both neutralizing antibodies against SARS-CoV-2 variants and specific T cell responses.

In February 2024, the Company reported positive interim data from this trial, indicating no serious adverse events and statistically significant increases in neutralizing antibodies against multiple SARS-CoV-2 variants ranging from the original Wuhan strain through Delta in the highly virulent Omicron SBB 1.5, as well as demonstrating robust cellular immune responses. Additional testing against the current variant of concern, the JN 1 variant is currently underway. Results from this trial are anticipated during the fourth quarter 2024, reflecting the 12-month monitoring of these patients.

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 as 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.

During 2023, initial data from stem cell transplant trial was presented at several international conferences, including the World Vaccine Congress in Washington, D.C. In addition, results were published in the peer-reviewed journal *Vaccines*. These findings demonstrated robust immunogenicity, illustrating the vaccine ability to strongly induce both antibody and T-cell responses essential for confirming protection, particularly in immunocompromised individuals. The *Vaccines* article also highlighted the unique feature of CM04S1, providing protective immune levels from the ancestral Wuhan strain through the Omicron XBB1.5 variant. Initial patient enrollments into this trial occurred at the City of Hope Medical Center in California.

Following the initiation of patient enrollment in the immunocompromised CLL in August 2023, this investigator-initiated trials continue to recruit and enroll patients more recently expanding to additional City of Hope locations. The trial is designed to evaluate CM04S1 among approximately 80 CLL patients directly comparing with the Pfizer-BioNTech mRNA vaccine. Typically, these patients are unable to generate adequate levels of protective antibodies following mRNA vaccination due to their underlying hematologic malignancy, placing them at extreme risk of developing clinically severe COVID-19. Consequently, many of these patients remain homebound more than three years since the pandemic began. Results from an interim analysis of the ongoing trial are anticipated during the first half 2024. Relative developing CM04S1 immunocompromised patients, GeoVax believes that an opportunity exists for an expedited regulatory path due to the Company's focus on such high-risk unserved populations.

In addition to the patients initially enrolled from City of Hope, there are now four additional sites actively recruiting patients in the Phase 2 trial. The four expansion sites include the Fred Hutchinson Cancer Center in Seattle, University of Massachusetts Medical Center in Worcester, Mass, Wake Forest Baptist Medical Center in Winston-Salem North Carolina, and Eastern Carolina Medical Center in Benson, North Carolina. While currently focused on optimizing patient enrollment from these sites, GeoVax has seen considerable interest, both domestically and internationally and participating in this clinical study.

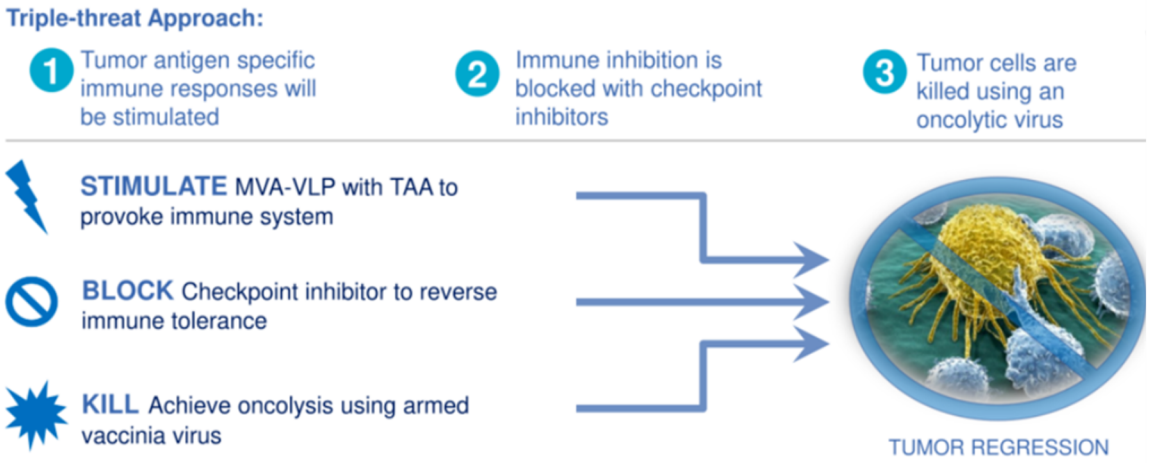
Project NextGen

In April 2023, the White House announced a $5 billion initiative to follow on from operation Warp Speed, seeking COVID-19 vaccines with enhanced breadth of protection against variants and improved durability, particularly in novel vaccine candidates already in clinical trials. GeoVax continues to be in active discussions related to formal participation in this program. Of the $5 billion set aside for funding, there remains over $3 billion still to be awarded. The Company anticipates partnering and collaborating on additional clinical and research efforts in support of worldwide commercialization and distribution of CM04S1.

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.

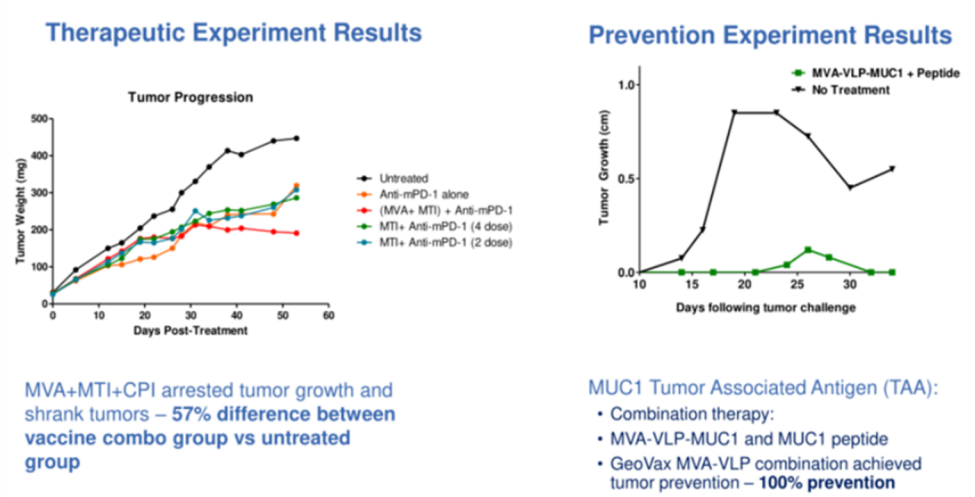
Figure 4
IMMUNOTHERAPY TECHNOLOGY



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, 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



Source: GeoVax Labs, Inc.

Gedeptin

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 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 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.

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 Mpox

The vaccine used and stockpiled for immunization against Mpox 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 Mpox. It is anticipated that the results will demonstrate successful protection, validating that GEO-CM04S1 is protective against both COVID-19 and Mpox. GeoVax also anticipates validating its hemorrhagic fever virus vaccines as protective against Mpox, potentially providing unique vaccines preventing both hemorrhagic fever virus and Mpox virus in a single vaccine. MVA (against Mpox 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.

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.

In January 2024, GeoVax announced that the U.S. Patent and Trademark Office has issued Patent No. 11,857,611 to GeoVax, pursuant to the Company's patent application No. 17/726,254 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." The claims granted by the patent cover compositions comprising GeoVax's modified vaccinia Ankara (MVA) vector expressing Plasmodium antigens and methods of inducing an immune response to malaria utilizing the compositions. The compositions and methods covered in the claims are useful both prophylactically and therapeutically and may be used to prevent and/or treat malaria.

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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