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®, presently in a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. GeoVax's lead infectious disease candidate is GEO-CM04S1, a next-generation COVID-19 vaccine targeting high-risk immunocompromised patient populations. GEO-CM04S1 is currently being evaluated in three Phase 2 clinical trials: (1) as a 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 August 9, 2023, GeoVax announced financial results for the quarter ended June 30, 2023 and provided a corporate update. The Company reported a net loss of $5.9 million, or $0.22 per share, versus $2.2 million, or $0.18 per share, for the comparable period in 2022. For the six months ended June 30, 2023, the Company's net loss was approximately $10 million ($0.38 per share) versus a net loss of $4.7 million ($0.47 per share) in 2022.
- During the first half, GeoVax continued enrollment in, and presented positive interim clinical data for, both of its lead programs—Gedeptin® cancer therapy (targeting advanced head and neck cancers) and GEO-CM04S1 (the Company's next-generation COVID-19 vaccine). The Company also announced the initiation of an important third Phase 2 clinical study for GEO-CM04S1 in patients with chronic lymphocytic leukemia (CLL), comparing against a mRNA vaccine.
- GeoVax's next-generation COVID-19 vaccine, which utilizes an MVA-vector containing the two antigens, S and N, induces broad and durable antibody and cellular immune responses that has the potential to offer a more robust, durable degree of protection than the current authorized COVID-19 vaccines, mostly in highly vulnerable immunocompromised patients.
- GeoVax has also made significant progress in developing a high-yield, high-capacity, continuous avian cell line system for manufacturing its MVA-based vaccines and immunotherapies. The Company has recently partnered with Advanced Bioscience Laboratories, Inc. to support current Good Manufacturing Practices (cGMP) production of its MVA-based products through late-stage development and eventual commercialization.
- The recent expansion of the Company's GEO-CM04S1 rights to include development for Mpox and smallpox enhances other rights previously secured from the NIH covering preclinical, clinical, and commercial uses of the NIH-MVA. This provides an opportunity to leverage the Company's MVA-based vaccine expertise and facilitate expansion of the global public health supply options for health threats posed by SARS-CoV-2, Mpox, and smallpox. This could provide GeoVax with the ability to respond to large-scale world needs in a timely manner.
- GeoVax's intellectual property portfolio contains over 115 granted or pending patent applications across 24 patent families. In July, GeoVax announced that the USPTO issued Patent No. 11,701,418 B2 to GeoVax titled "Replication-Deficient Modified Vaccinia Ankara (MVA) and Matrix Protein (VP40)", covering multiple strains of ebolavirus.
- At June 30, 2023, the Company reported cash balances of $17.8 million versus $27.6 million at December 31, 2022. GeoVax is funded into 2024 and anticipates further strengthening its balance sheet through supportive stock activities, business development initiatives, and non-dilutive opportunities related to government and NGO funding.

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GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (08/10/2023)	$0.54
52-week Range	$0.53 – 2.99
Shares Outstanding	26.4 million
Market Capitalization	$14.3 million
Avg. 10-day Volume	186,000
EPS (Qtr. ended 06/30/2023)	($0.22)
Employees	19

See page 19 for applicable disclosures.

SECOND QUARTER 2023 FINANCIAL RESULTS

On August 9, 2023, GeoVax Labs, Inc. announced its financial results for the three months ended June 30, 2023, and provided a corporate update.

Net loss for the three months ended June 30, 2023 was $5.9 million, or $0.22 per share versus $2.2 million, or $0.18 per share for the comparable period in 2022. For the six months ended June 30, 2023, GeoVax's net loss was approximately $10 million ($0.38 per share) versus a net loss of $4.7 million ($0.47 per share) in 2022.

Research and development (R&D) expenses were $4.7 million and $7.5 million for the three-month and six-month periods ended June 30, 2023 versus $1.3 million and $2.6 million for the comparable periods in 2022, with the increases due largely to the cost of conducting clinical trials for GEO-CM04S1 and Gedeptin, costs of manufacturing materials for use in clinical trials, added personnel costs, technology licensing fees, costs of preclinical research activities, as well as an overall higher level of activity.

General and administrative expenses were $1.5 million and $2.9 million for the three-month and six-month periods ended June 30, 2023 versus $935,311 and $2.1 million for the comparable periods in 2022, with the increases primarily due to higher personnel costs, investor relations consulting costs, patent costs, and other expenses supporting of a higher level of activity.

At June 30, 2023, the Company reported cash balances of $17.8 million versus $27.6 million at December 31, 2022. For the remainder of 2023, the Company is focused on accelerating efforts in support of its Gedeptin® and CM04S1 Phase 3 clinical programs, advancing its MVA vaccines specific for Mpox and smallpox into development, and further advancing its MVA manufacturing processes. GeoVax further expects to see opportunities to add additional capital in support of these programs.

QUARTERLY HIGHLIGHTS

- **Initiated New Clinical Trial for GEO-CM04S1**. In July, GeoVax announced that it commenced a Phase 2 COVID-19 vaccine booster investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355) in patients with chronic lymphocytic leukemia (CLL), a recognized high-risk group for whom current mRNA vaccines and monoclonal antibody (MAb) therapies seem inadequate relative to delivering protective immunity. Due to their medical status, CLL patients are generally not capable of mounting a sufficient antibody response to the antibody stimulation delivered from the mRNA vaccines and the MAb therapies. The new trial is expected to enroll approximately 80 patients, comparing GEO-CM04S1 to Pfizer/BioNTech's Bivalent vaccine. Patient enrollment is expected to be completed within six months. GEO-CM04S1, inducing both a strong antibody and strong cellular (T-cells) immune response, is anticipated to provide a more robust and durable protective immunity to CLL patients. Primarily funded by a private family foundation (with GeoVax supporting the analysis of samples), this trial is expected to have minimal effect on GeoVax's balance sheet. The study references the existing GeoVax IND, providing GeoVax full access to use of the data/results in its development program.

  On August 10, the Company announced that vaccinations have begun in an investigator-initiated clinical trial of GEO-CM04S1 in patients with CLL being conducted at City of Hope National Medical Center. The study is examining the use of two injections of GEO-CM04S1, three months apart, to assess immune responses in these vulnerable patients, with an mRNA vaccine (currently, the Pfizer-BioNTech Bivalent vaccine) as the control arm. Participants will be randomized 1:1 to receive two boosters with either the GEO-CM04S1 or the control vaccine. The primary immune response outcome will be assessed at 56 days following the first booster injection. Up to 40 participants in each arm will be vaccinated, with immune responses evaluated and compared at the interim and final analyses.

- **Gedeptin® Clinical Trial Data.** Interim data from the Phase 1/2 clinical trial of Gedeptin® was presented at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference in July. The ongoing Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT03754933) is evaluating the safety and efficacy of repeat cycles of Gedeptin® therapy in patients with recurrent head and neck cancers whose tumor(s) are accessible for injection and who have no curable treatment options. The poster presentation highlighted data from 8 patients enrolled in the study to date, with no dose-limiting toxicities or serious adverse events attributable to treatment, and impairment of tumor growth in targeted lesions observed in 5 of 7 patients (one patient remaining under study). There are approximately 67,000 new cases of head and neck cancers annually in the U.S. and approximately 13,000 deaths. Worldwide there are approximately 900,000 new cases of head and neck cancers annually and approximately 400,000 deaths.

  Pursuant to its Orphan Products Clinical Trials Grants Program, the study is being partially funded by the U.S. FDA. The FDA has also granted Gedeptin® orphan drug status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of the mouth, salivary gland, and other oral cavities. GeoVax expects to complete the current trial by year-end 2023, after which expanded development of Gedeptin® is predicted, both as monotherapy and combination therapy combined with other therapies to possibly include immune checkpoint inhibitors, angiogenesis inhibitors, radiation, chemotherapy, etc.

- **GEO-CM04S1 Clinical Trial Data**. In April, unpublished data from the open-label portion of the Phase 2 trial of GEO-CM04S1 in patients with hematologic cancers receiving cell transplants or CAR-T therapy (ClinicalTrials.gov Identifier: NCT04977024) was presented during the 23rd Annual World Vaccine Congress. This trial is investigating GEO-CM04S1 in a profoundly immunosuppressed patient population due to their pre-transplant induction regimens. Preliminary analysis indicates that GEO-CM04S1 is highly immunogenic in these patients, inducing both neutralizing antibodies and T cell responses, which are important to confer protection against severe COVID-19. These data support the planned progression of the Phase 2 clinical study, which is to include a direct comparison to currently approved mRNA vaccines and is expected to include multiple sites both within and outside the U.S. In the U.S. there are approximately 12 million to 15 million immune compromised individuals, worldwide there are an estimated 200 plus million.

  Further highlighting the need for next-generation COVID-19 vaccines, such as GEO-CM04S1, GeoVax scientists co-authored an article titled, "*MVA-Vectored Universal Beta-Coronavirus Vaccine Design & Development*", published in the June 2023 issue of the online journal *Vaccine Insights*. The article, linked here, provides expert insight into the emergence of SARS-CoV-2 (COVID-19), the risk of new "spillover events" from animal hosts, and how this risk can be addressed proactively. The authors describe the limitations of first-generation vaccines and the potential for MVA-vectored vaccines, such as GEO-CM04S1 to overcome these limitations.

  During second quarter, the White House announced Project Next Gen, a $5 billion initiative and the follow on from Operation Warp Speed, seeking COVID-19 vaccines with enhanced breadth of protection against variants and improved durability—being particularly interested in novel vaccine candidates already in clinical trials. GeoVax's CMO4S1 is a leading example of the desired next generation COVID-19 vaccine. The Company could have the opportunity for an expedited regulatory path due to its focus on high risk populations unserved by the current COVID-19 vaccines and monoclonal antibody therapies.

- **Mpox Vaccine Rights Added to GEO-CM04S1**. In April, GeoVax expanded its rights under its license agreement with City of Hope (COH) for GEO-CM04S1, granting GeoVax development and commercialization rights against orthopoxviruses in addition to SARS-CoV-2. Orthopoxviruses include Mpox, smallpox, and other viruses that cause disease in humans. GEO-CM04S1, which can induce strong antibody and T cell responses against the SARS-CoV-2 virus variants, also offers the possibility of protection against Mpox and smallpox diseases, further distinguishing GEO-CM04S1 versus current mRNA-based COVID-19 vaccines. These characteristics may be particularly important in vulnerable patient populations, such as the immune-compromised, and in geographic areas where both diseases are endemic. This type of vaccine could offer a simplified vaccine regimen for protection against diseases associated with SARS-CoV-2 and orthopoxviruses.

- **GEO-MVA (Mpox and smallpox vaccine).** Following the recent announcement that GeoVax was acquiring the rights from NIH to develop, manufacture, and commercialize MVA as a vaccine against Mpox and smallpox, the Company has advanced to active regulatory discussions related to an expedited regulatory path for registration. GeoVax seeks to be the first U.S. supplier of the vaccine, which would expand supply options for public health worldwide.

- **Manufacturing Development Progress**. In May, GeoVax announced it had entered into an agreement with Advanced Bioscience Laboratories, Inc. (ABL) to support current Good Manufacturing Practices (cGMP) production of the Company's vaccine candidates, including GEO-CM04S1. A subsidiary of Institut Mérieux, ABL is a pure-play contract development and manufacturing organization (CDMO) specialized in developing and manufacturing of gene therapies, oncolytic viruses, and vaccine candidates. ABL is well-positioned to support GeoVax's global development programs through late-stage development and eventual commercialization with cGMP facilities in the U.S. and Europe.

  Earlier in 2023, GeoVax announced significant progress in developing a high-yield, high-capacity, continuous avian cell line system for manufacturing its MVA-based vaccines and immunotherapies. The Company is working towards fully implementing a proprietary, continuous cell line manufacturing system to provide lower-cost, scalable versatility for broad MVA vaccine and immunotherapy applications. GeoVax is on track to expand MVA applications from stockpile-based solutions for niche medical markets to having the capability to handle large-scale worldwide requirements on a timely basis.

- **Preclinical Programs**. Data from recent nonhuman primate studies of GEO-MM01 against Marburg virus were presented during the 23rd Annual World Vaccine Congress. Specifically relevant was that immunization with GEO-MM01 conferred 80% survival in cynomolgus macaques following a lethal dose of Marburg virus. Vaccination protected nonhuman primates from viremia, weight loss, and death following challenge with a lethal Marburg virus dose. Evaluation of immune responses following vaccination demonstrated the presence of both neutralizing antibodies and functional T cells, indicating a breadth of response capable of offering significant protection.

- **Patent Portfolio Development**. In July, GeoVax announced that the U.S. Patent and Trademark Office issued Patent No. 11,701,418 B2 to GeoVax, pursuant to the Company's patent application No. 15/543,139 titled "*Replication-Deficient Modified Vaccinia Ankara (MVA) and Matrix Protein (VP40).*" The claims granted by the patent generally cover GeoVax's vector platform for expressing ebolavirus antigens in virus-like particles (VLPs) utilizing an MVA viral vector. The claims encompass multiple ebolavirus strains, including Sudan ebolavirus, Zaire ebolavirus, Taï Forest ebolavirus, and Reston ebolavirus. GeoVax previously demonstrated that a single intramuscular (IM) dose of its vaccine candidate, GEO-EM01, provided 100% protection in rhesus macaques challenged with a lethal dose of Zaire ebolavirus (EBOV). The Company's preclinical efficacy studies of its Sudan ebolavirus (SUDV) vaccine candidate also demonstrated that a single dose of the vaccine protected 100% of small animals challenged with a lethal dose of SUDV.

  GeoVax announced in early 2023 that the U.S. Patent and Trademark Office issued a Notice of Allowance for Patent Application No. 17/000,768 titled, "*Method for Generating a ZIKV Immune Response Utilizing a Recombinant Modified Vaccinia Ankara Vector Encoding the NS1 Protein*." Preclinical studies demonstrated that a single dose of GEO-ZM02 provided 100% protection against a lethal dose of the Zika virus.

RECENT COMPANY DEVELOPMENTS

- **August 10, 2023—**GeoVax Labs announced that vaccinations have begun in an investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355) of GEO-CM04S1 in patients with chronic lymphocytic leukemia (CLL), being conducted at City of Hope National Medical Center.

- **August 9, 2023—**Announced its financial results for the quarter ended June 30, 2023, and recent corporate highlights.

- **July 24, 2023—**Announced that the U.S. Patent and Trademark Office has issued Patent No. 11,701,418 B2 to GeoVax, pursuant to the Company's patent application No. 15/543,139 titled "Replication-Deficient Modified Vaccinia Ankara (MVA) and Matrix Protein (VP40)." The claims granted by the patent generally cover GeoVax's vector platform for expressing ebolavirus antigens in virus-like particles (VLPs) utilizing an MVA viral vector. The claims encompass multiple ebolavirus strains, including Sudan ebolavirus, Zaire ebolavirus, Taï Forest ebolavirus, and Reston ebolavirus.

- **July 20, 2023—**Announced the start of an investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355), titled "Randomized observer-blinded phase 2 trial of COVID-19 booster with GEO-CM04S1 or Pfizer-BioNTech Bivalent vaccine in patients with chronic lymphocytic leukemia," at City of Hope National Medical Center, led by Alexey Danilov, M.D., PhD as principal investigator. GEO-CM04S1, a multi-antigenic SARS-CoV-2 vaccine that targets the spike (S) and nucleocapsid (N) proteins of SARS-CoV-2, is actively under clinical study by GeoVax in severely immunocompromised individuals, as well as in healthy adults for use as a universal heterologous booster.

- **July 10, 2023—**Announced the presentation of Phase 1/2 clinical trial data for GeoVax's gene therapy candidate, Gedeptin® at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference in Montréal, QC, Canada. The presentation, titled "Phase 1/ 2 study of Ad/PNP with fludarabine for the treatment of head neck squamous cell carcinoma (HNSCC)", describes the evaluation of Gedeptin as an experimental therapy for refractory solid tumors.

- **June 28, 2023—**Announced that an abstract regarding GeoVax's gene therapy candidate, Gedeptin®, has been selected for poster presentation at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference, being held from July 7-8, 2023 at the Palais des congrès de Montréal in Montréal, QC, Canada.

- **June 27, 2023—**Announced the publication of an article titled, "MVA-Vectored Universal Beta-Coronavirus Vaccine Design & Development" in the June 2023 issue of the online journal *Vaccine Insights*. The article is co-authored by GeoVax's Chief Scientific Officer, Mark Newman, PhD, together with other GeoVax scientists, Mary Hauser, PhD, Arban Domi, PhD, Sreenivasa Oruganti, PhD, Pratima Kumari, PhD and Ashley Zuniga, PhD and can be accessed here: Vaccine Insights.

- **May 31, 2023—**Announced it has executed a Master Services Agreement (MSA) with Advanced Bioscience Laboratories, Inc. (ABL) to support current Good Manufacturing Practices (cGMP) production of the Company's vaccine candidates, including GEO-MVA and GEO-CM04S1. ABL, a subsidiary of Institut Mérieux, is a pure-play contract development and manufacturing organization (CDMO) specialized in development and manufacturing of gene therapies, oncolytic viruses and vaccine candidates. With cGMP facilities located in the U.S. and Europe, ABL is well-positioned to support GeoVax's global development programs.

- **May 25, 2023—**Announced that its Chief Medical Officer, Kelly T. McKee, M.D., will participate in the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting, in Chicago on June 2-6, 2023, and its Chairman and CEO, David Dodd, and other senior management will participate in the 2023 BIO International Convention (BIO), in Boston on June 5-8, 2023.

- **May 24, 2023—**Announced the presentation of updates on the development of its next-generation SARS-CoV-2 vaccine, GEO-CM04S1, including preliminary data from an ongoing Phase 2 clinical trial, during the Vaccines Summit Boston 2023 and the Congress for the International Society for the Advancement of Cytometry (CYTO) 2023 meetings.

- **May 15, 2023—**Announced that it will be represented during two upcoming scientific meetings, including Vaccines Summit Boston 2023 in Boston, MA, May 22-24, 2023 and CYTO 2023 in Montréal, Québec, Canada, May 20-24, 2023.

Three Phase 2 Clinical Trials Advancing In SARS-Cov-2 Vaccines

The Company's next-generation COVID-19 vaccine, GEO-CM04S1, sets itself apart from currently authorized vaccines by targeting both the antibody and cellular components of the immune system. By prioritizing this dual approach, GeoVax aims to provide a more robust and enduring protection compared to existing authorized vaccines. This distinction is of critical importance in addressing the needs of high-risk populations, such as individuals with compromised immune systems, who currently find the authorized vaccines and monoclonal antibodies insufficient. High-risk populations encompass individuals with different blood cancers, renal disease, sickle cell anemia, HIV-positive status, autoimmune conditions like lupus, and those undergoing immune suppressive therapy. These patient groups typically have compromised immune systems that may not mount sufficient responses to authorized mRNA vaccines; consequently, they face heightened vulnerability to various health risks.

GEO-CM04S1 continues to advance in three Phase 2 clinical studies: (1) as a primary vaccine for immunocompromised cancer patients, in direct comparison to either the Pfizer or Moderna mRNA vaccine; (2) the second as a booster for healthy patients who have previously received either the Pfizer or Moderna vaccine as their initial inoculation; and (3) in patients with chronic lymphocytic leukemia (CLL).

Most recently, in July 2023, the Company announced that it had commenced an investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355), titled "Randomized observer-blinded phase 2 trial of COVID-19 booster with GEO-CM04S1 or Pfizer-BioNTech Bivalent vaccine in patients with chronic lymphocytic leukemia," at City of Hope National Medical Center. Despite a high vaccination rate, chronic lymphocytic leukemia (CLL) patients may be at high risk for lethal COVID-19 infection due to poor immune response to COVID-19 infections or vaccination. The GEO-CM04S1 vaccine uses a modified vaccinia virus (MVA) backbone that may be more effective at inducing COVID-19 immunity in patients with poor humoral immune responses since MVA strongly induces T cell expansion even in the background of immunosuppression. Targeting both the spike and nucleocapsid protein antigens broaden the specificity of the immune responses and protects against the loss of efficacy associated with the significant sequence variation observed with the spike antigen.

The study will examine the use of two injections of GEO-CM04S1 three months apart to assess immune responses in these vulnerable patients, with the Pfizer-BioNTech Bivalent vaccine as the control arm. Participants will be randomized 1:1 to receive two boosters with either the GEO-CM04S1 or the control vaccine. The primary immune response outcome will be 56 days following the first booster injection. Up to 40 participants will be treated in each arm, with immune responses evaluated at the interim and final analyses in each arm.

Phase 2 Trial For Gedeptin® In Advanced Head and Neck Cancer

An ongoing Phase 1/2 trial is evaluating the safety and efficacy of repeat cycles of Gedeptin® therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC) with tumor(s) accessible for injection and no curable treatment options. Gedeptin® is a novel patented product/technology to treat 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 nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a very toxic antitumor compound *in situ*. A Phase 1 dose-ranging study evaluating the safety of a single cycle of Gedeptin® therapy found the therapy was well-tolerated with evidence of a reduction in tumor size in patients with solid tumors.

The target population for the initial indication includes head and neck cancer patients, who are receiving palliative care, having failed other therapies and medical interventions. There are approximately 67,000 new cases of head and neck cancers annually in the U.S, and approximately 13,000 deaths annually resulting from head-and-neck cancers. Worldwide, there are approximately 900,000 new cases of head and neck cancers annually, and approximately 400,000 deaths.

Patients afflicted with advanced head and neck cancer present a significant and urgent medical challenge that GeoVax is committed to addressing. The FDA's support in funding the initial phase of its clinical program, involving 10 patients, underscores the recognition of the medical need for this drug. The Company's primary focus is to successfully conclude the 10-patient study and anticipates completing this initial phase within the current year and conducting a thorough analysis of the results obtained. Subsequently, the Company expects to engage in discussions with the FDA, sharing the results and recommendations for expanding the program. Furthermore, GeoVax expects to explore the possibility of an expedited Biologics License Application (BLA) filing in collaboration with the FDA.

GeoVax holds the exclusive global rights for the use of Gedeptin® in all indications. Within the field of oncology, GeoVax sees significant opportunities to advance innovative approaches that cater to the diverse requirements of cancer patients worldwide.

In July 2023, GeoVax announced the presentation of Phase 1/2 clinical trial data for Gedeptin® at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference in Montréal, QC, Canada. The presentation, titled "Phase 1/2 study of Ad/PNP with fludarabine for the treatment of head neck squamous cell carcinoma (HNSCC)", describes the evaluation of Gedeptin as an experimental therapy for refractory solid tumors.

The ongoing Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT03754933) is evaluating the safety and efficacy of repeat cycles of Gedeptin® therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options. The protocol entails up to five treatment cycles, each consisting of three intra-tumoral injections of Gedeptin® over two days followed by infusion of a prodrug, fludarabine phosphate, once daily for three days. A completed 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.

Modified Vaccinia Ankara (MVA) For Immunization Against Monkeypox (Mpox) And Smallpox

Regarding GEO-MVA, GeoVax is developing a vaccine that targets both Mpox and smallpox. The Company's goal is to establish itself as the leading supplier of an MVA-based vaccine in the U.S., offering protection against Mpox and smallpox. By doing so, GeoVax aims to address the global demand for these vaccines, particularly in low and middle-income countries that have historically faced challenges in accessing essential vaccines.

MVA is used and stockpiled in the U.S. Strategic National Stockpile for immunization against the MPox and smallpox viruses. GeoVax had previously demonstrated that an experimental HIV vaccine, using NIH-MVA as the vaccine vector, protected non-human primates challenged with a lethal dose of the MPox virus. Further, in August 2022, City of Hope, which originally developed GEO-CM04S1, published results demonstrating that both their proprietary sMVA (synthetic MVA) and GEO-CM04S1 elicited robust orthopoxvirus-specific binding and neutralizing antibody responses. The authors concluded that GEO-CM04S1 and sMVA represent unique vaccine candidates to control the unforeseen global MPox outbreak.

GeoVax secured rights from the NIH covering preclinical, clinical, and commercial uses of the NIH-MVA against MPox or smallpox viruses. The Company is evaluating development and regulatory pathways towards expanding the public health options available to reduce and manage the risk of MPox worldwide with the intent to be the first U.S.-based supplier of a MVA-vaccine against MPox and smallpox.

POTENTIAL 2023 COMPANY MILESTONES

- GeoVax seeks to focus its efforts on accelerating support of the Gedeptin® and GEO-CM04S1 Phase 2 clinical programs and advancing GeoVax's MVA manufacturing process into operational validation.

- During the first half, the Company reported initial clinical results of the safety lead in for the GEO-CM04S1 immunocompromised trial. Publication of these findings is expected during the second half of the year.

- GeoVax further expects to report preclinical information related to the use of the Gedeptin® technology in conjunction with immune checkpoint inhibitors. With Gedeptin®, the Company has 8 patients of the 10 patients in the program—having expanded the program to three sites—and anticipates bringing in the last two for this initial 10-patient trial, where GeoVax seeks to have this accomplished in the near term. The Company expects to review the data this year and begin initial discussions with the FDA.

- GeoVax intends to provide updates relative to clarifying an expedited regulatory registration pathway for its GEO-MVA vaccines for Mpox and smallpox.

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 are focused within the areas summarized in Figure 1.

Figure 1
GEOVAX PIPELINE FOCUSED ON NEAR-TERM VALUE DRIVERS

	Product Candidate	Status
Coronavirus		
COVID-19 (Immunocompromised)	GEO-CM04S1	Phase 2
COVID-19 (Booster to mRNA)	GEO-CM04S1	Phase 2
Pan Coronavirus	GEO-CM02	IND-Enabling
Cancer Immunotherapy		
Solid Tumors (Advanced Head & Neck Cancer)*	Gedeptin®	Phase 1/2
Solid Tumors (MUC1)	MVA-VLP-MUC1	IND-Enabling
Infectious Disease		
Ebola, Marburg, Sudan**	GEO-EM01	IND-Enabling
Zika Virus**	GEO-ZM02	IND-Enabling
Lassa Fever**	GEO-LM01	Exploratory
Malaria**	GEO-MM02	Exploratory

*: Orphan Drug status granted; **: Indication within FDA Priority Review Voucher program

Source: GeoVax Labs, Inc.

GeoVax is capitalizing on the safety and efficacy of its technology platform to address the need for a COVID-19 vaccine. Moreover, the Company is applying its MVA-VLP technology to cancer immunotherapy and plans to accelerate this program with proceeds from its recent financing. Greater details on GeoVax's development efforts can be found in the base report (https://bit.ly/3IjlBC0). GeoVax's vaccine development activities have been financially supported by the U.S. Government in the form of research grants awarded directly to the Company, as well as indirect support for conducting human clinical trials.

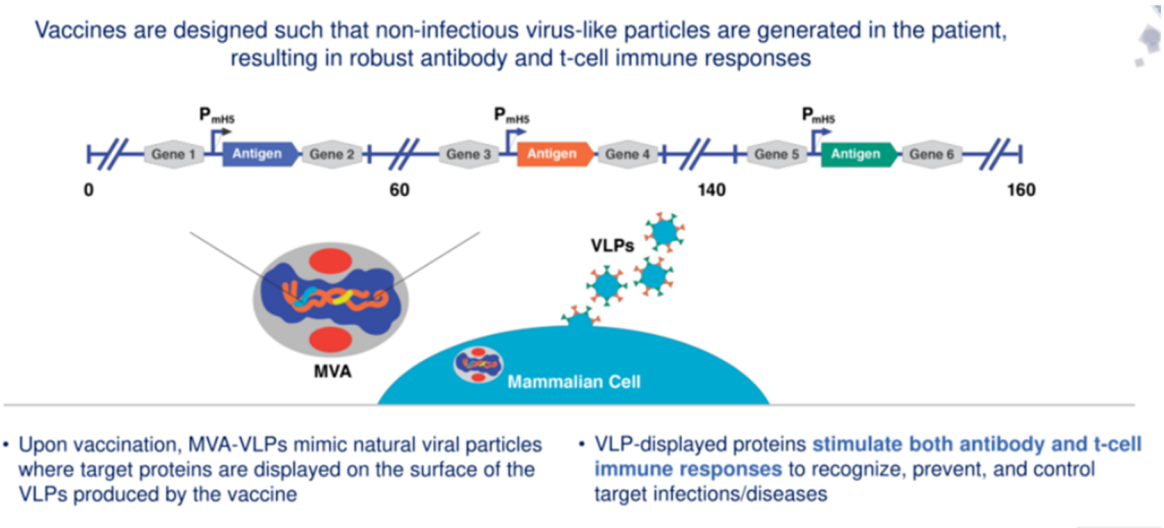
GeoVax's cash balance stands at approximately $17.8 million as of June 30, 2023, positioning the Company to support accelerated development of its COVID-19 vaccine development candidates, advance its cancer immunotherapy program, as well as other infectious disease vaccines.

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 largely 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 have 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 highly-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.

In February 2023, GeoVax announced significant progress in developing a high-yield, high-capacity, continuous avian cell line system for manufacturing its MVA (modified vaccinia Ankara)-based vaccines and immunotherapies. Currently, MVA vaccines are manufactured in cells cultured from chicken embryonic fibroblasts (CEF), a suboptimal and time-consuming process useful primarily for niche markets and stockpile reserves. After exploring various approaches to growing MVA in continuous cell lines in bioreactors more suitable for high-yield, commercial-scale manufacturing, GeoVax intends to accelerate activities towards fully implementing a proprietary, continuous cell line manufacturing system that it expects will provide lower-cost, scalable versatility for broad MVA vaccine and immunotherapy applications.

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.

The initial animal studies of the Company's MVA-VLP-MUC1 vaccine and ICI combination have been encouraging, showing that a combination of the MVA-VLP-MUC1 vaccine candidate with a MUC1 synthetic peptide was capable of breaking tolerance to human MUC1 in transgenic mice and inducing immune responses with efficacy against challenge in a lymphoma tumor model. The studies also demonstrated a significant reduction of the tumor burden in a mouse model for colorectal cancer. GeoVax plans to further these animal studies in collaboration to define the optimal course and schedule of vaccination to define a protocol that can be evaluated in a Phase 1 clinical trial.

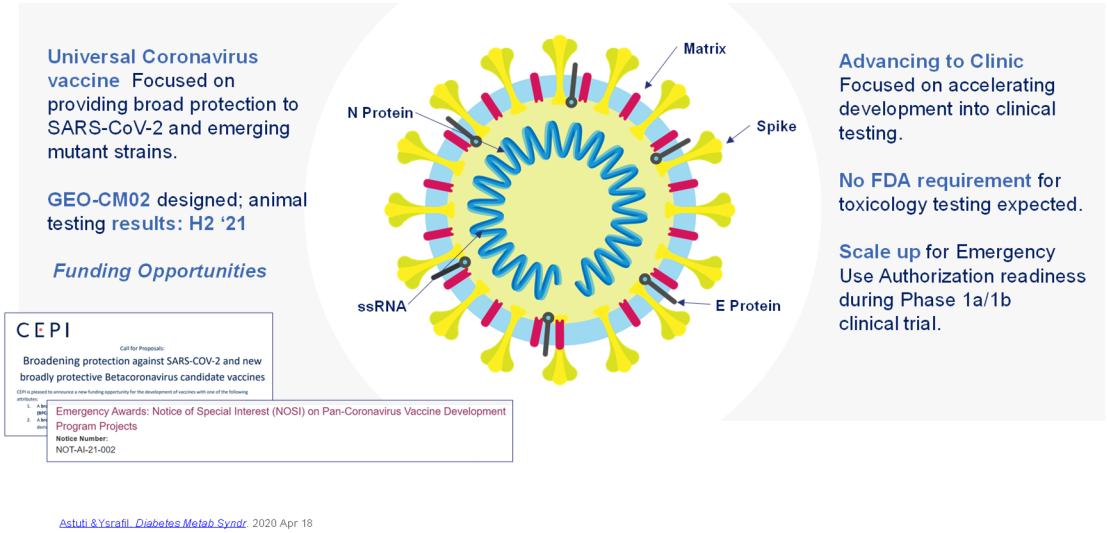
Patent update. The Company recently announced that the U.S. Patent and Trademark Office had issued a Notice of Allowance for Patent Application No. 16/068,527 entitled "Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen." In general, the claims to be granted in the patent cover GeoVax's vector platform for expressing tumor associated antigens in virus-like particles (VLPs) from a Modified Vaccinia Ankara (MVA) viral vector and encompass GeoVax's Mucin 1 (MUC1) tumor-associated antigen immunotherapy candidate.

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 August 2023, more than 693 million cases have been reported worldwide, resulting in over 6.9 million deaths. The U.S. is still considered one of the epicenters of the disease, with roughly 107 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. Figure 3 (page 13) summarizes key elements of the Company's COVID-19 vaccine technology.

Figure 3
UNIVERSAL SARS-COV-X VACCINE PROGRAM



Source: GeoVax Labs, Inc.

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.

GeoVax is involved in animal testing with three experimental vaccines, including in transgenic mice and hamsters (and all include infectious challenged). The product design that proves to induce the most protected immune response will be the basis for the initial clinical development. Additional designs are expected to include the incorporation of other coronavirus structural proteins and non-structural proteins based on data that is being generated within a population and immune responses from the current pandemic. The goal is to expand the induction of immune responses beyond the S protein, which is the basis for GeoVax's efforts and to develop a universal coronavirus vaccine.

The Company is in discussions with the Biomedical Advanced Research and Development Authority (BARDA) and other entities to support and accelerate its COVID-19 vaccine development efforts. While other COVID-19 vaccine candidates are in later stages of development, (with Pfizer, Moderna, and Johnson & Johnson's COVID-19 vaccines having been approved and being distributed), the GV-MVA-VLP platform offers unique advantages, including safety and breadth of responses. This makes the Company's platform ideal for immunization of those most vulnerable, including the immunocompromised and comorbid.

Three Phase 2 Clinical Trials Underway for SARS-CoV-2

GEO-CM04S1 for Immunocompromised Patients. GEO-CM04S1 is currently being evaluated in three Phase 2 clinical trials: (1) as a COVID-19 vaccine for immunocompromised patients; (2) as a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines; and (3) most recently, in patients with chronic lymphocytic leukemia (CLL).

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In July 2023, the Company announced that it had commenced an investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355), titled "Randomized observer-blinded phase 2 trial of COVID-19 booster with GEO-CM04S1 or Pfizer-BioNTech Bivalent vaccine in patients with chronic lymphocytic leukemia," at City of Hope National Medical Center.

Despite a high vaccination rate, chronic lymphocytic leukemia (CLL) patients may be at high risk for lethal COVID-19 infection due to poor immune response to COVID-19 infections or vaccination. The GEO-CM04S1 vaccine uses a modified vaccinia virus (MVA) backbone that may be more effective at inducing COVID-19 immunity in patients with poor humoral immune responses since MVA strongly induces T cell expansion even in the background of immunosuppression. Targeting both the spike and nucleocapsid protein antigens broaden the specificity of the immune responses and protects against the loss of efficacy associated with the significant sequence variation observed with the spike antigen.

The study will examine the use of two injections of GEO-CM04S1 three months apart to assess immune responses in these vulnerable patients, with the Pfizer-BioNTech Bivalent vaccine as the control arm. Participants will be randomized 1:1 to receive two boosters with either the GEO-CM04S1 or the control vaccine. The primary immune response outcome will be 56 days following the first booster injection. Up to 40 participants will be treated in each arm, with immune responses evaluated at the interim and final analyses in each arm.

IND-Enabling Activities Progressing for Pan Coronavirus Vaccine (GEO-CM02)

Beyond to the clinical programs for GEO-CM04S1 for COVID-19, GeoVax continues to assess GEO-CM02 as a possible single-dose universal coronavirus vaccine. This program was supported by a Small Business Innovation Research (SBIR) grant from the NIH during 2021. In small animal studies, the Company measured functional immune responses after a single dose that mediated protection from infection and pathogenesis, including protection against the more virulent Beta variant. Additional studies are planned in preparation for IND filing and subsequent human clinical trials.

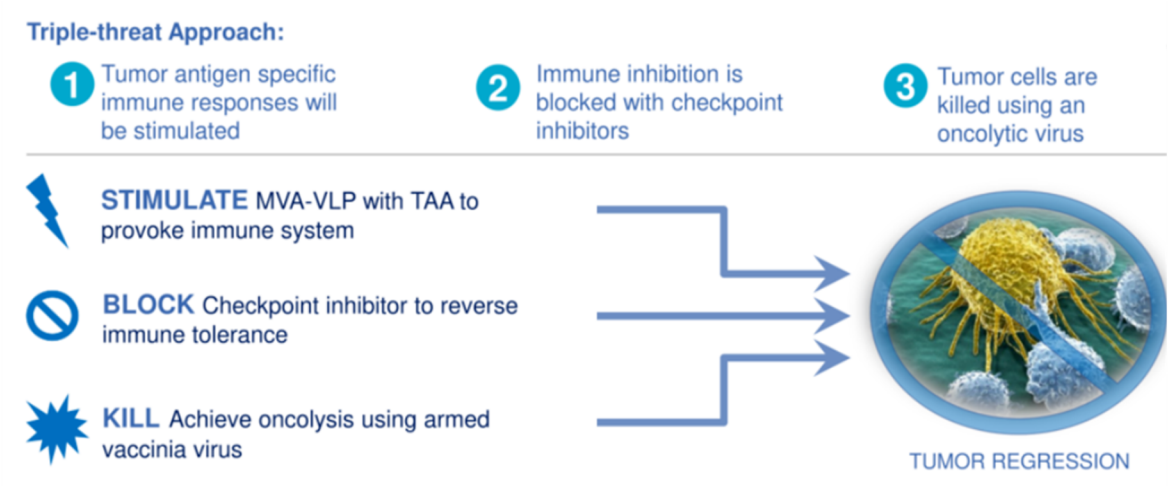
First-generation SARS-CoV-2 vaccines were designed to encode the spike (S) protein of the SARS-CoV-2 virus with the goal of inducing high levels of neutralizing antibodies. However, potential limitations of narrowly focusing on the spike (S) protein are becoming evident with emerging variants capable of partially escaping neutralization by vaccine induced antibodies. Consequently, the effectiveness of these vaccines against new SARS-CoV-2 variants and future coronavirus spillover events remains an enormous concern.

GeoVax's vaccine candidate (GEO-CM02) encodes the spike (S) protein as the neutralizing antibody target as well as the membrane (M) and envelope (E) proteins as T-cell targets and to support *in vivo* virus-like particle formation to augment potency. This strategy may provide the basis for generating a single dose universal coronavirus vaccine. Unique compared to other vaccines approved or under development, the GeoVax vaccine candidate is specifically designed to provide a broader and more durable level of protective immunity against SARS-CoV-2, which may protect against emerging variants while avoiding the potential side effects that can limit vaccine utility and acceptance.

Cancer Immunotherapy Vaccine Program

GeoVax is additionally developing the next generation of immunotherapies to address unmet medical needs in cancer (Figure 4, page 15). 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, thus resulting in immune responses that contribute to the regression of existing tumors and/or prevent the development and expansion of metastatic lesions.

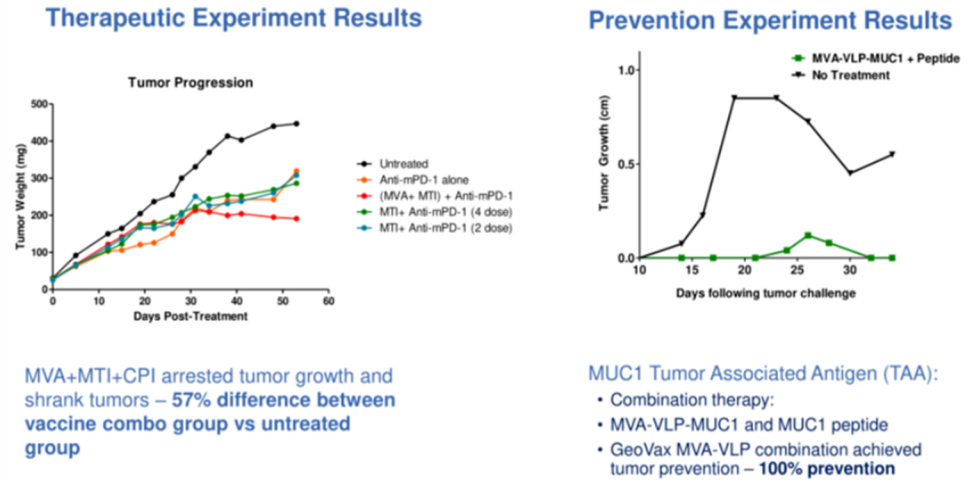
Figure 4
IMMUNOTHERAPY TECHNOLOGY



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 tested 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 that showed 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 reoccurring.

Figure 5
IMMUNONCOLOGY RESULTS



Source: GeoVax Labs, Inc.

Phase 1/2 Clinical Trial Underway for Advanced Head and Neck Cancer

A Phase 1/2 trial (NCT03754933) evaluating the safety and efficacy of repeat cycles of Gedeptin® therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC) that have tumor(s) accessible for injection and no curable treatment options, is ongoing at Stanford University in collaboration with Emory University. The trial design involves repeat administration using Gedeptin®, followed by systemic fludarabine, to gain additional information prior to expansion towards a larger patient trial. The initial stage of the study is being funded by the FDA under its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedeptin® Orphan Drug Status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland, and other oral cavities. This trial is currently being expanded to a multi-site trial with a focus on accelerated patient enrollment. In January 2022, GeoVax engaged Allucent, a global provider of clinical research solutions, to manage the ongoing Phase 1/2 trial and to assist with the expansion of clinical sites and acceleration of patient enrollment and evaluation.

Gedeptin® is a novel, patented product/technology for the treatment of solid tumors through a gene therapy strategy, known as Gene-Directed Enzyme Prodrug Therapy (GDEPT). In September 2021, GeoVax entered into an assignment and license agreement with PNP Therapeutics, Inc. (PNP), granting GeoVax exclusive rights to develop and commercialize Gedeptin®. The Gedeptin® technology was developed with funding support from the National Cancer Institute (NCI), part of the NIH. GeoVax's license to Gedeptin® includes the rights to expand the use of Gedeptin® to all human diseases and/or conditions including, but not limited to, other cancers.

In GDEPT, a vector is used to selectively transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a very toxic antitumor compound, *in situ*. A cycle of Gedeptin® therapy consists of three intra-tumoral injections of Gedeptin® over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days. A Phase 1 dose ranging study, evaluating the safety of a single cycle of Gedeptin® therapy, found the therapy to be well tolerated, with evidence of a reduction in tumor size in patients with solid tumors.

In February 2023, GeoVax announced that its clinical trial of Gedeptin® for patients with recurrent head and neck cancers is now actively enrolling patients at three major research centers: Stanford University, Emory University, and Thomas Jefferson University. The support of the FDA and collaborations with Stanford, Emory, and Jefferson enable GeoVax to evaluate Gedeptin® rapidly in 10 patients, with the potential to subsequently expand the trial to 25 patients. A successful outcome may lead to labeling discussions with the FDA and initiation of further Gedeptin® investigations, including in combination with immune checkpoint inhibitors, for additional cancerous and non-cancerous tumor indications.

In July 2023, interim data from the Phase 1/2 clinical trial of Gedeptin® was presented at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference. The ongoing Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT03754933) is evaluating the safety and efficacy of repeat cycles of Gedeptin therapy in patients with recurrent head and neck cancers whose tumor(s) are accessible for injection and who have no curable treatment options. The poster presentation highlighted data from 8 patients enrolled in the study to date, with no dose-limiting toxicities or serious adverse events attributable to treatment, and impairment of tumor growth in targeted lesions observed in 5 of 7 patients (one patient remaining under study).

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

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.

In agreement with the WHO, GeoVax believes that an ideal vaccine against major filoviruses and LASV must provide protection with a single dose. The MVA-VLP vaccines are well suited to meet this goal because they induce both antibody and cellular immune responses, which are needed to control and clear the infections. GeoVax's preclinical studies in rodents and non-human primates have demonstrated 100% single-dose protection in lethal challenge models for its EBOV, SUDV, and LASV vaccines.

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.

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 247 million infections and 619,000 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 SARS-CoV-2 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.

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 24 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, for year one of its agreement, 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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