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. Currently in two Phase 2 clinical trials, GEO-CM04S1 is being evaluated as a single-dose COVID-19 vaccine for immunocompromised patients, such as those suffering from hematologic cancers and other patient populations for whom the current authorized COVID-19 vaccines are insufficient. In addition, GEO-CM04S1 is in a Phase 2 clinical trial evaluating the vaccine as a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines. GeoVax has a leadership team who has driven significant value creation across multiple life science companies over the past several decades.

Key Points

- On November 9, 2022, GeoVax announced financial results for the third quarter ended September 30, 2022 and provided a corporate update. The Company reported a net loss of $3,968,102 ($0.17 per share) for the three months ended September 30, 2022 versus a net loss of $1,950,503 ($0.31 per share) for the same period in 2021. For the nine months ended September 30, 2022, the Company's net loss was $8,637,316 ($0.63 per share) versus a net loss of $4,827,314 ($0.80 per share) in 2021.
- GeoVax continues to focus on advancing its GEO-CM04S1 and Gedeptin® clinical programs, with the Company expanding into additional clinical sites and accelerating patient enrollment for both programs. GeoVax has also secured rights to the NIH-MVA for further development and commercial use against Monkeypox and Smallpox viruses, enabling the opportunity to leverage its MVA-based vaccine expertise and expand public health supply options.
- MVA is the vaccine used and stockpiled for immunization against Monkeypox. It is also the vaccine vector used in GeoVax's vaccines targeting COVID-19, Hemorrhagic fever viruses, HIV, Zika, and GeoVax's MVA-VLP-MUC1 cancer immunotherapy.
- For Gedeptin®, now that additional sites are on board, the focus is on accelerated and expanded patient enrollment, where GeoVax seeks to complete patient enrollment in 2023, followed by completing patient evaluations prior to the end of 2024.
- GeoVax's intellectual property portfolio contains over 115 granted or pending patent applications across 24 patent families.
- The Company's financing activities during the year have provided the Company with sufficient resources to advance its development programs, including producing additional drug product for use in its clinical trials. GeoVax is also well-positioned to advance the preclinical studies for its GEO-CM02 pan-coronavirus vaccine candidate and its MVA-VLP-MUC1 cancer immunotherapy program to further solidify its human vaccine and immunotherapy vaccines.
- GeoVax reported cash balances of $34.7 million on September 30, 2022 versus $11.4 million on December 31, 2021. Contributing to the increase in cash balances were aggregate net proceeds of $27.7 million from the sale of Company common stock and warrants during January and May, and $7.6 million from the exercise of warrants during August.

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Vaccines Serving Humanity

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GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (11/10/2022)	$0.78
52-week Range	$0.55 – 5.61
Shares Outstanding	26.3 million
Market Capitalization	$20 million
Avg. 10-day Volume	3.95 million
EPS (Qtr. ended 09/30/2022)	($0.17)
Employees	19

See page 16 for applicable disclosures.

THIRD QUARTER 2022 FINANCIAL RESULTS

GeoVax reported a net loss of $3,968,102 ($0.17 per share) for the three months ended September 30, 2022, versus a net loss of $1,950,503 ($0.31 per share) for the same period in 2021. For the nine months ended September 30, 2022, the Company's net loss was $8,637,316 ($0.63 per share) versus a net loss of $4,827,314 ($0.80 per share) in 2021. The increases in net losses during 2022 were primarily associated with the ramp up of the Company's organizational infrastructure and other costs associated with the Company's GEO-CM04S1 and Gedeptin® clinical trials.

Research and development expenses were $2,721,196 and $5,358,917 for the three-month and nine-month periods of 2022, respectively, versus $1,224,362 and $2,659,980 for the comparable periods of 2021, with the increases largely due to higher personnel and consulting costs, costs of conducting clinical trials for GEO-CM04S1 and Gedeptin®, and costs of manufacturing materials for use in clinical trials.

General and administrative expenses were $1,249,337 and $3,363,672 for the three-month and nine-month periods of 2022, respectively, versus $757,432 and $2,562,541 for the comparable periods of 2021, with the increases largely attributable to higher personnel costs and consulting costs, patent costs, investor relations costs and travel costs—all associated with a generally higher level of activity during 2022.

GeoVax reported cash balances of $34.7 million on September 30, 2022 versus $11.4 million on December 31, 2021. Contributing to the increase in cash balances during the nine-month period were aggregate net proceeds of $27.7 million from the sale of Company common stock and warrants during January and May, and $7.6 million from the exercise of warrants during August.

As a result of the Company's successful financings this year, GeoVax is well capitalized to complete its current Phase 2 clinical programs, including expansion of the Gedeptin® multi-site trial as well as expansion of the GEO-CM04S1 COVID-19 vaccine trial among immunocompromised patients to additional sites. The Company is focused on accelerating its programs with anticipated initial data readouts over the next six to nine months.

GeoVax remains focused on providing immunotherapies and vaccines that improve lives worldwide and preventing or treating some of the world's most challenging cancers and infectious diseases. As well, the Company recently initiated business development discussions towards partnering and collaborations to ensure worldwide access to its products.

2022 TO DATE HIGHLIGHTS

COVID-19 Vaccine Developments and Progress

GeoVax is focused on advancing its two Phase 2 clinical studies of GEO-CM04S1 against COVID-19: one as a primary vaccine for immunocompromised cancer patients, in direct comparison to the Pfizer mRNA vaccine (NCT04977024), and the second as a booster for healthy patients who have previously received either the Pfizer or Moderna vaccine as their initial inoculation (NCT04639466). GeoVax believes that the multi-punch approach has the potential to provide a more robust and durable immune response and protection in various high-risk populations, specifically immunocompromised individuals who will benefit from such a multi-pronged approach, resulting in broader and more durable protection.

GEO-CM04S1 uses synthetic Modified Vaccinia Ankara (MVA) technology similar to the Company's other vaccine programs under development. GEO-CM04S1 induces immunity to SARS-CoV-2 by stimulating the immune system to produce antibodies against SARS-CoV-2 that can block the virus from entering healthy cells, while the immune system can also grow new disease fighting T-cells that can recognize and destroy infected cells.

Earlier this year, data from a Phase 1 study of GEO-CM04S1 were published in *The Lancet Microbe*. This peer-reviewed publication reported data showing that GEO-CM04S1 produced robust neutralizing antibodies and T cells against SARS-CoV-2 with no significant side effects. These data confirm the strong dual action of the Company's vaccine, an important feature given the multiple spike antigen mutations, leading to variants of concern and inconsistent protection from existing FDA-approved vaccines. If a new mutation were to arise in the spike antigen that interferes with antibody recognition, a vaccinated individual with GEO-CM04S1 may still have substantial T-cell immunity against both the nucleocapsid and spike antigens.

In July 2022, additional analyses of data from the Phase 1 study of GEO-CM04S1 published in the peer-reviewed journal, *iScience*, showed that GEO-CM04S1 demonstrated potent and equivalent T-cell cross-reactivity against Delta and Omicron variants. These discoveries suggest that T-cell immunity stimulated by GEO-CM04S1 may represent a significant second line of defense to delivering long-term defense against SARS-CoV-2 variants.

Pan-Coronavirus Vaccine (GEO-CM02). During the third quarter, the Company also initiated new preclinical studies of its pan-coronavirus vaccine candidate (GEO-CM02) to prepare for an Investigational New Drug (IND) application and subsequent human clinical trials as a potential 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, GeoVax measured functional immune responses following a single dose that mediated protection from infection and pathogenesis, including protection against the more virulent Beta variant. The Company has initiated further preclinical studies to prepare for IND filing and subsequent human clinical trials.

Immuno-Oncology Developments

Gedeptin® is the Company's cancer therapy currently in an expanded multi-site evaluation among patients suffering from advanced head and neck cancers. The product has received Orphan Drug Designation from the FDA as well as the initial funding and support of the current clinical trial coming from the FDA Orphan Drugs Clinical Trials program. The focus is on accelerated and expanded patient enrollment. Now that additional Gedeptin® sites are on board, the Company seeks to complete patient enrollment in 2023, followed by completion of patient evaluations before the end of 2024. In the interim, GeoVax expects to engage with the FDA regarding the results with the focus on clarifying the opportunity for an expedited biologics license application filing.

Phase 1/2 Trial - Gedeptin®. 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 has broadened from a single site at Stanford University to additional sites at Emory University and Thomas Jefferson University. Funded in part by the U.S. Food & Drug Administration (FDA) under its Orphan Products Clinical Trials Grants Program, the trial is expected to guide the design of a larger study that also may involve patients with other anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland, and other oral cavities. To further evaluate the Company's additional immunotherapy candidate for solid tumors (MVA-VLP-MUC1), GeoVax recently began a preclinical study with Dr. Pinku Mukherjee at the University of North Carolina at Charlotte, to define the optimal course and schedule of vaccination for incorporation into a Phase 1 clinical protocol.

MVA-VLP-MUC1 for Solid Tumor Cancers. In March 2022, GeoVax announced that the U.S. Patent and Trademark Office issued Patent No. 11278607, pursuant to the Company's patent application No. 16/068,527 titled, "*Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen*." The claims granted by the patent generally 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. The Company uses its GV-MVA-VLPTM 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. GeoVax recently began an animal study at the University of North Carolina at Charlotte to define the optimal course and schedule of vaccination to define a protocol that can be evaluated in a Phase 1 clinical trial for its MVA-VLP-MUC1 immunotherapy candidate.

Hemorrhagic Fever Virus Vaccines Development and Progress

In July 2022, GeoVax announced the publication of a peer-reviewed animal efficacy study of its modified vaccinia Ankara (MVA) vectored vaccine against Sudan ebolavirus (SUDV) in *Nature Partner Journals (NPJ) Vaccines*. GeoVax's vaccine, MVA-VLP-SUDV, combines the advantages of the immunogenicity of a live attenuated vaccine vector with the authentic conformation of VLPs. The vaccine expresses minimal components to generate self-assembling VLPs in the vaccinee: the envelope glycoprotein GP and the matrix protein VP40. Guinea pigs vaccinated with one dose of MVA-VLP-SUDV generated SUDV-specific binding and neutralizing antibody responses as well as Fc-mediated protective effects. These responses were boosted by a second vaccine dose. All vaccinated animals receiving either one or two vaccine doses were protected from death and disease symptoms following challenge with a lethal dose of SUDV. These data demonstrate single dose protection and potency of the MVA-VLP platform for use in emergency situations to contain outbreaks. The anticipated final stage of preclinical testing involving nonhuman primates has recently been completed and results are expected to be discussed during upcoming scientific conferences during the fourth quarter of this year.

Modified Vaccinia Ankara (MVA): Monkeypox and Smallpox

MVA is the vaccine vector utilized by GeoVax in a number of its vaccine candidates, including those for COVID-19, various hemorrhagic fever viruses, the Company's MVA-VLP-MUC1 cancer immunotherapy and others. MVA is also the vaccine used and stockpiled for immunization against the Monkeypox and Smallpox viruses. The WHO recently declared monkeypox a public health emergency of international concern. Nations worldwide are enacting procedures and policies that support minimizing the health risks from Monkeypox to their populations. There are currently only two vaccines authorized in the U.S. for preventing Monkeypox, the primary vaccine being Modified Vaccinia Ankara or MVA, which is also the vaccine to utilize in numerous GeoVax's vaccines including its GEO-CM04S1 and GEO-CMO2, which target COVID-19. In addition, MVA is the vaccine vector use in hemorrhagic fever virus vaccines against Zaire ebolavirus, Sudan ebolavirus, and Marburg, as well as GeoVax's development stage Zika Virus vaccine and its MUC1 cancer immunotherapy.

Reacting to the global need to address the continued emerging threat from Monkeypox and the rare opportunity offered by MVA-based vaccines, GeoVax recently secured rights from the National Institutes of Health (NIH) covering preclinical, clinical, and commercial uses of the NIH-MVA against Monkeypox or Smallpox viruses. GeoVax is now evaluating development and regulatory pathways towards expanding the public health options available to reduce and manage the risk of Monkeypox worldwide. GeoVax believes that with the amount of information known about MVA, the safety profile of MVA, and the fact that is has been developed for use in immunocompromised population, that there could be an abbreviated pathway. Accordingly, the Company has commenced scaling up its master C batches, which would allow it to move into cGMP production and work with select regulatory agencies.

GeoVax previously demonstrated that an experimental HIV vaccine, utilizing NIH-MVA as the vaccine vector, protected non-human primates challenged with a lethal dose of the Monkeypox virus three years post vaccination. In August 2022, the City of Hope team, which originally developed GEO-CM04S1, published results demonstrating that both their proprietary sMVA (synthetic MVA) and GEO-CM04S1, which utilizes sMVA as the vaccine vector, elicited robust orthopoxvirus-specific binding and neutralizing antibody responses. They also reported that healthy adults, vaccinated with COH04S1 at different dose levels, developed robust orthopoxvirus-specific humoral and cellular immune responses that are durable for over six months post-vaccination. The authors conclude that "COH04S1 and sMVA represent unique vaccine candidates to control the unforeseen global MPXV outbreak."

RECENT DEVELOPMENTS

- **November 9, 2022—**GeoVax Labs, Inc. announced its financial results for the third quarter ended September 30, 2022.

- **October 26, 2022—**Announced that it will report third quarter 2022 financial results after the market close on Wednesday, November 9, 2022.

- **October 11, 2022—**Announced that Senior Scientist Sreenivasa Oruganti, Ph.D., will present at the Vaccines Summit-2022 taking place October 11-13, 2022, in Reston, VA.

- **October 6, 2022—**Announced that GeoVax's Chairman & CEO, David Dodd, will present at the Midcap Rodeo: Windy City Roundup 2022 in Chicago, IL and at the LD Micro Main Event XV in Los Angeles, CA.

- **September 7, 2022—**Announced that its Chairman & CEO, David Dodd, will present a company overview at the H.C. Wainwright 24th Annual Global Investment Conference on September 12 at 2:30 p.m. EST.

- **September 1, 2022—**Announced that it has appointed Nicole Lemerond, CFA, to its Board of Directors. Ms. Lemerond is a financial executive with over 25 years of experience in investment management, private equity, investment banking, mergers/acquisitions, and leveraged finance. She has significant experience executing complex transactions, managing diligence processes, raising capital and structuring balance sheets. Her breadth of industry expertise includes providers, payors, medical device manufacturers, HCIT providers, pharmaceutical and life sciences companies.

- **August 3, 2022—**GeoVax Labs, Inc. announced its financial results for the quarter ended June 30, 2022.

- **July 28, 2022—**Announced the publication of a peer-reviewed animal efficacy study of its modified vaccine Ankara (MVA) vectored vaccine against Sudan ebolavirus (SUDV). The study was published in *Nature Partner Journals (NPJ) Vaccines*.

- **July 26, 2022—**Announced that it will report second quarter 2022 financial results on Wednesday, August 3, 2022 after the market closes.

- **June 13, 2022**—Announced the appointment of John W. Sharkey, PhD to serve as Vice President, Business Development. Dr. Sharkey brings over 30 years of experience in the pharmaceutical and medical device industry, with specific expertise in executive management, business development, pharmaceutical and medical device development, regulatory affairs, manufacturing and business operations covering multiple therapeutic segments. Over his career, Dr. Sharkey has been a key contributor to the development, acquisition, or divestment of multiple products with annual revenues ranging from $5 million to more than $2 billion.

- **June 7, 2022—**Announced that its Chairman & CEO, David Dodd, will present at the BIO International Convention 2022 being held June 13-16 in San Diego.

- **May 25, 2022—**Announced that it has entered into a definitive agreement with a single healthcare-focused institutional investor for the issuance and sale of 3,030,304 shares of common stock at a purchase price of $1.65 per share (or pre-funded warrant in lieu thereof) in a registered direct offering priced at a premium to market under Nasdaq rules. In a concurrent private placement, GeoVax has also agreed to issue and sell to the investor 9,090,910 shares of common stock (or common stock equivalents) at the same purchase price as in the registered direct offering. In addition, the Company has agreed to issue to the investor in the offerings unregistered preferred investment options to purchase up to an aggregate of 12,121,214 shares of common stock. The aggregate gross proceeds to the Company of both offerings are expected to be approximately $20 million.

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 as 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 urgent 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 Company details on GeoVax's development efforts can be found in the base report, Executive Informational Overview (https://bit.ly/3IjIBC0). GeoVax's vaccine development activities have been (and continue to be) 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.

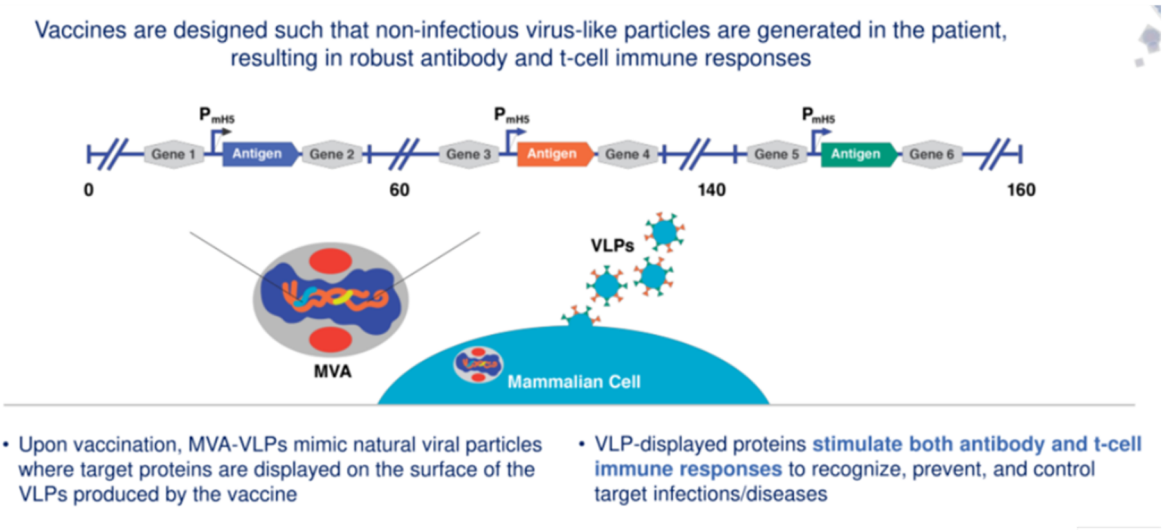
Following the Company's recent financings, GeoVax's cash balance now stands at approximately $34.7 million, positioning the Company to support accelerated development of its COVID-19 vaccine development candidates, advance its cancer immunotherapy program, as well as other infectious disease vaccines.

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)*, thereby 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.

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.

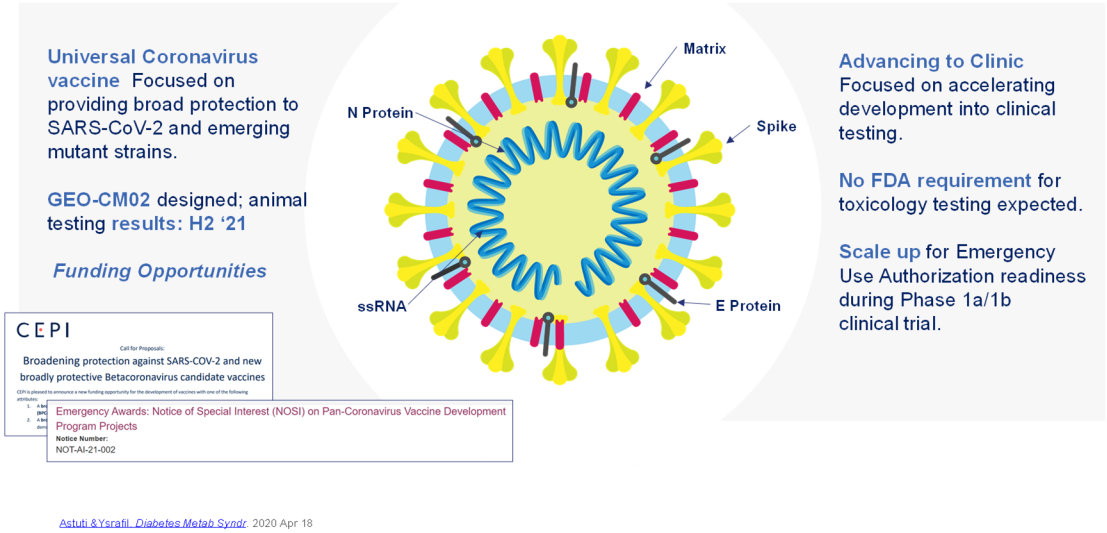
The initial animal studies of the Company's MVA-VLP-MUC1 vaccine and ICI combination have been encouraging, showing that a combination of the MVA-VLP-MUC1 vaccine candidate with a MUC1 synthetic peptide was capable of breaking tolerance to human MUC1 in transgenic mice and inducing immune responses with 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.

The Company announced during the last quarter 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 2022, more than 581 million cases have been reported worldwide, resulting in over 6.4 million deaths. The U.S. is still considered one of the epicenters of the disease, with roughly 92 million cases and 1 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 11) 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 currently 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.

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

GEO-CM04S1 for Immunocompromised Patients. GEO-CM04S1 is being studied in a first-of-its-kind Phase 2 clinical trial (NCT04977024) as a primary vaccine for immunocompromised cancer patients who have difficulty producing antibodies and largely depend on T cells to protect against the virus responsible for COVID-19. Additionally, GEO-CM04S1 is being evaluated in a Phase 2 vaccine booster trial format (NCT04639466), aimed at evaluating how GEO-CM04S1 may boost pre-existing vaccine immunity while also causing a strong immune response to nucleocapsid. GEO-CM04S1 is unique to other COVID-19 vaccines in that it targets both the spike and nucleocapsid proteins. In contrast, the current U.S. FDA-approved COVID-19 vaccines only target the spike protein.

In March 2022, data from a Phase 1 study of GEO-CM04S1 was published in the peer-reviewed journal, *The Lancet Microbe*. The publication reported data showing that GEO-CM04S1 produced robust neutralizing antibodies and T cells against SARS-CoV-2 with no significant side effects. These data confirm the strong dual action of the GeoVax vaccine, an important feature given the multiple mutations in spike, leading to variants of concern and inconsistent protection from existing FDA-approved vaccines. If a new mutation arises in the spike antigen that interferes with antibody recognition, a person vaccinated with GeoVax's vaccine may still have substantial T-cell immunity against both the nucleocapsid and spike antigens.

GEO-CM04S1 as a Booster Vaccine. In December 2021, patient enrollment began for the Phase 2 portion of a Phase 1/2 trial (NCT04639466) of GEO-CM04S1, evaluating its use as a universal booster vaccine to current FDA-approved two-shot mRNA vaccines from Pfizer/BioNTech and Moderna. The completed Phase 1 portion of the trial was designed as a dose-escalation safety study in healthy individuals who had not been previously infected with SARS-CoV-2. The ongoing Phase 2 booster study includes healthy individuals who were previously fully vaccinated with either the Pfizer/BioNTech or Moderna vaccine. The dose-escalation study is designed to specifically evaluate the safety profile and immunogenicity of GEO-CM04S1 as a booster. The immunological responses measured throughout the study will include the level of SARS-CoV-2 neutralizing antibodies against SARS-CoV-2 variants of concern (VOC), including the newly identified Omicron VOC, as well as specific T-cell responses.

On March 14, 2022, GeoVax announced the engagement of Allucent (formerly CATO SMS) to manage GeoVax's two ongoing Phase 2 clinical trials of its vaccine candidate, GEO-CM04S1, against SARS-CoV-2. Allucent is a global provider of clinical research solutions, including strategic consulting, full-service clinical trial operations, biometrics, and clinical pharmacology. With more than 30 years of experience focusing on the needs of small and emerging biopharmaceutical companies, Allucent effectively designs and executes studies (from strategy to approval) in complex indications and modalities across a variety of therapeutic areas with a proven center of excellence in oncology.

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 for 2022 to prepare for IND filing and subsequent human clinical trials.

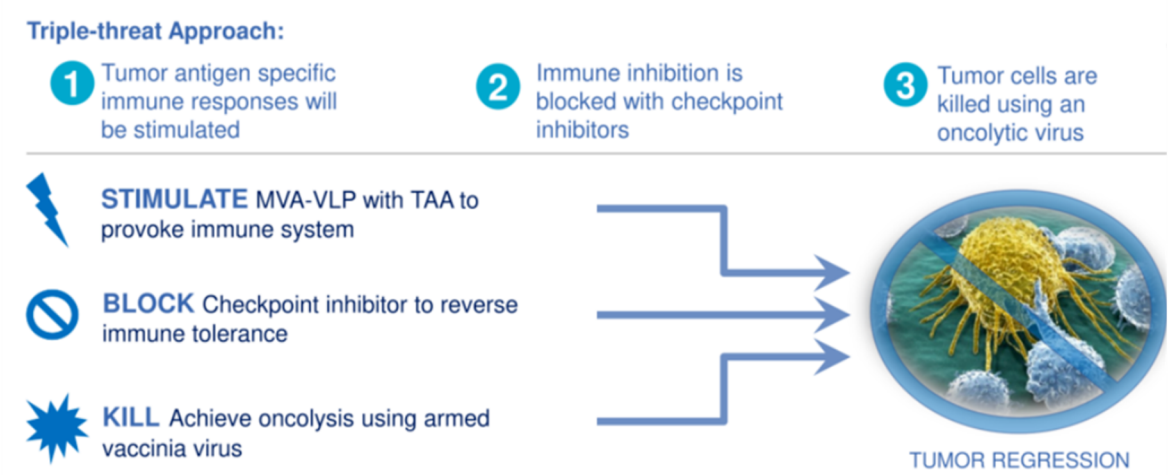
First-generation SARS-CoV-2 vaccines were designed to encode the spike (S) protein of the SARS-CoV-2 virus with the goal of inducing high levels of neutralizing antibodies. However, potential limitations of narrowly focusing on the spike (S) protein are becoming evident with emerging variants capable 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). 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.

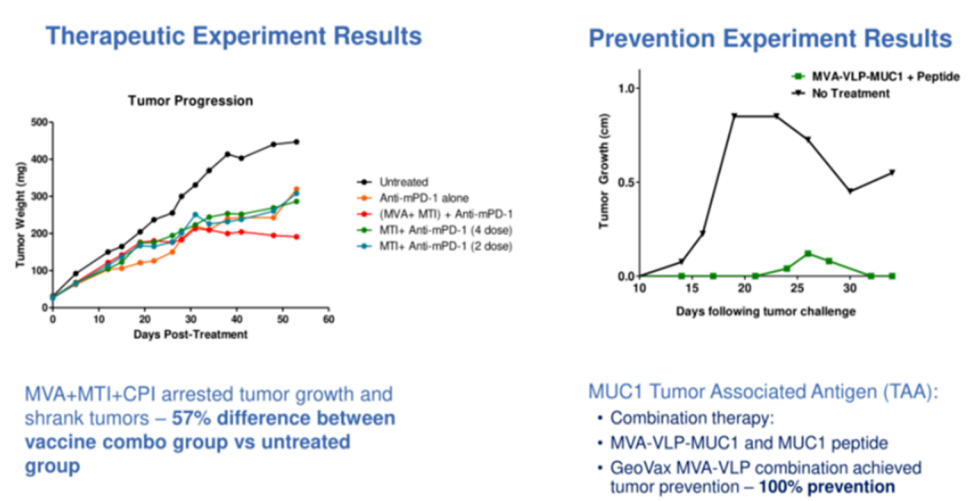
Figure 4
IMMUNOTHERAPY TECHNOLOGY



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 (page 14), 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 that provided almost 100% protection against tumors reoccurring. These results have encouraged the Company to move quickly to initiate clinical development programs.

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.

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 Monkeypox

The vaccine used and stockpiled for immunization against Monkeypox 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. Previous peer-reviewed publications examined the successful prevention of Monkeypox in non-human primate models by GeoVax MVA-based HIV vaccines:

> Earl, P.L., Americo, J.L., Wyatt, L.S., Anne Eller, L., Montefiori, D.C., Byrum, R., Piatak, M., Lifson, J.D., Rao Amara, R., Robinson, H.L., Huggins, J.W., Moss, B. Recombinant modified vaccinia virus Ankara provides durable protection against disease caused by an immunodeficiency virus as well as long-term immunity to an orthopoxvirus in a non-human primate. Virology 15:84-97, 2007.
>
> Nigam, P., Earl, P.L., Americo, J.L., Sharma, S., Wyatt, L.S., Edghill-Spano, Y., Chennareddi, L., Silvera, P., Moss, B., Robinson, H.L., Amara, R.R. DNA/MVA HIV-1 AIDS vaccine elicits long-lived vaccinia virus-specific immunity and confers protection against a lethal monkeypox challenge. Virology 366:73-83.

Evaluation is currently underway related to GEO-CM04S1 in preventing Monkeypox. It is anticipated that the results will demonstrate successful protection, validating that GEO-CM04S1 is protective against both COVID-19 and Monkeypox. GeoVax also anticipates validating its hemorrhagic fever virus vaccines as protective against Monkeypox, potentially providing unique vaccines preventing both hemorrhagic fever virus and Monkeypox 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.

GeoVax announced on April 26, 2022 that the U.S. Patent and Trademark Office has issued Patent No. 11,311,612 to GeoVax, pursuant to the Company's patent application No. 16/648,693 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." In general, the claims granted in the patent cover GeoVax's Modified Vaccinia Ankara (MVA) vector expressing certain antigens from the malaria parasite.

Worldwide, as of 2020, malaria causes 241 million infections and 627,000 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 recently decided to discontinue 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 will have 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 its 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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