

Company Description

GeoVax Labs, Inc. (“GeoVax” or “the Company”) is a clinical-stage biotechnology company developing preventive and therapeutic human vaccines and immunotherapies against infectious diseases and cancer. The Company recently significantly expanded its clinical stage portfolio through the in-licensing of two Phase 2 products/programs within SARS-CoV-2 and Head & Neck Cancer immunotherapy. The Company’s proprietary GV-MVA-VLP™ vector vaccine technology utilizes a Modified Vaccinia Ankara (MVA) vector, a large virus capable of carrying several vaccine antigens, which are expressed as non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (*in vivo*). VLPs mimic a natural infection, stimulating both the humoral (antibody) and cellular (T-cells) arms of the immune system to recognize, prevent, and control the target infection through durable immune responses. In addition to the GV-MVA-VLP™ technology, the recent license of the SARS-CoV-2 vaccine (GEO/COH04S1) provides the Company a complementary technology, sMVA (synthetic MVA), and the license of Gedeptin® adds the GDEPT (Gene Directed Enzyme Prodrug Therapy) technology to the GeoVax technology platform portfolio. GeoVax is capitalizing on these technologies and its vaccine/immunotherapy design expertise to address the need for a broadly-effective COVID-19 vaccine and is also developing vaccines against human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa Fever), and malaria, while also applying its MVA-VLP technology to cancer immunotherapy (immuno-oncology).

Key Points

- On November 11, 2021, GeoVax announced financial results from the quarter ended September 30, 2021 and provided a corporate update. For the three months ended September 30, 2021, the Company’s net loss was \$1,950,503 (\$0.31 per share) versus a net loss of \$570,648 (\$0.73 per share) for the same period in 2020. For the nine months ended September 30, 2021, GeoVax’s net loss was \$4,827,314 (\$0.80 per share) versus a net loss of \$1,621,546 (\$2.85 per share) in 2020.
- Revenues from grants and collaborations were \$30,414 and \$220,539 for the three-month and nine-month periods ended September 30, 2021, respectively, versus \$415,458 and \$1,572,037 in the equal periods of 2020. As of September 30, 2021, \$244,888 of funds were available for use related to a COVID-19 grant from NIAID and a Lassa Fever grant from the U.S. Army.
- Earlier this month, the Company announced that it had entered into an exclusive license agreement with City of Hope (“COH”), granting GeoVax exclusive rights to further develop and commercialize COH04S1, a synthetic, attenuated modified vaccinia Ankara (sMVA) vector expressing spike (S) and nucleocapsid (N) antigens of the SARS-CoV-2 virus, which shows potential to be used in the general population as a primary and/or general booster vaccine against COVID-19 worldwide. COH04S1 is currently in a Phase 2 clinical trial in immunocompromised patients.
- In September 2021, GeoVax entered into an Assignment and License Agreement with PNP Therapeutics, Inc., granting GeoVax exclusive rights to develop and commercialize Gedeptin® treat solid tumors, currently in a Phase 1/2 clinical trial for head and neck squamous cell carcinomas (HNSCC).
- GeoVax continues to strengthen its intellectual property portfolio, with over 70 granted or pending patent applications across 20 patent families. In October 2021, the Company announced that the USPTO has issued a Notice of Allowance for Patent Application No. 15/543,139 entitled “Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Ebola Virus Glycoprotein (GP) and Matrix Protein (VP40).” As well, on November 16, 2021, GeoVax announced that the USPTO has 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.”
- At September 30, 2021, GeoVax’s cash balance was \$18.1 million versus \$9.9 million at December 31, 2020.



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GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (11/17/2021)	\$4.78
52-week Range	\$2.56 - 8.71
Shares Outstanding	6.3 million
Market Capitalization	\$30.2 million
Avg. 10-day Volume	249,800
EPS (Year ended 09/30/21)	(\$0.31)
Employees	11

THIRD QUARTER 2021 FINANCIAL RESULTS

For the three months ended September 30, 2021, GeoVax reported a net loss of \$1,950,503 (\$0.31 per share) versus a net loss of \$570,648 (\$0.73 per share) for the same period in 2020. For the nine months ended September 30, 2021, the Company's net loss was \$4,827,314 (\$0.80 per share) versus a net loss of \$1,621,546 (\$2.85 per share) in 2020.

Grant and collaboration revenues for the three-month and nine-month periods ended September 30, 2021 were \$30,414 and \$220,539, respectively, versus \$415,458 and \$1,572,037 in the comparable periods of 2020. As of September 30, 2021, there is \$244,888 of approved funds remaining and available for use related to the Company's COVID-19 grant from NIAID and Lassa Fever grant from the U.S. Army.

Research and development expenses were \$1,224,362 and \$2,659,980 for the three-month and nine-month periods ended September 30, 2021, respectively, versus \$416,756 and \$1,687,113 for the comparable periods of 2020, with the increases primarily related to the Company's COVID-19 vaccine program, manufacturing process development, and a generally higher level of activity, offset in part by the timing and amount of external expenditures related to government grants. General and administrative expenses were \$757,432 and \$2,562,641 for the three-month and nine-month periods of 2021, respectively, versus \$435,013 and \$1,364,650 for the comparable periods of 2020, with the increase attributable to higher Delaware franchise taxes; legal, accounting and patent costs; insurance costs; consulting fees; NASDAQ listing fees; investor relations costs; and personnel costs.

Other income (expense) was \$877 and \$174,768 for the three-month and nine-month periods ended September 30, 2021, respectively, versus (\$134,337) and (\$141,820) for the comparable periods of 2020. The 2021 periods include a \$172,056 gain on extinguishment of debt, reflecting forgiveness of the Company's loan pursuant to the Paycheck Protection Program (PPP).

At September 30, 2021, GeoVax reported a cash balance of \$18.1 million versus \$9.9 million at December 31, 2020. Contributing to the increase in cash balances during 2021 were net proceeds of \$9.4 million from the sale of common stock in February, and an aggregate of \$3.4 million from the exercise of warrants during the nine-month period ended September 30, 2021.

RECENT DEVELOPMENTS

- On November 16, 2021, GeoVax announced that the U.S. Patent and Trademark Office has 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.
- On November 9, 2021, GeoVax announced that it had entered into an exclusive license agreement with City of Hope ("COH") granting GeoVax exclusive rights to further develop and commercialize COH04S1, a synthetic, attenuated modified vaccinia Ankara (sMVA) vector expressing spike (S) and nucleocapsid (N) antigens of the SARS-CoV-2 virus, which shows potential to be used in the general population as a primary and/or general booster vaccine against COVID-19 worldwide.
 - A Phase 2 clinical trial to evaluate the safety and immunogenicity of the COH04S1 investigational vaccine, compared to the Pfizer/BioNTech mRNA-based vaccine, in patients who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant, or chimeric antigen receptor (CAR) T cell therapy, is currently underway. The trial is also the first to compare an investigational multi-antigenic COVID-19 vaccine to the current FDA-approved mRNA vaccine from Pfizer/BioNTech in people who are immunocompromised. Such patients have often shown a weak antibody response after receiving currently available COVID-19 vaccines. The ongoing Phase 2 trial is designed to evaluate COH04S1 in immunocompromised patients. An additional Phase 1/2 trial to evaluate COH04S1 as a universal booster to current FDA-approved vaccines is anticipated to open soon for enrollment in healthy volunteers.

- On September 28, 2021, GeoVax announced that it had expanded its clinical-stage immuno-oncology pipeline and added a new technology platform through the acquisition of exclusive rights to develop and commercialize Gedeptin[®], a novel patented product for the treatment of solid tumors through a gene therapy strategy known as GDEPT (Gene-Directed Enzyme Prodrug Therapy).
 - 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. A cycle of Gedeptin[®] therapy consists of three intra-tumoral injections over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days.
 - A Phase 1/2 trial is currently enrolling to evaluate 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 FDA is funding the initial stage of the study pursuant to its Orphan Products Clinical Trials Grants Program. The FDA has granted Gedeptin[®] Orphan Drug status for the treatment HNSCC. GeoVax's license to Gedeptin[®] includes rights to expand its use to all human diseases and/or conditions including, but not limited to, other cancers.
- On October 14, 2021, the Company announced that the U.S. Patent and Trademark Office has issued a Notice of Allowance for Patent Application No. 15/543,139 entitled "Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Ebola Virus Glycoprotein (GP) and Matrix Protein (VP40)." GeoVax has 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 Ebola virus (EBOV). This is the first report that a replication-deficient MVA vector can confer full protection against a lethal EBOV challenge after a single-dose vaccination in macaques. This work was conducted in collaboration with researchers at the University of Texas Medical Branch (UTMB).
 - Separately, GeoVax is leading a multi-party collaboration for the development of its SUDV and Marburg virus (MARV) vaccine candidates. The collaboration, between GeoVax, researchers at UTMB and Battelle Memorial Institute, utilizes the suite of preclinical services from NIAID. Under the collaboration, GeoVax's SUDV and MARV vaccine candidates are being tested for immunogenicity and efficacy in the benchmark nonhuman primate model. GeoVax's vaccine against Lassa Fever virus (LASV) is progressing in preclinical studies with funding support from the U.S. Department of Defense.
- In August 2021, the Company presented data from ongoing studies of its preventive vaccine against COVID-19 during the European Society of Medicine (ESMED) General Assembly. The Company's initial vaccine candidate, GEO-CM02, encodes the Spike (S), Membrane (M) and Envelope (E) proteins from the SARS-CoV-2 virus. In this initial format, the simultaneous expression of the SARS-CoV-2 proteins supports the *in vivo* formation of virus like particles, or VLPs, which induce both antibody and T-cell responses. The Company also presented vaccine efficacy and immunogenicity data for GEO-CM02 from hamster and transgenic mice studies completed to date. Incorporation of sequence-conserved nonstructural proteins can provide targets for T-cell responses to further increase the breadth and function of vaccine-induced immune responses. This strategy provides the basis for generating a universal vaccine with augmented potential to alleviate the burden of disease caused by circulating coronaviruses.

TIMELINE OF EVENTS

- **November 16, 2021**—GeoVax announced that the U.S. Patent and Trademark Office has 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.”
 - **November 15, 2021**—Announced that it will be represented during presentations at the following upcoming scientific conferences.
 - On November 17, Mark Newman, PhD, GeoVax Chief Scientific Officer, will deliver a presentation entitled, Addressing Evolving SARS-CoV-2 Variants through a Universal Coronavirus Vaccine;
 - On November 30, Mark Newman, PhD, GeoVax Chief Scientific Officer, will participate in an expert panel discussion on design approaches to produce a universal SARS-CoV-2 vaccine and deliver a presentation on the topic, VLP-based COVID-19 vaccine development; and
 - On December 2, Mary Hauser, PhD, GeoVax Senior Scientist, will deliver a presentation entitled, Design and Evaluation of Vaccines Against Hemorrhagic Fevers using the MVA-VLP Platform.
 - **November 11, 2021**—Announced its financial results for the quarter ended September 30, 2021 and provided a corporate update.
 - **November 9, 2021**—Announced that it has entered into an exclusive license agreement with City of Hope, a world-renowned cancer research and treatment organization. The agreement grants GeoVax exclusive rights to further develop and commercialize a multi-antigenic SARS-CoV-2 investigational vaccine, developed at City of Hope for immunocompromised patients, which is currently being studied in an ongoing Phase 2 clinical trial and shows a strong potential to be used in the general population as a primary and/or general booster vaccine against COVID-19 worldwide.
 - **October 18, 2021**—Announced that Mark J. Newman, Ph.D., GeoVax’s Chief Scientific Officer, will participate in an interactive roundtable discussion on the topic “Is it feasible to develop universal/pan coronavirus vaccines?” and chair the session on clinical development and testing of COVID vaccines during the World Vaccine Congress Europe, being held October 19-21 in Barcelona, Spain.
 - **October 14, 2021**—Announced that the U.S. Patent and Trademark Office has issued a Notice of Allowance for Patent Application No. 15/543,139 entitled “Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Ebola Virus Glycoprotein (GP) and Matrix Protein (VP40).”
 - **September 28, 2021**—Announced that it has entered into an Assignment and License Agreement (the “License”) with PNP Therapeutics, Inc. (“PNP”), granting GeoVax exclusive rights to develop and commercialize Gedepin[®], a novel patented product for the treatment of solid tumors.
 - **September 7, 2021**—Announced that Chairman and CEO David Dodd will present at the H.C. Wainwright 23rd Annual Global Investment Conference, which is being held virtually from September 13-15, 2021.
 - **August 19, 2021**—Presented data from ongoing studies of its preventive vaccine against COVID-19. The presentation titled, “Design of a Universal SARS-CoV-2 Vaccine Against Evolving Variants,” was delivered virtually by Mark J. Newman, Ph.D., GeoVax’s Chief Scientific Officer, during the European Society of Medicine (ESMED) General Assembly, being held August 19-21 in Berlin, Germany.
 - **August 12, 2021**—Announced that the Company will be presenting at the SNN Network Summer Virtual Event 2021 on Wednesday, August 18, 2021 at 12:30 PM EST. David Dodd, Chairman and CEO, will be hosting the presentation and answering questions from investors.
 - **August 11, 2021**—Announced financial results for the quarter ended June 30, 2021.
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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 following areas (summarized in Figure 1): human immunodeficiency virus (HIV), hemorrhagic fever (HF) viruses (Lassa Fever, Sudan ebolavirus (SUDV), Marburg virus (MARV), and Malaria Vaccine), and Zika virus (ZIKV). 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/3ljlBCO>).

Figure 1
PIPELINE FOCUSED ON NEAR-TERM VALUE DRIVERS

		Status	Funding
Coronavirus			
COVID-19 (Immunocompromised)	GEO/COH04S1	Phase 2	Internal & Non-Dilutive
COVID-19 (Booster to mRNA)	GEO/COH04S1	Phase 2/IND Accepted	Internal
Pan Coronavirus	GEO-CM02	IND-Enabling	Internal & Non-Dilutive
Immuno-Oncology			
Solid Tumors (Head & Neck)*	Gedepin®	Phase 1/2	Internal & Non-Dilutive
MUC1 – Solid Tumors		IND-Enabling	Internal
Infectious Disease			
HIV (Preventive; HVTN)	GOVX-B11	Phase 2A	Non-Dilutive
HIV (Functional Cure; UCSF)	GOVX-B01	Phase 1	Non-Dilutive
Lassa Fever**	GEO-LM01	IND-Enabling	Primarily Non-Dilutive
Ebola, Marburg, Sudan**	GEO-EM01	IND-Enabling	Primarily Non-Dilutive
Zika Virus**	GEO-ZM02	IND-Enabling	Internal
Malaria**	GEO-MM01	Exploratory	Primarily Non-Dilutive

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

Source: GeoVax Labs, Inc.

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. In particular, GeoVax’s HIV program receives substantial federal support (with over \$50 million received to date from the National Institutes of Health (NIH)). Every one of GeoVax’s preventive vaccine trials have been sponsored by the NIH, with the NIH (through the HIV Vaccine Trials Network [HVTN], www.hvtn.org) running the Company’s trials—something that is unusual within the biotechnology space.

Following the Company’s recent financings, GeoVax’s cash balances now stands at approximately \$18.1 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.

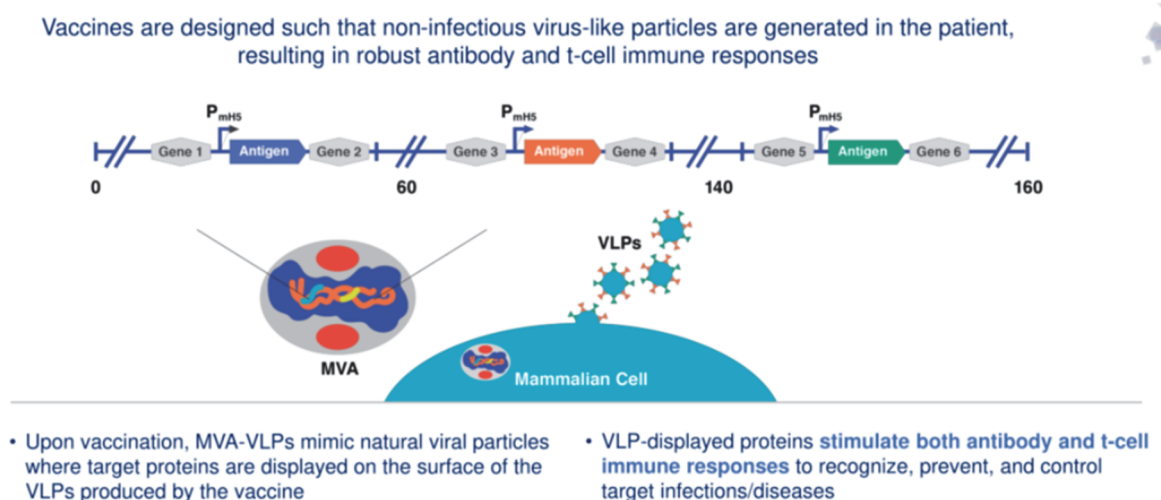
MVA-VLP TECHNOLOGY PLATFORM

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 (MVA) with the immunogenicity of VLPs and the durability of immune responses induced by vaccinia vectors. Human clinical trials of the Company’s HIV vaccines have demonstrated that its VLPs, expressed from the cells of the vaccinated individual, are safe and produce both strong and durable humoral and cellular immune response.

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. The GeoVax technology drives the production of the 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:

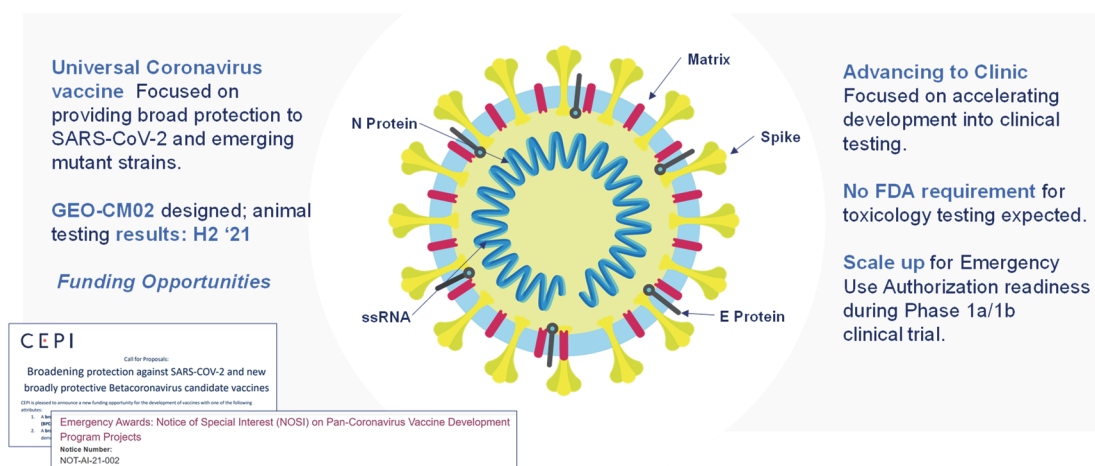
- **Safety.** Clinical testing of the GeoVax’s HIV vaccines have documented an optimal safety profile. This is consistent with the safety profile for MVA used as a smallpox vaccine and documented in more than 120,000 subjects throughout Europe.
- **Durability.** The Company’s vaccine technology promotes 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 selected 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.

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. COVID-19 is an infectious disease first identified in Wuhan, China in December 2019, and has resulted in an ongoing worldwide pandemic. As of November 2021, more than 254 million cases have been reported, resulting in nearly 5.1 million deaths. The U.S. is currently considered one of the epicenters of the disease, with roughly 47.3 million cases and 766,000 deaths so far. The World Health Organization (WHO) declared COVID-19 a global pandemic on March 11, 2020. 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 summarizes key elements of the Company’s COVID-19 vaccine technology.

Figure 3
UNIVERSAL SARS-COV-X VACCINE PROGRAM



Astuti & Ysrafili, Diabetes Metab Syndr. 2020 Apr 18

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. The 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.

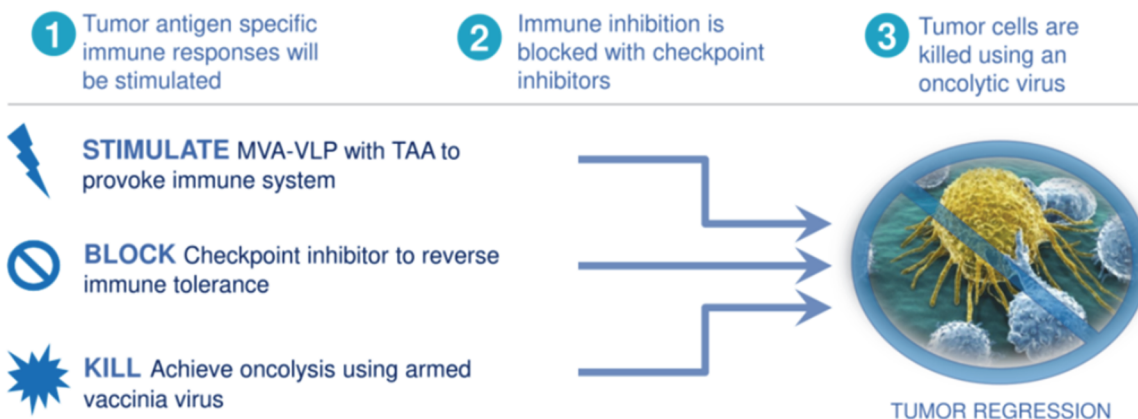
GeoVax is in discussions with the Biomedical Advanced Research and Development Authority (BARDA) and other entities to support and accelerate its COVID-19 vaccine development efforts. While other COVID-19 vaccine candidates are in later stages of development, (with Pfizer, Moderna, and Johnson & Johnson’s 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. GeoVax’s recently completed financing will allow it to aggressively pursue preclinical evaluation of its vaccine candidates while continuing negotiations in support of clinical development.

Cancer Immunotherapy Vaccine Program

GeoVax is also 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 but also 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

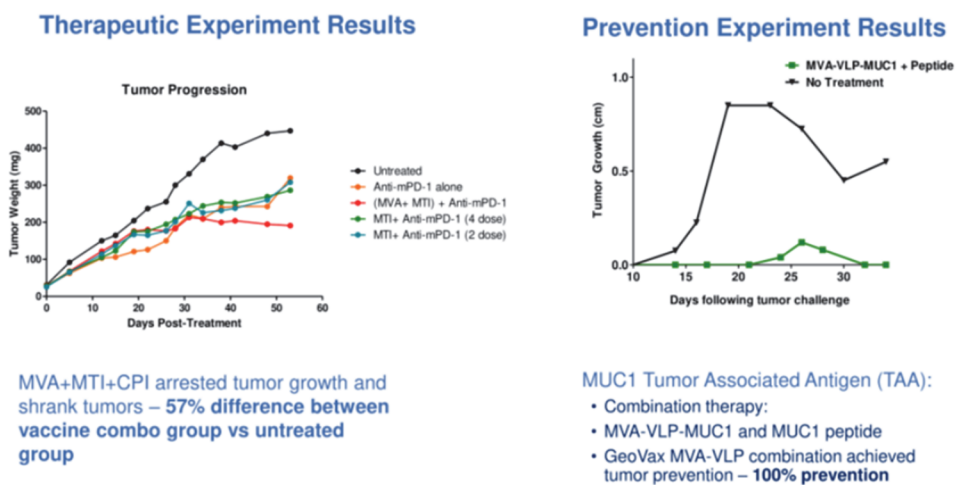
Triple-threat Approach:



Source: GeoVax Labs, Inc.

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

From an investment perspective, the Company sees these efforts as a key component for strengthening the valuation and providing future value growth opportunities. To fully exploit its immuno-oncology program, GeoVax intends to focus on the advancement of its immuno-oncology programs and to seek additional, complementary technologies and clinical-stage products in the oncology space and intends to use a portion of the proceeds from its recent financing to accelerate development of its immuno-oncology program.

HPV

In July 2018, GeoVax began collaborating with Emory University to develop a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). The GeoVax/Emory collaboration will include testing GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV.

HIV/AIDS Vaccine Program

HIV (Preventive Vaccine)

GeoVax's most advanced program is a preventive vaccine (GOVX-B11) for the clade B subtype of HIV, the most common form of HIV in the Americas, Western and Central Europe, Australia, and Japan. The vaccine consists of a recombinant DNA vaccine (used to prime immune responses) and a recombinant MVA vaccine (used to boost the primed responses), with both the DNA and MVA vaccines producing non-infectious VLPs. The vaccine was developed by Emory University, the NIH, and the CDC, and was licensed by GeoVax for commercialization.

GOVX-B11 has successfully completed Phase 1 and Phase 2a human clinical trials, in which the vaccine was demonstrated to be safe and potent, inducing high level and durable antibody and cellular immune responses. These trials are supported by the NIH and conducted by the HVTN—the world’s largest publicly-funded international collaborative effort focused on developing HIV vaccines.

The most recently completed trial (HVTN 114) was designed to test the ability of booster vaccinations, given on average 6.9 years after the original, to increase the antibody responses induced by GOVX-B11. This trial demonstrated that late protein boosts significantly enhanced the antibody responses by more than 600-fold for the most effective regimen tested, which might play a role in protecting individuals against HIV.

GOVX-B11 has successfully completed Phase 1 and Phase 2a human clinical trials, in which the vaccine was demonstrated to be safe and potent, inducing high level and durable antibody and cellular immune responses. The GOVXB11 vaccine was subsequently used to test multiple innovative prime-boost strategies and GeoVax is awaiting the start of a new Phase 1 trial (HVTN 132) to further evaluate the HIV vaccine strategies. The HIV vaccine clinical efforts are all supported by the NIH and conducted by the HIV Vaccine Trials Network (HVTN)—the world’s largest publicly-funded international collaborative effort focused on developing HIV vaccines. GeoVax has also developed similar vaccines designed for use against the clade C subtype of HIV that predominate in Africa, Asia, and India.

HIV (Therapeutic Vaccine)

GeoVax believes that its vaccine platform may prove useful as a component of a combination therapy to provide a cure for HIV. To this end, the Company entered into a functional cure collaborative effort led by the University of California, San Francisco (UCSF), with funding from amfAR, The Foundation for AIDS Research.

Collaboration with UCSF

In November 2019, GeoVax entered into an agreement with the University of California, San Francisco (UCSF), for a collaborative effort to develop a functional cure for HIV. On August 24, 2020, GeoVax announced the initiation of the Phase 1 clinical study to test a therapeutic regimen involving a combination of vaccinations (DNA priming and MVA boosting), administration of broadly neutralizing antibodies (bNAbs), and a toll-like receptor 9 (TLR9) agonist. As with the AGT trial, GeoVax will provide its novel boost component (MVA62B) for use in the studies.

Hemorrhagic Fever (HF) Vaccine Programs

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.

On August 13, 2020, GeoVax announced a collaboration with University of Texas Medical Branch (UTMB) and Battelle, supported by NIAID, to further develop its SUDV and MARV vaccine candidates, and the Company has an ongoing grant from the U.S. Department of Defense supporting development of its LASV vaccine. Clinical development of the Company’s EBOV vaccine will initiate as priorities and resources are allocated in support of this program.

Malaria Vaccine Program

Worldwide, malaria causes 229 million infections and 409,000 deaths every year (mostly in children living in sub-Saharan Africa). The Company believes that the optimal malaria vaccine candidate should contain antigens from multiple stages of the malaria life cycle, and induce functional antibodies associated with protection and strong cell mediated immunity—all attributes that GeoVax's MVA-VLP malaria vaccine candidates have demonstrated in animal models. GeoVax is collaborating with the Burnet Institute, a leading infectious disease research institute in Australia, as well as with Leidos, Inc. (under a contract from United States Agency for International Development [USAID] Malaria Vaccine Development Program) for the potential development of a vaccine to prevent both malaria infection and transmission.

ZIKA Virus (ZIKV) Vaccine Program

GeoVax is developing an MVA-Zika vaccine (GEO-ZM02). To date, the Company has demonstrated 100% protection of mice vaccinated with a single-dose of the Zika vaccine and exposed to a lethal dose of ZIKV. Continued development of the ZIKV vaccine will occur as priorities and resources are allocated in support of this program. Potential collaboration in the development of the Company's Zika vaccine remains within the Southern Hemisphere, where the virus continues to present a critical risk.

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 70 granted or pending patent applications spread over 20 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.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved in an investment in the Company as well as for copies of this report or the updated Base Report from October 22, 2020, please contact GeoVax by calling (678) 384-7220.



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