Company Description

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

Key Points

- On August 6, 2024, GeoVax announced second quarter 2024 financial results and provided a corporate update. Net loss for the three months ended June 30, 2024 was $5,064,042, or $1.99 per share versus $5,927,620, or $3.79 per share, for the comparable period in 2023.
- GeoVax has made significant strides during the first half of 2024, highlighted by the recent receipt of the BARDA Project NextGen award to evaluate GEO-CM04S1, the Company's next-generation, dual-antigen COVID-19 vaccine. In addition, GeoVax has partnered with Allucent, a global CRO, to initiate the trial and advance GEO-CM04S1 into the BARDA-funded 10,000-patient Phase 2b clinical study. With over $350 million secured for the trial, this U.S. government recognition not only validates GeoVax's clinical strategy but also provides the necessary resources to accelerate its development.
- GEO-CM04S1 has demonstrated potent, broadly reactive, and long-lasting antibody and T cell immune responses in individuals with both healthy and compromised immune systems. Given the increasing understanding that robust T cell responses are crucial for antibody recall and protection against severe disease and hospitalization, GeoVax believes that GEO-CM04S1 stands-out as a next-generation COVID-19 vaccine with the ability to greatly enhance patient care.
- With support from an oncology clinical advisory committee and following a thorough review of Gedeptin's safety and efficacy data, GeoVax is poised to advance an expanded Phase 2 clinical trial evaluating Gedeptin in patients with first-recurrence head and neck cancer.
- GeoVax continues to strengthen its global intellectual property position, with over 115 granted or pending patent applications spread over twenty-four patent families.
- The Company anticipates forming business partnerships and collaborations to support the global development, commercialization, and distribution of its products.
- GeoVax reported cash balances of $1,561,712 at June 30, 2024 versus $6,452,589 at December 31, 2023.

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

GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (08/08/2024)	$1.70
52-week Range	$1.09 - 9.75
Shares Outstanding	5 million
Market Capitalization	$8.5 million
Avg. Volume	3,141,385
EPS (Qtr. ended 06/30/2024)	($1.99)
Employees	19

See page 16 for applicable disclosures.

SECOND QUARTER 2024 FINANCIAL RESULTS

On August 6, 2024, GeoVax Labs, Inc. announced second quarter 2024 financial results and provided a corporate update. Net loss for the three-month period ended June 30, 2024, was $5,064,042, or $1.99 per share versus $5,927,620, or $3.79 per share, for the comparable period in 2023. For the six-month period ended June 30, 2024, the Company's net loss was $10,914,174, or $4.68 per share versus $9,965,536, or $5.66 per share in 2023.

Research and development expenses were $4,276,868 and $8,702,596 for the three-month and six-month periods ended June 30, 2024 versus $4,719,728 and $7,538,917 for the comparable period in 2023, with the changes primarily due to timing of costs related to manufacturing of materials for use in the clinical trials of GEO-CM04S1 and Gedeptin, as well as costs of various contracted research activities.

General and administrative expenses were $1,086,030 and $2,543,383 for the three-month and six-month periods ended June 30, 2024 versus $1,459,093 and $2,910,518 for the comparable periods in 2023, with the overall decrease primarily due to lower stock-based compensation expense, consulting costs, legal and patent costs, and travel costs.

GeoVax reported cash balances of $1,561,712 at June 30, 2024 versus $6,452,589 at December 31, 2023.

The Company continues to work towards creating groundbreaking cancer treatments and vaccines for infectious diseases, targeting urgent medical gaps. It plans to focus on initial indications conducive to accelerated registration processes.

SECOND QUARTER BUSINESS ACHIEVEMENTS

GEO-CM04S1

- **Received BARDA Project NextGen award.** During the quarter, GeoVax received the BARDA Project NextGen award through the Rapid Response Partnership Vehicle (RRPV) to advance the development of GEO-CM04S1, its dual-antigen next-generation COVID-19 vaccine, in a Phase 2b clinical trial. This award, initially approximately $24.3 million and potentially increasing to $45 million, will fund the manufacturing of clinical materials and support the Phase 2b clinical trial, including regulatory activities.

  Under the agreement, GeoVax will sponsor a 10,000-participant, randomized, double-blind Phase 2b study to compare the efficacy, safety, and immunogenicity of GEO-CM04S1 with an FDA-approved mRNA COVID-19 vaccine. Preparations for the study are underway and its execution will be funded by BARDA under its Clinical Studies Network. The RRPV is a consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), which is part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS).

  Funding for this award is provided by Project NextGen, a $5 billion initiative by HHS aimed at advancing a pipeline of innovative vaccines and therapeutics that offer broader and more durable protection against COVID-19 compared to the first-generation vaccines and medicines.

  The aim with GEO-CM04S1 is to provide a more practical public health friendly COVID-19 vaccine than that offered from the first generation vaccines. GeoVax believes that this is achieved by stimulating a robust and durable immune response across multiple virus variants as a result of the induction of both the antibody and cellular arms of the immune system against multiple virus antigens.

  BARDA funding provides a complete clinical pathway for at least one significant program for GEO-CM04S1. This provides GeoVax with some flexibility with regard to its other development programs.

- **Announced Project NextGen CRO partnership with Allucent.** GeoVax announced a Project NextGen CRO partnership with Allucent, a global clinical research organization (CRO), to conduct the Phase 2b clinical trial of GEO-CM04S1. The combined value of the awards to GeoVax and Allucent for the clinical evaluation of GEO-CM04S1 is between $367 million and $388 million.

  GeoVax's involvement in this project is entirely or partially funded by federal funds from the Department of Health and Human Services, Administration for Strategic Preparedness and Response (ASPR), and the Biomedical Advanced Research and Development Authority (BARDA) under Other Transaction (OT) number 75A50123D00005. Allucent's participation is also entirely or partially funded by federal funds from BARDA under contract 75A50120D00016/75A50123F33005.

- **Presented data on GEO-CM04S1.** GeoVax presented data on GEO-CM04S1 at the 24th Annual World Vaccine Congress in April 2024. The presentation, titled "Vaccine Induction of Broadly Specific Antibody and T Cell Responses to Combat SARS-CoV-2 Variation," focused on GEO-CM04S1's unique immune system-driven mechanism and its potential for broad efficacy. The presentation highlighted that vaccine-induced immunity protects against infection, serious disease symptoms, and death from both the original Wuhan variant and the Omicron XBB.1.5 variant, which is the basis of the currently approved mRNA booster vaccines.

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

Gedeptin®

- **Completed review of Gedeptin clinical results.** The Company recently announced its decision to advance Gedeptin into an expanded Phase 2 clinical trial for patients with first-recurrence head and neck cancer. The primary goal of this trial is to establish the efficacy of neoadjuvant Gedeptin therapy combined with an immune checkpoint inhibitor in treating squamous cell head and neck cancer. The Company has begun necessary planning activities, including protocol development, manufacturing, and CRO selection, with trial activation anticipated in the first half of 2025. The Company anticipates funding the expanded Phase 2 trial through a combination of internal funding, potential partnering, and potential non-diluted funding resources.

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

Vaccine Manufacturing Process Development

- **The first lot of GEO-CM04S1 has been produced using a commercial manufacturing platform.** This is a critical step towards implementing a validated chicken embryonic fibroblast (CEF) based production system for the Company's MVA-based vaccines. This milestone signifies the successful transfer and scale-up of manufacturing from the research-focused Center for Biomedicine & Genetics at City of Hope to Oxford Biomedica, the Company's cGMP (current Good Manufacturing Practices) manufacturing partner.

RECENT COMPANY DEVELOPMENTS

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

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

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

July 16, 2024—Announced that the Company was invited to present at the next Emerging Growth Conference being held July 17-18, 2024. This live, interactive online event gave existing shareholders and the investment community the opportunity to interact with the Company's Chairman and CEO, David Dodd, in real time. Mr. Dodd presented at 12:00pm ET on Thursday, July 18, 2024. Following his presentation, Mr. Dodd opened the floor for questions.

July 11, 2024—Announced that GeoVax has entered into a definitive securities purchase agreement with a certain institutional investor for the purchase and sale of 1,085,000 shares of the Company's common stock (or common stock equivalents) at a price of $2.86 per share in a registered direct offering priced at-the-market under Nasdaq rules. In addition, in a concurrent private placement, the Company will issue warrants to purchase up to 2,170,000 shares of common stock. The warrants have an exercise price of $2.86 per share, will be exercisable immediately following the date of issuance and will have a term of five years following the date of stockholder approval. Roth Capital Partners is acting as the exclusive placement agent for the offering.

July 9, 2024—Provided a business update for the first half of 2024. In June 2024, GeoVax announced that it had received an award through the Rapid Response Partnership Vehicle (RRPV) to advance the development of its dual-antigen next-generation COVID-19 vaccine, GEO-CM04S1, in a Phase 2b clinical trial. Funded by the Biomedical Advanced Research and Development Authority (BARDA), this 10,000-participant, randomized, double-blinded study will compare the efficacy, safety, and immunogenicity of GEO-CM04S1 with an FDA-approved mRNA COVID-19 vaccine. The study is sponsored by GeoVax, with execution funded by BARDA and conducted in partnership with the clinical research organization Allucent, a global clinical research organization (CRO). BARDA has provided approximately $24.3 million to GeoVax for manufacturing clinical materials and regulatory activities, which may increase to $45 million. The combined value of awards to GeoVax and Allucent for the clinical evaluation is approximately $367-388 million. This funding is part of Project NextGen, a $5 billion HHS initiative to develop innovative vaccines and therapeutics with broader and more durable protection against COVID-19. GeoVax's vaccine candidate aims to offer broader protection among variants of concern and longer-lasting immunity.

June 27, 2024—Announced that it will partner with Allucent, a global clinical research organization (CRO), to conduct a Phase 2b clinical trial of GEO-CM04S1, GeoVax's dual-antigen next-generation COVID-19 vaccine. GeoVax previously announced that it received an award through the Rapid Response Partnership Vehicle (RRPV) to advance development of GEO-CM04S1, GeoVax's dual-antigen next-generation COVID-19 vaccine, in a Phase 2b clinical trial. The RRPV is a consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Under the agreement, GeoVax will sponsor a 10,000-participant, randomized, Phase 2b double-blinded study to evaluate the relative efficacy of GEO-CM04S1 compared to an approved/authorized COVID-19 vaccine to prevent symptomatic, PCR-confirmed SARS-CoV-2 infection. As part of BARDA's Clinical Studies Network, Allucent will initiate and implement the BARDA-funded study. The combined value of the awards to GeoVax and Allucent toward the clinical evaluation of GEO-CM04S1 is approximately $367 million.

June 18, 2024—Announced that GeoVax has received an award through the Rapid Response Partnership Vehicle (RRPV) to advance development of GEO-CM04S1, GeoVax's dual-antigen next-generation COVID-19 vaccine, in a Phase 2b clinical trial.

May 29, 2024—Announced that its Chairman & CEO, David Dodd, will present at the BIO International Convention 2024 being held June 3-6 in San Diego. During the conference, members of the GeoVax management team will host one-on-one meetings with registered attendees to explore collaborative and strategic opportunities around the Company's development portfolio, including GEO-CM04S1, a multi-antigenic, next generation COVID-19 vaccine, currently being investigated in three Phase 2 studies and Gedeptin®, an adenovirus-vectored bacterial purine phosphorylase designed to locally activate a systemically administered chemotherapeutic prodrug, which is currently in a Phase 2 study for the treatment of advanced head and neck (H&N) cancers.

May 17, 2024—Announced that GeoVax has entered into a definitive securities purchase agreement with a certain institutional investor for the purchase and sale of 802,844 shares of the Company's common stock (or common stock equivalents) at a price of $1.68 per share in a registered direct offering priced at-the-market under Nasdaq rules. In addition, in a concurrent private placement, the Company will issue warrants to purchase up to 1,605,688 shares of common stock. The warrants have an exercise price of $1.68 per share, will be exercisable immediately following the date of issuance and will have a term of five years following the date of issuance.

POTENTIAL NEAR TEM MILESTONES

The Company aims to continue to accelerate efforts supporting the Phase 2 clinical programs for Gedeptin and CM04S1. Additionally, it plans to advance its MVA vaccine specific to Mpox and smallpox and make further progress on its advanced MVA manufacturing system. GeoVax also expects to participate in various oncology conferences, presenting Gedeptin clinical data and engaging in partnering discussions.

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

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

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

GeoVax further expects to progress its GEO-CM04S1 and GEO-MVA cell-line manufacturing.

Company Background

GeoVax Labs, Inc. is a clinical-stage biotechnology company focused on developing human cancer therapies and infectious disease vaccines. Its technology, targeting infectious diseases and cancer, employs the Company's proprietary MVA vector vaccine technology platform and the patented Gedeptin® gene-therapy technology. The vaccine vector technology utilizes a Modified Vaccinia Ankara (MVA) vector, a large virus capable of carrying several vaccine antigens. MVA is a replication-defective live vector that expresses non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (*in vivo*). VLPs mimic a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection through durable immune responses. The Company's development efforts, both clinical stage as well as preclinical stage, are focused within the areas summarized in Figure 1 (page 7).

Figure 1

GEOVAX PIPELINE: CLINICAL DEVELOPMENT PROGRAMS

Product	Indication	Trial	Status
GEO-CM04S1	COVID-19	BARDA Project NextGen - 10,000 Patient Clinical Study to Evaluate GEO-CM04S1 COVID-19 Vaccine	Phase 2b In Process to Initiate
		Primary Vaccine for: Immunocompromised/Stem Cell Transplant Patients (NCT04977024)	Phase 2 Currently Enrolling
		Booster Vaccine for: Immunocompromised/Chronic Lymphocytic Leukemia Patients (NCT05672355)	Phase 2 Currently Enrolling
		Booster Vaccine for: Healthy Adult Patients (NCT04639466)	Phase 2 Enrollment Closed
Gedeptin®	Advanced Head & Neck Cancer	Effect on Targeted Tumors (NCT03754933)	Phase 1/2 Enrollment Closed
Gedeptin®	Squamous Cell Head & Neck Cancer	First Reoccurrence Therapy in Combination with Immune Checkpoint	Phase 2 Trial Design in Process

GEOVAX PIPELINE: PRECLINICAL DEVELOPMENT PROGRAMS

Product	Target	Completion Testing Status
GEO-MVA-MUC1	Solid Tumor Cancers	Humanized Mouse Model
GEO-CM02	Vaccine for Pan-Coronavirus	Humanized Mouse Model
GEO-EM01 - Z	Vaccine for Ebola Zaire	Non-Human Primate
GEO-EM01 - S	Vaccine for Ebola Sudan	Non-Human Primate
GEO-MM01	Vaccine for Marburg	Non-Human Primate
GEO-ZM02	Vaccine for Zika	Mouse Model
GEO-MVA	Vaccine for Mpox & Smallpox	Regulatory Strategy and Manufacturing Scale-Up

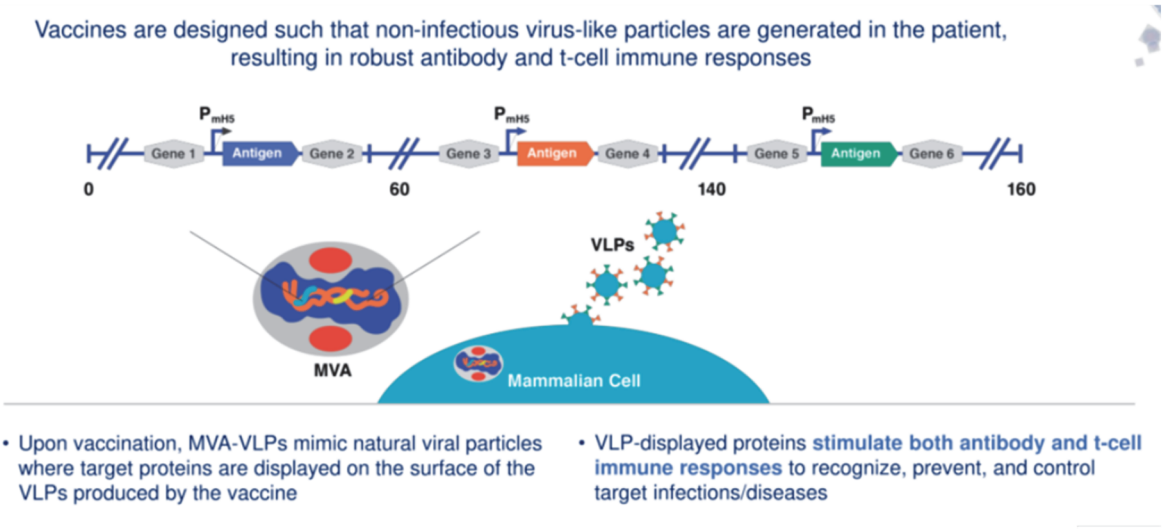
Source: GeoVax Labs, Inc.

MVA/MVA-VLP TECHNOLOGY PLATFORM

Vaccines are most often made of agents (antigens) that resemble disease-causing microorganisms and are traditionally created from weakened or killed forms of the virus. Newer vaccines use recombinant DNA technology to produce vaccine antigens from specific portions of the DNA sequence of the target pathogen. The most successful of these purified antigens have been non-infectious VLPs used in vaccines, such as the hepatitis B vaccines (Merck's Recombivax® and GlaxoSmithKline's [GSK's] Engerix®) and human papillomavirus vaccine (GSKs Cervarix® and Merck's Gardasil®).

GeoVax's MVA-VLP vector vaccine technology platform combines the safety of a replication-defective live vector with the immunogenicity of VLPs and the durability of immune responses induced by vaccinia vectors. VLPs train the body's immune system to identify and attack the authentic virus should it appear, and to recognize and kill infected cells to control infection and decrease the length and severity of disease. Among the most challenging aspects of VLP-based vaccines is to design the vaccines in such a way that the VLPs are recognized by the immune system the same way it would an authentic virus. GeoVax's technology drives the production of VLPs in the body of the person being vaccinated (*in vivo)*, thus more closely mimicking a viral infection and inducing the appropriate types of immune responses. Figure 2 provides a graphical depiction GeoVax's GV-MVA-VLP™ vaccine technology.

Figure 2
GV-MVA-VLP™ VACCINE TECHNOLOGY



Source: GeoVax Labs, Inc.

Multiple studies have demonstrated the VLPs for enveloped viruses, such as HIV, Ebola, Sudan, Marburg, or Lassa fever, produced using the MVA-VLP platform are identical in appearance to the authentic virus because they include viral protein antigens and the viral envelope, consisting of membranes from the vaccinated individual's cells. In contrast, VLPs produced externally have no envelope or an envelope derived from the cultured cells used to produce them. Based on its efforts to date, GeoVax believes its technology provides unique advantages by producing VLPs that more closely resemble the authentic virus, enabling the body's immune system to recognize the authentic virus more readily. In addition, GeoVax's MVA-VLP platform has unique advantages, summarized as follows:

- *Safety.* Clinical testing of GeoVax's HIV vaccines has documented an optimal safety profile. This is consistent with the safety profile for MVA used as a smallpox vaccine and documented in more than 120,000 subjects throughout Europe.

- *Durability.* The Company's vaccine technology promotes durable and long-lasting immune responses.

- *Limited pre-existing immunity to vector.* Following the eradication of smallpox in 1980, smallpox vaccinations ended, which left individuals born after 1980 (except for select populations, such as vaccinated laboratory workers, first responders, etc.) unvaccinated and without pre-existing immunity.

- *No need for adjuvants*. MVA stimulates strong innate immune responses without the use of adjuvants.

- *Thermal stability.* MVA is stable in both liquid and lyophilized formats (> 6 years of storage).

- *Genetic stability and manufacturability*. MVA is genetically stable when properly engineered and can be reliably manufactured using the most modern technologies that support scalability, consistency, and efficiency.

MVA-VLP-MUC1 for Solid Tumor Cancers

The Company uses its MVA/MVA-VLP vaccine platform to express abnormal, aberrantly glycosylated forms of the cell surface-associated MUC1 protein that is associated with a wide range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung with the goal of raising therapeutic anti-tumor antibodies and T cell responses in cancer patients. GeoVax's cancer immunotherapy program is based on the concept of combining a tumor-associated antigen vaccine with a potent anti-tumor agent, such as an Immune Checkpoint Inhibitor (ICI), with the goal of achieving regression of tumor growth and development.

Coronavirus (COVID-19) Vaccine Program

In January 2020, GeoVax announced initiation efforts to develop a vaccine against Coronavirus Disease 2019 (COVID-19) caused by the SARS-CoV-2 coronavirus. As of May 2024, more than 775 million cases have been reported worldwide, resulting in over seven million deaths. In the U.S. there has been 111 million cases and 1.2 million deaths so far. GeoVax has constructed novel candidate vaccines against SARS-CoV-2 based on the MVA-VLP platform. Its technology is designed to: (1) induce both neutralizing antibodies and cellular immune response; (2) induce a Th1 based cellular immune response to prevent immunopathology; (3) potentially cross-protect against other coronaviruses; and (4) induce full protection after a single dose in less than two weeks.

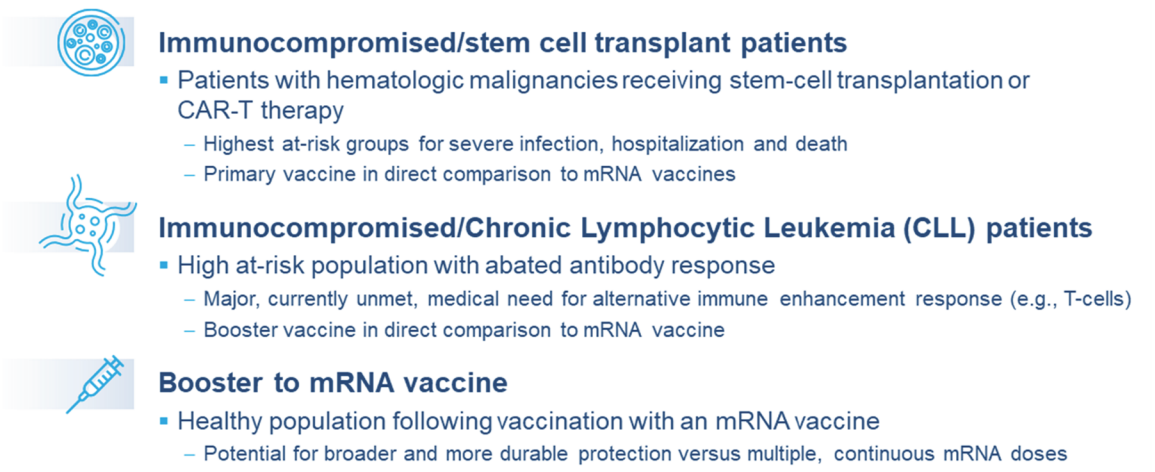
The experimental COVID-19 vaccine, using the Company's MVA-VLP technology, encodes the S protein, which is the basis for all the first-generation products in use today and the targeted neutralizing antibodies. This is used in combination with the membrane (M protein) and the envelop (E protein). The M and E proteins provide the structural components required for the VLP formation in the body. They also serve as additional targets for the cellular immune responses. This design represents a first critical step towards the COVID vaccines that could induce broad, specific immune responses that are not significantly impacted by the variants that are arising as the S protein evolves within a population. GeoVax is working with this approach to attempt to circumvent the evolution of COVID-19, rather than to chase the new variants with modifier vaccines, as is commonly done today with flu vaccines.

GEO-CM04S1

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

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

Figure 3
GEO-CMS04S1: PHASE 2 CLINICAL TRIALS



Source: GeoVax Labs, Inc.

Worldwide, there are an estimated 240 million plus individuals, including those with various blood cancers, renal disease, autoimmune diseases such as lupus, which includes transplant patients and others with disease or therapy-induced immunosuppression. Many of these patients are limited in their ability to respond adequately to the approved mRNA vaccine, placing them at significantly increased risk of severe COVID-19 infection hospitalization and potential death. It was reported in February 2024's edition of *JAMA* that the number of immunocompromised adults in the U.S. has been updated, indicating a population of 23 million versus the previous estimate of 15 million.

Project NextGen Update

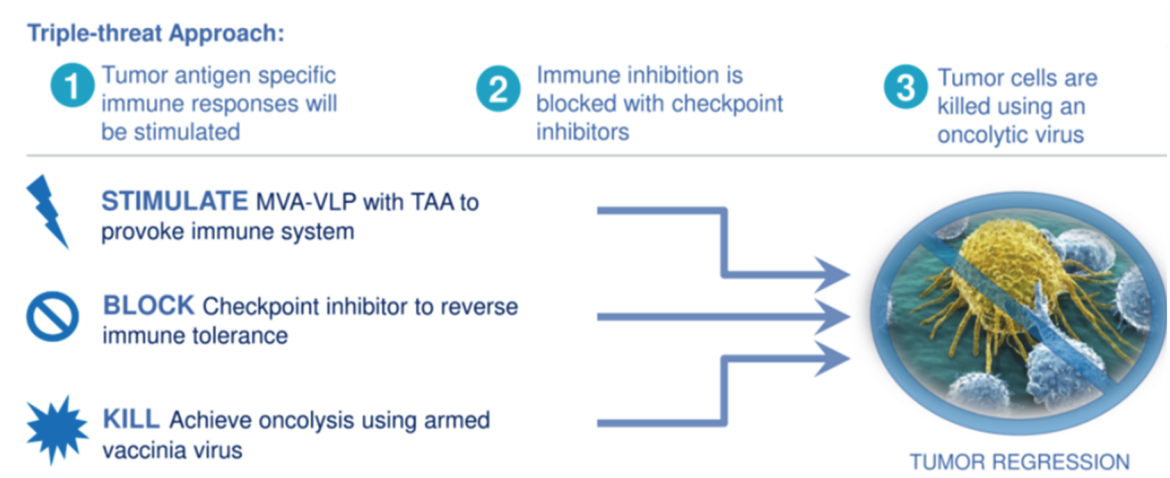
On June 18, 2024, GeoVax announced it had received an award from the Rapid Response Partnership Vehicle (RRPV), funded by BARDA, to advance its next-generation COVID-19 vaccine, GEO-CM04S1, in a Phase 2b clinical trial. GeoVax will conduct a 10,000-participant study comparing GEO-CM04S1 with an FDA-approved mRNA vaccine, fully funded by BARDA. The award includes $24.3 million, potentially increasing to $45 million, for manufacturing and regulatory support, and $343 million from Project NextGen for trial execution. In total, the value of the award exceeds $360 million with the potential to increase to over $380 million. GeoVax believes that its vaccine holds tremendous potential to address limitations of current vaccines, particularly for immunocompromised individuals. The project is funded by HHS's Project NextGen initiative.

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

Cancer Immunotherapy Vaccine Program

GeoVax is additionally developing the next generation of immunotherapies to address unmet medical needs in cancer (Figure 4). The Company believes that its MVA-VLP vector platform is well-suited for inducing immune responses in select tumor associated antigens (TAA). The VLPs are produced within the body of the vaccinated individual and are composed of a structural protein from a virus as well as a tumor associated antigen. These present the immune system with concentrated forms of the TAA to increase potency of the vaccine and to induce both antibody and T-cell cellular immune response. GeoVax seeks to combine a vaccine with a potential antitumor agent, such as a checkpoint inhibitors, resulting in immune responses that contribute to the regression of existing tumors and/or prevent the development and expansion of metastatic lesions.

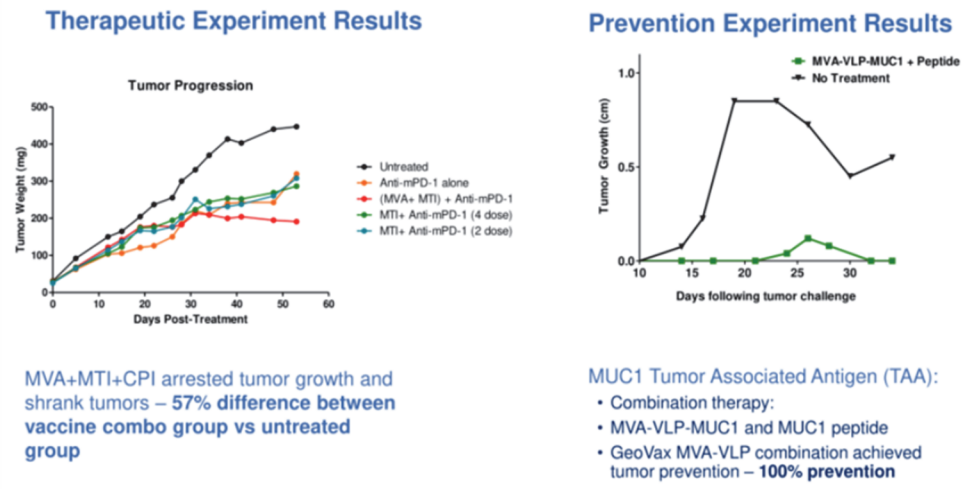
Figure 4
IMMUNOTHERAPY TECHNOLOGY



Source: GeoVax Labs, Inc.

The initial focus is on the MUC1 TAA's, which is a well-studied target for both antibody and cellular immunity (noting that there are multiple associated antigens, which the Company intends to investigate with this approach). As shown in Figure 5 (page 12), GeoVax has constructed a MUC1 MVA-VLP vaccine and has evaluated it in combination with two different experimental peptide vaccines and a checkpoint inhibitor in transgenic mouse models, which allow for the evaluation of the vaccine's effect against humanized tumors in a humanized mouse. In the treatment model, shown using the MVA-MT1 peptide, the combination induced responses showing a 57% decrease in tumor growth when the animals were immunized with both the MVA MUC1 and the tumor associated peptide (compared to the control animal). The combination was superior to either the peptide alone or the tumor checkpoint inhibitor alone. In a prevention model, designed as a post treatment recurrence setting in cancer treatment, the GeoVax VLP MUC1 induced immune responses provided almost 100% protection against tumors recurring.

Figure 5
IMMUNONCOLOGY RESULTS



Source: GeoVax Labs, Inc.

Gedeptin

During the quarterly, the Company completed review of Gedeptin clinical results. Additionally, GeoVax recently announced its decision to advance Gedeptin into an expanded Phase 2 clinical trial for patients with first-recurrence head and neck cancer. The primary goal of this trial is to establish the efficacy of neoadjuvant Gedeptin therapy combined with an immune checkpoint inhibitor in treating squamous cell head and neck cancer. The Company has begun necessary planning activities, including protocol development, manufacturing, and CRO selection, with trial activation anticipated in the first half of 2025. The Company anticipates funding the expanded Phase 2 trial through a combination of internal funding, potential partnering, and potential non-diluted funding resources.

In 2023, GeoVax announced the closure of enrollment for its Phase 1/2 trial of Gedeptin among advanced head and neck cancer patients. This initial targeted patient population represents those who are in end-stage care—the 15,000 U.S. and 400,000 worldwide of patients, which represents a critical unmet medical need. Many of these patients are unable to swallow food and have difficulty speaking, and they typically have exhausted existing therapies and standard of care and are receiving palliative care.

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

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

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

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

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

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

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

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

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

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

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

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

Modified Vaccinia Ankara (MVA) and Mpox

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

Malaria Vaccine Program

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

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

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

ZIKA Virus (ZIKV) Vaccine Program

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

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

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

Partnerships

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

Patent Portfolio

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

Corporate Background

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

Risks and Disclosures

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

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

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

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