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GeoVax Labs, Inc.

Initiating Coverage With $6 Price Target

May 08, 2023

Healthcare

GOVX

NASDAQ

Rating

Outperform

Initiation

Current Price

$0.63

Target Price

$6.00

Market Capitalization
16.5M

Shares Outstanding
26.44M

Float
26.3M

Institutional Holdings
15.8%

12-Month Low/High
$0.53/$4.30

Average 90-Day Volume
289520

Fiscal Year End
03/31/2024

Revenues ($ MIL)

Period	2022A	2023E	2024E
Q1	0.1	0.0A	0.0E
Q2	0.0	0.0E	0.0E
Q3	0.0	0.0E	0.0E
Q4	0.0	0.0E	0.0E
	0.0	0.0E	0.0E

EPS ($)

Period	2022A	2023E	2024E
Q1	(0.34)	(0.15)A	(0.15)E
Q2	(0.18)	(0.17)E	(0.18)E
Q3	(0.17)	(0.19)E	(0.16)E
Q4	(0.23)	(0.14)E	(0.19)E
	(0.83)	(0.65)E	(0.68)E

Initiating Coverage of GOVX. GeoVax Labs is developing gene therapies, immunotherapies, and vaccines for cancer and infectious diseases. Gedeptin, its lead cancer product, is a gene-directed therapy for cancer. The treatment delivers a gene to the cancer cells that converts an inactive prodrug into an active cytotoxic drug within the tumor cells.

Gedeptin Uses A Proprietary Gene Delivery Technology. Gedeptin uses an adenovirus vector to deliver a gene to cancer cells that converts an inactive prodrug into an active cytotoxic drug within the tumor cells. This increases the drug's potency inside the cancer cells while avoiding healthy tissue. Gedeptin is currently in a Phase 1/2 trial for advanced head and neck cancers, and has been granted Orphan Drug Designation for oral and pharyngeal cancers.

Next Generation Vaccine For COVID-19. The lead product in the infectious disease platform is CM04S1, a next-generation COVID-19 vaccine that delivers both the Spike (S) antigen as well as the Nucleocapsid (N) antigen. CM04S1 is currently a Phase 2 trial in immunocompromised patients with hematological cancers and conditions where the current vaccines are not effective. Its second Phase 2 trial is evaluating CM04S1 as a booster for healthy patients who previously received an mRNA vaccine as their primary vaccine.

MVA and MVA-VLP Platforms For Vaccine Development. GeoVax is developing vaccines with its MVA (modified vaccina Ankara) and MVA-VLP (viral-like particle) technologies. These proprietary technologies are being developed for faster and more efficient vaccine development that would allow for rapid responses to viral outbreaks. Products in development include vaccines for smallpox/monkeypox, and hemorrhagic fevers (Ebola, Marburg, Sudan, Lassa fever).

Conclusion. We believe the company fundamentals have been improving as the environment for small capitalization biotechnology company stocks has been in a long decline. We expect GOVX to be driven by the clinical milestones in its development programs, Gedeptin and CM04S1. Our valuation for the stock is based on the potential for Gedeptin in head and neck cancer. We have excluded CM04S1 from our models and see the program as additional upside as clinical milestones ahead are reached. Our price target is $6 per share.

Equity Research

Robert LeBoyer, Senior Vice President, Equity Research Analyst, Biotechnology
(212) 896-4625, rleboyer@noblelsp.com

Noble Life Science Partners

Trading: (561) 998-5489 Sales: (561) 998-5491
www.noblelsp.com

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GeoVax Labs, Inc. (GOVX) | Current Price: $0.63 | Outperform | May 08, 2023

Company Summary: GeoVax Labs is developing gene therapies, immunotherapies, and vaccines for cancer and infectious diseases. Gedeptin, its lead cancer product, is a gene-directed therapy for cancer. The treatment delivers a gene to the cancer cells that converts an inactive prodrug into an active cytotoxic drug within the tumor cells. Gedeptin is in a Phase 1/2 trial for advanced head and neck cancer.

GeoVax's second technology platform is in vaccines against infectious diseases. CM04S1 is a next-generation COVID-19 vaccine utilizing a proprietary, synthetic MVA vector that delivers multiple SARS-CoV-2 proteins to induce a broad immunity with a durable response. CM04S1 is in a Phase 2 trial for immunocompromised patients who do not respond to the approved mRNA vaccines and a second Phase 2 trial as a booster in healthy patients who have received the approved mRNA vaccines. Clinical data presentations have shown the vaccine has a broader, longer lasting immune response than the current authorized vaccines.

The company is also in preclinical development with MVA vaccine manufacturing technology that would enable vaccines to be made faster and more cost-effectively. MVA-based vaccines are currently made through a slow manufacturing process that requires stockpiling to maintain supplies for emergency use. GeoVax's vaccine technology would shorten the production time and reduce the need to stockpile supplies. It would also reduce the need to replace expired vaccine stock. The vaccines currently in development are for infectious diseases such as COVID-19, Monkeypox (Mpox) and Smallpox as well as Hemorrhagic Fever Viruses, such as Marburg virus, Ebola (Zaire and Sudan), and Lassa fever.

Gedeptin is an oncology product made with the gene delivery strategy known as Gene-Directed Enzyme Prodrug Therapy or GDEPT. This proprietary technology uses an adenovirus vector to deliver the E. coli purine nucleoside phosphorylase (E. coli PNP) gene to cancer cells. The gene produces an enzyme that activates chemotherapy drugs inside cancer cells, increasing potency at the cancer site and avoiding healthy tissue.

Gedeptin is currently in a Phase 1/2 trial for advanced head and neck cancers. A completed Phase 1 portion of the trial enrolled patients with recurrent head and neck squamous cell carcinoma. Treatment cohorts received increasing doses of a single cycle of Gedeptin followed by fludarabine. Preliminary data showed safety and tolerability, with tumor reduction.

The current trial is testing multiple cycles of Gedeptin in head and neck cancer patients. It has a target enrollment of 10 patients, with 8 patients enrolled as of 1Q23. Enrollment is expected to be completed by the end of 3Q23, with Phase 2 starting in 2024.

Gedeptin has also been granted Orphan Drug Designation for intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gums, floor of the mouth, salivary glands, and other oral cavities. The current 10-patient clinical program has received funding from the FDA's Orphan Products Clinical Trials Grant Program.

CM04S1. The lead product in the infectious disease platform is CM04S1, a next-generation COVID-19 vaccine for high-risk immunocompromised patients. CM04S1 was originally developed at City of Hope Comprehensive Cancer Center using Modified Virus Ankara (MVA) as a vector to deliver the Spike (S) antigen and the Nucleocapsid (N) antigen for both humoral and cellular immunity. This has shown a broader, robust, and durable immune response. The vaccine targets both the S domain and the N domain, a region of the virus that is highly conserved and does not appear to vary significantly as new strains develop. The first placebo-controlled Phase 1 trial showed it to be safe and immunogenic. Importantly, recent data updates have shown efficacy against the newer variants as well as the original Wuhan virus.

CM04S1 is currently in two Phase 2 trials. The first is a single-dose trial for immunocompromised patients with hematological cancers and conditions where the current COVID-19 vaccines are not sufficiently effective. The second trial is evaluating CM04S1 as a booster for healthy patients who previously received an mRNA vaccine as their primary vaccine.

Pipeline Products and Additional research. Modified Vaccinia Ankara (MVA) is a vaccine vector originally developed for use as a vaccine for smallpox in the 1970s. It is a pox virus that has been modified to make it incapable of reproducing in the human body or causing infection, while retaining the ability to carry antigens and deliver them to target cells. MVA also stimulates an immune response and has been used as a standard vector for delivering antigens in many vaccines.

GeoVax has licensed a second MVA from the National Institutes of Health (NIH) for use in developing its other infectious disease vaccines. Its MVA-VLP platform uses the MVA to carry multiple genes. These genes then express viral proteins that assemble into virus-like particles (VLP), stimulating an immune response against the virus after vaccination. The vaccines stimulate both humoral and cellular immunity similar to a killed or attenuated virus-based vaccine with improved safety. Vaccines in development using this technology include preventive vaccines for Zika virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa) and malaria.

GeoVax is also developing a manufacturing technology that would enable MVA to be made more rapidly. The current process that grows the virus utilizing chicken embryo fibroblasts, requiring long production times. This new process could significantly increase supply capability over the current process. A smallpox/monkeypox vaccine that could be sold to the US National Stockpile is in development. This vaccine could reduce the need to stockpile large quantities of vaccines for emergency use and potentially be more cost-effective.

Intellectual Property. The company has a patent portfolio of 24 patent families, with over 115 granted or pending patents. These patent families cover its gene delivery and MVA technologies, products that use the technologies, manufacturing methods, and technical aspects of the products.

Valuation and Conclusion. We believe the company fundamentals have been improving as the environment for small capitalization biotechnology company stocks has been in a long decline. We expect GOVX to be driven by the clinical milestones in its development programs, Gedeptin and CM04S1. Our valuation for the stock is based on the potential for Gedeptin in head and neck cancer. We have not included any valuation for CM04S1 as a COVID-19 vaccine at this time. We feel the data presented is promising and see this program as additional upside as clinical milestones ahead are reached. Our price target is $6 per share.

Figure 1. GeoVax Product Pipeline

Product	Field	Indication		Development	Pre-clinical	Phase I	Phase II	Phase III	Marketed
Gedeptin	Cancer	Head and neck cancer	Adenovirus						
MVA-VLP-MUC1		Solid tumors (MUC1)	MVA-VLP			IND enabling			
GEO-CM04S1	COVID-19	Immunocompromised COVID-19	Synthetic MVA						
GEO-CM04S1		Booster for COVID-19	Synthetic MVA						
GEO-CM02		Pan Coronavirus	MVA-VLP			IND enabling			
GEO-MVA	Infectious Diseases	Monkeypox, Smallpox	MVA			IND enabling			
GEO-EM01		Ebola, Marburg, Sudan	MVA-VLP						
GEO-LM01		Lasaa Fever	MVA-VLP						
GEO-ZM02		Zika virus	MVA			IND enabling			
GEO-MM02		Malaria	MVA-VLP						

Source: GeoVax Labs, Inc.

Company Background. GeoVax was founded in 2001 and has been a public company since 2006, uplisting to the Nasdaq market in 2020. In September 2021, it in-licensed technology from PNP Inc. to deliver a gene that converts an inactive prodrug to an active chemotherapy agent. This is the Gene Directed Enzyme Prodrug Therapy, or GDEPT.

The first product made with GDEPT, Gedeptin, is in a Phase 1/2 trial in advanced head and neck cancer (recurrent head and neck squamous cell carcinoma, HNSCC) with tumors accessible for injection. Positive safety and tolerability data from a single-cycle Phase 1 was published in Annals of Oncology in 2015. The trial is now enrolling patients in multiple-cycle Phase 1/2. Orphan Drug Designation has been granted for use in oral cancers.

In November 2021, GeoVax in-licensed a multi-antigen COVID-19 vaccine from City of Hope. The product, CM04S1, uses a proprietary version of Modified Virus Ankara (synthetic-MVA) as a vector to deliver both the Spike (S) antigen and the Nucleocapsid (N) antigen. In contrast, the current vaccines utilizing mRNA technology only incorporate the Spike protein.

Data presented in 2022 show CM04S1 stimulates both humoral and cellular immunity for a broader, robust, and durable immune response. CM04S1 is in a Phase 2 trial for immunocompromised patients who do not respond to the current authorized vaccines. A second Phase 2 trial is testing CM04S1 as a booster after the current mRNA vaccines.

GeoVax has multiple vaccines in development for infectious diseases using the MVA vector to carry antigens or genes to produce antigens. MVA was originally developed as a vaccine for smallpox and has been developed by GeoVax as a vector for vaccines against infectious diseases. These include several hemorrhagic fever viruses (Marburg, Ebola, and Lassa fever), Zika virus, and a vaccine for smallpox/monkeypox.

GeoVax is developing a new manufacturing process to produce MVA faster and more efficiently. MVA vaccines are currently manufactured in cells cultures utilizing chicken embryonic fibroblasts (CEF). This is a laborious process that prevents large quantities from being produced quickly. As a result, vaccines needed to respond to public health emergencies must be made in advance and stockpiled. The GeoVax manufacturing technology would allow for faster production and better responses to infectious disease outbreaks. It would also reduce the need for stockpiling.

Gedeptin Uses Gene Therapy To Deliver PNP

In 2021, GeoVax in-licensed a technology known as GDEPT, or Gene Directed Enzyme Prodrug Therapy. The GDEPT technology uses an adenovirus vector, a commonly utilized vector to deliver genes to target cells. The lead product, Gedeptin, delivers a gene to cancer cells that produces an enzyme to convert an inactive prodrug into an active cytotoxic one. This produces effective concentrations of active drug within the tumor cell while minimizing exposure to healthy tissue and causing side effects. The non-replicating adenovirus cannot reproduce within the body so that the gene does not significantly spread outside of the tumor mass where it is administered via intratumoral injection.

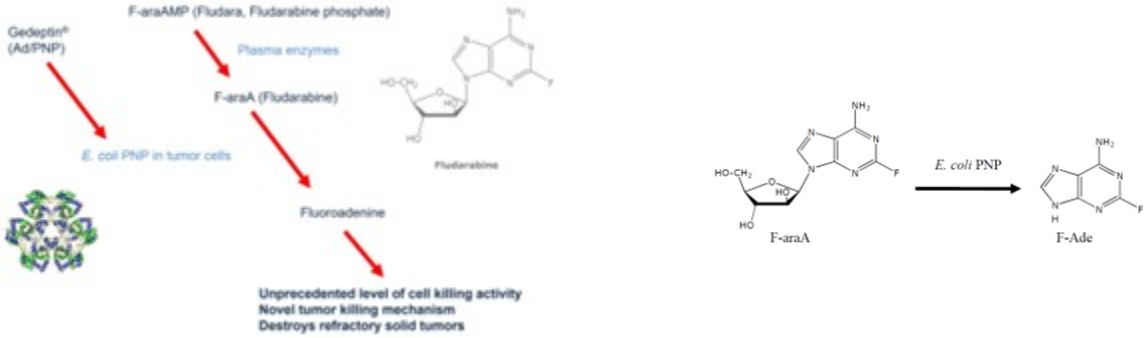
Preclinical models tested the GDEPT technology with purine nucleosides, a category of chemotherapy drugs used to stop cancer DNA from replicating for cell division. These molecules are similar enough to the normal nucleosides used by the cell to synthesize new DNA but prevent additional nucleosides from being added. When the purine analogue is incorporated into the DNA chain, it stops replication and causes the cell to die.

Gedeptin, the lead product, uses the proprietary adenovirus vector to carry the enzyme E. coli PNP (E. coli purine nucleoside phosphorylase). After the gene is delivered to the cell, the chemotherapy drug fludarabine is delivered intravenously and taken up by the cancer cells. When the gene expresses the E. coli PNP enzyme, the inactive prodrug is converted into fluoroadenine, a potent cytotoxic metabolite. By delivering a non-human enzyme to convert a drug to an active form within the cancer cells, the drug's activity is restricted to the cancer cells. This protects healthy cells from the drug's side effects.

Preclinical models have shown antitumor activity when only 2-3% of the tumor cells express E. coli PNP. Once the cells die, they break down and release their contents within the tumor. This spreads the cytotoxic compound to the nearby cells, creating a "bystander effect" which kills neighboring cells and shrinks the tumor. This activity is brief, limiting the effect and preventing cell death beyond the tumor. Gedeptin is currently in development for head and neck cancer.

Safety. The vector used in Gedeptin is a non-replicating adenovirus that has been modified to carry non-human genes for delivery. The adenovirus cannot reproduce within the body and is a commonly used carrier for gene therapy. The gene it delivers, PNP, is a non-human gene is derived from E. coli that is not found anywhere it is not delivered. This restricts conversion from prodrug to the active chemotherapy drug to the cells where Gedeptin has been administered, protecting healthy tissue from the effects of the active compound. We believe this is consistent with the safety and tolerability data that has been reported to date.

Figure 2. Gedeptin Delivers A Gene To Metabolize Fludarabine To An Active Form In Cancer Cells. The E. coli PNP gene metabolizes fludarabine into fluoroadenine, a highly cytotoxic compound with anti-tumor activity. Inside the cancer cells, intratumorly administered PNP expresses an enzyme that cleaves fludarabine into fluoroadenine, an active metabolite. As the cell replicates its DNA for cell division, fluoroadenine is mistaken for a normal nucleoside and incorporated into the DNA chain. This stops the DNA from replicating and kills the cell.



Source: GeoVax Labs, Inc.

Clinical Trials: Early Data Shows Efficacy and Safety

The first clinical development program was designed as a Phase 1/2 trial to establish safety and test dosage levels of the Gedeptin/Fludara regimen. The study is being partially funded by the FDA's Orphan Products Clinical Trials Grants Program. GeoVax has also been granted Orphan Drug Designation for intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gums, floor of the mouth, salivary glands, and other oral cavities.

Phase 1 Showed Safety and Tumor Shrinkage. In the Phase 1 portion, patients received a single cycle of Gedeptin followed by an infusion of Fludara (fludarabine phosphate). Four dose levels were tested in 10 patients with head and neck cancer and 2 with melanoma. The two higher dose levels showed tumor shrinkage that indicated a dose-response effect. The regimen was well tolerated at all levels, with no dose-limiting toxicities and no discontinuations.

Phase 2 Is Continuing To Enroll Patients. The Phase 2 portion of the trial is enrolling patients with recurrent head and neck small cell carcinoma (HNSCC). Patients receive Gedeptin injected intratumorally twice on Day 1 and once on Day 2. Fludara is administered by infusion daily on Days 3, 4, and 5. Patients receive repeat cycles every 4 weeks for 5 cycles or until tumor resolution, tumor progression, toxicity limits, or death. Tumor response in the injected tumors is assessed by physical examination and radiographic imaging.

The trial began at Stanford University Medical Center and has recently added two additional clinical sites, Emory Medical Center and Thomas Jefferson University Medical Center. The target enrollment for this phase was 10 patients, with 8 enrolled as of 1Q23 with enrollment expected to be completed by the end of Q3 2023. When the trial data is evaluated, a meeting with the FDA will be scheduled to determine the requirements for the next trial and an a BLA filing.

Additional Gedeptin Phase 2 Trials. GeoVax has stated that it is developing Gedeptin for additional tumor indications and in combination with immune checkpoint inhibitors (ICIs). The ICI drugs allow the immune system to recognize cancer cells, but the response rates are low due to lack of immune cells in the tumor to carry out the killing steps. In our view, since Gedeptin kills cells directly, we would expect the dead cells to stimulate an immune response within the tumor microenvironment. Gedeptin could potentially be tested in combination with ICI drugs to improve their response rates and overall survival.

MVA-VLP-MUC1 Is In Preclinical Development As A Cancer Vaccine. The mucin short variant (MUC1) is a glycoprotein in the mucin family produced by epithelial cells in the lining of the lungs, gastrointestinal tract, and other organs. Mucin secretions normally protect the tissues from infection, although mutations and overexpression of MUC1 are associated with cancers of the breast, ovaries, lung, and pancreas. This has potential for targeting MUC1 with therapeutic agents and vaccines.

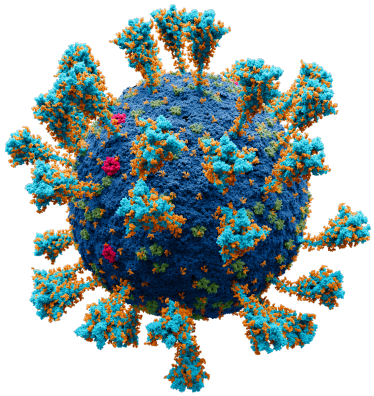
GeoVax has developed an MVA-VLP-MUC1 vaccine candidate. It is conducting preclinical work in collaboration with University of North Carolina (UNC) to characterize the drug and conduct studies to file an IND.

CM04S1 Program – Booster and Vaccine For COVID-19 Immunocompromised Patients

Although the COVID-19 pandemic lockdown has passed, new variants continue to emerge. While none have been as deadly as the original Wuhan strain, new variants have shown enough genomic differences from the original strain to make mRNA vaccines ineffective. In April 2023, President Biden and the Department of Health and Human Services announced that it will be allocating $5 billion to “Project NextGen” to fund development of new vaccines for COVID-19 and infectious diseases. The program establishes multi-year collaborations with the private sector, similar to Operation Warp Speed.

GeoVax is developing CM04S1 as a next-generation vaccine for prevention of COVID-19 in immunocompromised patients that do not respond to the approved vaccines. This includes patients that do not have sufficient immune capability to respond due treatment for hematological cancers or patients that have been on immunosuppressive drugs after organ transplants. These patients are at high risk yet remain unprotected against COVID-19.

Exhibit 3. CM04S1 Contains Antigens For S and N Surface Proteins. The CM04S1 vaccine uses the MVA to carry the antigens from both the spike (S) protein nucleocapsid (N), stimulating both the antibody and T cell responses. The vaccine targets the S domain as well as epitopes that are more highly conserved from the original Wuhan strain to newer strains, such as Omicron. Below, the structure of the SARS-CoV-2 virus shows the membrane in cobalt blue, E protein in crimson, M protein in green, glucose in orange, and Spike (S) protein in turquoise. The Nucleocapsid (N) protein is inside the virus and is not visible.



Source: Wikimedia commons.

CM04S1 Differs From Current Vaccines. The mRNA vaccines from Pfizer and Moderna were developed against the Spike (S) protein on the surface of SARS-CoV-2 that mediates viral attachment and entry into healthy cells. The S protein is a very large, complex protein that is highly immunogenic, making it the target of most vaccine development efforts. However, its genome also mutates and has led to the emergence of new variants over time. The N protein is one of the major structural proteins inside the virus that binds to viral RNA for packaging in the viral capsid. It is highly conserved and has not varied significantly as new strains emerge.

CM04S1 was developed at City of Hope using a proprietary synthetic Modified Vaccinia Ankara (MVA). This modified virus has payload capacity to carry genes for both the spike (S) and nucleocapsid (N) proteins in a single vaccine. Delivering genes for both proteins allows CM04S1 to elicit broad antibody and T-cell responses against both S and N proteins. In addition, the vaccine targets conserved regions of the N protein to provide protection even as changes to spike protein avoid recognition by the immune system. The MVA itself is highly immunogenic, and induces a broad, durable immune response that could provide additional protection against any variants of the SARS-CoV-2 virus.

CM04S1 Is In Two Phase 2 Clinical Trials. GeoVax is developing CM04S1 for patients that do not respond to the current mRNA vaccines and as a long-lasting booster in healthy people who have already received the mRNA vaccines. These applications are currently in two Phase 2 trials.

Trial In Immunocompromised Patients. CM04S1 is in a Phase 2 trial testing the vaccine in immunocompromised patients who have hematological malignancies or are on immunosuppressive drugs. These patients are at high risk COVID-19 due to their weakened immune systems but remain unprotected. The trial (NNCT04977024) has been designed to evaluate safety and immunogenicity compared with the Pfizer or Moderna vaccines. Patients enrolled have previously received an allogenic hematopoietic cell transplant, an autologous hematopoietic cell transplant, or CAR-T therapy.

The trial is currently expanding to multiple sites within the U.S. and international locations during 2023. Enrollment is expected to be completed by year-end 2023. In April 2023, a clinical update was presented at the Annual World Vaccine Congress in Washington, DC. Data from the immunocompromised patient trial showed that CM04S1 is highly immunogenic with neutralizing antibodies and T cell responses.

Phase 1 Results Showed Safety And A Robust Immune Response. In March 2022, results from the Phase 1 study were published in the journal Lancet Microbe. The placebo-controlled study tested 3 dose levels of vaccine, administered as 2 injections 28 days apart. Blood samples were collected on days 14, 56, 90, and 120. Out of 39 evaluable participants that received two injections, 100% of the CM04S1 patients had humoral and cellular responses against the SARS-CoV-2 virus. Adverse events were moderate in severity with no difference between first and second injections.

Importantly, the results showed recognition of both early and late variants of SARS-CoV-2, including the Omicron variant. Both CM04S1 and the sMVA (used as the vector for CM04S1) also led to robust binding, cellular immune responses, and neutralizing antibodies against orthopox virus. The responses were durable for over 6 months, with potential for MVA use in controlling the monkeypox outbreak.

Phase 2 booster trial. The Phase 2 Booster trial is testing CM04S1 as a booster for healthy patients who have previously received the two initial vaccinations with either the Pfizer or Moderna vaccines. Current COVID-19 vaccination practice is to restore immunity with a booster of the same initial vaccine. In the GeoVax booster trial, patients receiving CM04S1 could stimulate immunity to more antigens than the first vaccination. This is intended to provide broader, long-lasting, durable protection to make multiple boosters during a single year unnecessary.

The Phase 2 booster study will have 60 healthy subjects 18 years of age or older who were previously vaccinated with two doses regimen of either Pfizer or Moderna vaccine. This is a dose-escalation trial to evaluate the safety and immunogenicity of the booster. Responses measured throughout the study will include T cell responses, and levels neutralizing antibodies against SARS-CoV-2, including variants such as Omicron and Delta.

Modified Virus Ankara (MVA) and Virus Like Particle Platform (GV-MVA-VLP)

The Modified Vaccinia Ankara (MVA) is a highly antigenic vector that has become a standard carrier used in development of vaccines for many viral illnesses. In addition to the synthetic version in CM04S1 from City of Hope, GeoVax has licensed a version of MVA from the NIH for use in developing its infectious disease and oncology vaccines. NIAID has awarded GeoVax a MBIR grant to support its development efforts with MVA-VLP.

MVA was originally developed for use as a vaccine for smallpox in the 1970s. It was developed by attenuating the standard smallpox vaccine in chicken embryos or embryo fibroblasts until the virus could only replicate in avian cells. The virus is incapable of reproducing or causing harm in the human body but can still carry antigens or genes and deliver them to a target cell genome. Its large payload capacity has made it a standard vector used in vaccine development, having been used to carry genes for many vaccines. MVA is currently approved for use in smallpox and monkeypox. An MVA vaccine, Jynneos (from Bavarian Nordic), is currently stockpiled by the Department of Human Services in the National Stockpile for emergency use against smallpox and monkeypox.

New Manufacturing Technology. GeoVax is also developing a high yield, commercial scale manufacturing process using continuous cell lines to produce MVA in industry standard bioreactors. This would be an improvement over the current process where MVA is produced utilizing Chicken Embryonic Fibroblasts.

The new production method would provide a proprietary system that could make commercial lots of MVA with increased consistency, capacity, and flexibility. This would give GeoVax the capability to develop vaccines for infectious disease outbreaks or pandemics, allowing a fast response to disease outbreaks without the need for stockpiling. It would also provide MVA for broad use in vaccines and therapeutic applications.

GeoVax is in preclinical development of an MVA vaccine for smallpox/monkeypox vaccine that could compete with the current vaccine in the US National Stockpile. This MVA vaccine could provide protection without the need to maintain large inventories of vaccine or replenish expired supplies when they reach the end of their shelf-life. This could be a more cost effective than the currently available vaccine.

The GV-MVA-VLP Platform

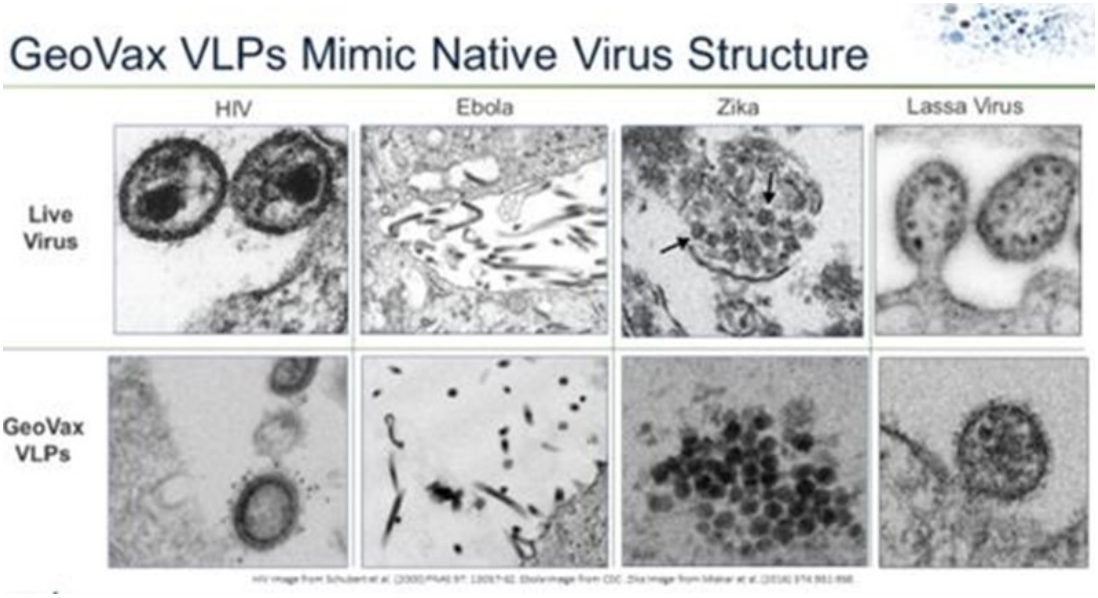
Many vaccines in use today contain antigenic portions of a virus that have been produced using recombinant DNA technology. These antigens are then purified and inserted into a vector for use as a vaccine, rather than using a weakened or killed virus. Virus-like particles (VLPs) are structures that closely resemble viruses but are non-infectious because they contain no viral genetic material. While they can occur naturally, they can also be synthesized utilizing the individual expression of viral structural proteins, which then self-assemble into a VLP. These stimulate an immune response without the risk of viral infection but can be cumbersome to manufacture.

The GeoVax MVA-VLP is a novel vaccine platform that delivers genes to produce the VLPs within a person's cells. After vaccination, the genes express the viral proteins which then assemble into VLPs. These VLPs are similar enough to the virus to be recognized and elicit immune protection but are not infectious or capable of replicating in the body.

The GeoVax MVA-VLP vaccines have been shown to stimulate both humoral and cellular immunity. Preclinical studies have shown immune responses that are similar to live-attenuated virus vaccines, with high immunogenicity and greater safety from the MVA vector.

Another potential advantage is that GeoVax has designed VLPs for enveloped viruses that include the protein antigens and an envelope consisting of membranes from the individual's cells. This increases their similarity to the virus produced in the individual's cell after infection. Most VLPs produced through recombinant DNA technology in bioreactors do not have viral envelopes or may have the envelope from the host cell line the antigens were cultured in. This difference may provide an advantage for the MVA-VLP vaccines in immune recognition.

F**igure 4. GeoVax VLPs Compared With Live Virus** The electron micrographs below show examples of actual viruses compared with VLPs for these viruses expressed by GeoVax MVA-VLP vaccines.



Source: GeoVax Labs, Inc.

Additional Research Programs In Hemorrhagic Fever Virus Vaccines

Ebola Zaire, Ebola Sudan, Marburg and Lassa Fever. GeoVax is in preclinical development for vaccines using the GV-MVA-VLP technology against Ebola (EBOV, formerly designated as Zaire ebolavirus), Sudan (SUDV), and Marburg viruses (MARV). These are the highly virulent species of the *Filoviridae* family, causing hemorrhagic fever illnesses with up to a 90% fatality rate.

Preclinical studies in rodents and nonhuman primates for the MVA-VLP-EBOV vaccine candidate have shown significant levels of protection against lethal doses of Ebola virus. These were followed by studies testing the vaccine against Sudan virus, MVA-VLP-SUDV, and Marburg virus (MVA-VLP-MARV). Animal models with guinea pigs given lethal doses demonstrated 100% protection from death.

In April 2023, preclinical data from a study in Marburg disease was presented at the 23rd Annual World Vaccine Congress in Washington, DC. Data was presented from preclinical testing for GEO-MM01, the Marburg vaccine, in Marburg virus and Sudan Ebola virus infection. In this study, cynomolgus macaque monkeys received a lethal dose of Sudan or Marburg virus. The vaccine protected against viremia, weight loss, and death in 80% of the animals tested. The immune response profiles of the subjects showed stimulation of neutralizing antibodies and functional T-cell, indicating the response the vaccine provided protection. We see this study as a successful proof-of-concept for the vaccine and MVA-VLP technology.

GEO-MM02 for Malaria GeoVax has collaborated with the Burnet Institute, an infectious disease research institute in Australia to develop an MVA-VLP vaccine for malaria. Vaccine design and construction were completed by GeoVax, with preclinical testing done by Burnet. Although this is a substantial global market, further development will depend on grants or other funding sources.

Conclusions and Valuation

GeoVax reported its 1Q23 financial results of a loss of $4.0 million or $(0.15) per share. Cash and equivalents on March 31, 2023 were $23.9 million, and based on our estimates, should be sufficient to fund operations through 1Q24. This does not

include any non-dilutive funding that could be received to support CM04S1 under the new $5 billion in Project NextGen funding for COVID-19 vaccine development. We expect the company to raise additional capital as market conditions improve and have allowed for periodic share increases in our earnings projections.

We value GEOX based on our estimated revenues from Gedeptin in the head and neck cancer indication. We anticipate the Phase 1/2 trial results in 1H24, followed by a Phase 2/3 trial beginning in late 2024, with product approval in 2026.

We estimate the population of head and neck cancer patients to be about 70,000 new cases per year. Our revenue models are based on use in the advanced or recurrent patients, estimated to be about 20% of the cases, or about 14,000 patients. Our market penetration estimates are intentionally conservative, allowing for slow adoption and competition from other new treatments.

New gene therapy treatments range widely in price, with a price of $225,000 per eye for Lexterna (voretigen eneparvovec-rzpl, a gene therapy for retinal dystrophy) to $2.1 million for Zolgensma (onasemnogen abeparvovec, a gene therapy for spinal muscular atrophy). We expect the actual price to reflect the efficacy and competing therapies at the time of approval. Our revenue models are on the low end of the potential price range at $150,000 for a course of Gedeptin, similar to the cost of immunotherapies for cancer treatment.

Our market share is intentionally modest, allowing for slow product uptake and competition from other therapies. We discount our revenues by 50% to allow for clinical development risk, then use the discounted revenues to estimate annual earnings. Our price target is based on our estimated EPS of $1.10 per share in FY2027, the first full year of sales after product launch. We discount this estimate at 30% per year to allow for company risk, industry risk, and market risk. Our price target is $6 per share.

GeoVax Labs, Inc: Income Statement (in thousands, except per share data)															
Fiscal Year Ended December	**2021A**	**1Q22A**	**2Q22A**	**3Q22A**	**4Q22A**	**2022A**	**1Q23A**	**2Q23E**	**3Q23E**	**4Q23E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**
Revenues															
Grant and collaboration revenu	386	82				82									
Product sales															
Gedeptin														126,000	189,000
GM04S1 (COVID- 19)															
Total Revenues	386	82				82								126,000	189,000
Expenses															
Cost of goods sold														25,200	31,815
COGS/Revenues														*20%*	*17%*
Research and development	15,554	1,331	1,307	2,721	3,765	9,123	2,819	3,200	3,600	4,100	13,719	23,100	32,600	43,400	50,400
General and administrative	3,577	1,179	935	1,249	1,623	4,987	1,451	1,550	1,650	1,750	6,401	9,300	15,400	28,300	40,600
Total expenses	**19,131**	**2,510**	**2,242**	**3,971**	**5,388**	**14,110**	**4,271**	**4,750**	**5,250**	**5,850**	**20,121**	**32,400**	**48,000**	**96,900**	**122,815**
Operating Income (Loss)	**(18,746)**	**(2,428)**	**(2,242)**	**(3,971)**	**(5,388)**	**(14,029)**	**(4,271)**	**(4,750)**	**(5,250)**	**(5,850)**	**(20,121)**	**(32,400)**	**(48,000)**	**29,100**	**66,185**
Interest income, net	4	1	1	2	4	7	233	275	250	175	933	725	840	905	1,245
Gain on debt extinguishment	172														
Total other income	**176**	**1**	**1**	**2**	**4**	**7**	**233**	**275**	**250**	**175**	**933**	**725**	**840**	**905**	**1,245**
Pretax Income	**(18,570)**	**(2,428)**	**(2,242)**	**(3,968)**	**(5,384)**	**(14,021)**	**(4,038)**	**(4,475)**	**(5,000)**	**(5,675)**	**(19,188)**	**(31,675)**	**(47,160)**	**30,005**	**67,430**
Net Income	**(18,570)**	**(2,428)**	**(2,242)**	**(3,968)**	**(5,384)**	**(14,021)**	**(4,038)**	**(4,475)**	**(5,000)**	**(5,675)**	**(19,188)**	**(31,675)**	**(47,160)**	**30,005**	**67,430**
GAAP EPS (basic)	**(3.04)**	**(0.34)**	**(0.18)**	**(0.17)**	**(0.23)**	**(0.83)**	**(0.15)**	**(0.17)**	**(0.19)**	**(0.14)**	**(0.65)**	**(0.68)**	**(0.78)**	**0.49**	**1.10**
GAAP EPS (diluted)	**(3.04)**	**(0.34)**	**(0.18)**	**(0.17)**	**(0.23)**	**(0.83)**	**(0.15)**	**(0.17)**	**(0.19)**	**(0.14)**	**(0.65)**	**(0.68)**	**(0.78)**	**0.49**	**1.10**
Weighted Average Shares (bas	6,100	7,109	12,722	23,462	23,485	16,973	26,339	26,365	26,391	41,418	30,128	46,524	60,736	60,980	61,224
Weighted Average Shares (dilu	6,100	7,109	12,722	23,462	23,485	16,973	26,339	26,365	26,391	41,418	30,128	46,524	60,736	60,980	61,224

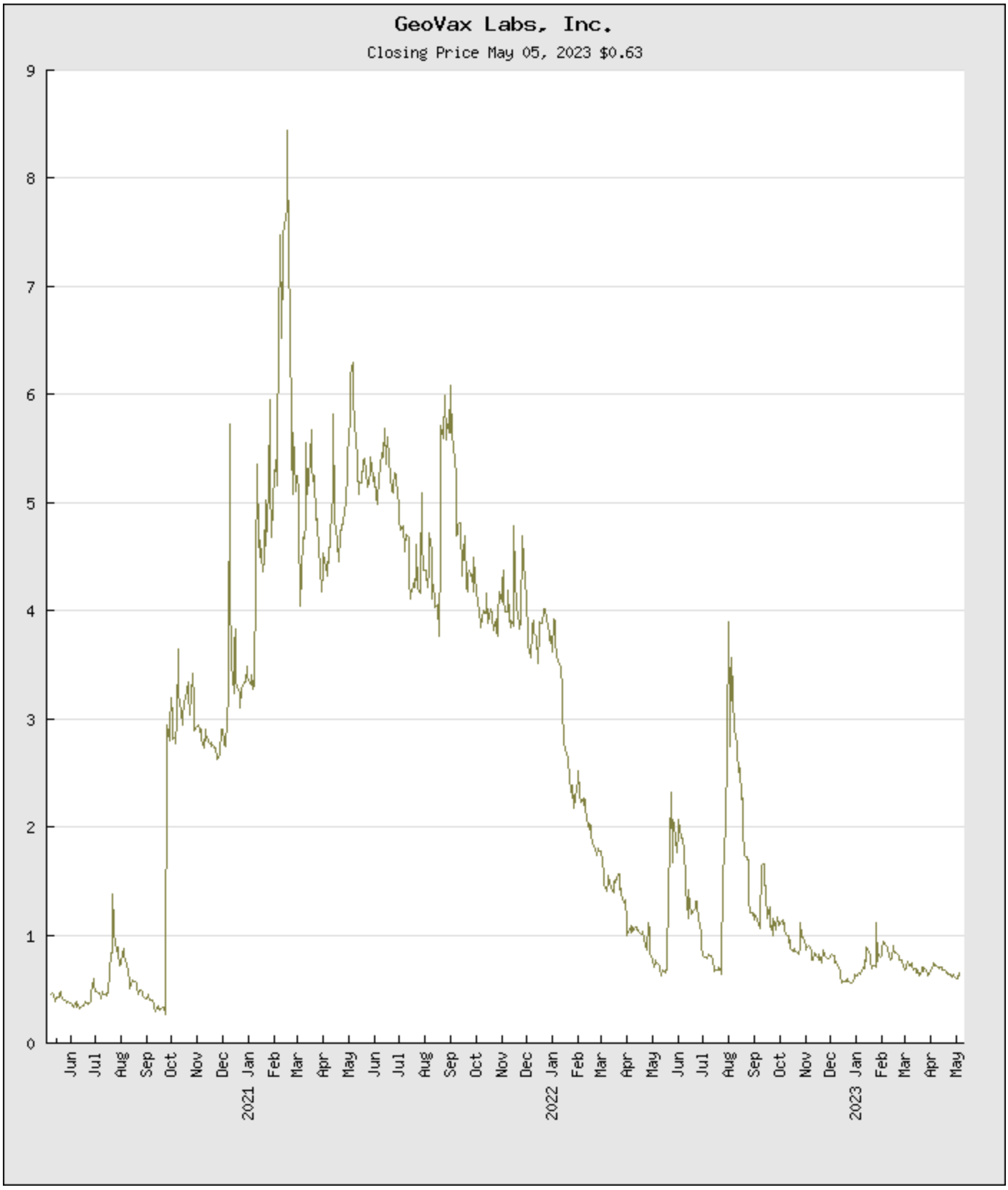
Source: Company SEC filings and Noble Capital Markets estimates

GeoVax Labs, Inc: Balance Sheet (in thousands)											
Assets	**2022E**	**1Q23A**	**2Q23E**	**3Q23E**	**4Q23E**	**2023E**	**1Q24E**	**2Q24E**	**3Q24E**	**4Q24E**	**2024E**
Cash and Cash Equivilents	$27,613	$23,850	$19,755	$15,305	$25,030	$25,030	$19,251	$12,630	$29,983	$21,212	$21,212
Grant funds and other receivables											
Prepaid expenses and other assets	1,326	2,139	2,139	2,139	2,139	2,139	2,139	2,139	2,139	2,139	2,139
Total current assets	$28,939	$25,989	$21,894	$17,444	$27,169	$27,169	$21,390	$14,769	$32,122	$23,351	$23,351
Property and equipment, net	235	218	218	218	218	218	218	218	218	218	218
Deposits	2,174	1,198	1,198	1,198	1,198	1,198	1,198	1,198	1,198	1,198	1,198
Total assets	$31,348	$27,404	$23,310	$18,860	$28,585	$28,585	$22,805	$16,184	$33,538	$24,767	$24,767
Liabilities											
Accounts payable	1,748	1,288	1,288	1,288	1,288	1,288	1,288	1,288	1,288	1,288	1,288
Accrued expenses	3,000	3,251	3,251	3,251	3,251	3,251	3,251	3,251	3,251	3,251	3,251
Current portion of notes payable											
Total Current Liabilities	$4,748	$4,539	$4,539	$4,539	$4,539	$4,539	$4,539	$4,539	$4,539	$4,539	$4,539
Accured expenses - noncurrent											
Note payable, net of current portion											
Total Liabilities	$4,748	$4,539	4,539	4,539	4,539	$4,539	$4,539	$4,539	$4,539	$4,539	$4,539
Stockholders' equity											
Common stock	26	26	26	26	26	26	26	26	26	26	26
Additional paid-in capital	104,971	105,274	105,654	106,204	121,604	121,604	122,176	122,879	148,633	149,462	149,462
Accumulated deficit	(78,397)	(82,435)	(86,910)	(91,910)	(97,585)	(97,585)	(103,935)	(111,260)	(119,660)	(129,260)	(129,260)
Total Equity	26,600	22,865	18,770	14,320	24,046	24,046	18,267	11,645	28,999	20,228	20,228
Total Liab & Equity	$31,348	$27,404	$23,310	$18,860	$28,585	$28,585	$22,806	$16,184	$33,538	$24,767	$24,767
Shares Issued (in thousdands)	16,973	26,339	26,365	26,391	41,418	30,128	41,459	41,501	51,542	51,594	46,524
Shares Outstanding (in thousands)	16,973	26,339	26,365	26,391	41,418	30,128	41,459	41,501	51,542	51,594	46,524

Source: Company reports and Noble Capital Markets estimates

GeoVax Labs, Inc: Cash Flow Statement (dollars in thousands)											
Cash flows from operating activities:	**2022A**	**1Q23A**	**2Q23E**	**3Q23E**	**4Q23E**	**2023E**	**1Q24E**	**2Q24E**	**3Q24E**	**4Q24E**	**2024E**
Net income (loss)	(14,021)	(4,038)	(8,513)	(13,513)	(19,188)	(19,188)	(6,350)	(13,675)	(22,075)	(31,675)	(31,675)
Stock-based compensation (employees and dire	902	246	600	1,150	1,550	1,550	450	1,050	1,700	2,400	2,400
Stock-based compensation (consultants)											
Depreciation and amortization	56	17	17	17	17	17	17	17	17	17	17
Changes in assets and liabilities:											
Grant funds and other recievables	49										
Prepaid expenses and other current assets	(1,166)	(756)	(756)	(756)	(756)	(756)					
Accounts payable and accrued expenses	(2,163)	(209)	(209)	(209)	(209)	(209)					
Deposits and other assets	(2,687)	976	976	976	976	976					
Net Cash Used in Operating Activities	**(19,030)**	**(3,763)**	**(7,884)**	**(12,334)**	**(17,609)**	**(17,609)**	**(5,883)**	**(12,608)**	**(20,358)**	**(29,258)**	**(29,258)**
Cash flows from investing activities:											
Purchase of property and equipment	(134)										
Net cash provided by investing activities	**(134)**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Cash flows from financing activities:											
Net proceeds from the sale of common stock and	27,727	0	26	26	15,026	15,026	104	207	25,311	25,440	25,440
Net proceeds form warrant exercise	7,626										
Net cash provided by financing activities	35,353	0	26	26	15,026	15,026	104	207	25,311	25,440	25,440
Net Increase (decrease) in cash and cash equivil	16,189	(3,763)	(7,858)	(12,308)	(2,583)	(2,583)	(5,779)	(12,400)	4,953	(3,818)	(3,818)
Cash and equivalents, beginning of period	11,424	27,613	27,613	27,613	27,613	27,613	25,030	25,030	25,030	25,030	25,030
Cash and equivalents, end of period	27,613	23,850	19,755	15,305	25,030	25,030	19,251	12,630	29,983	21,212	21,212

Source: Company SEC filings and Noble Capital Markets estimates


GeoVax Labs, Inc.
Closing Price May 05, 2023 $0.63
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The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or under-served needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclicality, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

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Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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Outperform: potential return is >15% above the current price	92%	24%
Market Perform: potential return is -15% to 15% of the current price	8%	1%
Underperform: potential return is >15% below the current price	0%	0%

NOTE: On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

Noble Capital Markets, Inc.
150 E Palmetto Park Rd, Suite 110
Boca Raton, FL 33432
561-994-1191

Report ID: 25814