

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended December 31, 2024

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File No. 001-39563

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

87-0455038

(IRS Employer
Identification Number)

1900 Lake Park Drive, Suite 380

Smyrna, GA

(Address of principal executive offices)

30080

(Zip Code)

(678) 384-7220

Registrant's telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock \$0.001 par value	GOVX	The Nasdaq Capital Market
Warrants to Purchase Common Stock	GOVXW	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2024, based on the closing price on that date was \$13,192,305.

Number of shares of Common Stock outstanding as of March 25, 2025: 13,839,478

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with respect to its 2025 Annual Meeting of Stockholders are incorporated by reference in Part III of this document.

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This Annual Report on Form 10-K (Annual Report) (including the following section regarding Management’s Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as “expects,” “believes,” “looks forward to,” “may,” “estimates,” “continues,” “anticipates,” “intends,” “should,” “plans,” “could,” “target,” “potential,” “is likely,” “will,” and similar expressions or variations of such words are intended to identify forward-looking statements but are not the exclusive means of identifying forward-looking statements in this Annual Report. Additionally, statements concerning future matters, including statements regarding our business, our financial position, the research and development of our products and other statements regarding matters that are not historical are forward-looking statements.

Although forward-looking statements in this Annual Report reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include without limitation those discussed under the heading “Risk Factors” below, as well as those discussed elsewhere in this Annual Report. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report. Readers are urged to carefully review and consider the various disclosures made in this Annual Report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

PART I

ITEM 1. BUSINESS

Overview

GeoVax Labs, Inc. (GeoVax, us, we or the Company) is a clinical-stage biotechnology company developing human vaccines and immunotherapies against infectious diseases and solid tumor cancers using novel proprietary platforms. The Company’s lead clinical program is GEO-CM04S1, a next-generation COVID-19 vaccine for which GeoVax has been awarded a BARDA-funded contract to sponsor a 10,000-participant, randomized, Phase 2b clinical trial to evaluate the efficacy of GEO-CM04S1 versus a COVID-19 vaccine approved by the U.S. Food and Drug Administration (FDA). The study is anticipated to commence in the second half of 2025. GEO-CM04S1 is also currently being evaluated in three Phase 2 clinical trials, including:

- A primary vaccine for immunocompromised patients, such as those with hematologic cancers and other patient populations for whom the current authorized COVID-19 vaccines are inadequate.
- A booster vaccine in patients with chronic lymphocytic leukemia (CLL), which recently demonstrated superior immune responses versus an mRNA vaccine following an interim Data Safety Monitoring Board (DSMB) review.
- A more robust booster vaccine among healthy adults who previously received an mRNA vaccine, with data readouts anticipated in mid-2025.

The Company’s lead clinical program in oncology is evaluating a novel oncolytic solid tumor gene-directed therapy, Gedeptin®, having recently completed a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. A Phase 2 clinical trial in first recurrent head and neck cancer, evaluating Gedeptin® combined with an immune checkpoint inhibitor is planned. Additionally, the Company is developing GEO-MVA, a vaccine targeting Mpox and smallpox, with clinical evaluation expected to begin in 2025.

GeoVax’s portfolio of wholly owned, co-owned, and in-licensed intellectual property, stands at over 135 granted or pending patent applications spread over 23 patent families, which are discussed in greater detail in the “Our Intellectual Property” section.

Our Product Development Pipeline

The tables below summarize the status of our product development programs, which are discussed in greater detail in the following pages.

Clinical Development Programs

Product	Indication	Clinical Trial	Status		
GEO-CM04S1	COVID-19	BARDA Project NextGen 10,000 Patient Comparison Study	Phase 2b Initiation 2H 2025		
		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 Adults (NCT04639466)	Phase 2 enrollment closed, data expected mid-2025		
		Gedepstin [®]	Head & Neck Cancer*	ICI Combination Therapy (NCT TBD)	Phase 2 planned

Preclinical Development Programs

Product	Indication	Status
GEO-MVA	Mpox & Smallpox Vaccine	Regulatory Discussions & Manufacturing Scale-up
GEO-EM01-Z	Ebola Zaire Vaccine**	Non-Human Primate (completed)
GEO-EM01-S	Ebola Sudan Vaccine**	Non-Human Primate (completed)
GEO-MM01	Marburg Vaccine**	Non-Human Primate (completed)
GEO-ZM02	Zika Vaccine**	Mouse Model (completed)

* Orphan Drug status granted

** Indication within FDA Priority Review Voucher program

Our Coronavirus Vaccine Programs

Severe respiratory illnesses caused by the SARS-CoV-2 virus, remain a serious public health issue of international concern. SARS-CoV-2 is an enveloped, single-stranded, positive-sense RNA virus belonging to the family *Coronaviridae* within the genus beta-coronavirus. The genome of SARS-CoV-2 encodes one large Spike (S) protein that plays a pivotal role during viral attachment to the host receptor and entry into host cells. The S protein is the basis for most approved vaccines used to protect against SARS-CoV-2. Neutralizing antibodies targeting the receptor binding domain (RBD) subunit of the S protein block the virus from binding to host cells. Over 90% of all neutralizing antibodies produced in response to infection are directed to the RBD subunit.

Vaccines currently authorized for use in the United States are primarily designed to induce antibodies specific for the S protein of SARS-CoV-2 but rely on different mechanisms for presentation or expression of the S antigen, including recombinant proteins, whole inactivated virus, defective adenovirus vectors (three different types) or mRNA. Unfortunately, the continued adaptation and mutation of SARS-CoV-2 has resulted in the emergence of variants that are not optimally neutralized by antibodies induced by currently available vaccines, reducing clinical efficacy. This has required the continued adjustment of vaccine composition and the repeated administration of booster doses. Moreover, these current vaccines tend to stimulate only modest T-cell responses, which have been shown to be critical for induction of long-term immune memory and for protection against severe COVID-19 disease. Recently, the FDA indicated the likely need for continued vaccine adjustments and boosters at least annually, similar to the approach used for influenza virus vaccines.

Modified Vaccinia Ankara (MVA) is the viral vaccine vector platform utilized in a number of our vaccine candidates, including our next generation SARS-CoV-2 product, GEO-CM04S1. There are several potential advantages to SARS-CoV-2 vaccines based on MVA vectors:

- MVA has a large genetic coding capacity which provides the foundation for vaccines based on multiple SARS-CoV-2 proteins, instead of the singular focus on the S protein. This approach is intended to induce immune responses with greater breadth of specificity.
- MVA is known to effectively induce durable T-cell responses in addition to antibodies.
- MVA does not replicate in human cells, which contributes to it being an extremely safe vaccine platform for human vaccines.

As a result of the combination of these properties, MVA is an ideal vaccine vector platform for the design of the next generation COVID-19 vaccines. This is especially true when the need to correct for suboptimal vaccine-induced immune responses of certain patient populations with compromised immune systems is considered, including patients suffering from and/or being treated for a variety of cancers, organ transplant patients, and renal dialysis patients.

GEO-CM04S1 -- BARDA Project NextGen Award – Phase 2b Trial

In June 2024, we announced our receipt of an award through the Rapid Response Partnership Vehicle (RRPV) to advance development of GEO-CM04S1 in a Phase 2b clinical trial. Under the agreement with Advanced Technology International, the RRPV’s consortium management firm (ATI-RRPV Contract), GeoVax will sponsor a 10,000-participant, randomized, Phase 2b double-blinded study to assess the clinical efficacy, safety, and immunogenicity of GEO-CM04S1 compared with an FDA-approved mRNA COVID-19 vaccine. 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) in the U.S. Department of Health and Human Services (HHS).

Preparations for the study are underway and expected to initiate in the second half of 2025. Execution of the study will be fully funded by BARDA under its Clinical Studies Network. The direct award to GeoVax (currently \$26.2 million but which may increase to as much as \$45 million) will fund the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. BARDA has made a separate award of \$343 million from the Project NextGen program to Allucent, a global clinical research organization (CRO), to execute the clinical trial as part of BARDA’s Clinical Studies Network. The combined value of the awards to GeoVax and Allucent toward the clinical evaluation of GEO-CM04S1 is therefore expected to be \$369-388 million.

Funding for this project is provided under Project NextGen, a \$5 billion initiative by HHS to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19 than the first generation COVID vaccines and medicines. GeoVax’s vaccine candidate provides many of the features identified, including broader protection among variants of concern (VOC) and a longer duration of protection.

GeoVax’s role in this project is being funded in whole or in part with federal funds from BARDA under Other Transaction (OT) 75A50123D00005. Allucent’s role in the project is being funded in whole or in part with federal funds from BARDA, under contract 75A50120D00016/75A50123F33005.

GEO-CM04S1 for Immunocompromised/Cell Transplant Patients – The CDC and other global public health agencies identify immunocompromised patients, including patients with cancer, particularly those who have received treatment for hematologic malignancy, as highest risk for SARS-CoV-2 disease. SARS-CoV-2 infection can be very serious in these vulnerable patient groups, with hematologic cancer patients, including those receiving autologous (auto) and allogeneic (allo) hematopoietic cell transplant (HCT), and recipients of chimeric antigen receptor (CAR)-T cell therapies among the most vulnerable.

Our vaccine candidate, GEO-CM04S1, is based on a synthetic, attenuated Modified Vaccinia Ankara (sMVA) vector expressing both spike (S) and nucleocapsid (N) antigens of the SARS-CoV-2 virus and was initially developed at City of Hope (COH) Medical Center for immunocompromised patients. In a placebo-controlled Phase 1 clinical trial of healthy adults conducted by COH, GEO-CM04S1 was shown to be safe and immunogenic. In November 2021, GeoVax entered into a license agreement with COH, granting GeoVax exclusive worldwide rights to further develop and commercialize the vaccine.

Stem Cell Transplant Study. GEO-CM04S1 is being studied in an ongoing Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT04977024) to evaluate its safety and immunogenicity as a primary vaccine, compared to either the Pfizer/BioNTech or Moderna mRNA-based vaccine, in blood cancer patients who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant or CAR T cell therapy. MVA-vector based vaccines tend to produce an immune response quickly – in less than 14 days – with only mild side effects. The trial is the first to compare an investigational multi-antigenic SARS-CoV-2 vaccine to the current FDA-approved mRNA vaccines from Pfizer/BioNTech and Moderna in people who are immunocompromised. Such patients have often shown a suboptimal immune response after receiving currently available COVID-19 vaccines.

CLL Study. GEO-CM04S1 is also being studied in an investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355), as a booster vaccine in immunocompromised patients with chronic lymphocytic leukemia (CLL). Despite a high vaccination rate, CLL patients may be at high risk for lethal COVID-19 infection due to their compromised ability to generate protective antibody responses against COVID infections or to currently available vaccines. GEO-CM04S1 may be more effective at inducing protective immunity in CLL patients since MVA strongly induces T cell expansion even in the background of immunosuppression. Targeting both the S and N protein antigens broaden the specificity of the immune responses and may mitigate against the loss of efficacy associated with the inadequate antibody responses. The study is examining the use of two injections of GEO-CM04S1 three months apart to assess immune responses in these vulnerable patients, with the Pfizer-BioNTech Bivalent vaccine as the control arm.

In November 2024, the Data Safety Monitoring Board (DSMB) for this study conducted an interim data review. Following its review, the DSMB recommended that the study should continue enrollment of the experimental arm utilizing GEO-CM04S1, but that the mRNA control arm of the study should be halted as it failed to meet the predetermined primary immune endpoint. This suggests a potentially superior immune response in this vulnerable population. Further enrollment of the remaining patient participants is expected to be completed during 2025.

GEO-CM04S1 as a Booster Vaccine – GEO-CM04S1 is also being studied in a Phase 2 trial (ClinicalTrials.gov Identifier: NCT04639466), evaluating its use as a heterologous booster vaccine to current FDA-approved mRNA vaccines from Pfizer/BioNTech and Moderna.

Because GEO-CM04S1 is designed to stimulate potent humoral and cellular immune responses against both the S and N proteins of SARS-CoV-2, GeoVax believes its administration as a booster will induce a broader and more sustained immune response than that seen after mRNA vaccine boosting. In addition, GEO-CM04S1 may offer better protection against the significant sequence variation observed with the S antigen because the N antigen tends not to change significantly amongst variants.

The Phase 1 trial of GEO-CM04S1 (known at the time as COH-CM04S1) was designed as a dose-escalation safety study in healthy individuals between the ages of 18 to 55, who had not been previously infected or vaccinated with SARS-CoV-2. The primary objectives were to evaluate the safety, tolerability and immunogenicity of the GEO-CM04S1 administered at three different dose levels by intramuscular (IM) injection.

The Phase 2 booster study includes 63 healthy adults who were previously vaccinated with one of the FDA-approved SARS-CoV-2 mRNA vaccines, manufactured by either Pfizer/BioNTech or Moderna. The study is designed as a comparison trial to evaluate the safety profile and immunogenicity of 2 dose levels of GEO-CM04S1 when administered as a heterologous booster. The immunological responses measured throughout the study will include SARS-CoV-2 binding antibodies, as well as neutralizing antibody and T-cell responses against SARS-CoV-2 variants of concern (VOC), including the Delta and contemporaneous Omicron variants.

In February 2024, we announced positive initial safety and immune response findings at one month following vaccine administration. While the study is designed to evaluate the safety and immunogenicity of two GEO-CM04S1 dose levels. The trial remains blinded to dose of vaccine received, with study subjects being followed for a total of one year. To date, there have been no serious adverse events, and adverse events were in line with other routine vaccinations. The immunological responses measured throughout the study period include binding antibodies, as well as neutralizing antibodies against multiple SARS-CoV-2 variants (including contemporaneous Omicron variants) and specific T-cell responses. Consolidated data from all subjects tested one-month post-vaccination documented statistically significant increases in neutralizing antibody responses against multiple SARS-CoV-2 variants, ranging from the original Wuhan strain through Delta and Omicron XBB 1.5; additional testing against the JN.1 variant is underway.

Patient enrollment for this study has been completed. We expect data from this trial, which included a 1-year follow-up, to be available in mid-2025.

Gedepin® - Solid Tumor Cancer Therapy

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

In GDEPT, a replication-deficient adenovirus vector is used to infect and transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert an inactive prodrug into an active antitumor compound, *in situ*. A cycle of Gedeptin therapy consists of intra-tumoral injections of Gedeptin followed by administration of a prodrug, fludarabine phosphate, over a pre-defined time period. A Phase 1 dose ranging study, evaluating the safety of a single cycle of Gedeptin therapy, found the therapy to be well tolerated, with evidence of a reduction in tumor size in patients with solid tumors.

We recently completed a multi-site Phase 1b/2a trial (PNP-002) (ClinicalTrials.gov Identifier: NCT03754933), evaluating the safety and efficacy of repeat cycles of Gedeptin therapy in patients with advanced head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options. The PNP-002 trial design involved repeat administration using Gedeptin followed by systemic fludarabine phosphate, in order to gain preliminary information on the utility of multiple cycles of Gedeptin therapy. This trial was intended to guide the design of larger studies involving patients at earlier stages in the disease process. This trial was funded in part by the FDA pursuant to its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedeptin orphan drug status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities.

During 2024 we convened a special clinical advisory board to conduct a comprehensive review of the PNP-002 trial results, together with the previously completed Phase 1 trial (PNP-001). This review concluded that Gedeptin demonstrated an acceptable safety and efficacy profile to support continued development. In addition, the therapy has demonstrated sufficient tumor stabilization/reduction activity to support plans to advance clinical development of Gedeptin therapy in an expanded Phase 2 clinical trial.

We have initiated activities in support of a Phase 2 clinical study, evaluating Gedeptin therapy in combination with an approved immune check point inhibitor (ICI) in first recurrent head and neck cancer scheduled for resection with curative intent. Key endpoints will include pathologic response rates and overall treatment outcomes. This study is anticipated to be a single cycle trial with surgery to follow in approximately 36 patients with pathologic response rate as the primary endpoint. We have initiated the necessary planning activities, including protocol development, manufacturing and CRO selection, with the trial activation anticipated in the second half of 2025.

GEO-MVA – Mpox and Smallpox Vaccine

MVA was originally developed for use as a 3rd generation smallpox vaccine nearly 50 years ago. Its preferred use is for individuals with compromised immune systems; individuals that would be put at risk if administered the normal smallpox vaccine (vaccinia) which can replicate in human cells. It is also approved as the vaccine for other orthopox vaccines, including Mpox. As such, an added potential benefit of our vaccines is that in those regions where Mpox and/or smallpox are of concern, vaccines built on an MVA vaccine platform offer the prospect of protection against Mpox and smallpox.

In response to the global need to address the continued emerging threat from Mpox and the unique opportunity offered by MVA-based vaccines, in November 2022, GeoVax secured rights from the NIH covering preclinical, clinical and commercial uses of the NIH-MVA against Mpox or smallpox viruses. GeoVax previously demonstrated that an experimental HIV vaccine, utilizing NIH-MVA as the vaccine vector, protected non-human primates challenged with a lethal dose of the Mpox virus 3 years post-vaccination. Further, in August 2022, the City of Hope team, which originally developed GEO-CM04S1, published results demonstrating that both their proprietary sMVA (synthetic MVA) and GEO-CM04S1 (referred to as “COH04S1” in the publication) elicited robust orthopoxvirus-specific binding and neutralizing antibody responses. The authors concluded that GEO-CM04S1 and sMVA represent unique vaccine candidates to control the unforeseen global Mpox outbreak.

MVA is the vaccine currently used and stockpiled in the U.S. Strategic National Stockpile for immunization against the Mpox and smallpox viruses. The 2022 Mpox pandemic significantly depleted the U.S. Strategic National Stockpile of vaccines, exposing vulnerabilities in the nation's preparedness for emerging health threats. Compounding this issue is the nation's reliance on a single foreign manufacturer for smallpox and Mpox vaccines. This dependency poses a strategic risk, especially considering the current Clade I Mpox outbreak in Africa, characterized by a mortality rate as high as 10%, increasingly migrating to other regions worldwide.

GeoVax is now evaluating development and regulatory pathways towards expanding the public health options available to reduce and manage the risk of Mpox worldwide. The Company intends to successfully develop and commercialize GEO-MVA, becoming the first U.S.-based supplier of MVA as a vaccine against Mpox and smallpox. Clinical evaluation of the vaccine is expected to begin in 2025. We have recently produced a cGMP clinical batch of GEO-MVA to support our clinical programs.

Other Infectious Disease Programs (Preclinical)

Hemorrhagic Fever Virus Vaccines (Ebola Zaire, Ebola Sudan, Marburg) -- Ebola (EBOV, formerly designated as Zaire ebolavirus), Sudan (SUDV), and Marburg viruses (MARV) are the most virulent species of the *Filoviridae* family, causing hemorrhagic fever illnesses with up to a 90% fatality rate in humans. In December 2019, FDA approved the first live recombinant Ebola vaccine for prevention of Ebola disease by Zaire virus. This rVSV-ZEBOV showed safety concerns in Phase 1 trials and by virtue of being replication competent could pose threats to immunocompromised individuals, such as those infected with HIV living in West Africa where recent Ebola epidemics started.

To address the unmet need for a product that can respond to future hemorrhagic fever outbreaks, we are developing vaccines utilizing our GV-MVA-VLP™ platform. As previously noted, the MVA vector itself is considered safe, having originally been developed for use in immunocompromised individuals as a smallpox vaccine. We expect our vaccines may not only protect at-risk individuals against EBOV, SUDV and MARV, but also potentially reduce or modify the severity of other re-emerging pathogens such as Bundibugyo, Ivory Coast, and Reston viruses, based on antigenic cross reactivity and the elicitation of T cells to the more conserved matrix proteins (e.g., VP40 or Z) in addition to standard GP proteins used by us and other manufacturers. Thus, the GeoVax GV-MVA-VLP™ approach could offer a unique combination of advantages to achieve breadth and safety of a pan-filo vaccine. In addition to protecting historically higher-risk populations in Africa, it is also intended to prevent the spread of disease to the U.S. and globally, and for preparedness against terrorist release of any of bio-threat pathogens in the U.S. and globally.

Our initial preclinical studies in rodents and nonhuman primates for our GEO-EM01-Z vaccine candidate have shown significant levels of protection against lethal doses of EBOV. Recent studies in lethal challenge guinea pig models demonstrated that GeoVax vaccines GEO-EM01-S and GEO-MM01 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. The nonhuman primate studies conducted in collaboration with National Institute of Allergy and Infectious Diseases (NIAID) and the U.S. Department of Defense (DoD) have been completed and potential clinical development programs are being considered.

GEO-ZM02 for Zika – Zika disease is an emerging infectious disease caused by the Zika virus (ZIKV) and has been linked to an increase in microcephaly in infants and Guillain-Barre syndrome (a neurodegenerative disease) in adults. ZIKV is a member of the *Flaviviridae* family, which includes medically important pathogens such as dengue fever, yellow fever, Japanese encephalitis, tick-borne encephalitis, and West Nile viruses. Public health officials recommend avoiding exposure to ZIKV, delaying pregnancy, and following basic supportive care (fluids, rest, and acetaminophen) after infection.

To address the unmet need for a ZIKV vaccine, we are developing novel vaccine candidates constructed using our 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. Our Zika vaccine is designed based on the NS1 gene product to eliminate the risk of Antibody Dependent Enhancement (ADE), which is a serious side effect observed when a vaccinated individual doesn't have a fully protective immune response which actually causes a more virulent reaction if infected.

Our initial preclinical studies in rodents using our 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 GEO-ZM02 will be dependent upon partnering support.

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

Malaria Vaccine – Exploratory Research – According to data from the World Health Organization (WHO), globally, malaria causes 227 million infections and 619,000 deaths annually. Despite decades of vaccine research, vaccine candidates have failed to induce substantial protection. 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 hallmarks of an ideal vaccine-induced immune response.

We have 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 vaccine design, construction, and characterization were performed at GeoVax with immunogenicity and challenge studies in animal models conducted at Burnet Institute using their unique functional assays.

HIV – Due to our corporate refocusing of development efforts prioritizing our SARS-CoV-2 and cancer immunotherapy programs, and to a lack of continuing government support for our HIV vaccine development efforts, in 2022 we suspended active development of these programs. Our technology and intellectual property will remain available for out-license or partnering, but we are no longer devoting any significant corporate resources to this program.

Of interest, results from a clinical study of a combinational HIV therapy that included GeoVax's HIV booster vaccine candidate, MVA62B were presented at the Conference on Retroviruses and Opportunistic Infections (CROI) held February 19-22, 2023 in Seattle, Washington. The data presented were part of an effort led by researchers at the University of California, San Francisco (UCSF), to develop a combinational therapy aimed at inducing remission in HIV-positive individuals (a “functional cure”). The primary objectives of the proof-of-concept trial were to assess the safety and tolerability of the combinational therapy and to determine the viral load “set-point” during antiviral treatment interruption. Secondary objectives were to assess immune responses and changes in viral reservoir status. The clinical trial was led by Steven Deeks, M.D. of UCSF, a world leader in therapeutic approaches to HIV infections, and was one of the most comprehensive tests to date for the ability of synergistic approaches to control HIV infection. The studies were conducted with funding from amfAR, The Foundation for AIDS Research. The overall goal of this trial was to induce immune responses that could potentially control HIV replication in patients in the absence of antiviral drugs. The data presented by the UCSF researchers indicated very high levels of immunogenicity (particularly T cell immunity), despite the fact these occurred in technically immunocompromised patients. These results further validate the ability of the MVA-VLP platform to stimulate a robust T-cell response to various diseases.

Further development of our Hemorrhagic Fever, Zika, Malaria and HIV programs will be dependent upon additional funding support via federal grants, corporate collaborations, or other sources.

Our GV-MVA-VLP™ Platform

GeoVax's GV-MVA-VLP™ vaccine platform utilizes Modified Vaccinia Ankara (MVA), a large virus capable of carrying several vaccine antigens, that expresses proteins that assemble into virus-like particles (VLP) immunogens in the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic the virus production that occurs in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

Vaccines typically contain agents (antigens) that resemble disease-causing microorganisms. Traditional vaccines are often made from weakened or killed forms of the virus or from its surface proteins. Some newer vaccines use recombinant DNA (deoxyribonucleic acid) technology to generate vaccine antigens in bacteria or cultured cells from specific portions of the DNA sequence of the target pathogen. The generated antigens are then purified and formulated for use in a vaccine. We believe the most successful of these purified antigens have been non-infectious virus-like particles (VLPs) as exemplified by vaccines for hepatitis B (Merck's Recombivax® and GSK's Engerix®) and Papilloma viruses (GSK's Cervarix®, and Merck's Gardasil®). Our approach uses recombinant DNA and/or recombinant MVA to produce VLPs in the person being vaccinated (*in vivo*) reducing complexity and costs of manufacturing. In human clinical trials of our HIV vaccines, we believe we have demonstrated that our VLPs, expressed from within the cells of the person being vaccinated, can be safe, yet elicit both strong and durable humoral and cellular immune response.

VLPs mimic authentic viruses in form but are not infectious or capable of replicating and can cause the body's immune system to recognize and kill targeted viruses to prevent an infection. VLPs can also train the immune system to recognize and kill virus-infected cells to control infection and reduce the length and severity of disease. One of the biggest challenges with VLP-based vaccines is to design the vaccines in such a way that the VLPs will be recognized by the immune system in the same way as the authentic virus would be. We design our vaccines such that, when VLPs for enveloped viruses like HIV, Ebola or Marburg are produced *in vivo* (in the cells of the recipient), they include not only the protein antigens, but also an envelope consisting of membranes from the vaccinated individual's cells. In this way, they are highly similar to the virus generated in a person's body during a natural infection. VLPs produced *in vitro* (in a pharmaceutical plant), by contrast, have no envelope or, envelopes from the cultured cells (typically hamster or insect cells) used to produce them. We believe our technology therefore provides distinct advantages by producing VLPs that more closely resemble the authentic viruses. We believe this feature of our immunogens

allows the body’s immune system to more readily recognize the virus. By producing VLPs *in vivo*, we believe we also avoid potential purification issues associated with *in vitro* production of VLPs.

Figure 1 below shows examples of thin section electron micrographs of actual viruses and VLPs for these viruses expressed by GeoVax MVA-VLP vaccines.

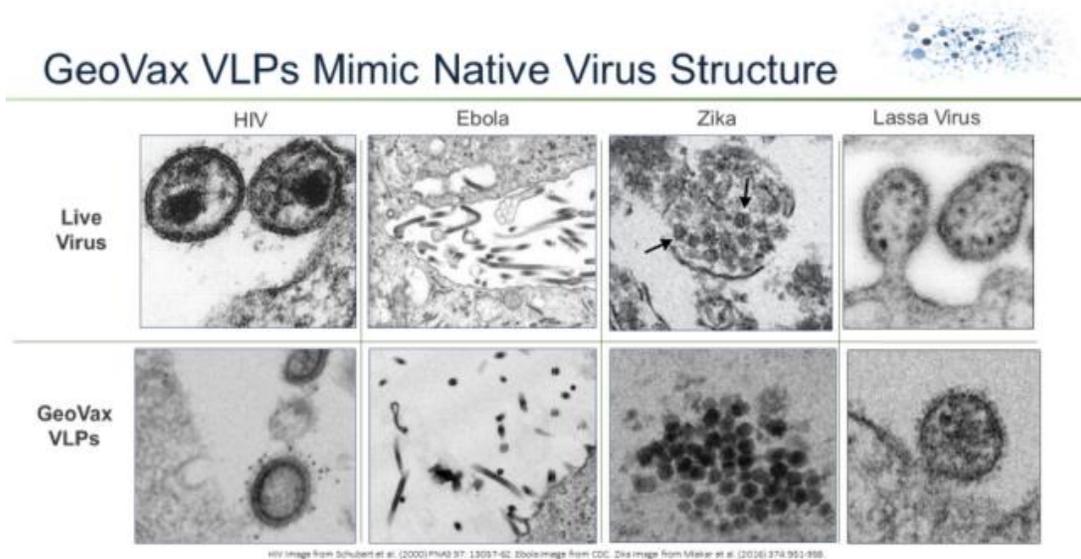


Figure 1. Comparison of MVA-VLPs and native virus structures

In the MVA-VLP platform, we take advantage of MVA’s large “coding capacity” to insert genes that encode multiple proteins, the combination of which is adequate to support the generation of VLPs by the MVA infected cells. Utility has been demonstrated for multiple vaccine candidates wherein the MVA-encoded viral matrix proteins and glycoproteins assemble into VLPs. MVA was originally developed as a safer smallpox vaccine for use in immune-compromised individuals. It was developed by attenuating the standard smallpox vaccine by passaging it (over 500 passages) in chicken embryos or chicken embryo fibroblasts, resulting in a virus with limited ability to replicate in human cells (thus safe) but with high replication capability in avian cells (thus cost effective for manufacturing). The modifications also resulted in the loss of immune evasion genes which assist the spread of wild type smallpox infections, even in the presence of human immune responses.

We collaborated with the laboratory of Dr. Bernard Moss at NIH/NIAID on four different generations of MVA vectors, spanning over 15 years of collaboration, to effectively express vaccine proteins that assemble into VLPs. These efforts led to the development of different shuttle vectors and the identification of multiple insertion sites for introducing foreign genes encoding the vaccine target proteins into MVA in a manner that optimizes each product for manufacturing stability. Each MVA-VLP vaccine has up to two expression cassettes, each encoding one or more antigens selected from pathogens of interest. At a minimum, each vaccine expresses two antigens required for VLP formation. In the case of HIV and hemorrhagic fever vaccines for example, a viral matrix protein and an envelope glycoprotein. We use a synthetic early late promoter that provides high, yet not lethal, levels of insert expression, which is initiated immediately after infection in cells of the vaccinated individual.

Our GV-MVA-VLP™ vaccine platform affords other advantages:

- **Safety:** Safety for MVA, generally, has been shown in more than 120,000 subjects in Europe, including immunocompromised individuals during the initial development of MVA and more recently with the development of MVA as a safer vaccine against smallpox. Our HIV vaccines demonstrated outstanding safety in multiple human clinical trials.
- **Durability:** Our technology raises highly durable (long-lasting) vaccine responses. We hypothesize that elicitation of durable vaccine responses is conferred on responding B cells by the vaccinia parent of MVA, which raises highly durable responses for smallpox.
- **Limited pre-existing immunity to vector:** Following the eradication of smallpox in 1980, smallpox vaccinations subsequently ended, leaving all but those born before 1980 and selected populations (such as vaccinated laboratory workers and first responders) unvaccinated and without pre-existing immunity to MVA-derived vaccines. A potential interference of pre-existing immunity to a vector may be more problematic with those vectors related to parent viruses used in routine vaccinations (e.g., measles) or constitute common viruses that infect people of all ages (e.g., cytomegalovirus).
- **Repeated use of the platform for different vaccines used in sequence.** In mouse experiments, we have shown that two of our vaccines (e.g., GV-MVA-VLP-Zika followed by GV-MVA-VLP-Ebola) can be given at < 4 week intervals without any negative impact on their immunogenicity (lack of vector immunity).

- **No need for adjuvants:** MVA generally stimulates strong innate immune responses and does not require the use of adjuvants.
- **Protection against Mpox and Smallpox:** MVA vectored vaccines have been previously shown to provide potential protection against Mpox and Smallpox.
- **Thermal stability:** MVA is stable in both liquid and lyophilized formats (> 6 years of storage).
- **Genetic stability and manufacturability:** If appropriately engineered, MVA is genetically stable and can reliably be manufactured in either the established Chick Embryo Fibroblast cell substrate, or novel continuous cell lines that support scalability as well as greater process consistency and efficiency.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in our ongoing research and development activities and in the manufacture of our products. Complying with these regulations involves considerable expertise, time and expense.

In the United States, drugs and biologics are subject to rigorous federal and state regulation. Our products are regulated under the Federal Food, Drug and Cosmetic Act (FD&C Act), the Public Health Service Act, and the regulations promulgated under these statutes, and other federal and state statutes and regulations. These laws govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of medications and medical devices. Product development and approval within this regulatory framework is difficult to predict, takes several years and involves great expense. The steps required before a human vaccine may be marketed in the United States include:

- Preclinical laboratory tests, *in vivo* preclinical studies and formulation studies;
- Manufacturing and testing of the product under strict compliance with current Good Manufacturing Practice (cGMP) regulations;
- Submission to the FDA of an Investigational New Drug application for human clinical testing which must become effective before human clinical trials can commence;
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- The submission of a Biologics License Application (BLA) to the FDA, along with the required user fees; and
- FDA approval of the BLA prior to any commercial sale or shipment of the product

Before marketing any drug or biologic for human use in the United States, the product sponsor must obtain FDA approval. In addition, each manufacturing establishment must be registered with the FDA and must pass a pre-approval inspection before introducing any new drug or biologic into commercial distribution.

The Emergency Use Authorization (EUA) authority granted to the FDA allows the FDA to help strengthen the nation's public health protections against certain threats by facilitating the availability and use of medical countermeasures needed during public health emergencies. Under Section 564 of the FD&C Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when there are no adequate, approved, and available alternatives. This potentially may provide a faster pathway to market for our COVID-19 or other infectious disease vaccine candidates. This was the approval pathway followed by Pfizer-BioNTech and Moderna for their respective COVID-19 vaccines.

Because GeoVax does not manufacture vaccines for human use within our own facilities, we must ensure compliance both in our own operations and in the outsourced manufacturing operations. All FDA-regulated manufacturing establishments (both domestic establishments and foreign establishments that export products to the United States) are subject to inspections by the FDA and must comply with the FDA's cGMP regulations for products, drugs and devices.

The FDA determines compliance with applicable statutes and regulations through documentation review, investigations, and inspections. Several enforcement mechanisms are available to the FDA, ranging from a simple demand to correct a minor deficiency to mandatory recalls, closure of facilities, and even criminal charges for the most serious violations.

Even if FDA regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Whether or not the FDA has approved the drug, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval.

We also are subject to various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted.

Recent Government Initiatives

US Regulators and Senior White House and Congressional Leaders have recently announced multiple objectives and initiatives that may impact GeoVax. These include:

- The reshoring and protection of the domestic biotech ecosystem – GeoVax represents the first domestic source for Smallpox and Mpox production which is currently controlled by a single foreign entity.
- Replenishing the US stockpile with additional vaccines addressing Mpox, Smallpox and Hemorrhagic Fevers – GeoVax has multiple products in advanced stages of development.
- Assisting African countries in their quest to prevent an array of debilitating illnesses including those caused by hemorrhagic fever viruses Fevers – GeoVax has multiple products in advanced stages of development.

FDA Tropical Disease Priority Review Voucher Program

Section 524 of the FD&C Act authorizes the FDA to award priority review vouchers (PRVs) to sponsors of approved tropical disease product applications that meet certain criteria. To qualify for a PRV, a sponsor's application must be for a drug or biological product for the prevention or treatment of a "tropical disease," must otherwise qualify for priority review, and must contain no active ingredient (including any salt or ester of an active ingredient) that has been approved in any other application under Section 505(b)(1) of the FD&C Act or Section 351 of the Public Health Services Act. Priority review means that the FDA aims to render a decision in 6 months.

The PRV may be sold. For example, a small company might win a voucher for developing a drug for a neglected disease and sell the voucher to a large company for use on a commercial disease. The price of the voucher depends on supply and demand. The voucher's value derives from three factors: shifting sales earlier, longer effective patent life due to earlier entry, and competitive benefits from earlier entry relative to competitors. Top-selling treatments can yield billions in sales each year, so being approved months earlier can be worth hundreds of millions of dollars to the voucher. Since the first voucher sale in 2014, the price of the vouchers has ranged from \$68 million to \$350 million.

GeoVax believes that its vaccine programs in Ebola, Sudan, Marburg, Malaria and Zika may each be eligible for a PRV and we intend to apply for a PRV at the appropriate time. There can be no assurance, however, that we will qualify or be approved for a PRV.

Manufacturing

To be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at an acceptable cost. To date, we have not commercialized any products, nor have we demonstrated that we can manufacture commercial quantities of our product candidates in accordance with regulatory requirements. If we cannot manufacture products in suitable quantities and in accordance with regulatory standards, either on our own or through contracts with third parties, it may delay clinical trials, regulatory approvals and marketing efforts for such products. Such delays could adversely affect our competitive position and our chances of achieving profitability. We cannot be sure that we can manufacture, either on our own or through contracts with third parties, such products at a cost or in quantities that are commercially viable.

Rather than establishing the necessary facilities to manufacture any of the clinical or commercial supplies of our products, our strategy is to rely on established, recognized third-party contract manufacturers to produce materials needed for research and clinical trials. We have arrangements with third party manufacturers for the supply of products for use in our planned clinical trials. These suppliers operate under the FDA's Good Manufacturing Practices and (in the case of European manufacturers) similar regulations of the European Medicines Agency. We anticipate that these suppliers will be able to provide sufficient supplies to complete our currently planned clinical trials. Various contractors are generally available in the United States and Europe for manufacture of materials for clinical trial evaluation, however, it may be difficult to replace existing contractors for certain manufacturing and testing activities and costs for contracted services may increase substantially if we switch to other contractors.

The raw materials and other supplies that are used in the production process for our vaccines and that we use in our research activities are generally available from a number of commercial suppliers and we believe we will be able to obtain sufficient quantities of such materials and supplies for all foreseeable clinical investigations.

Transition to high-yield, scalable MVA manufacturing process – Currently, MVA vaccines are manufactured in primary cell cultures of chicken embryonic fibroblasts (CEF) derived from SPF eggs, a suboptimal and time-consuming process useful primarily for niche markets and stockpile reserves. After exploring various approaches to growing MVA, utilizing continuous avian cell lines in bioreactors more suitable for high-yield, commercial-scale manufacturing, we have accelerated activities towards fully implementing a proprietary, continuous avian cell line manufacturing system that will provide lower-cost, scalable versatility for broad MVA vaccine and immunotherapy applications. To this end, in September 2023, we announced the signing of a commercial multi-product license agreement for ProBioGen's AGE suspension cell line, an innovative and proven platform that should enable high-yield and scalable production, ensuring efficient industrial manufacturing processes. The AGE1 cell line's versatility allows it to support a wide range of viruses and vaccine types, enhancing its suitability for various vaccines in development and as a replacement for traditional production systems. MVA grows particularly well on this cell line, making it even more advantageous for vaccine development. The Company's transition to an innovative advanced MVA manufacturing process is anticipated to provide scalable, flexible, and cost-effective vaccine production, reducing reliance on foreign vaccine manufacturers and reinforcing domestic biosecurity.

Developing a high-yield, high-capacity process to produce MVA-based vaccines and immunotherapies constitutes a transformational development – for GeoVax, biomedicine, and the public's health. By advancing our MVA manufacturing to a modern, interchangeable process, we are on course to expand MVA applications from stockpile-based solutions for niche medical markets to respond to world needs on a timely basis, whenever and wherever they arise. We believe that this capability puts us in the position to be the first supplier of MVA-based vaccines to implement such a transformative manufacturing process and becoming the first U.S.-based supplier of the MVA vaccine to prevent Mpox, smallpox and other pox-related viruses.

Competition

Our product candidates face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions. We compete in an industry that is characterized by rapid technological change; evolving industry standards; emerging competition; and new product introductions. Competitors have existing products and technologies that will compete with our pipeline candidates and technologies and may develop and commercialize additional products and technologies that will compete with our pipeline candidates and technologies. Because competing companies and institutions may have greater financial resources than us, they may be able to provide broader services and product lines; and make greater investments in research and development. Competitors may also have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. They may also have greater name recognition and better access to customers.

We face general market competition from several subsectors of the vaccine development field, including large, multinational pharmaceutical companies including Sanofi, GSK, Merck, Janssen, Mitsubishi Tanabe, Takeda, and Pfizer; mid-size pharmaceutical companies and emerging biotechnology companies including Dynavax, Novavax Inc., Moderna, BioNTech and Bavarian Nordic; and academic and not-for-profit vaccine researchers and developers including the NIH. The industry is typified by extensive collaboration, licensing, and merger and acquisition activity despite the intense competition.

More than forty COVID-19 vaccines are currently authorized for use in one or more countries around the world, including three in the United States (from Pfizer/BioNTech, Moderna, and Janssen). All these vaccines are based on the S protein of the SARS-CoV-2 virus but rely on different mechanisms for presentation or expression of the S antigen, including whole, inactivated virus, defective adenovirus vectors (three different types) or mRNA. The WHO reports that there are 180 COVID products in clinical development.

A number of companies are developing various types of therapeutic vaccines or other immunotherapy approaches to treat cancer including Advaxis, Immune Design, Oncothyreon, Bavarian Nordic, Roche Pharmaceuticals, Merck & Co, Bristol Myers Squibb, and AstraZeneca plc.

There are currently no FDA licensed and commercialized Zika vaccines, or hemorrhagic fever virus vaccines (other than for Ebola Zaire) available in the world market. We are aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, which are actively engaged in vaccine research and development in these areas. For hemorrhagic fever viruses, these include NewLink Genetics and Merck, Johnson & Johnson, Novavax, Inovio and

GlaxoSmithKline. For Zika, these include NewLink Genetics, Inovio, Merck, Butantan Institute and NIH (NIAID). In December 2019, the FDA approved the first vaccine (ERVEBO®) for prevention of Ebola Zaire, developed by Merck.

In October 2021, the WHO approved the first malaria vaccine, RTS, S. It requires 4 doses and is based on a single antigen and has modest efficacy (approximately 50%, depending on the age of subjects), the WHO has defined a Road Map for developing and licensing of next generation malaria vaccines. More recently, a vaccine, R21/Matrix-M™, jointly developed by Oxford University and the Serum Institute of India has met the WHO targeted efficacy to block both infection and transmission of malaria with at least a 75% efficacy rate.

Our Intellectual Property

Our commercial success depends in part on our ability, and our licensors' ability, to obtain and maintain proprietary protection for our clinical product candidates, including our MVA-VLP-based vaccines, our in-licensed synthetic MVA COVID-19 vaccine candidate, and our in-licensed Gedeptin gene-directed enzyme prodrug therapy, and methods of treatment using the same.

We, and in collaboration with our licensors for our in-licensed assets, seek patent protection on each of our product and developmental candidates and, where applicable, on combinations with other therapeutic and/or antigenic agents and dosing schedules. Our success also depends on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. patent applications and, where appropriate, foreign patent applications covering our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. We collaborate with our licensors to ensure the filing of U.S. patent applications and, where appropriate, foreign patent applications covering our in-licensed technology, inventions, and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit, where appropriate, from statutory frameworks in the United States, Europe, and other countries that provide a period of clinical data exclusivity to compensate for the time required for regulatory approval of our clinical product candidates.

We continually assess and refine our intellectual property strategies as we develop new technologies and product candidates. We plan to file additional patent applications based on our intellectual property strategies where appropriate, including where we seek to improve our basic technology, adapt to competition, or to improve business opportunities. Further, we plan to file patent applications, as we consider appropriate under the circumstances, to protect new technologies that we develop. Our patent filing strategy typically includes seeking patent protection in the United States and, wherein appropriate, in additional countries where we believe such protection is likely to be useful.

Currently, our owned, co-owned, and in-licensed patent estate, on a worldwide basis, includes 18 granted or allowed U.S. patent applications, 18 pending U.S. patent applications; 31 granted foreign patents, 67 pending foreign patent applications, 1 Patent Cooperation Treaty (PCT) application, and 1 U.S. provisional application spread over 23 patent families. The term of individual patents depends upon the laws of the countries in which they are obtained. In the countries in which we currently file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application which serves as a priority application. In addition, we plan to seek patent term adjustments, restorations, and/or patent term extensions where applicable in the United States and other jurisdictions. For example, depending upon the timing, duration, and specifics of FDA approval of our vaccine products, some of our U.S. patents may be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Amendments," and codified as 35 U.S.C. § 156. 35 U.S.C. § 156 permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an Investigational New Drug (IND) application and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved vaccine product is eligible for such an extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office (USPTO), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. A similar kind of patent extension, referred to as a Supplementary Protection Certificate, is available in Europe. Legal frameworks are also available in certain other jurisdictions to extend the term of a patent. We currently intend to seek patent term extensions on any of our, or our exclusively licensed, issued patents in any jurisdiction where we have a qualifying patent and the extension is available; however, there is no guarantee that the applicable regulatory authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Further, even if our patent is extended, the patent, including the extended portion of the patent, may be held invalid or unenforceable by a court of final jurisdiction in the United States or a foreign country.

We wholly own one granted U.S. patent (US 11,701,418) directed to preventive vaccines against Ebola virus, and one granted U.S. patent (US 11,896,657) directed to Marburg virus and uses thereof. These patents, where issued, valid, and enforceable, will expire in 2036, exclusive of any patent term extensions.

We wholly own one granted U.S. patent (US 11,638,750) directed to preventive vaccines against Zika virus and uses thereof. This patent where issued, valid, and enforceable, will expire in 2037, exclusive of any patent term adjustments.

We wholly own two granted U.S. patents (U.S. 11,311,612 and US 11,857,611), and an allowed U.S. patent application directed to preventive vaccines against malaria and use thereof. These applications, where issued, valid, and enforceable, will expire in 2038, exclusive of any patent term adjustments or extensions.

We wholly own two patent families, which include three granted U.S. patents (U.S. 11,278,607, U.S. 11,413,341 and U.S. 12,247,214), and granted foreign applications in Australia, Europe (validated in Germany, Spain, France, Great Britain, Italy, Poland, Turkey, and Switzerland), China, Japan, and India directed to our immuno-oncology vaccine compositions and methods of use thereof. Applications are pending in the United States, Canada, China, and Hong Kong. The patent applications of these families, where issued, valid, and enforceable, will expire between 2037-2040, exclusive of any patent term adjustments or extensions.

We wholly own one pending patent family directed to various MVA-based vaccines for the treatment of SARS CoV-2. Applications have been filed in the United States, Argentina, Australia, Brazil, Canada, China, Hong Kong, the European Patent Office, Israel, Japan, South Korea, Mexico, South Africa, and Taiwan. The patent applications in these families, if issued, valid, and enforceable, will expire in 2041, exclusive of any patent term adjustments or extensions. We have non-exclusively in-licensed from the NIH 2 patent families directed to certain aspects of our MVA-viral backbone used in our SARS-CoV2 vaccine, which will expire between 2027 and 2032. We have non-exclusively in-licensed from the NIH 2 patent families relating to coronavirus spike protein compositions relevant to our MVA SARS-CoV2 vaccine candidates. The patent applications for these families, where issued, valid, and enforceable, will expire between 2037 and 2041, exclusive of any patent term adjustments or extensions.

We also wholly own one pending PCT application directed to pan-betacoronavirus MVA-based vaccines. This patent family if issued, valid and enforceable, will expire in 2045, exclusive of any patent term adjustments or extensions.

We co-own with Leidos, Inc. one patent family directed to viral constructs for use in enhancing T-cell priming during vaccination. Applications have been filed in United States, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, and Taiwan. The patent applications in this patent family, if issued, valid, and enforceable, will expire in 2042, exclusive of any patent term adjustments or extensions.

The MVA backbone that we have been using in several of our vaccines was provided to us by the laboratory of Dr. Bernard Moss of the NIAID, Laboratory of Viral Diseases (LVD). We have a non-exclusive commercial license to the NIH MVA backbone for our SARS CoV-2 vaccine with the NIAID of the NIH on behalf of the United States, which includes the use of certain patents and patent applications arising from the Moss laboratory and the provided materials. This non-exclusive commercial license was further amended in December 2023 to expand the Field of Use to include the use of our SARS-CoV-2 vaccine against smallpox and/or Mpox. We also have a non-exclusive research and development license to use the MVA backbone for our other vaccine candidates. If we later decide to commercialize vaccine candidates that are under the research and development license, we will need to negotiate appropriate commercialization licenses. These in-licensed NIH patents and patent applications, if and where issued, valid, and enforceable, will expire between 2027 and 2032.

In November 2022, we executed a Material Transfer Agreement (MTA) with the NIH for the clinical and commercial use of an unmodified (parental) MVA 1974/NIH Clone I as a vaccine against monkeypox virus. The MTA is royalty-free, non-exclusive, and worldwide.

We have exclusively in-licensed five patent families from COH in the field of vaccine products targeted for prevention, reduction, amelioration or treatment of coronaviruses, including SARS-CoV-2, pursuant to an Exclusive License Agreement entered into on November 9, 2021, and as further amended on April 11, 2023. The in-licensed patent families are directed to synthetic MVA vectors, including synthetic MVA vaccines encoding one or more SARS-CoV-2 antigens, and their methods of production and use including for the prevention of a coronavirus and monkeypox infection, and encompass COH04S1, a multi-antigenic pan-SARS vaccine currently undergoing Phase 2 human clinical trials. These in-licensed COH patent families, if issued, valid, and enforceable, will expire between 2041 and 2043, exclusive of any patent term adjustments or extensions.

We have also exclusively in-licensed two additional patent families from COH in the field of vaccine products targeted for prevention, reduction, amelioration or treatment of SARS-CoV-2 variants. The in-licensed patent families are directed to synthetic MVA vectors, including synthetic MVA vaccines encoding one or more SARS-CoV-2 variant antigens, and their methods of production and use. Applications have been filed in the United States. These in-licensed COH patent families, if issued, valid, and enforceable, will expire in 2042, exclusive of any patent term adjustments or extensions.

We have exclusively in-licensed two patent families from the University of Alabama at Birmingham (UAB) and the Southern Research Institute (SRI) pursuant to an Assignment and License Agreement with PNP entered into on September 28, 2021. The two patent families are directed to the use of tail-mutant purine nucleoside phosphorylase enzymes and fludarabine for the treatment of cancer, and cover aspects of the use of our Gedeptin clinical product candidate. These in-licensed patent families, where issued, valid, and enforceable, will expire between 2029 and 2032, exclusive of any patent term adjustments or extensions.

We cannot be certain that any of the current pending patent applications we have or have licensed, or any new patent applications we may file or license, will ever be issued in the United States or any other country. Even if issued, there can be no assurance that those patents will be sufficiently broad to prevent others from using our products or processes. Furthermore, our patents, as well as those we have licensed or may license in the future, may be held invalid or unenforceable by a court, or third parties could obtain patents that we would need to either license or to design around, which we may be unable to do. Current and future competitors may have licensed or filed patent applications or received patents and may acquire additional patents or proprietary rights relating to products or processes competitive to ours. In addition, any claims relating to the infringement of third-party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, divert management's attention and resources and require us to enter royalty or license agreements which are not advantageous to us, if available at all.

We also expect to benefit, where appropriate, from statutory frameworks in the United States, Europe, and other countries that provide a period of regulatory exclusivity to compensate for the time and cost required in securing regulatory approval of our clinical products. For example, in 2010, the United States enacted the Biologics Price Competition and Innovation Act (BPCIA). Under the BPCIA, innovator manufacturers of biological products may be granted 12 years of exclusive use before biosimilar versions of such products can be licensed for marketing in the U.S. This means that the FDA may not approve an application for a biosimilar version of our products until 12 years after the date the product is approved for sale (with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results accepted by the FDA), although a biosimilar application may be submitted four years after the date we receive approval from the FDA to sell our product. Additionally, the BPCIA establishes procedures by which potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The BPCIA also provides incentives to biosimilar applicants by providing a period of exclusivity to the first biosimilar of a product approved by the FDA. The 12-year data exclusivity provision of the BPCIA does not prevent a competitor from seeking marketing approval of one of our products, or a product similar thereto, by submitting its own, original BLA.

We intend to benefit, where applicable, from additional market exclusivity provisions in various jurisdictions that reward the treatments of rare diseases. For example, in the United States under the Orphan Drug Act of 1983, the FDA may grant orphan designation to a vaccine product intended to prevent or treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication; in the latter case, because health care professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite our orphan exclusivity.

We are not a party to any litigation, opposition, interference, or other potentially adverse proceeding with regard to our patent positions. However, if we become involved in litigation, interference proceedings, oppositions or other intellectual property proceedings, for example as a result of an alleged infringement or a third-party alleging an earlier date of invention, we may have to spend significant amounts of money and time and, in the event of an adverse ruling, we could be subject to liability for damages, invalidation of our intellectual property and injunctive relief that could prevent us from using technologies or developing products, any of which could have a significant adverse effect on our business, financial conditions or results of

operations. In addition, any claims relating to the infringement of third-party proprietary rights, or earlier date of invention, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, divert management's attention and resources and require us to enter royalty or license agreements which are not advantageous if available at all.

In addition to patents, we rely upon unpatented, proprietary trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees, and consultants, and invention assignment agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Primary License Agreements

City of Hope License – On November 9, 2021, we entered into an Exclusive License Agreement (COH License) with COH, a California nonprofit public benefit corporation, under which the Company obtained exclusive worldwide rights to further develop and commercialize COH04S1, a multi-antigenic SARS-CoV-2 vaccine currently undergoing Phase 2 human clinical trials. The COH License grants GeoVax exclusive rights to key patents, know-how, regulatory filings and clinical materials for use against COVID-19. The terms of the COH License include milestone payments due upon the achievement of selected development, regulatory and sales events. The Company will also pay COH an annual royalty on net sales of products covered by the patents licensed from COH on a country-by-country and licensed product-by-licensed product basis, subject to specified reductions.

Gedeptin License – On September 28, 2021, we entered into an Assignment and License Agreement (Gedeptin License) with PNP under which the Company obtained exclusive worldwide rights to key intellectual property, including Gedeptin patents, know-how, regulatory filings, clinical materials, and trademarks. The Gedeptin patent portfolio was originally licensed from UAB and SRI by PNP. Under the terms of the Gedeptin License, the Company is the successor to PNP under the Exclusive License Agreement between UAB, SRI and PNP, and has acquired the exclusive rights to develop and commercialize Gedeptin, a novel patented product for the treatment of solid tumors.

The terms of the Gedeptin License include milestone payments due upon the achievement of selected development and regulatory events. The Company will also pay tiered percentage annual royalties in the low-to-mid teens on Net Sales (as defined in the Gedeptin License) of products covered under the Gedeptin License on a country-by-country and product-by-product basis, subject to specified reductions. The Gedeptin License will remain in effect during the original term, which concludes upon FDA approval of a generic or biosimilar product, and then will automatically renew for 5-year additional terms, subject to customary termination rights.

NIH Licenses – On December 16, 2022, the Company entered into a Clinical Materials Transfer Agreement (MVA Vaccine Agreement) under which the Company has the right to develop and commercialize the unmodified (parental) MVA 1974/NTH Clone 1 strain as a vaccine against Mpox and smallpox.

On November 25, 2020, the Company entered into a Patent and Biological Materials License Agreement for Internal Research Use (Research License) with HHS, as represented by NIAID, in support of the Company's non-clinical development of vaccines against numerous pathogens. The Research License allows GeoVax to use these materials and patent rights owned by agencies of the HHS in combination with the Company's proprietary technology for the creation of preventive and/or therapeutic MVA-VLP vaccines against Ebola-Zaire virus, Ebola-Sudan virus, Lassa virus, Marburg virus, Zika virus and malaria. The agreement also extends to the Company's research and development efforts in certain oncology areas. The agreement provides GeoVax with nonexclusive rights for the nonclinical development and manufacturing of its vaccine and immunotherapy candidates using HHS patents and materials.

On October 22, 2020, the Company entered into a Patent and Biological Materials License Agreement (COVID License) with HHS, as represented by NIAID, in support of the Company's development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The COVID License allows GeoVax to use these materials and patent rights owned by agencies of the HHS in combination with the Company's proprietary technology for the creation of a preventive MVA-VLP vaccine that primes and/or boosts the immune system against COVID-19. The COVID License provides GeoVax with nonexclusive rights to develop, manufacture and commercialize its COVID-19 vaccine and includes access to NIAID's patent rights in the stabilized S protein, which is the protein that SARS-CoV-2 uses to gain entry into human tissue. In December 2023, the COVID License was amended to expand GeoVax's commercial license to include Mpox and smallpox as additional indications.

Research and Development

Our expenditures for research and development activities were \$23.7 million and \$20.7 million during the years ended December 31, 2024 and 2023, respectively. As our vaccines continue to go through the process to obtain regulatory approval, we expect our research and development costs to increase. We have not yet formulated any plans for marketing and sales of any vaccine candidate we may successfully develop. Compliance with environmental protection laws and regulations has not had a material effect on our capital expenditures, earnings or competitive position to date.

Scientific Advisors

We seek advice from our Scientific Advisory Board, which consists of leading scientists, on scientific and medical matters. The current members of our Scientific Advisory Board are:

Name	Position/Institutional Affiliation
Olivera J. Finn, PhD	Distinguished Professor of Immunology and Surgery, University of Pittsburgh
Teresa Lambe, PhD, OBE, FMedSci	Calleva Head of Vaccine Immunology, Oxford Vaccine Group, University of Oxford
Harriet L. Robinson, PhD	Chief Scientific Officer Emeritus, GeoVax
Scott C. Weaver, PhD	Director, University of Texas Medical Branch Institute for Human Infections and Immunity

Human Capital Resources

We currently have seventeen full-time employees. None of our employees are covered by collective bargaining agreements and we believe that our employee relations are good. We also engage consultants and independent contractors to fulfill key roles and/or provide expert services on both an ongoing and short-term basis.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive compensation, opportunity for equity ownership, and a robust employment package that promotes wellness across all aspects of their lives, including healthcare, retirement planning, and paid time off.

Corporate Background

Our primary business is conducted by our wholly owned subsidiary, GeoVax, Inc., which was incorporated under the laws of Georgia in June 2001. Our address is 1900 Lake Park Drive, Smyrna, Georgia 30080, and our telephone number at that address is 678-384-7220. The predecessor of our parent company, GeoVax Labs, Inc. (the reporting entity) was originally incorporated in June 1988 under the laws of Illinois as Dauphin Technology, Inc. (Dauphin). 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. We currently do not conduct any business other than GeoVax, Inc.'s business of developing new products for the treatment or prevention of human diseases. Our principal offices are in Smyrna, Georgia (metropolitan Atlanta).

Available Information

Our website address is www.geovax.com. We make our filings with the U.S. Securities and Exchange Commission (SEC), such as proxy statements, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports available on this website under "Investors – SEC Reports," free of charge, as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. We also make available our Code of Business Conduct on this website under the heading "Investors – Corporate Governance". Information contained on our website is not incorporated into this Annual Report.

ITEM 1A. RISK FACTORS

Ownership of our securities involves a high degree of risk. You should carefully review and consider the risks, uncertainties and other factors described below before you decide whether to own our securities. Any of these factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock, and you may lose some or all of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, may also impair our business operations. You should also refer to the other information contained in this Form 10-K, including our financial statements and the related notes.

Risks Related to Our Business and Capital Requirements

We have a history of operating losses, and we expect losses to continue for the foreseeable future.

As a research and development-focused company, we have had no product revenue to date and revenues from our government grants and other collaborations have not generated sufficient cash flows to cover operating expenses. Since our inception, we have incurred operating losses each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with our operations. We incurred a net loss of approximately \$25 million for the year ended December 31, 2024. We expect to incur additional operating losses and expect cumulative losses to increase as our research and development, preclinical, clinical, and manufacturing efforts expand. Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of our product candidates, conduct preclinical tests and clinical trials, obtain the necessary regulatory approvals, and manufacture and market or otherwise commercialize our products. Unless we are able to successfully meet these challenges, we will not be profitable and may not remain in business.

We have received a going concern opinion from our auditors.

We have received a "going concern" opinion from our independent registered public accounting firm, reflecting substantial doubt about our ability to continue as a going concern. Our consolidated financial statements contemplate that we will continue as a going concern and do not contain any adjustments that might result if we were unable to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional capital and implement our business plan. If we are unable to achieve or sustain profitability or to secure additional financing on acceptable terms, we may not be able to meet our obligations as they come due, raising substantial doubts as to our ability to continue as a going concern. Any such inability to continue as a going concern may result in our stockholders losing their entire investment. There is no guarantee that we will become profitable or secure additional financing on acceptable terms.

Our business will require continued funding. If we do not receive adequate funding, we may not be able to continue our operations.

To date, we have financed our operations principally through the sale of our equity securities and through government grants and clinical trial support. We will require substantial additional financing at various intervals for our operations, including clinical trials, operating expenses, intellectual property protection and enforcement, for pursuit of regulatory approvals, and for establishing or contracting out manufacturing, marketing and sales functions. There is no assurance that such additional funding will be available on terms acceptable to us or at all. If we are not able to secure the significant funding that is required to maintain and continue our operations at current levels, or at levels that may be required in the future, we may be required to delay clinical studies or clinical trials, curtail operations, or obtain funds through collaborative arrangements that may require us to relinquish rights to some of our products or potential markets.

We may pursue additional support from the federal government for our vaccine and immunotherapy development programs; however, as we progress to the later stages of our development activities, government financial support may be more difficult to obtain, or may not be available at all. Therefore, it will be necessary for us to look to other sources of funding to finance our development activities.

We will need to raise additional funds to significantly advance our vaccine development programs and to continue our operations. In order to meet our operating cash flow needs we plan to seek sources of non-dilutive capital through government grant programs and clinical trial support. We may also plan additional offerings of our equity securities, debt, or convertible debt instruments. To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience dilution, and debt financings, if available, may involve restrictive covenants and substantial fixed payments or may otherwise further constrain our financial flexibility. Should the financing we require to sustain our working capital needs be unavailable or prohibitively

expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

A significant portion of the funding to further develop GEO-CM04S1, our next-generation COVID-19 vaccine candidate, is currently expected to come from the U.S. government. If the government were to eliminate, reduce, or delay funding available to us under the ATI-RRPV Contract, this could have a significant negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate or obtain alternative sources of funding.

We anticipate that a significant portion of the funding for the continued development of GEO-CM04S1, our next generation self-COVID-19 vaccine candidate, will stem from the ATI-RRPV Contract. As awarded, the ATI-RRPV Contract currently makes available an aggregate amount of up to \$26.2 million (which may increase to as much as \$45 million), for reimbursement of costs incurred for manufacturing of clinical materials and support for a 10,000 patient Phase 2b clinical trial, including regulatory activities. BARDA has made a separate award of \$343 million to Allucent, a global CRO, to execute the clinical trial as part of BARDA's Clinical Studies Network. As of December 31, 2024, we have recognized approximately \$4.0 million in revenue pursuant to the ATI-RRPV Contract based on costs incurred.

As a standard government contract, BARDA is entitled to terminate the ATI-RRPV Contract for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. Further, BARDA may suspend or terminate the ATI-RRPV Contract should we fail to achieve key milestones or fail to comply with the operating procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols, and there can also be no assurance that BARDA will not terminate or suspend the ATI-RRPV Contract.

If the ATI-RRPV Contract is terminated or suspended, or if there is any government decision not to continue funding or reduction or delay in funding under the ATI-RRPV Contract, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us, or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities for GEO-CM04S1, which could materially harm our business.

Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business.

We rely upon a combination of information technology systems and traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including, but not limited to, personal information and intellectual property). We have also outsourced elements of our operations to third parties, including elements of our information technology systems and, as a result, we manage a number of independent vendor relationships with third parties who may or could have access to our confidential information. Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, or data loss from inadvertent or intentional actions by our employees or vendors. Our information technology and information security systems and records are also potentially vulnerable to malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of expertise and motives (including, but not limited to, financial crime, industrial espionage, and market manipulation).

While we have invested, and continue to invest, a portion of our limited funds in our information technology and information security systems, there can be no assurance that our efforts will prevent security breaches, service interruptions, or data losses. Any security breaches, service interruptions, or data losses could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities.

Risks Related to Development and Commercialization of Product Candidates and Dependence on Third Parties

Our products are still being developed and are unproven. These products may not be successful.

To become profitable, we must generate revenue through sales of our products. However, our products are in varying stages of development and testing. Our products have not been proven in human clinical trials and have not been approved by any government agency for sale. If we cannot successfully develop and prove our products and processes, or if we do not develop other sources of revenue, we will not become profitable and at some point, we would discontinue operations.

We depend upon key personnel who may terminate their employment with us at any time. If we were to lose the services of any of these individuals, our business and operations may be adversely affected.

The success of our business strategy will depend to a significant degree upon the continued services of key management, technical and scientific personnel and our ability to attract and retain additional qualified personnel and managers. Competition for qualified personnel is intense among companies, academic institutions and other organizations. The ability to attract and retain personnel is adversely affected by our financial challenges. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test, commercialize and market our products and product candidates.

Regulatory and legal uncertainties could result in significant costs or otherwise harm our business.

To manufacture and sell our products, we must comply with extensive domestic and international regulation. In order to sell our products in the United States, approval from the FDA is required. Satisfaction of regulatory requirements, including FDA requirements, typically takes many years, and if approval is obtained at all, it is dependent upon the type, complexity and novelty of the product, and requires the expenditure of substantial resources. We cannot predict whether our products will be approved by the FDA. Even if they are approved, we cannot predict the time frame for approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to meet than FDA requirements. As with the FDA, we cannot predict if or when we may obtain these regulatory approvals. If we cannot demonstrate that our products can be used safely and successfully in a broad segment of the patient population on a long-term basis, our products would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles. For example, the current U.S. presidential administration has committed to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS and the FDA. Further, in an effort to contain the U.S. federal budget deficit, the pharmaceutical industry could be considered a potential source of savings and could be the target of legislative proposals aimed at reducing federal expenditures. Efforts by the current administration or Congress to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

We face intense competition and rapid technological change that could result in products that are superior to, or earlier to the market than, the products we will be commercializing or developing.

The market for vaccines that protect against or treat human infectious diseases is intensely competitive and is subject to rapid and significant technological change. We have numerous competitors in the United States and abroad, including, among others, large companies with substantially greater resources than us. If any of our competitors develop products with efficacy or safety profiles significantly better than our products, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed. Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to ours.

Our product candidates are based on new medical technology and, consequently, are inherently risky. Concerns about the safety and efficacy of our products could limit our future success.

We are subject to the risks of failure inherent in the development of product candidates based on new medical technologies. These risks include the possibility that the products we create will not be effective, that our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals, and that our product candidates will be difficult to manufacture on a large scale or will be uneconomical to market.

Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long-term follow-up data may reveal previously unidentified complications associated with our products. The responses of potential physicians and others to information about complications could materially adversely affect the market acceptance of our products, which in turn would materially harm our business.

We may experience delays in our clinical trials that could adversely affect our financial results and our commercial prospects.

We do not know whether planned pre-clinical and clinical trials will begin on time or whether we will complete any of our trials on schedule, if at all. Product development costs will increase if we have delays in testing or approvals, or if we need to perform more or larger clinical trials than planned. Significant delays may adversely affect our financial results and the commercial prospects for our products and delay our ability to become profitable.

We rely heavily on independent clinical investigators, vaccine manufacturers, and other third-party service providers for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

Failure to obtain timely regulatory approvals required to exploit the commercial potential of our products could increase our future development costs or impair our future sales.

None of our vaccines are approved by the FDA for sale in the United States or by other regulatory authorities for sale in foreign countries. To exploit the commercial potential of our technologies, we are conducting and planning to conduct additional pre-clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials could delay or preclude regulatory approval and restrict our ability to commercialize our technology or products. Any such failure may severely harm our business. In addition, any approvals we obtain may not cover all of the clinical indications for which approval is sought or may contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post-approval study requirements.

State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless we are in full compliance with these laws, we could face enforcement action, fines, and other penalties and could receive adverse publicity, all of which could harm our business.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

In the United States and foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act includes a number of provisions that are intended to lower healthcare costs, including provisions relating to prescription drug prices and government spending on medical products.

Since its enactment, there have also been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the former Trump administration to repeal or replace certain aspects of the statute. We continue to evaluate the effect that the Affordable Care Act and subsequent changes to the statute has on our business. Changes in legislation, regulation or policy increase the likelihood that we will fail to appropriately adapt to changes in our compliance obligations, particularly

when such changes happen abruptly, such as following a change in government. It is uncertain the extent to which any such changes may impact our business or financial condition.

There has also been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products. There have been several Congressional inquiries and proposed bills, as well as state efforts, designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In June 2017, the FDA issued a Drug Competition Action plan intended to lower prescription drug prices by encouraging competition from generic versions of existing products. In July 2018, the FDA issued a Biosimilar Action Plan, intended to similarly promote competition to prescription biologics from biosimilars.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, in September 2017, the California State Assembly approved SB17, which requires pharmaceutical companies to notify health insurers and government health plans at least 60 days before any scheduled increases in the prices of their products if they exceed 16% over a two-year period, and further requiring pharmaceutical companies to explain the reasons for such increase. Effective in 2016, Vermont passed a law requiring certain manufacturers identified by the state to justify their price increases.

We expect that these, and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

We may not be successful in establishing collaborations for product candidates we seek to commercialize, which could adversely affect our ability to discover, develop, and commercialize products.

We expect to seek collaborations for the development and commercialization of product candidates in the future. The timing and terms of any collaboration will depend on the evaluation by prospective collaborators of the clinical trial results and other aspects of a product's safety and efficacy profile. If we are unable to reach agreements with suitable collaborators for any product candidate, we will be forced to fund the entire development and commercialization of such product candidates, ourselves, and we may not have the resources to do so. If resource constraints require us to enter into a collaboration agreement early in the development of a product candidate, we may be forced to accept a more limited share of any revenues the product may eventually generate. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish collaborations or other alternative arrangements for any product candidate. Even if we are successful in establishing collaborations, we may not be able to ensure fulfillment by collaborators of their obligations or our expectations.

We do not have manufacturing, sales or marketing experience.

We do not have experience in manufacturing, selling, or marketing. To obtain the expertise necessary to successfully manufacture, market, and sell our products, we must develop our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to execute our current operating plan is dependent on numerous factors, including, the performance of third-party collaborators, vendors and contractors.

Our products under development may not gain market acceptance.

Our products may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Significant factors in determining whether we will be able to compete successfully include:

- the efficacy and safety of our products;
- the time and scope of regulatory approval;
- reimbursement coverage from Medicare, Medicaid, insurance companies and others;
- the price and cost-effectiveness of our products, especially as compared to any competitive products; and
- the ability to maintain patent protection.

We may be required to defend lawsuits or pay damages for product liability claims.

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. We carry product liability insurance and we expect to continue such policies. However, product liability claims, regardless of their merits, could exceed policy limits, divert management's attention, and adversely affect our reputation and demand for our products.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.

Market acceptance of products we develop, if approved, will depend on reimbursement policies and may be affected by, among other things, future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any products that we may develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize products that we develop.

Risks Related to Our Intellectual Property

Our success depends on our ability to obtain, maintain, protect, and enforce our intellectual property and our proprietary technologies.

In general, our commercial success will depend in part on our and our licensors' ability to obtain, maintain, protect, and enforce our intellectual property and proprietary technologies, including patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing, misappropriating, or otherwise violating the intellectual property rights of others. If we or our licensors are unable to obtain, maintain, protect, or enforce our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed, which could have a material adverse impact on our business, results of operations, financial conditions, and prospects. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents if issued will not be infringed, misappropriated, violated, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our intellectual property is uncertain. Only limited protection may be available and may not adequately obtain, maintain, protect, and enforce our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly obtain, maintain, protect, and enforce the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our in-licensed pending patent applications will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that claims that may ultimately issue from our patent applications will not be found invalid or unenforceable if challenged. If we or our licensors are unable to obtain or maintain patent protection with respect to our product candidates, our business, financial condition, results of operations, and prospects could be materially harmed.

We could lose our license rights to our important intellectual property if we do not fulfill our contractual obligations to our licensors.

Our rights to significant parts of the technology we use in our products are licensed from third parties and are subject to termination if we do not fulfill our contractual obligations to our licensors. Termination of intellectual property rights under any of our license agreements could adversely impact our ability to produce or protect our products. Our obligations under our license agreements include requirements that we make milestone payments to our licensors upon the achievement of clinical development and regulatory approval milestones, royalties as we sell commercial products, and reimbursement of patent filing and maintenance expenses. Should we become bankrupt or otherwise unable to fulfill our contractual obligations, our licensors could terminate our rights to critical technology that we rely upon.

Other parties may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling products.

Our success will depend in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use and sale of biologic products have been subject to substantial patent litigation in the biopharmaceutical industry. Such lawsuits often relate to the validity or infringement of patents or other proprietary rights of third parties. Pharmaceutical companies, biotechnology companies, universities, research institutions or other third parties may have filed patent applications or may have been granted patents that cover aspects of our products or our licensors' products, product candidates or other technologies.

Future or existing patents issued to third parties may contain patent claims that cover our products or their use or manufacture. In particular, the patent landscape in the COVID-19 vaccine space is crowded, and a large number of patent applications have been filed by numerous entities since January 2020, including for the use of certain SARS-CoV-2 antigens and antigenic combinations, including from Moderna, Janssen Pharmaceuticals, Inc., Sementis LTD., VaxBio, Inc., Oxford University, BioNTech, Ichan School of Medicine at Mount Sinai, Diosynvax LTD., The University of Alberta, University of Texas, and Tonix Pharmaceuticals. If a third party were to assert an infringement claim against us in the future with respect to our current products or with respect to products that we may develop or license, such litigation or interference proceedings could force us to:

- stop or delay selling, manufacturing or using products that incorporate, or are made using the challenged intellectual property;
- pay damages; or
- enter into licensing or royalty agreements that may not be available on acceptable terms, if at all.

Any litigation or interference proceedings, regardless of their outcome, may delay the regulatory approval process, be costly and require significant time and attention of our key management and technical personnel.

Any inability to protect our or our licensors' intellectual property rights in the United States and foreign countries could limit our ability to prevent others from manufacturing or selling our products.

We will rely on trade secrets, unpatented proprietary know-how, continuing technological innovation and, in some cases, patent protection to preserve our competitive position. Our patents and licensed patent rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products with acceptable patent protection. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. If patents containing competitive or conflicting claims are issued to third parties, we may be prevented from commercializing the products covered by such patents or may be required to obtain or develop alternate technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies.

Some of our patent families and our in-licensed patent families are in an early stage of prosecution and cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents are issued from such applications, and then only to the extent the issued claims cover the third-party technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies. There can be no assurance that the patents if issued will not be infringed, misappropriated, violated, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our intellectual property is uncertain. Only limited protection may be available and may not adequately obtain, maintain, protect, and enforce our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly obtain, maintain, protect, and enforce the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We may not be able to prevent third parties from infringing or using our intellectual property, and the parties from whom we may license intellectual property may not be able to prevent third parties from infringing or using the licensed intellectual property. We generally attempt to control and limit access to, and the distribution of, our product documentation and other proprietary information. Despite efforts to protect this proprietary information, unauthorized parties may obtain and use information that we may regard as proprietary. Other parties may independently develop similar know-how or may even obtain access to these technologies.

The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

Furthermore, even if our or our licensors' patent applications are granted, the patent term may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates have been or are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing, and regulatory review of product candidates, patents protecting our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing biotechnology patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation can increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Because patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent United States Supreme Court and Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, recent Federal Circuit rulings such as *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc), *Wyeth & Cordis Corp. v. Abbott Labs*, 720 F.3d 1380 (Fed. Cir. 2013), *Enzo Life Scis., Inc. v. Roche Molecular Sys.*, 928 F.3d 1340 (Fed. Cir. 2019), and *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), and *Amgen Inc. v. Sanofi*, 598 U.S. 594

(2023) have significantly heightened the standard for securing broad claims to pharmaceutical and biological products. In addition, recent Federal Circuit rulings such as *In re Collect*, 81 F.4th 1216 (Fed. Cir. 2023) have expanded the bases for invalidating a patent under the judicially created doctrine of obviousness-type double patenting.

In addition to heightened patentability requirements, recent Supreme Court and Federal Circuit cases relating to biosimilar product approval under the BPCIA, have held that the “patent dance” provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar, are discretionary, and a biosimilar applicant can opt out by refusing to provide a copy of its application and manufacturing information to the biologic sponsor (see *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017)). It may be that we do not learn of a biosimilar application until after FDA publishes its approval (see *Immunex v. Samsung Bioepis*, 2:19-cv-117555-CCC-MF (D.N.J. Apr. 30, 2019)). In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

The patent protection and patent prosecution for our product candidates is dependent in part on third parties.

We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors, fail to establish, maintain, or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for some of our in-licensed patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors fail to appropriately prosecute and maintain patent protection for patents covering our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the research resulting in certain of our in-licensed patent rights and technology was funded in part by the United States government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The United States government also has the right to take title to these

inventions if the applicable licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Risks Related to Our Securities

The market price of our Common Stock is highly volatile.

The market price of our Common Stock has been, and is expected to continue to be, highly volatile. Certain factors, including announcements of new developments by us or other companies, regulatory matters, new or existing medicines or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of Common Stock by us, and subsequent sales of Common Stock by the holders of our options and warrants could have an adverse effect on the market price of our shares.

In addition, the securities markets from time-to-time experience significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our Common Stock.

The sale or issuance of additional shares of our Common Stock or other equity securities could result in additional dilution to our stockholders.

In order to meet our operating cash flow needs, we may plan additional offerings of our equity securities, debt, or convertible debt instruments. The sale of additional equity securities could result in significant additional dilution to our stockholders. The incurrence of indebtedness could result in debt service obligations and operating and financing covenants that would restrict our operations. We cannot assure investors that financing will be available in amounts or on terms acceptable to us, if at all.

We are obligated to issue additional shares of our Common Stock in connection with our outstanding warrants if the warrant holders choose to exercise them. There are pre-funded warrants currently exercisable for approximately 2.1 million shares and other warrants currently exercisable for approximately 10.1 million shares with a weighted average exercise price of \$2.61 per share. The exercise of these warrants will cause us to issue additional shares of our Common Stock and will dilute the percentage ownership of our shareholders.

Certain provisions of our certificate of incorporation which authorize the issuance of shares of preferred stock may make it more difficult for a third party to effect a change in control.

Our certificate of incorporation authorizes our Board of Directors to issue up to 10,000,000 shares of preferred stock. The shares of preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by the stockholders. These terms may include voting rights, including the right to vote as a series on particular matters, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The issuance of any newly issued preferred stock could diminish the rights of holders of our Common Stock, and therefore could reduce the value of our Common Stock. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell assets to, a third party. The ability of our Board of Directors to issue preferred stock could make it more difficult, delay, discourage, prevent or make it costlier to acquire or effect a change-in-control, which in turn could prevent the stockholders from recognizing a gain in the event that a favorable offer is extended and could materially and negatively affect the market price of our Common Stock.

We have never paid dividends and have no plans to do so.

Holders of shares of our Common Stock are entitled to receive such dividends as may be declared by our Board of Directors. To date, we have paid no cash dividends on our shares of Common Stock and we do not expect to pay cash dividends on our Common Stock in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any potential return investors may have in our Common Stock will be in the form of appreciation, if any, in the market value of their shares of Common Stock.

Public company compliance may make it more difficult for us to attract and retain officers and directors.

The Sarbanes-Oxley Act, the Dodd-Frank Act, the JOBS Act, the FAST Act, and rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, we expect these rules and regulations, and amendments to them, to contribute to our compliance costs and to make certain activities more time consuming and costly. As a public company, we also expect that these rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

Our Certificate of Incorporation and Bylaws may be amended by the affirmative vote of a majority of our stockholders.

Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended by the affirmative vote of the holders of a majority of the outstanding shares entitled to vote, and a majority of the outstanding shares of each class entitled to vote as a class, unless the articles require the vote of a larger percentage of shares. Our Certificate of Incorporation, as amended, does not require the vote of a larger percentage of shares. As permitted under the Delaware General Corporation Law, our Bylaws give our board of directors the power to adopt, amend, or repeal our Bylaws. Our stockholders entitled to vote have concurrent power to adopt, amend, or repeal our Bylaws.

Broker-dealers may be discouraged from effecting transactions in shares of our Common Stock if we are considered to be a penny stock and thus subject to the penny stock rules.

The SEC has adopted a number of rules to regulate "penny stocks" that restrict transactions involving stock which is deemed to be penny stock. Such rules include Rules 3a51-1, 15g-1, 15g-2, 15g-3, 15g-4, 15g-5, 15g-6, 15g-7, and 15g-9 under the Exchange Act. These rules may have the effect of reducing the liquidity of penny stocks. "Penny stocks" generally are equity securities with a price of less than \$5.00 per share (other than securities registered on certain national securities exchanges or quoted on Nasdaq if current price and volume information with respect to transactions in such securities is provided by the exchange or system). Our securities have in the past constituted, and may again in the future, if we are delisted from Nasdaq, constitute, "penny stock" within the meaning of the rules. The additional sales practice and disclosure requirements imposed upon U.S. broker-dealers may discourage broker-dealers from effecting transactions in shares of our Common Stock, which could severely limit the market liquidity of such shares and impede their sale in the secondary market.

A U.S. broker-dealer selling penny stock to anyone other than an established customer or "accredited investor" (generally, an individual with net worth in excess of \$1,000,000 (exclusive of personal residence) or an annual income exceeding \$200,000, or \$300,000 together with his or her spouse) must make a special suitability determination for the purchaser and must receive the purchaser's written consent to the transaction prior to sale, unless the broker-dealer or the transaction is otherwise exempt. In addition, the "penny stock" regulations require the U.S. broker-dealer to deliver, prior to any transaction involving a "penny stock", a disclosure schedule prepared in accordance with SEC standards relating to the "penny stock" market, unless the broker-dealer or the transaction is otherwise exempt. A U.S. broker-dealer is also required to disclose commissions payable to the U.S. broker-dealer and the registered representative and current quotations for the securities. Finally, a U.S. broker-dealer is required to submit monthly statements disclosing recent price information with respect to the "penny stock" held in a customer's account and information with respect to the limited market in "penny stocks".

Stockholders should be aware that, according to the SEC, the market for "penny stocks" has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) "boiler room" practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, resulting in investor losses. Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities.

If we are not able to comply with the applicable continued listing requirements or standards of Nasdaq, our Common Stock and related warrants could be delisted from the exchange.

Our Common Stock (GOVX) and related warrants (GOVXW) are currently listed on Nasdaq. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director

independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to continue to comply with the applicable listing standards.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 1C. CYBERSECURITY

Risk oversight and management is a key role for the Board and its committees. The Board is responsible for identifying and understanding the Company's principal risks and ensuring that appropriate systems are implemented to monitor, manage and mitigate those risks. The committees of the Board have oversight over risks within their respective mandates.

Oversight of cybersecurity is integrated into the responsibilities of the Board. The Nominating and Governance Committee (NGC) has been assigned oversight of cybersecurity matters, particularly as they relate to financial risk and controls, integrity of financial data and public disclosures, and security of overall digital data.

Management is responsible for the implementation of risk management strategies and for the operational oversight of company-wide cybersecurity strategy, policy, and standards to assess and prepare us to address cybersecurity risks. We have evolving processes for assessing, identifying and managing cybersecurity risks, which are built into our information technology function and are designed to help protect our information assets and operations from cyber threats, protect employee and corporate information from unauthorized access or attack, as well as secure our networks and systems. Such processes include physical, procedural and technical safeguards, response plans, and routine review of our policies and procedures to identify risks and refine our practices. The Company's information technology function (including cybersecurity) is centralized under the Chief Financial Officer, who has over three decades of business leadership experience including oversight of information technology functions. We also engage independent third parties to assess and implement our cybersecurity procedures and enhance our oversight.

The NGC receives periodic updates from management regarding cybersecurity matters and is notified between such updates regarding any significant new cybersecurity threats or incidents. We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

ITEM 2. PROPERTIES

Our principal executive offices are located in Smyrna, Georgia, where we lease approximately 8,400 square feet of office and laboratory space. Our lease for the premises is currently scheduled to terminate on December 31, 2025. We do not currently own any real property. We believe that our current facilities are adequate to meet our immediate needs and that if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may from time to time become involved in various legal proceedings such as those arising in the ordinary course of business.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "GOVX."

Holder

On March 25, 2025, there were 24 holders of record of our common stock. The majority of our shares of common stock are held by brokers and other institutions on behalf of stockholders, and we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

We have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, for reinvestment in our business. We will not be permitted to pay dividends on our common stock unless all dividends on any preferred stock that may be issued have been paid in full. We currently do not have any plans to issue additional preferred stock. Any credit agreements which we may enter into may also restrict our ability to pay dividends. The payment of dividends in the future will be subject to the discretion of our board of directors and will depend, among other things, on our financial condition, results of operations, cash requirements, future prospects and any other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during the period covered by this report that have not previously been reported on a Current Report on Form 8-K or a Quarterly Report on Form 10-Q.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of 2024.

ITEM 6. RESERVED

Not Applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and the related notes beginning on page F-1. This discussion contains forward-looking statements that involve risks and uncertainties because they are based on current expectations and relate to future events and our future financial performance. Our actual results may differ materially from those anticipated in these forward-looking statements because of many important factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report.

Overview and Recent Developments

GeoVax is a clinical-stage biotechnology company developing human vaccines and immunotherapies against infectious diseases and solid tumor cancers using novel proprietary platforms. GeoVax's most advanced product candidates include a next-generation COVID-19 vaccine, a gene-directed therapy for solid tumor cancers, and a vaccine against Mpox and smallpox. Additional research and development programs include preventive vaccines for hemorrhagic fever viruses (Ebola Zaire, Ebola Sudan and Marburg), and Zika virus.

Our corporate strategy is to advance, protect and exploit our differentiated vaccine/immunotherapy technologies leading to the successful development of preventive and therapeutic vaccines and immunotherapies against infectious diseases and various cancers. Our goal is to advance products through human clinical testing, and to seek partnership or licensing arrangements for achieving regulatory approval and commercialization. We also leverage third party resources through collaborations and partnerships for preclinical and clinical testing with multiple government, academic and corporate entities.

Our programs are in various stages of development, the most significant of which are summarized below along with recent developments:

- GEO-CM04S1 – Next Generation COVID-19 Vaccine:
 - In June 2024, GeoVax announced the receipt of an award through the RRPV to advance development of GEO-CM04S1 in a Phase 2b clinical trial. Under the ATI-RRPV Contract, GeoVax will sponsor a 10,000-participant, randomized, Phase 2b double-blinded study to assess the clinical efficacy, safety, and immunogenicity of GEO-CM04S1 compared with an FDA-approved mRNA COVID-19 vaccine. The RRPV is a consortium funded by BARDA, part of the ASPR in the HHS. The direct award to GeoVax, currently approximately \$26.2 million and which may increase to as much as \$45 million, is funding the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. BARDA has made a separate award of approximately \$343 million through its Clinical Studies Network to Allucent, a global clinical research organization, to execute the clinical trial as part of BARDA's Clinical Studies Network. Target clinical sites are confirmed and manufacturing activities are underway for production of the vaccine product needed for study activation.
 - GEO-CM04S1 is currently undergoing a Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT04977024), evaluating its safety and efficacy as a preventive COVID-19 vaccine in high-risk immunocompromised patients (i.e. patients with blood cancers who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant or CAR T cell therapy). Data published from the safety lead-in portion of the trial indicates that GEO-CM04S1 is highly immunogenic in these patients, inducing broad and durable neutralizing antibody and T cell responses.
 - GEO-CM04S1 is also undergoing the Phase 2 portion of a Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT04639466), evaluating two vaccine dose levels as a heterologous COVID-19 booster vaccine to current FDA-approved mRNA vaccines from Pfizer/BioNTech and Moderna. In February 2024, we announced positive interim safety and immune responses findings following vaccine administration. Consolidated data (blinded to vaccine dose) from all subjects tested one-month post-vaccination, documented statistically significant increases in neutralizing antibody responses against multiple SARS-CoV-2 variants, ranging from the original Wuhan strain through Delta and Omicron XBB 1.5.
 - An investigator-initiated Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT05672355) of GEO-CM04S1 is evaluating its use as a COVID-19 vaccine booster in patients with CLL compared to the Pfizer/BioNTech mRNA-based vaccine.
- Gedeptin[®]:
 - Gedeptin recently completed a Phase 1/2 clinical trial (PNP-002) (ClinicalTrials.gov Identifier: NCT03754933) for treatment of patients with advanced HNSCC. This trial is being funded in part by the FDA pursuant to its Orphan Products Clinical Trials Grants Program.
 - In July 2024, we announced that a special clinical advisory board completed a comprehensive review of the PNP-002 trial results, together with the previously completed Phase 1 trial (PNP-001). This review concluded that Gedeptin demonstrated an acceptable safety and efficacy profile to support continued development. In addition, the therapy has

demonstrated sufficient tumor stabilization/reduction activity to support plans to advance clinical development of Gedeptin therapy in an expanded Phase 2 clinical trial.

- We have initiated activities in support of a Phase 2 trial in first-recurrence head and neck cancer. The primary goal of this trial will be to establish efficacy of neoadjuvant Gedeptin therapy combined with an immune checkpoint inhibitor in squamous cell head and neck cancer. This trial is anticipated to be a single cycle trial with surgery to follow in approximately 36 patients with pathologic response rate as the primary endpoint. We have initiated the necessary planning activities, including protocol development, manufacturing and CRO selection.
- GEO-MVA:
 - GEO-MVA is the Company vaccine candidate in development for protection against Mpox and smallpox. MVA is the vaccine recommended by both the WHO and the U.S. Centers for Disease Control and Prevention against both Mpox and smallpox, recognized for its safety and efficacy among all patient populations, including pregnant women, children and immunocompromised individuals. MVA is the vaccine currently used and stockpiled in the United States Strategic National Stockpile for immunization against potential bioterrorism threats based on the smallpox virus.
 - A clinical batch of GEO-MVA has recently been produced under cGMP production. We expect to begin clinical evaluation of the vaccine during 2025.
- Our additional research programs for vaccines and immunotherapies at various stages of preclinical development.

Financial Overview

Revenue

Our revenues to date have been related to government grants and contracts and other collaborative arrangements in support of our product development activities. We have not generated any revenue to date from the sale of the products we are developing. Our product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that we advance to clinical testing will require regulatory approval prior to commercial use and will require significant costs for commercialization.

Research and development expenses

Since our inception, we have focused and we continue to focus significant resources on our research and development activities, including developing our vector platform and analytical testing methods, conducting preclinical studies, developing manufacturing processes, and conducting clinical trials. Research and development costs are expensed as incurred and consist primarily of the following:

- personnel costs in our research and development functions, including salaries, benefits and stock-based compensation;
- expenses incurred under agreements with CROs, for the conduct of clinical trials;
- expenses incurred under agreements with contract manufacturing organizations (CMOs) that manufacture product used in clinical trials;
- expenses incurred in procuring materials and for analytical and release testing services required to produce vaccine candidates used in clinical trials;
- process development expenses to improve the efficiency and yield of the bulk vaccine;
- laboratory supplies, vendor expenses and other third-party contract expenses related to preclinical research activities;
- technology license fees;
- consultant expenses for services supporting our clinical, regulatory and manufacturing activities; and
- facilities, depreciation and other general overhead expenses.

We expect our research and development expenditures to increase as we advance our existing and future product candidates into and through clinical trials and pursue regulatory approval, especially with regard to the ongoing and planned GEO-CM04S1, Gedeptin and GEO-MVA clinical programs. We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with biotechnology research and development. Due to these uncertainties, our future expenditures are likely to be highly volatile in future periods depending on the outcomes of the trials and studies. As we obtain data from preclinical studies and clinical trials, we may elect to discontinue or delay certain development programs to focus our resources on more promising product candidates. Completion of preclinical studies and human clinical trials may take several years or more, but the length of time can vary substantially depending upon several factors. The duration and the cost of future clinical trials may vary significantly over the life of the project because of differences arising during development of the human clinical trial protocols, including the length of time required to enroll suitable patient subjects, the number of patients that ultimately participate in the clinical trial, the duration of patient follow-up, and the number of clinical sites included in the clinical trials.

General and administrative expenses

Our general and administrative expenses consist primarily of personnel costs in our executive, finance, business development and other administrative functions, including stock-based compensation. Other general and administrative expenses include consulting fees, professional service fees for accounting and legal services, lease expenses related to our offices, insurance premiums, intellectual property costs incurred in connection with filing and prosecuting patent applications, depreciation and other costs. We expect our general and administrative expenses will increase in the future as we support expanded research and development activities, prepare for potential commercialization of our current and future product candidates, maintain compliance with requirements of Nasdaq and the SEC, and other general corporate activities.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and adjusts them as necessary. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are summarized in Note 2 to our consolidated financial statements for the year ended December 31, 2024, which are included in this Annual Report. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue Recognition

We recognize revenue in accordance with FASB Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which created a new Topic, Accounting Standards Codification Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

We receive payments from government entities under non-refundable grants in support of our vaccine development programs. We record revenue associated with these grants when the reimbursable costs are incurred and we have complied with all conditions necessary to receive the grant funds. From time to time, we may enter into collaborative research and development agreements for specific vaccine development approaches and/or disease indications whereby we receive third-party funding for preclinical research under certain of these arrangements. Each agreement is evaluated in accordance with the process defined by ASU 2014-09 and revenue is recognized accordingly.

Stock-Based Compensation

We account for stock-based transactions in which the Company receives services from employees, directors or others in exchange for equity instruments based on the fair value of the award at the grant date. Stock-based compensation cost for awards of common stock is estimated based on the price of the underlying common stock on the date of issuance. Stock-based compensation cost for stock options or warrants is estimated at the grant date based on each instrument's fair value as calculated by using the Black-Scholes option pricing model. We recognize stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period for the award. See Note 7 to our consolidated financial statements for the year ended December 31, 2024 for additional stock-based compensation information.

Research and Development Expense

Research and development costs are charged to expense as incurred and consist of costs incurred in the discovery, development, testing and manufacturing of our product candidates. These expenses consist primarily of (i) salaries, benefits, and stock-based compensation for personnel, (ii) laboratory supplies and facility-related expenses to conduct development, (iii) fees paid to third-party service providers to perform, monitor and accumulate data related to our preclinical studies and clinical trials, (iv) costs related to sponsored research agreements, (v) costs to procure and manufacture materials used in clinical trials, and (vi) license fees and other expenses associated with technology license agreements.

The Company accrues for estimated costs of research and development activities conducted by third-party service providers, which may include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including clinical trial participant enrollment, completion of events, invoices received and other events. Advance payments for research and development activities are deferred and included in prepaid expenses and other assets. The deferred amounts are expensed as the related goods are delivered or the services are performed.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	2024	2023	Change
Revenue from government contract	\$ 3,954,576	\$ -	\$ 3,954,576
Operating expenses:			
Research and development	23,713,602	20,720,766	2,992,836
General and administrative	5,385,254	6,022,173	(636,919)
Total operating expenses	29,098,856	26,742,939	2,355,917
Loss from operations	(25,144,280)	(26,742,939)	1,598,659
Interest income	173,359	776,177	(602,818)
Interest expense	(21,375)	-	(21,375)
Net loss	\$(24,992,296)	\$(25,966,762)	\$ 974,466

Revenue from Government Contract

During the year ended December 31, 2024, we reported \$3,974,576 of revenues associated with the ATI-RRPV Contract. There were no revenues reported during the comparable 2023 period.

Research and Development Expenses

Our research and development expenses were \$23,713,602 for the year ended December 31, 2024, as compared to \$20,720,766 for 2023, representing an increase of \$2,992,836 (14%). The increase during 2024 relates to program-specific costs associated with the ATI-RRPV Contract, Gedeptin and GEO-MVA, partially offset by lower costs for the GEO-CM04S1 clinical trials not covered by the ATI-RRPV Contract. The majority of the higher program costs relate to the ATI-RRPV Contract and include costs of manufacturing materials for use in our clinical trials, analytical expenses, third-party contracted research and consulting costs. Research and development expense for 2024 and 2023 includes stock-based compensation expense of \$222,202 and \$291,094, respectively, associated with employee stock options.

General and Administrative Expenses

Our general and administrative expenses were \$5,385,254 for the year ended December 31, 2024, as compared to \$6,022,173 for 2023, representing a decrease of \$636,919 (11%). The decrease during 2024 relates primarily to lower stock-based compensation expense, consulting costs, patent costs and franchise tax cost. General and administrative expense for 2024 and 2023 includes stock-based compensation expense of \$306,442 and \$783,863, respectively, associated with employee and consultant stock options and stock awards.

Other Income

Interest income was \$173,359 and \$776,177 for the years ended December 31, 2024 and 2023, respectively. The variances between years are primarily attributable to the cash available for investment and to interest rate fluctuations. Interest expense was \$21,375 and \$-0-, for the years ended December 31, 2024 and 2023, respectively, associated with certain notes payable issued during May 2024 and repaid in August 2024.

Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of December 31, 2024 and 2023, and our cash flows for the years then ended:

Liquidity and Capital Resources	As of December 31,	
	2024	2023
Cash and cash equivalents	\$ 5,506,941	\$ 6,452,589
Working capital	4,827,551	4,365,861

Cash Flow Data	Year Ended December 31,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (24,675,511)	\$ (25,173,639)
Investing activities	(20,653)	(48,946)
Financing activities	23,750,516	4,062,442
Net decrease in cash and cash equivalents	<u>\$ (945,648)</u>	<u>\$ (21,160,143)</u>

Operating Activities – Net cash used in operating activities of \$24,675,511 for 2024 was primarily due to our net loss of \$24,992,296, offset by non-cash items such as depreciation expense and stock-based compensation expense, and by changes in our working capital accounts. Net cash used in operating activities of \$25,173,639 for 2023 was primarily due to our net loss of \$25,966,762, offset by non-cash items such as depreciation expense and stock-based compensation expense, and by changes in our working capital accounts.

Investing Activities – Net cash used in investing activities was \$20,653 and \$48,946 for 2024 and 2023, respectively, and relates to purchases of laboratory equipment.

Financing Activities – Net cash provided by financing activities was \$23,750,516 for 2024, consisting of primarily of net proceeds from offerings of our common stock and the exercise of warrants. Net cash provided by financing activities was \$4,062,442 for 2023, consisting of net proceeds from the exercise of warrants.

Funding Requirements and Sources of Capital

To date, we have not generated any product revenue. We do not know when, or if, we will generate any product revenue and we do not expect to generate significant product revenue unless and until we obtain regulatory approval and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks incident to the development of new products, and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We anticipate that we will need substantial additional funding in connection with our continuing operations. We have funded our operations to date primarily from sales of our equity securities and from government grants and clinical trial assistance.

During 2024, we closed four registered direct offerings of our common stock and warrants, as well as established the ATM Program (see footnote 6 to the consolidated financial statements included in this Annual Report). Net proceeds to us from these offerings, after deducting commissions to the placement agent and sales agent, as applicable, and other related offering expenses, were approximately \$21.4 million. We also received approximately \$2.4 million upon the exercise of warrants.

During 2024, we entered into the ATI-RRPV Contract, which is intended to advance development of GEO-CM04S1 in a Phase 2b clinical trial. Pursuant to the ATI-RRPV Contract, we expect to receive direct funding of \$26.2 million (which may increase up to as much as \$45 million) to fund the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. Through December 31, 2024, we have recognized approximately \$4.0 million in revenue pursuant to the ATI-RRPV Contract based on costs incurred. BARDA has made a separate award of approximately \$343 million through its Clinical Studies Network to Allucent, a global clinical research organization, to execute the clinical trial as part of BARDA's Clinical Studies Network.

During the first quarter of 2025, we received approximately \$3.8 million of net proceeds from sales of our common stock through the ATM Program. Additionally, on March 25, 2025, we closed a registered direct offering of our common stock and warrants for net proceeds of approximately \$4.1 million.

As of the date of this Annual Report, we believe that our existing cash and cash equivalents are sufficient to fund our operations into the third quarter of 2025. We plan to pursue additional cash resources through public or private equity or debt financings, government grants/contracts, arrangements with strategic partners, or from other sources.

There can be no assurance that necessary funding will be available on favorable terms or at all. These factors collectively raise substantial doubt about the Company's ability to continue as a going concern. Management believes that we will be successful in securing the additional capital required to continue the Company's planned operations, but that our plans do not fully alleviate the substantial doubt about the Company's ability to operate as a going concern.

We will need to continue to raise additional capital to support our future operating activities, including progression of our development programs, preparation for commercialization, and other operating costs. We may fund a significant portion of our ongoing operations through partnering and collaboration agreements which, while reducing our risks and extending our cash runway, would also reduce our share of eventual revenues, if any, from our vaccine candidates. Additionally, we may be able to fund certain activities with assistance from government programs.

The sale of additional equity would result in additional dilution to our stockholders. We may also fund our operations through debt financing, which would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we would otherwise prefer to develop and market ourselves. Any of these actions could harm our business, results of operations and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and is based on assumptions that may prove to be wrong; actual results could vary materially. Our projection takes into consideration contractual commitments we have made, and expect to make, in the normal course of operating our business, which include (i) obligations to our employees, (ii) our lease obligations, (iii) payments due under license agreements for various technologies and patent rights associated with our product development activities, (iv) arrangements with CROs, CMOs, and other third-party vendors for clinical trials services and production of materials for use in our clinical trials, and (v) other various firm purchase commitments and contractual obligations related to production and testing of our product candidates and the general operation of our business.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use our available capital resources sooner than we expect. Our future capital requirements will depend on many factors, which include but are not limited to:

- the timing and costs of our ongoing and planned clinical trials;
- the timing and costs of manufacturing material for use in clinical trials;
- the timing and/or changes in funding we receive pursuant to the ATI-RRPV Contract;
- the number and scope of our research programs and the speed at which they are advanced;
- the progress and success of our preclinical and clinical development activities;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs to attract and retain skilled personnel;
- the costs to maintain and expand our infrastructure to support our operations, our product development, and planned future commercialization efforts;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the costs associated with any products or technologies that we may in-license or acquire; and
- the costs and timing of regulatory approvals.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that are likely or reasonably likely to have a material effect on our financial condition or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of United States interest rates, particularly because a significant portion of our investments are in institutional money market

funds. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income received without significantly increasing risk. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any derivative financial instruments or foreign currency instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and supplemental schedule and notes thereto as of December 31, 2024 and 2023 and for the two-year period ended December 31, 2024 together with the independent registered public accounting firm's report thereon, are set forth on pages F-1 to F-17 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There were no disagreements with our accountants on matters of accounting or financial disclosure, or other reportable events requiring disclosure under this Item 9.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that financial information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized, and reported within the required time periods, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2024, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework (2013)*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As a result of this assessment, management concluded that, as of December 31, 2024, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

ITEM 9B. OTHER INFORMATION

Insider Adoption or Termination of Trading Arrangements

During the three months ended December 31, 2024, none of our Section 16 officers or directors adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is included in our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC under the captions “Directors and Executive Officers” and “Corporate Governance” and is incorporated herein by this reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is included in our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC under the captions “Corporate Governance” and “Executive Compensation” and is incorporated herein by this reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is included in our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC under the captions “Security Ownership of Principal Stockholders, Directors and Executive Officers” and is incorporated herein by this reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is included in our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC under the captions “Corporate Governance” and “Certain Relationships and Related Party Transactions” and is incorporated herein by this reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is included in our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC under the caption “Ratification of Appointment of the Independent Registered Public Accounting Firm” and is incorporated herein by this reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

	<u>Page</u>
(1) Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2024 and 2023	F-4
Consolidated Statements of Operations for the years ended December 31, 2024 and 2023	F-5
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2024 and 2023	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2024 and 2023	F-7
Notes to Consolidated Financial Statements	F-8

(2) Financial Statement Schedules

The following financial statement schedule is set forth on page F-17 of this Annual Report on Form 10-K: Schedule II—Valuation and Qualifying Accounts for the years ended December 31, 2024 and 2023.

All other financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

(3) Exhibits Required by Item 601 of Regulation S-K

<u>Exhibit Number</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation filed April 12, 2024 (22)
3.2	Bylaws (as amended May 23, 2024) (24)
4.1*	Description of Registrant's Securities
4.2	Form of Stock Certificate representing the Company's Common Stock, par value \$0.001 per share (21)
4.3	Form of Common Stock Purchase Warrant, dated September 29, 2020 (10)
4.4	Form of Warrant Agent Agreement (9)
4.5	Form of Warrant issued to certain Management Creditors, dated September 29, 2020 (9)
4.6	Form of Common Stock Purchase Warrant, dated September 28, 2021 (14)
4.7	Form of Common Stock Purchase Warrant, dated May 21, 2024 (23)
4.8	Form of Common Stock Purchase Warrant, dated July 12, 2024 (25)
4.9	Form of Common Stock Purchase Warrant, dated August 21, 2024 (27)
4.10	Form of Common Stock Purchase Warrant, dated August 30, 2024 (28)
4.11	Form of Pre-Funded Warrant, dated March 25, 2025 (31)
4.12	Form of Common Stock Purchase Warrant, dated March 25, 2025 (31)
4.13	Warrant Amendment Agreement, dated March 23, 2025 (31)
10.1**	Employment Agreement between GeoVax Labs, Inc. and David A. Dodd (4)
10.2**	Employment Agreement between GeoVax, Inc. and Mark W. Reynolds (2)
10.2.1**	Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Mark W. Reynolds (3)
10.3**	Employment Agreement between GeoVax, Inc. and Mark J. Newman, PhD (16)
10.3.1**	Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Mark J. Newman, PhD (17)
10.4**	Employment Agreement between GeoVax, Inc. and Kelly T. McKee, MD (19)
10.4.1**	Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Kelly T. McKee, MD (19)
10.5**	Employment Agreement between GeoVax, Inc. and John W. Sharkey, PhD (17)
10.5.1**	Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and John W. Sharkey, PhD (17)
10.6**	GeoVax Labs, Inc. 2020 Stock Incentive Plan (8)
10.6.1**	GeoVax Labs, Inc. 2023 Stock Incentive Plan (18)
10.7	Patent and Biological Materials License Agreement with the National Institute of Allergy and Infectious Diseases, dated October 22, 2020 (11) ***
10.8	Patent and Biological Materials License Agreement for Internal Research Use with the National Institute of Allergy and Infectious Diseases, dated November 25, 2020 (12) ***
10.9	Office and Laboratory Lease between UCB, Inc. and GeoVax, Inc. (7)
10.9.1	Amendment to Office Lease Agreement between UCB, Inc. and GeoVax, Inc. (19)
10.10	Summary of the GeoVax Labs, Inc. Director Compensation Plan (16)

10.11	Assignment and License Agreement by and between GeoVax, Inc. and PNP Therapeutics, Inc. dated September 28, 2021 (14) ***
10.12	License Agreement by and between GeoVax, Inc. and City of Hope, dated November 9, 2021 (15) ***
10.12.1	Amendment to License Agreement, dated April 11, 2023, between GeoVax, Inc. and City of Hope (20) ***
10.13	Securities Purchase Agreement, dated May 16, 2024 (23)
10.14	Securities Purchase Agreement, dated July 11, 2024 (25)
10.15	Securities Purchase Agreement, dated August 20, 2024 (27)
10.16	Securities Purchase Agreement, dated August 28, 2024 (28)
10.17	Securities Purchase Agreement, dated March 23, 2025 (31)
10.18	RRPV Base Agreement No. 2024-564, dated April 2, 2024, by and between GeoVax, Inc. and Advanced Technology International (26)
10.19	RRPV Project Award No. 001, dated June 12, 2024, by and between Advanced Technology International (RRPV Consortium Management Firm) and GeoVax, Inc. (26) ***
10.20	Sales Agreement, by and between the Company and A.G.P./Alliance Global Partners (29)
10.21	Placement Agency Agreement between the Company and A.G.P./Alliance Global Partners (31)
14.1	Code of Ethics (5)
19.1*	Insider Trading Policy
21.1	Subsidiaries of the Registrant (6)
23.1*	Consent of Wipfli LLP (U.S. PCAOB Auditor Firm ID 344)
31.1 *	Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
31.2 *	Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
32.1 *	Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
32.2 *	Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Compensation Recoupment Policy (30)
101.INS	Inline XBRL Instance Document (1)
101.SCH	Inline XBRL Taxonomy Extension Schema Document (1)
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (1)
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (1)
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (1)
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (1)
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Indicates a management contract or compensatory plan or arrangement.

*** Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted as the Company has determined (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the Company if publicly disclosed.

- (1) These interactive data files shall not be deemed filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under these sections.
- (2) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 8, 2010.
- (3) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 23, 2013.
- (4) Incorporated by reference from the registrant's Current Report on Form 8-K filed September 7, 2018.
- (5) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 26, 2019.
- (6) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 7, 2019.
- (7) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 24, 2020.
- (8) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 12, 2021.
- (9) Incorporated by reference from Amendment No. 3 to the registrant's Registration Statement on Form S-1 (File No. 333-239958) filed September 8, 2020.
- (10) Incorporated by reference from Amendment No. 4 to the registrant's Registration Statement on Form S-1 (File No. 333-239958) filed September 23, 2020.
- (11) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 26, 2020.
- (12) Incorporated by reference from the registrant's Current Report on Form 8-K filed November 30, 2020.
- (13) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 23, 2021.
- (14) Incorporated by reference from the registrant's Current Report on Form 8-K filed September 29, 2021.
- (15) Incorporated by reference from the registrant's Current Report on Form 8-K filed November 10, 2021.
- (16) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 9, 2022.
- (17) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed August 3, 2022.

- (18) Incorporated by reference from the registrant's Current Report on Form 8-K filed December 8, 2022.
- (19) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 23, 2023.
- (20) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed May 4, 2023.
- (21) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 31, 2024.
- (22) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed May 14, 2024.
- (23) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 21, 2024.
- (24) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 23, 2024.
- (25) Incorporated by reference from the registrant's Current Report on Form 8-K filed July 12, 2024.
- (26) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed August 6, 2024.
- (27) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 21, 2024.
- (28) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 30, 2024.
- (29) Incorporated by reference from the registrant's Current Report on Form 8-K filed September 25, 2024.
- (30) Incorporated by reference from the registrant's Annual Report on Form 10-K filed February 29, 2024.
- (31) Incorporated by reference from the registrant's Current Report on Form 8-K filed March 25, 2025.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GEOVAX LABS, INC.

By: /s/ David A. Dodd
Name: David A. Dodd
Title: President and Chief Executive Officer

Date: March 27, 2025

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been duly signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Position</u>	<u>Date</u>
<u>/s/ David A. Dodd</u> David A. Dodd	Director President and Chief Executive Officer (Principal Executive Officer)	March 27, 2025
<u>/s/ Mark W. Reynolds</u> Mark W. Reynolds	Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2025
<u>/s/ Randal D. Chase</u> Randal D. Chase	Director	March 27, 2025
<u>/s/ Dean G. Kollintzas</u> Dean G. Kollintzas	Director	March 27, 2025
<u>/s/ Nicole Lemerond</u> Nicole Lemerond	Director	March 27, 2025
<u>/s/ Robert T. McNally</u> Robert T. McNally	Director	March 27, 2025
<u>/s/ Jayne Morgan</u> Jayne Morgan	Director	March 27, 2025
<u>/s/ John N. Spencer, Jr.</u> John N. Spencer, Jr.	Director	March 27, 2025

GEOVAX LABS, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of GeoVax Labs, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of GeoVax Labs, Inc. and subsidiary (the “Company”) as of December 31, 2024 and 2023, and the related consolidated statements of operations, stockholders’ equity and cash flows for the years then ended and the related notes to the consolidated financial statements and schedule (collectively, the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of a Matter*Substantial Doubt about the Company’s Ability to Continue as a Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company expects to continue to generate operating losses in the foreseeable future and will require additional funding to continue its research and development activities. This raises substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

/s/ WIPFLI LLP

We have served as the Company's auditor since 2005.

Atlanta, Georgia
March 27, 2025

GEOVAX LABS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,506,941	\$ 6,452,589
Government contract receivable	659,409	-
Prepaid expenses	1,768,533	1,433,153
Total current assets	7,934,883	7,885,742
Property and equipment, net	149,974	209,689
Other assets	71,010	1,187,788
Total assets	\$ 8,155,867	\$ 9,283,219
 LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,849,760	\$ 2,802,950
Accrued expenses	1,257,572	716,931
Total current liabilities	3,107,332	3,519,881
Commitments (Note 5)		
Stockholders' equity:		
Common stock, \$.001 par value:		
Authorized shares – 150,000,000 and 600,000,000 at December 31, 2024 and 2023, respectively		
Issued and outstanding shares – 10,536,875 and 1,977,152 at December 31, 2024 and 2023, respectively	10,537	1,977
Additional paid-in capital	134,394,079	110,125,146
Accumulated deficit	(129,356,081)	(104,363,785)
Total stockholders' equity	5,048,535	5,763,338
Total liabilities and stockholders' equity	\$ 8,155,867	\$ 9,283,219

See accompanying notes to consolidated financial statements.

GEOVAX LABS. INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2024	2023
Revenue from government contract	\$ 3,954,576	\$ -
Operating expenses:		
Research and development	23,713,602	20,720,766
General and administrative	5,385,254	6,022,173
Total operating expenses	29,098,856	26,742,939
Loss from operations	(25,144,280)	(26,742,939)
Other income (expense):		
Interest income	173,359	776,177
Interest expense	(21,375)	-
Total other income (expense)	151,984	776,177
Net loss	\$ (24,992,296)	\$ (25,966,762)
Basic and diluted:		
Net loss per common share	\$ (4.82)	\$ (14.29)
Weighted average shares outstanding	5,187,038	1,817,282

See accompanying notes to consolidated financial statements.

GEOVAX LABS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	1,755,664	\$ 1,756	\$ 104,995,301	\$ (78,397,023)	\$ 26,600,034
Issuance of common stock upon warrant exercise	197,467	197	4,062,245	-	4,062,442
Issuance of common stock for services	24,021	24	212,476	-	212,500
Stock option expense	-	-	855,124	-	855,124
Net loss for the year ended December 31, 2023	-	-	-	(25,966,762)	(25,966,762)
Balance at December 31, 2023	1,977,152	\$ 1,977	\$ 110,125,146	\$(104,363,785)	\$ 5,763,338
Sale of common stock and warrants for cash	4,889,030	4,890	21,393,493	-	21,398,383
Issuance of common stock upon warrant exercise	3,608,568	3,608	2,363,525	-	2,367,133
Issuance of common stock for services	6,703	7	37,493	-	37,500
Fractional share roundup following reverse split	55,422	55	(55)	-	-
Stock option expense	-	-	474,477	-	474,477
Net loss for the year ended December 31, 2024	-	-	-	(24,992,296)	(24,992,296)
Balance at December 31, 2024	10,536,875	\$ 10,537	\$ 134,394,079	\$ (129,356,081)	\$ 5,048,535

See accompanying notes to consolidated financial statements.

GEOVAX LABS. INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$(24,992,296)	\$(25,966,762)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	95,368	74,169
Stock-based compensation expense	528,644	1,074,957
Changes in assets and liabilities:		
Government contract receivable	(659,409)	-
Prepaid expenses and other current assets	(352,047)	(114,488)
Other assets	1,116,778	986,498
Accounts payable and accrued expenses	(412,549)	(1,228,013)
Total adjustments	316,785	793,123
Net cash used in operating activities	(24,675,511)	(25,173,639)
Cash flows from investing activities:		
Purchase of equipment	(20,653)	(48,946)
Net cash used in investing activities	(20,653)	(48,946)
Cash flows from financing activities:		
Net proceeds from issuance of notes payable – related parties	135,000	-
Repayment of notes payable – related parties	(150,000)	-
Net proceeds from sale of common stock and warrants	21,398,383	-
Net proceeds from warrant exercises	2,367,133	4,062,442
Net cash provided by financing activities	23,750,516	4,062,442
Net decrease in cash and cash equivalents	(945,648)	(21,160,143)
Cash and cash equivalents at beginning of period	6,452,589	27,612,732
Cash and cash equivalents at end of period	\$ 5,506,941	\$ 6,452,589

See accompanying notes to consolidated financial statements.

GEOVAX LABS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2024 and 2023

1. Nature of Business

GeoVax Labs, Inc., headquartered in the Atlanta, Georgia metropolitan area, is a clinical-stage biotechnology company incorporated under the laws of the State of Delaware. GeoVax Labs, Inc. and its wholly owned subsidiary, GeoVax, Inc., a Georgia corporation, are collectively referred to herein as “GeoVax” or the “Company”.

The Company is focused on developing immunotherapies and vaccines against infectious diseases and cancers using novel vector vaccine platforms. GeoVax’s lead clinical program is GEO-CM04S1, a next-generation COVID-19 vaccine for which the Company was recently awarded a U.S. government-funded contract (See Note 10) to sponsor a 10,000-participant Phase 2b clinical trial to evaluate the efficacy of GEO-CM04S1 versus an approved COVID-19 vaccine. In addition, GEO-CM04S1 is currently in three Phase 2 clinical trials, being evaluated as (1) a primary vaccine for immunocompromised patients such as those suffering from hematologic cancers and other patient populations for whom the current authorized COVID-19 vaccines are insufficient, (2) a booster vaccine in patients with chronic lymphocytic leukemia (CLL) and (3) a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines. In oncology GeoVax’s lead clinical program is Gedeptin®, a novel oncolytic solid tumor gene-directed therapy, which recently completed a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. A Phase 2 clinical trial in first recurrent head and neck cancer, evaluating Gedeptin® combined with an immune checkpoint inhibitor is planned to initiate in mid-2025.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of GeoVax Labs, Inc. together with GeoVax, Inc. All intercompany transactions have been eliminated in consolidation.

Basis of Presentation and Going Concern

We are devoting substantially all of our present efforts to research and development of our vaccine and immunotherapy candidates and will require additional funding to continue our research and development activities. We believe that our existing cash resources will be sufficient to continue our planned operations into the third quarter of 2025. We plan to pursue additional capital resources through public or private equity or debt financing, government grants/contracts, arrangements with strategic partners, or from other sources. There can be no assurance that additional funding will be available on favorable terms or at all. These factors collectively raise substantial doubt about the Company’s ability to continue as a going concern. Management believes that we will be successful in securing the additional capital required to continue the Company’s planned operations, but that our plans do not fully alleviate the substantial doubt about the Company’s ability to operate as a going concern.

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the issue date of these financial statements. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

The accompanying consolidated financial statements, and all share and per share information contained herein, have been retroactively restated to reflect the reverse stock split described in Note 6.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets

and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Our cash and cash equivalents consist primarily of bank deposits and money market accounts. The recorded values approximate fair market values due to the short maturities.

Fair Value of Financial Instruments and Concentration of Credit Risk

Financial instruments that subject us to concentration of credit risk consist primarily of cash and cash equivalents, which are maintained by high credit quality financial institutions. The carrying values reported in the balance sheets for cash and cash equivalents approximate fair values.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Expenditures for maintenance and repairs are charged to operations as incurred, while additions and improvements are capitalized. We calculate depreciation using the straight-line method over the estimated useful lives of the assets. We amortize leasehold improvements using the straight-line method over the term of the related lease.

We recognize leases in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 842, which requires lessees to classify leases as either financing or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification determines whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. In the case of our facility lease agreement which has an effective term of less than 12 months, we made an accounting policy election to not recognize lease assets and liabilities and record lease expense on a straight-line basis over the lease term.

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future net cash flows expected to be generated by such assets. If we consider such assets to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the expected future net cash flows from the assets.

Accrued Expenses

As part of the process of preparing our financial statements, we estimate expenses that we believe we have incurred, but have not yet been billed by our third-party vendors. This process involves identifying services and activities that have been performed by such vendors on our behalf and estimating the level to which they have been performed and the associated cost incurred for such service as of each balance sheet date.

Net Loss Per Share

Basic and diluted loss per common share are computed based on the weighted average number of common shares outstanding, including any common shares that may be issuable upon exercise of prefunded warrants. Additional potentially dilutive securities, which include stock options and stock purchase warrants, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. The securities that could potentially dilute basic earnings per share in the future and that have been excluded from the computation of diluted net loss per share totaled 6,951,395 and 1,731,391 shares at December 31, 2024 and 2023, respectively.

Revenue Recognition

We recognize revenue in accordance with FASB ASC Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

We have received payments from government entities under non-refundable grants and contracts in support of our vaccine development programs. We record revenue associated with these grants and contracts when the reimbursable costs are incurred and we have complied with all conditions necessary to receive the funds. From time to time, we may enter into collaborative research and development agreements for specific vaccine development approaches and/or disease indications whereby we receive third-party funding for preclinical research under certain of these arrangements. Each agreement is evaluated in accordance with the process defined by ASC Topic 606 and revenue is recognized accordingly.

Research and Development Expense

Research and development costs are charged to expense as incurred and consist of costs incurred in the discovery, development, testing and manufacturing of our product candidates. These expenses consist primarily of (i) salaries, benefits, and stock-based compensation for personnel, (ii) laboratory supplies and facility-related expenses to conduct development, (iii) fees paid to third-party service providers to perform, monitor and accumulate data related to our preclinical studies and clinical trials, (iv) costs related to sponsored research agreements, (v) costs to procure and manufacture materials used in clinical trials, and (vi) license fees and other expenses associated with technology license agreements.

We accrue estimated costs of research and development activities conducted by third-party service providers, which may include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies or trials, including clinical trial participant enrollment, completion of events, invoices received and other events. Advance payments for research and development activities are deferred and included in prepaid expenses and other assets. The deferred amounts are expensed as the related goods are delivered or the services are performed.

Patent Costs

Our expenditures relating to obtaining and protecting patents are charged to expense when incurred and are included in general and administrative expense.

Period-to-Period Comparisons

Our operating results are expected to fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results for future periods.

Income Taxes

We account for income taxes using the liability method. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance unless, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will be realized.

Stock-Based Compensation

We account for stock-based transactions in which the Company receives services from employees, directors or others in exchange for equity instruments based on the fair value of the award at the grant date. Stock-based compensation cost for awards of common stock is estimated based on the price of the underlying common stock on the date of issuance. Stock-based compensation cost for stock options or warrants is estimated at the grant date based on each instrument's fair value as calculated by the Black-Scholes option pricing model. We recognize stock-based compensation cost as expense ratably on a

straight-line basis over the requisite service period for the award. See Note 7 for additional stock-based compensation information.

Other Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements which we expect to have a material impact on our financial statements, nor do we believe that any recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on our financial statements.

3. Balance Sheet Components

Prepaid Expenses – Prepaid expenses consist of the following as of December 31, 2024 and 2023:

	2024	2023
Prepaid clinical trial costs (current portion)	\$1,524,813	\$1,282,746
Prepaid insurance premiums	220,675	110,695
Prepaid rent	13,045	13,045
Other prepaid expenses	10,000	26,667
Total prepaid expenses	<u>\$1,768,533</u>	<u>\$1,433,153</u>

Property and Equipment – Property and equipment consist of the following as of December 31, 2024 and 2023:

	2024	2023
Equipment and furnishings	\$ 795,411	\$ 774,758
Leasehold improvements	115,605	115,605
Total property and equipment	911,016	890,363
Accumulated depreciation and amortization	(761,042)	(680,674)
Total property and equipment, net	<u>\$ 149,974</u>	<u>\$ 209,689</u>

Depreciation expense was \$80,368 and \$74,169 during the years ended December 31, 2024 and 2023, respectively.

Other Assets – Other assets consist of the following as of December 31, 2024 and 2023:

	2024	2023
Prepaid clinical trial costs (noncurrent portion)	\$ -	\$1,106,778
Prepaid technology license fees	60,000	70,000
Deposits	11,010	11,010
Total other assets	<u>\$ 71,010</u>	<u>\$1,187,788</u>

Accrued Expenses – Accrued expenses consist of the following as of December 31, 2024 and 2023:

	2024	2023
Payroll-related liabilities	\$ 986,691	\$ 114,337
Other accrued expenses	270,881	602,594
Total accrued expenses	<u>\$1,257,572</u>	<u>\$ 716,931</u>

4. Notes Payable – Related Parties

On May 10, 2024, we issued 10% Original Issue Discount Promissory Notes (the “Notes”) with an aggregate principal amount of \$150,000 to members of our Board of Directors and senior management, in exchange for gross cash proceeds to us of \$135,000. The Notes were unsecured, bore interest at a rate of 15% per annum, and matured upon of the earlier of (i) six months from the issue date or (ii) three days following the date the Company completes an offering of its common stock with gross proceeds of not less than \$5 million (a “Qualified Financing Event”). On August 22, 2024, following the successful completion of a Qualified Financing Event, we repaid the aggregate principal amount of the Notes in full, together with accrued interest. Total interest expense recorded during 2024 was \$21,375, consisting of \$15,000 of debt discount amortization and \$6,375 of accrued interest.

5. Commitments

Operating Lease. We lease approximately 8,400 square feet of office and laboratory space pursuant to an operating lease which expires on December 31, 2025. Rent expense for the years ended December 31, 2024 and 2023 was \$187,527 and

\$182,106, respectively. Future minimum lease payments total approximately \$193,000 in 2025 although the lease may be terminated at any time by either party with one hundred eighty days written notice.

License Agreements. We have entered into license agreements for various technologies and patent rights associated with our product development activities. These agreements may contain provisions for upfront payments, milestone fees due upon the achievement of selected development and regulatory events, minimum annual royalties or other fees, and royalties based on future net sales. Due to the uncertainty of the achievement and timing of the contingent events requiring payment under these agreements, the amounts to be paid by us in the future are not determinable.

Other Commitments. In the normal course of business, we enter into various contracts and purchase commitments including those with contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”) for clinical trials services and production of materials for use in our clinical trials. Most contracts are generally cancellable, with notice, at the Company’s option. Payments due upon cancellation may consist of payments for services provided or expenses incurred to date, or cancellation penalties depending on the time of cancellation.

6. Stockholders’ Equity

Reverse Stock Split and Reduction of Authorized Shares of Common Stock

At a special meeting of our stockholders held on January 16, 2024, our stockholders approved an amendment to our certificate of incorporation to (i) reduce our authorized shares of common stock from 600,000,000 to 150,000,000 and (ii) effect a one-for-fifteen reverse split of our common stock. The amendment to our certificate of incorporation was filed with the Delaware Secretary of State on January 30, 2024 and our common stock began trading on the split-adjusted basis on January 31, 2024. The accompanying consolidated financial statements, and all share and per share information contained herein, have been retroactively restated to reflect the reverse stock split.

Common Stock and Warrant Offerings

On May 21, 2024, we closed a registered direct offering of 220,000 shares of common stock and pre-funded warrants to purchase an aggregate of 582,844 shares of common stock (the “May 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 1,605,688 shares of common stock at an exercise price of \$1.68 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately \$1.2 million.

On July 12, 2024, we closed a registered direct offering of 458,632 shares of common stock and pre-funded warrants to purchase an aggregate of 626,368 shares of common stock (the “July 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 2,170,000 shares of common stock at an exercise price of \$2.86 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately \$2.8 million.

On August 21, 2024, we closed a registered direct offering of 1,360,731 shares of common stock and pre-funded warrants to purchase an aggregate of 339,269 shares of common stock (the “August 21, 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 1,700,000 shares of common stock at an exercise price of \$5.00 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately \$7.9 million.

On August 30, 2024, we closed a registered direct offering of 837,500 shares of common stock and pre-funded warrants to purchase an aggregate of 138,110 shares of common stock (the “August 30, 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 975,610 shares of common stock at an exercise price of \$5.00 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately \$4.6 million.

On September 25, 2024, we entered into a sales agreement and established an “At-the-Market” continuous offering program (the “ATM Program”), pursuant to which the Company may, from time to time, offer and sell shares of its common stock through its sales agent. The Company’s common stock will be sold at prevailing market prices at the time of the sale and, as a result, prices will vary. The sales agent will be paid a 3% commission on each sale under the ATM Program. During 2024 we sold 2,012,167 shares of our common stock through the ATM Program for net proceeds of approximately \$4.9 million.

Warrant Exercises

On December 2, 2023, we entered into a warrant exercise inducement letter with the holder of certain warrants issued during 2022, pursuant to which the holder agreed to fully exercise each warrant (aggregate of 704,499 shares) at a reduced exercise price of \$6.21 per share in consideration for our agreement to issue a new warrant (the “December 2023 Warrant”) to purchase 1,408,998 shares of common stock at an exercise price of \$6.21 per share. Upon exercise of their existing warrants, at the holder’s direction we issued to them 197,467 shares of common stock and held 507,032 shares in abeyance (in the form of a prefunded warrant, the “December 2023 Pre-Funded Warrants”). Net proceeds to us after deducting placement agent commissions and other offering expenses were approximately \$4.1 million. The December 2023 Pre-Funded Warrants were fully exercised during February, March and June 2024.

During June 2024, we issued (i) 582,844 shares of our common stock upon the exercise of the May 2024 Pre-Funded Warrants; (ii) 2,549 shares of our common stock upon the cashless exercise of 4,000 warrants issued in June 2020, and (iii) 826,998 shares of our common stock upon the partial exercise of the December 2023 Warrants, with net cash proceeds to us of approximately \$1.4 million.

During July 2024, we issued 626,368 shares of our common stock upon the exercise of the July 2024 Pre-Funded Warrants.

During August 2024, we issued (i) 477,379 shares of our common stock upon the exercise of the August 21, 2024 Pre-Funded Warrants and the August 30, 2024 Pre-Funded Warrants; (ii) 3,398 shares of our common stock upon the cashless exercise of 4,000 warrants issued in June 2020, and (iii) 582,000 shares of our common stock upon the exercise of the remaining December 2023 Warrants, with net cash proceeds to us of approximately \$978,000.

Other Common Stock Transactions – During 2024 and 2023 we issued 6,703 and 24,021 shares, respectively, of our common stock pursuant to consulting agreements. During January 2024 we issued 55,422 shares of our common stock for the roundup of fractional shares associated with the reverse stock split.

Common Stock Reserved for Future Issuance – Common stock reserved for future issuance consists of the following at December 31, 2024:

	Shares
Stock warrants outstanding	6,617,747
Stock options outstanding	333,648
Stock options authorized for future grants	1,700,000
Total	<u>8,651,395</u>

Stock Options

We have stock-based incentive plans (the “Stock Incentive Plans”) pursuant to which our Board of Directors may grant stock options or other stock awards to our employees, directors and consultants. A total of 2,033,648 shares of our common stock are reserved for future issuance pursuant to the Stock Incentive Plans. The exercise price for any option granted may not be less than fair value (110% of fair value for ISO’s granted to certain employees). Options have a maximum ten-year term.

A summary of the Company’s stock option activity during 2024 is presented below.

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (yrs)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	134,609	\$ 28.41	8.2	\$ -0-
Granted	200,000	2.23		
Exercised	-	-		
Forfeited or expired	(961)	30.17		
Outstanding at December 31, 2024	<u>333,648</u>	<u>\$ 12.71</u>	<u>8.6</u>	<u>\$ 58,500</u>
Exercisable at December 31, 2024	<u>117,905</u>	<u>\$ 30.67</u>	<u>7.1</u>	<u>\$ -</u>

Stock Warrants

A summary of the Company's warrant activity during 2024 is presented below.

	Common Warrants				
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (yrs)	Pre-Funded Warrants Number of Shares	Total Warrants
Outstanding at December 31, 2023	1,596,781	\$ 14.58	5.0	-	2,103,813
Issued	6,451,298	3.45		1,686,591	8,137,889
Exercised	(1,416,998)*	1.68		(2,193,623)	(3,610,621)
Forfeited/Expired	(13,334)	89.92		-	(13,334)
Outstanding at December 31, 2024	6,617,747	\$ 5.13	4.6	-	6,617,747

* Includes 8,000 warrants exercised on a cashless basis for 5,947 shares of common stock.

The table below summarizes additional information concerning warrants outstanding as of December 31, 2024.

Issue Date	Number of Shares	Exercise Price	Expiration
September 2020	159,781	\$ 75.00	September 2025
September 2021	6,668	195.00	September 2026
May 2024	1,605,688	1.68	May 2029
July 2024	2,170,000	2.13	January 2030
August 2024	2,675,610	5.00	August 2029
Outstanding at December 31, 2024	6,617,747		

7. Stock-Based Compensation Expense

Stock-based compensation expense related to stock options is recognized on a straight-line basis over the requisite service period for the award and is allocated to research and development expense or general and administrative expense based upon the classification of the individual to whom the award is granted. We also have issued shares of restricted common stock to consultants and recognize the related expense over the terms of the related agreements.

We use the Black-Scholes model for determining the grant date fair value of our stock option grants. This model utilizes certain information, such as the interest rate on a risk-free security with a term generally equivalent to the expected life of the option being valued and requires certain other assumptions, such as the expected amount of time an option will be outstanding until it is exercised or expired, to calculate the fair value of stock options granted. We granted no stock options during 2023. The significant assumptions we used in our fair value calculations for stock options granted during 2024 were as follows:

Weighted average risk-free interest rates	3.8%
Expected dividend yield	0.0%
Expected life of option	7.0 yrs
Expected volatility	204.2%

The weighted-average grant date fair values of stock options granted during 2024 and 2023 were \$2.22 and \$-0-, respectively. As of December 31, 2024, there is \$515,969 of unrecognized compensation expense that will be recognized over a weighted-average period of 1.8 years.

The following table summarizes our total stock-based compensation expense for employees, directors and consultants for the years ended December 31, 2024 and 2023:

	2024	2023
Stock options:		
Research and development	\$ 222,202	\$ 291,094
General and administrative	252,275	564,030
Total stock option expense	474,477	855,124
Stock awards:		
General and administrative	54,167	219,833
Total stock-based compensation expense	<u>\$ 528,644</u>	<u>\$ 1,074,957</u>

8. Retirement Plan

We participate in a multi-employer defined contribution retirement plan (the “401k Plan”) administered by a third-party service provider, and the Company contributes to the 401k Plan on behalf of its employees based upon a matching formula. During the years ended December 31, 2024 and 2023 our contributions to the 401k Plan were \$106,191 and \$95,658, respectively.

9. Income Taxes

At December 31, 2024, we have a consolidated federal net operating loss (“NOL”) carryforward of approximately \$116.8 million available to offset against future taxable income of which approximately \$28.3 million expires in varying amounts in 2025 through 2037. Additionally, we have approximately \$5.5 million in research and development (“R&D”) tax credits that expire in 2025 through 2044 unless utilized earlier. No income taxes have been paid to date. Section 382 of the Internal Revenue Code contains provisions that may limit our utilization of our NOL and R&D tax credit carryforwards in any given year as a result of significant changes in ownership interests that have occurred in past periods or may occur in future periods.

Deferred income taxes reflect the net effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. We have established a full valuation allowance equal to the amount of our net deferred tax assets due to uncertainties with respect to our ability to generate sufficient taxable income to realize these assets in the future. The table below presents significant components of our deferred tax assets and liabilities at December 31, 2024 and 2023.

	2024	2023
Deferred tax assets:		
Net operating loss carryforward	\$ 30,374,640	\$ 25,527,210
Research and development tax credit carryforward	5,506,154	3,870,460
Stock-based compensation expense	676,250	552,886
Accrued expenses	256,540	29,728
Total deferred tax assets	36,813,584	29,980,284
Deferred tax liabilities		
Depreciation	29,812	45,122
Net deferred tax assets	36,783,772	29,935,162
Valuation allowance	(36,783,772)	(29,935,162)
Net deferred tax asset after reduction for valuation allowance	<u>\$ -0-</u>	<u>\$ -0-</u>

A reconciliation of the U.S. federal income tax rate to the Company’s effective tax rate is as follows:

	2024	2023
U.S. federal statutory rate applied to pretax loss	21.0%	21.0%
State income tax (benefit)	4.0	3.9
Permanent differences	(0.0)	(0.0)
NOL carryforward expiration	(4.1)	(4.3)
R&D tax credits, net of expiration	6.5	6.4
Change in valuation allowance and other adjustments	(27.4)	(27.0)
Effective tax rate	<u>0.0%</u>	<u>0.0%</u>

10. Revenue from Government Contract

In June 2024, GeoVax was awarded a contract through the Rapid Response Partnership Vehicle (RRPV) to advance the clinical development of GEO-CM04S1, the Company's next-generation COVID-19 vaccine. 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) in the U.S. Department of Health and Human Services (HHS). Under the agreement with Advanced Technology International, the RRPV's consortium management firm (the "ATI-RRPV Contract"), GeoVax will sponsor a 10,000-participant, randomized, Phase 2b double-blinded study to assess the clinical efficacy, safety, and immunogenicity of GEO-CM04S1 compared with a U.S. Food and Drug Administration (FDA)-approved mRNA COVID-19 vaccine.

The direct award to GeoVax, currently approximately \$26.2 million and which may increase to as much as \$45 million, is funding the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. BARDA has made a separate award through its Clinical Studies Network to fully fund the execution of the study by Allucent, a global clinical research organization; the funding provided directly to Allucent will not be recognized in GeoVax's financial statements. During 2024, GeoVax recognized revenue of \$3,954,546 associated with the ATI-RRPV Contract. We record revenue associated with this contract as the reimbursable costs are incurred.

11. Subsequent Events

ATM Program. Subsequent to December 31, 2024, we have sold 1,952,603 shares of common stock under the ATM Program, for net proceeds of approximately \$3.8 million.

March 2025 Offering. On March 25, 2025, we closed a registered direct offering of 1,350,000 shares of common stock, pre-funded warrants to purchase an aggregate of 2,085,115 shares of common stock, and common warrants to purchase up to 3,435,115 shares of common stock at an exercise price of \$1.31 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately \$4.1 million.

GEOVAX LABS, INC.
SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

For the Years Ended December 31, 2024 and 2023

Description	Balance at Beginning Of Period	Additions (Reductions)		Deductions	Balance at End Of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
Reserve Deducted in the Balance Sheet From the Asset to Which it Applies:					
Allowance for Deferred Tax Assets					
Year ended December 31, 2024	\$ 29,935,162	\$ 6,848,610	\$ -0-	\$ -0-	\$ 36,783,772
Year ended December 31, 2023	\$ 22,909,470	\$ 7,025,692	\$ -0-	\$ -0-	\$ 29,935,162