



GeoVax Labs, Inc.

**2020
Annual Report**



June 14, 2021

Dear GeoVax Stockholders,

I am pleased to provide our 2020 Annual Report on Form 10-K, which contains a detailed review of our vaccine and immunotherapy development pipeline. During 2020 and the early months of 2021, GeoVax made substantial progress in various areas of product development. Our MVA-VLP vaccine platform (GV-MVA-VLP™) continues to be validated through our product portfolio advancement, our corporate and academic collaborators, and promising preclinical and clinical testing results.

In September 2020, we completed a public offering of our common stock (GOVX) and publicly traded warrants (GOVXW) with net proceeds of \$11.2 million, which allowed us to simultaneously up-list our stock to the Nasdaq Capital Market. During the first quarter of 2021, we further supplemented our cash resources with net proceeds of \$9.4 million from a follow-on offering of our common stock, and \$3.2 million from the exercise of outstanding warrants. As of March 31, 2021, we reported cash balances \$20.8 million, which positions us well for further advancing our development programs as highlighted below.

Coronavirus Vaccine – Our SARS-CoV-2 (COVID-19) vaccine is based on our GV-MVA-VLP™ technology, which enables insertion of multiple antigen fragments, potentially allowing for broad-spectrum virus prevention. Unlike other vaccines that target only the COVID-19 spike protein, our vaccines are designed to provoke a response to multiple COVID-19 antigens, which means our vaccines could be less susceptible to viral mutations. Our vaccines are intended to be used as either a primary vaccine or to boost other COVID-19 vaccines as part of vaccination strategies to provide immunity to a range of coronavirus variants.

In January 2021, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), awarded GeoVax a Small Business Innovative Research (SBIR) grant in support of our development of a COVID-19 vaccine. The Phase 1 grant, titled, “Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19,” is supporting the ongoing design, construction, and preclinical testing of our vaccine candidates in preparation for human clinical trials.

Even with the recent Emergency Use Authorization of COVID-19 vaccines against the current pandemic, we believe there remains a critical and significant opportunity for a pan-coronavirus vaccine with the attributes our technology can offer. Our small animal studies are continuing, with results expected later this year, and based on results we’ve seen thus far, we recently submitted an application to NIH for additional support for advanced testing, with this goal in mind.

Cancer Immunotherapy – Our cancer immunotherapy program is based on the concept of combining a tumor-associated antigen vaccine with a potent anti-tumor agent, such as an Immune Checkpoint Inhibitor (“ICI”), with the goal of achieving regression of tumor growth and development. The initial animal studies, based upon a GeoVax-MUC1 vaccine/ICI combination, have been encouraging. In February 2021, we filed a U.S. patent application, covering updates to our MVA viral vector technology to amplify an immune response to a cancer antigen via vaccination, which could strengthen our intellectual property position in this space. Following our recent fund-raising activities, immuno-oncology is an important focus area for the Company, and we are engaging with multiple collaborators. We expect to provide further details on our progress and plans to advance to human clinical testing in the near future.

Lassa Fever – We continue to progress using grant funding from the U.S. Department of Defense for our Lassa Fever (LASV) vaccine program. The project award supports generation of immunogenicity and efficacy data for

our vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparation for human clinical trials. This work is in collaboration with U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation. We expect to announce results from this work during the second half of 2021.

Sudan ebolavirus and Marburg virus – In August 2020, we announced a multi-party collaboration for the development of our Sudan ebolavirus (SUDV) and Marburg virus (MARV) vaccine candidates. The collaboration, between GeoVax, researchers at the University of Texas Medical Branch (UTMB), and Battelle Memorial Institute, utilizes the suite of preclinical services from NIAID. Under the collaboration, GeoVax’s SUDV and MARV vaccine candidates are being tested for immunogenicity and efficacy in the benchmark nonhuman primate model. This work builds upon earlier studies in rodents and nonhuman primates for our Ebola virus (EBOV) vaccine candidate that demonstrated 100% protection against a lethal dose of EBOV upon a single immunization. We expect to announce results from this work during the second half of 2021.

Malaria Vaccine – We continue to collaborate individually with Leidos, Inc. and the Burnet Institute in development of malaria vaccine candidates using our GV-MVA-VLPTM vaccine platform. The collaboration with Leidos has been funded by a grant to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). Several of these vaccine candidates have recently entered initial animal testing with results expected during the second half of 2021.

HIV Vaccine Programs

HIV Preventive Vaccine – NIAID has funded multiple clinical trials of our HIV preventive vaccine (GOVX-B11) through the HIV Vaccine Trials Network (HVTN). HVTN 132 is designed to further evaluate the safety and immunogenicity of adding “protein boost” components to the GOVX-B11 vaccination regimen. The start of HVTN 132 has been delayed due to COVID-19, and we await further information from NIAID and HVTN on when the trial may commence.

HIV Immunotherapy – We are part of efforts to develop a combination therapy to induce remission in HIV-positive individuals (a “functional cure”). In August 2020, a consortium led by researchers at the University of California, San Francisco (UCSF) began enrolling patients in a Phase 1 human clinical trial using our vaccine as part of a combination therapy intended to induce remission in HIV-positive individuals. Similar to HVTN 132, this trial has been affected by the pandemic, so we await further information regarding the status of patient enrollment and trial results. Our prior collaboration with American Gene Technologies International, Inc. (AGT) was recently discontinued due to AGT’s remodeling of their clinical trial plans, but we remain open to additional collaborations for use of our technology in this important area.

Licenses and Intellectual Property

In October 2020, we signed a license agreement with NIAID allowing us to use the materials and patent rights owned by agencies of the United States Department of Health and Human Services (HHS) in combination with our proprietary technology for the creation of a preventive vaccine that primes and/or boosts the immune system against COVID-19. The agreement provides GeoVax with nonexclusive rights to develop, manufacture and commercialize our COVID-19 vaccine.

In November 2020, we signed another license agreement with NIAID in support of our non-clinical development of preventive and/or therapeutic vaccines against numerous pathogens including Ebola-Zaire, Ebola-Sudan, Lassa virus, Marburg virus, Zika virus and malaria. The agreement also extends to our research and development efforts in certain oncology areas.

In February 2021, we filed international and U.S. patent applications in our key focus areas of SARS-CoV-2 (COVID-19) and cancer immunotherapy. Following these filings, our wholly owned, co-owned, and in-licensed

intellectual property portfolio now stands at over 70 granted or pending patent applications spread over 20 patent families.

Summary

In conclusion, we remain enthusiastic about the future of our company and look forward to sharing additional news of our progress. Thank you for your continued support.

Sincerely,



David A. Dodd
Chairman, President and CEO

Forward-Looking Statements

This letter contains forward-looking statements regarding GeoVax's business plans. The words "could be," "believe," "promising," "may," "estimate" "continue," "anticipate," "intend," "should," "plan," "could," "target," "potential," "is likely," "will," "expect" and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Actual results may differ materially from those included in these statements due to a variety of factors, including whether: GeoVax and its collaborators are able to complete their work within the expected timeframes, GeoVax is able to obtain the patent protection sought, GeoVax's COVID-19 vaccines can provoke responses to multiple COVID-19 antigens, and those vaccines can be used effectively as a primary or booster to other COVID-19 vaccines, GeoVax's viral vector technology adequately amplifies immune responses to cancer antigens, GeoVax can develop and manufacture its vaccines with the desired characteristics in a timely manner, GeoVax's vaccines will be safe for human use, GeoVax's vaccines will effectively prevent targeted infections in humans, GeoVax's vaccines will receive regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete vaccine development, there is development of competitive products that may be more effective or easier to use than GeoVax's products, GeoVax will be able to enter into favorable manufacturing and distribution agreements, the impact of the COVID-19 pandemic continues, and other factors, over which GeoVax has no control.

Further information on our risk factors is contained in our periodic reports on Form 10-K (attached hereto), Form 10-Q, and current reports on Form 8-K that we have filed and will file with the SEC. Any forward-looking statement made by us herein speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

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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, 2020
- 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.

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, 2020, based on the closing price on that date was \$7,608,741.

Number of shares of Common Stock outstanding as of March 23, 2021: 6,315,467

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with respect to its 2021 Annual Meeting of Stockholders are incorporated by reference in Part III

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This 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,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” 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 is a clinical-stage biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases using a novel vector vaccine platform (Modified Vaccinia Ankara-Virus Like Particle or “GV-MVA-VLP™”). During January 2020, we began a program to develop a vaccine for prevention of novel coronavirus (COVID-19) infection. That effort has resulted in four COVID-19 vaccine candidates. These COVID-19 vaccine candidates have been designed and constructed and are being tested using relevant experimental animal challenge models. Additional development programs are focused on preventive vaccines against hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa fever), Zika virus and malaria; preventive and therapeutic vaccines against Human Immunodeficiency Virus (HIV); as well as immunotherapies for solid tumor cancers.

For our infectious disease vaccines, our recombinant MVA vector expresses target proteins on highly immunogenic VLPs (Virus-Like Particles) in the person being vaccinated, with the intended result of producing durable immune responses with the safety characteristics of the replication deficient MVA vector and cost-effective manufacturing.

In cancer immunotherapy, we believe that stimulating the immune system to treat cancers is a compelling concept and that the opportunity for immune-activating technologies is promising, especially in light of advancements such as checkpoint inhibitors leading the way in oncology. Despite drug approvals in limited indications and promising results in clinical trials, there remains a significant need and opportunity for further advancements. We believe our GV-MVA-VLP™ platform is well-suited for delivery of tumor-associated antigens and we plan to pursue development of our platform in this space.

Our most advanced vaccine program is focused on prevention of the clade B subtype of HIV prevalent in the regions of the Americas, Western Europe, Japan and Australia; our HIV vaccine candidate, GOVX-B11, will be included in an upcoming clinical trial (HVTN 132) managed by the HIV Vaccine Clinical Trials Network (HVTN) with support from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), which we expect may begin in late 2021. Additionally, during August 2020 a consortium led by researchers at the University of California, San Francisco (UCSF) began a clinical trial using our vaccine as part of a combinational therapy to induce remission in HIV-positive individuals. Through the efforts of our collaborator, American Gene Technologies International, Inc. (AGT), we expect that our HIV vaccine will also enter clinical trials during 2021 in combination with AGT’s gene therapy technology to seek a functional cure for HIV.

Our other vaccine and immunotherapy programs are at various other stages of development as described below.

Our corporate strategy is to advance, protect and exploit our differentiated vaccine/immunotherapy platform leading to the successful development of preventive and therapeutic vaccines against infectious diseases and various cancers. With our design and development capabilities, we are progressing and validating an array of cancer and infectious disease immunotherapy and vaccine product candidates. Our goal is to advance products through regulatory registration and commercialization while maintaining consideration of collaborations and partnering that will maximize the financial value return to our stockholders. We also seek to leverage third party resources through collaborations and partnerships for preclinical and clinical testing, as well as strategic supply chain relationships with various government, academic and industry entities to ensure and achieve the highest level of expertise and quality in support of our developments.

Our current and recent collaborators and partners include the NIAID/NIH, U.S. Department of Defense (DoD), U.S. Army Research Institute of Infectious Disease (USAMRIID), U.S. Naval Research Laboratory (USNRL), Emory University, University of Pittsburgh, Georgia State University Research Foundation (GSURF), University of Texas Medical Branch (UTMB), the Institute of Human Virology (IHV) at the University of Maryland, the Scripps Research Institute (Scripps), Burnet Institute in Australia, the Geneva Foundation, American Gene Technologies International, Inc. (AGT), ViaMune, Inc., Leidos, Inc., University of California San Francisco (UCSF), the HIV Vaccines Trial Network (HVTN), and the Centers for Disease Control and Prevention (CDC),

Our Differentiated Vaccine and Immunotherapy Platform

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, Marburg or Lassa fever 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.

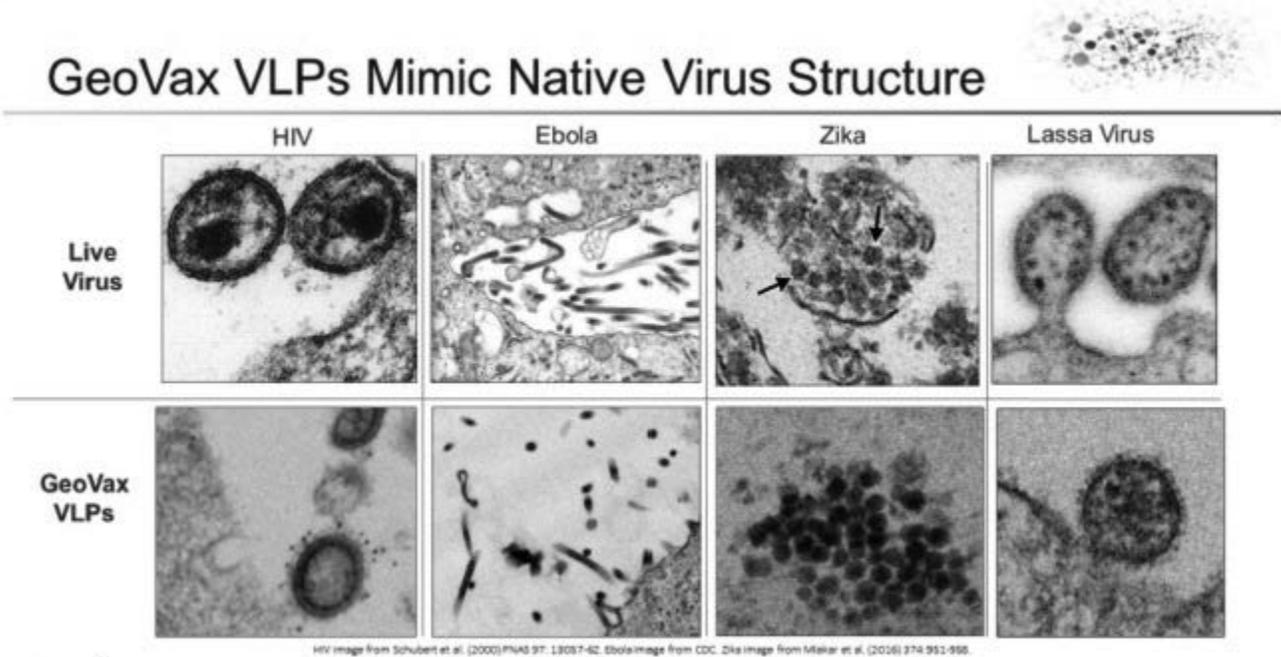


Figure 1. Comparison of MVA-VLPs and native virus structures

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 deletions 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:** Our HIV vaccines have demonstrated outstanding safety in multiple human clinical trials. 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.
- **Durability:** Our technology raises highly durable (long-lasting) vaccine responses, the most durable in the field of vectored HIV vaccines. 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.
- **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.

Our Product Development Pipeline

Our primary focus is to advance, independently and in partnerships, the products developed from our GV-MVA-VLP™ platform. We are currently developing a number of vaccines and immunotherapies for prevention or treatment of infectious diseases and cancer. The table below summarizes the status of our product development programs, which are discussed in greater detail in the following pages.

<u>Product Area / Indication</u>	<u>Stage of Development</u>	<u>Collaborators / Sponsors</u>
<u>Cancer</u>		
HPV-related cancers	Preclinical	Emory
MUC1-expressing tumors	Preclinical completed	Univ. of Pittsburgh, ViaMune
Cyclin B1-expressing tumors	Preclinical	
Checkpoint inhibitors	Preclinical	Leidos
<u>Infectious Diseases</u>		
HIV (preventive)	Phase 2a completed	NIH, HVTN, Emory
HIV (immunotherapy)	Phase 1	AGT, UCSF
Zika	Preclinical completed	NIH, CDC
Malaria	Preclinical	Leidos, Burnet Institute
Ebola, Marburg, Sudan	Preclinical completed	NIH, USAMRIID, UTMB
Lassa Fever	Preclinical	NIH, DoD, Scripps, IHV, UTMB, USNRL, Geneva Foundation
Coronavirus (COVID-19)	Preclinical	UTMB

We are seeking to develop a broad product pipeline based on our GV-MVA-VLP™ platform and have been pleased with the results, particularly considering the challenges we have faced in obtaining sufficient capital prior to our underwritten public offering in September 2020, and the related relatively small number of scientifically skilled employees we employ. These constraints have made it necessary to set priorities as to our primary focuses, and those will change as opportunities, resources, and other circumstances dictate. During 2019, for example, in addition to working with our collaborators/sponsors, we chose to focus a portion of our management time and budget in the area of immuno-oncology. More recently, the emergence of novel coronavirus (COVID-19) led us to decide to devote our management time and resources, and our platform, to address this epidemic. At times, some of our development programs are paused as we shift our focus due to our limited resources.

Our Cancer Immunotherapy Programs

Cancer is the second most common cause of death in the US, exceeded only by heart disease. Its global burden is expected to rise to 22 million new cases per year by 2030. There have been multiple technology advancements and product approvals that have highlighted the potential of immunology approaches to treat cancer. Monoclonal antibodies (mAbs) such as Herceptin® and dendritic cell therapy Provenge® for prostate cancer have had varying degrees of success. Dendritic or other cell-based therapy is a highly personalized medicine involving removing cells from the patient, modifying and multiplying them, and then returning them to the body. In addition to the high cost and complex processes to manufacture products, this approach has not been shown to generate high levels of cancer-specific T cells.

The field of immuno-oncology has received new momentum with the discovery and initial launch of a form of immune checkpoint inhibitors (ICIs), a type of monoclonal antibodies (Mabs). Tumors hijack the body's natural immune checkpoints by over expressing immune checkpoint ligands (proteins that bind to and activate the inhibitory activity of immune checkpoints), as a mechanism of immune resistance, especially against the T cells that are specific for tumor antigens and can kill cancer cells. ICIs block the interaction of immune checkpoints with their ligands on tumor cells, allowing otherwise poorly functional T cells to resume proliferation, cytokine production and killing of tumor cells.

More recently, a new category of immunotherapies called adoptive cell transfer, CAR-T technology for example, has provided further evidence of the merit of providing an enhanced T cell presence to fight cancer. Unfortunately, they have also been associated with significant side effects. Moreover, adoptive cell transfer such as CAR-T, like dendritic cell therapy, involves removing T cells from a patient, modifying them to better target a cancer cell, multiplying the T cells, then returning them to the patient. These complex therapeutic products need to be manufactured and released for each patient, leading to expensive manufacturing and increased supply chain complexity.

Unlike conventional therapies (e.g. radiation, chemotherapy, antibody, etc.), therapeutic cancer vaccines have the potential to induce responses that not only result in the control and even clearance of tumors but also establish immunological memory that can suppress and prevent tumor recurrence. Convenience, safety, and low toxicity of cancer vaccines could make them invaluable tools to be included in future immunotherapy approaches for treating tumors. Currently, there are only a few vectored cancer vaccines being tested in combination with ICIs, all of which are in early clinical stages.

Collaborations with University of Pittsburgh and ViaMune – We have established a collaboration with Dr. Olivera Finn, a leading expert in cancer immunotherapy at the University of Pittsburgh. Dr. Finn was one of the first to show that many tumors express an abnormal form of cell surface-associated Mucin 1 (MUC1) protein that is recognized by the immune system as foreign. Given this, we are developing our GV-MVA-VLP™ vaccine platform to deliver abnormal forms of MUC1 with the goal of raising therapeutic anti-tumor antibodies and T cell responses in cancer patients. Our collaboration with Dr. Finn has shown that a combination of our MVA-VLP-MUC1 vaccine candidate with a MUC1 synthetic peptide was capable of breaking tolerance to human MUC1 in huMUC1 transgenic mice and inducing immune responses with protective efficacy against challenge in a lymphoma tumor model (experiments were performed at the University of Pittsburgh).

We are also collaborating with ViaMune, Inc., which has developed a fully synthetic MUC1 vaccine candidate (MTI). The collaboration will assess each companies' vaccine platform, separately, and in combination, with the goal of developing a tumor MUC1 vaccine that can produce a broad spectrum of anti-tumor antibody and T cell responses. The resulting MUC1 vaccine could be combined with ICIs as a novel vaccination strategy for cancer patients with advanced MUC1+ tumors. We have produced a MVA-VLP-MUC1 vaccine candidate, demonstrated VLP production by electron microscopy using MUC1 immunogold staining, and showed that the VLPs express a hypo-glycosylated form of MUC1 in human cell lines. Preclinical studies of the combined MTI and MVA-VLP-MUC1 vaccines conducted at the University of North Carolina at Charlotte have shown the combination of our vaccine with MTI and ICI have significantly reduced the tumor burden in a mouse model for colorectal cancer.

Collaboration with Emory Vaccine Center – In July 2018, we began collaborating with Emory University on the development of a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). This is an important research area as there are currently no medical treatments for chronic HPV infections, which can lead to the formation of cancerous tumors. The GeoVax/Emory collaboration will include testing GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV in the laboratory of Dr. Rafi Ahmed, Director of the Emory Vaccine Center. Dr. Ahmed, a member of the National Academy of Sciences, is a world-renowned immunologist whose work during the past decade has been highly influential in shaping understanding of memory T cell differentiation and T and B cell-mediated antiviral immunity. We believe our collaboration with Emory on the HPV project is extremely valuable as it was Dr. Ahmed who first discovered in 2006 that the PD-1 pathway could also be exploited by many pathogens to repress normal T cell function during chronic viral infection. This led to development of numerous blockbuster anti-PD1 antibodies currently being used for treatment of various cancers and which hold promise as adjunctive therapy for several chronic infectious diseases. To increase the therapeutic efficacy of our HPV vaccine, we intend to apply a combination strategy which could include co-administration of anti-PD1 antibodies and/or other newly discovered immunotherapy drugs to improve a patient's own anti-cancer immune response.

Collaboration with Leidos – In November 2018, we began collaborating with Leidos, Inc. on a research program evaluating the combination of the companies' respective technologies in the field of cancer immunotherapy. Currently, there are major limitations on cancer immunotherapies which include high costs (limiting patient access, straining both the healthcare system and the patient's own finances), the need for multiple injections, and significant side effects. Moreover, monotherapy with one checkpoint inhibitor drug can induce drug resistance in some patients making it necessary to

combine with other drugs and treatments, which in turn may further increase toxicity. We have shown that our MVA platform can be safe in humans without any major side effects and believe that delivery of the immune checkpoint inhibitors with or without the tumor-associated antigens may overcome some of the challenges associated with the use of immune checkpoint inhibitors in cancers or other chronic infectious diseases. The GeoVax/Leidos collaboration includes the design, construction, and characterization of multiple immunotherapeutic vaccine candidates using our GV-MVA-VLP™ vaccine platform combined with certain novel peptide PD-1 checkpoint inhibitors developed by Leidos. We believe this effort may lead to expanded efforts in cancer immunotherapy, treatments for chronic Hepatitis B infections, or other diseases where an immunological-based therapeutic approach would be beneficial.

Our Infectious Disease Vaccine Programs

Our COVID-19 Vaccine Program

Coronaviruses are common in many species of animals including mammals, avian and bats. In rare occasions these viruses can evolve to cross the animal species and infect humans and quickly spread from person to person resulting in lethal respiratory infections. Recent epidemic with SARS and MERS coronaviruses resulted in 774 and 858 deaths, respectively. In January 2020, WHO identified a novel coronavirus, SARS-CoV-2 (or COVID-19), in the city of Wuhan, China. On January 31, World Health Organization (WHO) declared the novel coronavirus to be a global health emergency, and on March 11, 2020 WHO declared a global pandemic. As of late March, 2021, more than 120 million people worldwide have been infected and nearly 2.7 million people have died as a result of COVID-19 infections. The situation is fluid, with the infection and death statistics changing significantly on a regular basis.

During January 2020, we initiated vaccine development for prevention and/or control of COVID-2019 infection. Using our GV-MVA-VLP™ vaccine platform and expertise, multiple COVID-19 vaccine candidates have been designed and constructed, and are being tested in animal challenge models. Preclinical small animal studies are currently being conducted in collaboration with researchers at the University of Texas Medical Branch at Galveston. (UTMB) and at BioQual, Inc.

In January 2021, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), awarded the Company a Small Business Innovative Research (SBIR) grant in support of our development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The Phase 1 grant, titled, “*Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19,*” will support the ongoing design, construction and preclinical testing of our vaccine candidates in preparation for human clinical trials. The efficacy testing will be performed in collaboration with UTMB.

There are currently three COVID-19 vaccines approved by the FDA for use in the United States. These first generation of SARS-CoV-2 vaccines are based on the ‘Spike (S)’ protein and are designed to induce antibodies that block infection of human cells, an effect referred to as virus neutralization. The GV-MVA-VLP platform provides the opportunity to design and test vaccine candidates that differ significantly through the inclusion of multiple SARS-CoV-2 proteins that are presented to the immune system as VLPs. Unique among other vaccines approved or under development, the experimental GeoVax candidates are therefore specifically designed to provide a broader and more long-lived level of protective immunity against SARS-CoV-2 which should protect against emerging variants while avoiding the potential side effects that can limit vaccine utility and acceptance.

Our HIV/AIDS Vaccine Programs

About HIV/AIDS. An estimated 37 million people are living with HIV worldwide, with approximately 1.8 million newly infected annually. Since the beginning of the epidemic, more than 70 million people have been infected with the HIV virus and about 35 million have died of HIV. The United States currently has an estimated 1.1 million HIV-infected individuals, with approximately 40,000 new infections per year. Gay and bisexual men bear the greatest burden by risk group, representing nearly 70% of new infections in the U.S. African-Americans also bear a disproportionate burden, representing 43% of people living with HIV, yet representing just 12% of the total population.

There are several AIDS-causing HIV virus subtypes, or clades, that are found in different regions of the world. These clades are identified as clades A, B, C and so on. The predominant clade found in Europe, North America, parts of South America, Japan and Australia is clade B, whereas the predominant clades in Africa are clades A and C. In India, the predominant clade is clade C. Genetic differences between the clades may mean that vaccines or treatments developed against HIV of one clade may only be partially effective or ineffective against HIV of other clades. Thus, there is often a geographical focus to designing and developing HIV vaccines.

At present, the standard approach to treating HIV infection is to inhibit viral replication through the use of combinations of drugs – antiretroviral therapies (ART). Available drugs include reverse transcriptase inhibitors, protease inhibitors, integration inhibitors and inhibitors of cell entry. However, HIV is prone to genetic changes that can produce strains that are resistant to currently approved drugs. When HIV acquires resistance to one drug within a class, it can often become resistant to the entire class, meaning that it may be impossible to re-establish control of a genetically altered strain by substituting different drugs in the same class. Furthermore, these treatments continue to have significant limitations which include toxicity, patient non-adherence to the treatment regimens and cost. Thus, over time, viruses acquire drug-resistant mutations, and many patients develop intolerance to the medications or simply give up taking the medications due to cost, inconvenience or side effects.

There is no approved vaccine to prevent HIV infection. Prevention of HIV infection remains a worldwide unmet medical need, even in the United States and other first world countries where effective antiretroviral therapies are available. ART do not eliminate HIV infection, requiring individuals to remain on such drugs for their entire lives. Uptake and successful long-term adherence to therapy is also limited. Only 30% of those infected with HIV in the US ultimately remain in HIV care with their viral load sufficiently suppressed to prevent spread of HIV. Furthermore, the financial burden to the U.S. taxpayer for HIV education, prevention, and treatment costs is borne through multiple federal agencies, totaling over \$25 billion annually.

According to the International AIDS Vaccine Initiative (IAVI), the cost and complexity of new treatment advances for HIV/AIDS puts them out of reach for most people in the countries where treatment is most needed. In industrialized nations, where drugs are more readily available, side effects and increased rates of viral resistance have raised concerns about their long-term use. Vaccines are seen by many as the most promising way to end the HIV/AIDS pandemic. We expect that vaccines, once developed, will be used universally and administered worldwide by organizations that provide healthcare services, including hospitals, medical clinics, the military, prisons and schools.

Our Preventive HIV Vaccine Program

Clade B Preventive HIV Vaccine Program. Our most clinically advanced vaccine is GOVX-B11, designed to protect against the clade B subtype of the HIV virus prevalent in the Americas, Western Europe, Japan and Australia. GOVX-B11 consists of a recombinant DNA vaccine used to prime immune responses and a recombinant MVA vaccine (MVA62B) used to boost the primed responses. Both the DNA and MVA vaccines induce the production of non-infectious VLPs by the cells of the vaccinated person.

Phase 1 and Phase 2a human clinical trials of GOVX-B11 were conducted by the HVTN. The HVTN is the largest worldwide clinical trials network dedicated to the development and testing of HIV/AIDS vaccines. Support for the HVTN comes from the NIAID, part of the NIH. The HVTN's HIV Vaccine Trial Units are located at leading research institutions in 27 cities on four continents. In these trials, totaling approximately 500 participants, GOVX-B11 was tested at various doses and regimens. The vaccine was demonstrated to be safe, well-tolerated and immunogenic, inducing both antibody and cellular immune responses.

In January 2017 HVTN began the next human clinical trial (HVTN 114) in the path toward pivotal efficacy trials. HVTN 114 enrolled individuals who previously participated in the HVTN 205 Phase 2a trial of the GOVX-B11 vaccine, which concluded in 2012. HVTN 114 tested the ability of late booster vaccines (additional vaccinations) to increase the antibody responses elicited by the GOVX B11 vaccine regimen. These “late booster vaccines” consisted of the GeoVax MVA62B vaccine with or without a recombinantly produced HIV envelope glycoprotein (gp120) protein vaccine. The gp120 protein, AIDSVAX® B/E, is the same protein used to boost immune responses in the partially protective RV144 trial completed in Thailand and publicly reported in 2009. Participants in HVTN 114 received either (a) a MVA62B booster, (b) a combined booster of MVA62B and AIDSVAX® B/E, or (c) AIDSVAX® B/E alone. HVTN 114 was completed during 2018 and results were presented during the HIV Research for Prevention (HIVR4P) conference in Madrid, Spain in October 2018. The study demonstrated the most effective booster vaccine to be the combination of MVA62B live vector and AIDSVAX B/E proteins, which increased titers of antibodies to the HIV envelope gp120 by more than 600-fold.

Following completion of HVTN 114, the HVTN is moving forward with plans for an additional Phase 1 trial, designated HVTN 132, which will be a multi-center, randomized, double-blind trial, enrolling up to 70 healthy adults. The primary objectives of HVTN 132 will be to further assess the safety, tolerability and immunogenicity (elicited antibody responses) of a prime-boost regimen of GOVX-B11, in combination with gp120 booster vaccines. The protein booster vaccines are being tested for their ability to enhance the antibody response elicited by GOVX-B11 to gp120. The gp120 proteins to be evaluated in the trial were developed by Duke University and by the Institute of Human Virology of the University of Maryland School of Medicine. HVTN 132 will be conducted by the HVTN with support from NIAID and is expected to commence patient enrollment in late 2021.

Clade C Preventive HIV Vaccine Program. We also are developing DNA/MVA vaccines designed for use against the clade C subtype of HIV that predominates in South Africa and India. NIAID has previously awarded GeoVax SBIR grants in support of this effort, but further development of these vaccines will be dependent upon additional funding support.

Our HIV Immunotherapy Program – Seeking a Cure

Finding a cure for HIV/AIDS remains an elusive goal. Current ART, though highly effective at suppressing HIV viral load, are unable to eliminate latent forms of HIV that are invisible to the immune system and inaccessible to antiretroviral drugs. Long-term use of ART can lead to loss of drug effectiveness and can come with severe, debilitating side effects. The lifetime medical costs saved by preventing (or curing) a single HIV infection in the U.S. are estimated to approach \$400,000. Therefore, any new treatment regimen that allows patients to reduce, modify, or discontinue their antiretroviral therapy could offer measurable quality of life benefits to the patient and tremendous value to the marketplace.

Collaboration with AGT – In March 2017, we entered into collaboration with American Gene Technologies International, Inc. (AGT) whereby AGT intends to conduct a Phase 1 human clinical trial with our combined technologies, with the ultimate goal of developing a functional cure for HIV infection. In the AGT trial, the GeoVax vaccine will be used to stimulate virus specific CD4+ T cells *in vivo*, which will then be harvested from the patient, genetically modified *ex vivo* using AGT’s technology, and reinfused to the patient. The primary objectives of the trial will be to assess the safety of the therapy, with secondary objectives to assess the immune responses as a measure of efficacy. In a previous Phase 1 clinical trial (GV-TH-01), we demonstrated that our vaccine can stimulate production of CD4+ T cells in HIV infected patients– the intended use of the GV-MVA-VLP™ HIV vaccine in the AGT study. AGT began patient enrollment for their Phase 1 in September 2020. We expect our vaccine to be added to the AGT trial in 2021.

Collaboration with UCSF – In November 2019, we entered into an agreement with the University of California, San Francisco (UCSF), whereby we will participate in a collaborative effort led by researchers at UCSF to develop a combinational therapy aimed at inducing remission in HIV-positive individuals (a “functional cure”). The studies will be conducted with funding from amfAR, The Foundation for AIDS Research. The proposed clinical trial will enroll 20 HIV-infected adults who are on stable and effective ART. The therapeutic regimen to be tested involves a combination of vaccines, drugs and biologics. GeoVax will provide the MVA62B vaccine for use in the studies. The primary objectives of the trial will be to assess the safety and tolerability of the combinational therapy and to determine the viral load “set-point” during ART interruption. Secondary objectives will be to assess immune responses and changes in viral reservoir status. Patient enrollment for the clinical trial commenced in August 2020.

Our Filovirus (Ebola, Sudan, Marburg) Vaccine Program

Ebola (EBOV, formerly designated as Zaire ebolavirus), Sudan (SUDV), and Marburg viruses (MARV) are the most virulent species of the *Filoviridae* family. They can cause up to a 90% fatality rate in humans and are epizootic in Central and West Africa with 29 outbreaks since 1976. The most severe Ebola outbreak (2013-16 in Western Africa) caused 28,616 cases and 11,310 deaths (case fatality rate of 40%). During 2018-20, an outbreak in the Democratic Republic of the Congo caused 3,470 cases and 2,280 deaths (66% fatality rate). Additional outbreaks are certain in future due to indigenous reservoirs of the virus (e.g. fruit bats), the zoonotic nature of the virus, weak local infrastructure for healthcare systems, high population mobility, political unrest, cultural beliefs and burial practices, and for those not at natural risk, the risk of intentional release by a bioterrorist.

We believe an ideal vaccine against major filoviruses must activate both humoral and cellular arms of the immune system. It should include the induction of antibodies to slow the initial rate of infection and a cellular immune response to help clear the infection. Moreover, it should address strain variations by providing broad coverage against potential epizootic filovirus strains, and it should be safe not only in healthy individuals (e.g. travelers or health care workers), but also in immunocompromised persons (e.g., HIV infected) and those with other underlying health concerns.

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. The less advanced adeno-vectored vaccine candidates require relatively cumbersome heterologous prime/boost regimens, for example with MVA, to elicit durable protective immunity. The use of Ad5 vectors also has been associated with concerns over increased susceptibility to HIV infection in areas with high HIV incidence. Even with rVSV-ZEBOV showing promise in the 2013-2015 epidemic, the world would benefit by being prepared with a safer and effective vaccine, to prevent or alleviate the effects of the current and future epidemics.

To address the unmet need for a product that can respond to future filovirus epidemics we are developing innovative vaccines utilizing our GV-MVA-VLP™ platform. We are addressing strain variations, and induction of broad humoral and cellular response through development of monovalent vaccines, which we may also investigate blending together as a single vaccine to provide broad coverage, potentially with a single dose. The MVA vector itself is considered safe, having originally been developed for use in immunocompromised individuals as a smallpox vaccine. We expect our vaccines to not only protect at-risk individuals against EBOV, SUDV and MARV, but also potentially reduce or modify the severity of other re-emerging filovirus 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 people in Africa, it is intended to prevent the spread of disease to the US, and for preparedness against terrorist release of any of bio-threat pathogens.

Our initial preclinical studies in rodents and nonhuman primates for our EBOV vaccine candidate have shown 100% protection against a lethal dose of EBOV upon a single immunization. These studies were conducted with support from NIAID and USAMRIID. We have also designed and constructed vaccine candidates for SUDV and MARV. In an independent, peer-reviewed paper published by Lazaro Frias et al (J Virol. 2018 June 1; 92(11): e00363-18), the authors concluded that the MVA-VLP-Ebola and MVA-VLP-Sudan vaccines are the best-in class vaccine in development.

In July 2019, we reported positive results (100% protection) from preclinical challenge studies of our MARV vaccine candidate. In this study, our MARV vaccine was administered by intramuscular (IM) inoculations to guinea pigs, with a control group receiving saline injections. Eight weeks after inoculation, animals in each group were exposed to a lethal dose of MARV. Within 8 days post-challenge, all animals in the control group had developed moribund conditions and had to be euthanized. At the conclusion of the study (21 days post-challenge), all vaccinated animals survived, with no weight loss or other health issues. The study was conducted in collaboration with researchers at UTMB. Similar to MARV vaccine, our Sudan vaccine provided 100% protection in guinea pig challenge studies with near sterile immunity which is unprecedented for a replication deficient MVA virus.

Further development of our filovirus vaccines will be dependent upon additional funding support.

Our Lassa Fever Vaccine Program

Lassa fever virus (LASV), a member of the *Arenaviridae* family, causes severe and often fatal hemorrhagic illnesses in an overlapping region with Ebola. Lassa Fever is an acute viral hemorrhagic illness caused by LASV. In contrast to the unpredictable epidemics of filoviruses, LASV is endemic in West Africa with an annual incidence of >300,000 infections, resulting in 5,000-10,000 deaths. Data from a recent independent study suggest that the number of annual Lassa Fever cases may be much higher, reaching 3 million infections and 67,000 deaths, putting as many as 200 million persons at risk.

Our initial preclinical studies in rodents for our LASV vaccine candidate have shown 100% single-dose protection against a lethal dose of LASV challenge composed of multiple strains delivered directly into the brain. The study was conducted at the Institute of Human Virology at the University of Maryland School of Medicine in Baltimore. Multiple repeats of the study confirmed the findings.

Subsequent to these initial findings, in April 2018 NIAID awarded GeoVax a SBIR grant in support of further advancing our Lassa vaccine development program. The work was performed in collaboration with the Institute of Human Virology at the University of Maryland, The Scripps Research Institute, and the University of Texas Medical Branch.

In September 2018, the U.S. Department of Defense (DoD) awarded GeoVax a \$2,442,307 cooperative agreement in support of our LASV vaccine development program. The grant was awarded by the U.S. Army Medical Research Acquisition Activity pursuant to the Peer Reviewed Medical Research Program (PRMRP), part of the Congressionally Directed Medical Research Programs (CDMRP). In addition to the grant funds provided directly to GeoVax, DoD will also fund testing of the GeoVax vaccine by U.S. Army scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), under a separate subaward. The project award is supporting generation of immunogenicity and efficacy data for our vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparation for human clinical trials. The work is ongoing and is being performed in collaboration with USAMRIID and the Geneva Foundation.

Further development of our Lassa Fever vaccine beyond the work being funded by the U.S. DoD will be dependent upon additional funding and/or partnering support.

Our Zika Vaccine Program

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. ZIKV, which was first discovered in 1947 in the Zika forest of Uganda, was considered only a minor public health concern for 60 years. During 2015 and 2016, with its appearance and rapid spread in the Americas, it has emerged as a serious threat with pandemic potential. Symptoms of Zika infection have historically been mild. In the recent epidemic, however, an alarming association between ZIKV infection and fetal brain abnormalities including microcephaly has been observed. No approved preventive or therapeutic products are currently available to fight the Zika epidemic. Public health officials recommend avoiding exposure to ZIKV, delaying pregnancy, and following basic supportive care (fluids, rest, and acetaminophen) after infection. A vaccine is needed to prevent a Zika pandemic.

To address the unmet need for a ZIKV vaccine, we are developing novel vaccine candidates constructed using our 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 MVA-NS1 vaccine candidate demonstrated 100% single-dose protection against a lethal dose of ZIKV delivered directly into the brain. The study was conducted and funded by the US Centers for Disease Control and Prevention (CDC), which also provided technical assistance. In June 2017 NIAID awarded GeoVax a SBIR grant in support of preclinical testing of our MVA-NS1 vaccine in nonhuman primates in preparation for human clinical trials. In rhesus macaques vaccination with MVA-NS1 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 our ZIKV vaccine will be dependent upon partnering support.

Our Malaria Vaccine Programs

Malaria is a mosquito-borne disease caused by *Plasmodium* parasites. Symptoms are fever, chills, sweating, vomiting and flu-like illness. If untreated, severe complications (severe anemia, cerebral malaria and organ failure) will lead to death. Over 3 billion people in 106 countries and territories live at risk of malaria infection. According to the World Health Organization (WHO), an estimated 229 million new cases of malaria were recorded worldwide in 2019, resulting in 409,000 deaths. Current treatments include bed net distributions, drug treatment and mosquito spraying. Malaria parasites develop resistance to drugs and insecticides. Vaccines have shown to be the most cost-effective ways to fight and eliminate infectious diseases (Smallpox, polio, etc.), but after many decades of research and development, there is only one commercial malaria vaccine, known as "RTS, S" or by the tradename "Mosquirix". It requires four injections and has low efficacy (approximately 30%) which wanes over time. Current experimental vaccine candidates have limitations such as poor immunogenicity, based on limited number of antigens (generally 1-5 antigens), do not target multiple stages of the parasite life cycle, and do not induce strong durable functional antibodies and T cell responses. Therefore, identification of appropriate antigens and vaccine technologies remains critical for development of an effective malaria vaccine.

An ideal malaria vaccine candidate should contain antigens from multiple stages of the malaria parasite's life cycle, and should induce both functional antibodies (predominantly IgG1 and IgG3 subtypes shown to be associated with protection) and strong cell mediated immunity (e.g. Th1 biased CD4+ and CD8+) to reduce parasitemia by clearing infected cells (liver cells or erythrocytes). We have shown (in animal models and humans) that GV-MVA-VLP™ vaccines for non-malarial disease targets induces a Th1 biased response with both durable functional antibodies and CD4+ and CD8+ T cell responses and that multiple antigens can be included in a single vaccine. As such, we believe the GeoVax MVA-VLP platform is well-suited for use in the malaria vaccine field.

Collaboration with Burnet Institute – During 2017 we established a collaboration with the Burnet Institute, a leading infectious diseases research institute in Australia, for the development of a vaccine to prevent malaria infection. The project includes 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 is being performed at GeoVax with immunogenicity and challenge studies in animal models conducted at Burnet Institute using their unique functional assays that provide key information on vaccine efficacy. This project is ongoing.

Collaboration with Leidos – In February 2019, we began a collaboration with Leidos, Inc. to develop malaria vaccine candidates. The work is supported under a contract to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). Leidos has been tasked by USAID to advance promising vaccine candidates against *P. falciparum* malaria and selected the GeoVax GV-MVA-VLP™ platform as part of this development effort. The collaboration with Leidos complements our ongoing malaria vaccine development project with Burnet Institute and offers a separate opportunity for success. This project is ongoing.

Support from the United States Government

Grants and Contracts.

We have been the recipient of multiple federal grants and contracts in support of our vaccine development programs. Our most recent awards are as follows:

Lassa DoD Grant. In September 2018, the U.S. Department of Defense (DoD) awarded us a \$2,442,307 cooperative agreement in support of our LASV vaccine development program. The grant was awarded by the U.S. Army Medical Research Acquisition Activity pursuant to the Peer Reviewed Medical Research Program (PRMRP), part of the Congressionally Directed Medical Research Programs (CDMRP). In addition to the grant funds provided directly to GeoVax, DoD will also fund testing of our vaccine by U.S. Army scientists under a separate subaward. The award, entitled “*Advanced Preclinical Development and Production of Master Seed Virus of GEO-LM01, a Novel MVA-VLP Vaccine Against Lassa Fever*”, will support generation of immunogenicity and efficacy data for our vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing process development and cGMP production of vaccine seed stock in preparation for human clinical trials.

Lassa SBIR Grant. In April 2018, NIAID awarded us a \$300,000 SBIR grant entitled “*Construction and efficacy testing of novel recombinant vaccine designs for eliciting both broadly neutralizing antibodies and T cells against Lassa virus.*”

COVID-19 SBIR Grant. In January 2021, NIAID awarded us a \$299,927 Phase I SBIR grant in support of our development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The grant, titled, “*Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19,*” will support the ongoing design, construction and preclinical testing of our vaccine candidates in preparation for human clinical trials. The efficacy testing will be performed in collaboration with UTMB.

Malaria Contract with Leidos – In March 2019, we entered into a \$196,126 subcontract with Leidos, Inc., supported by a contract to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). Leidos has been tasked by USAID to advance promising vaccine candidates against *P. falciparum* malaria and selected the GeoVax GV-MVA-VLP™ platform as part of this development effort. In January 2020, the work was extended through an additional subcontract for \$385,193.

Zika SBIR Grant. In June 2017, NIAID awarded us a SBIR grant entitled “*Advanced Preclinical Testing of a Novel Recombinant Vaccine Against Zika Virus.*” The initial grant award was \$300,000 for the first year of a two-year project period beginning June 24, 2017, with a total project budget of \$600,000. In May 2018, the second-year grant of \$300,000 was awarded to us.

HIV Staged Vaccine Development Contract. In August 2016, NIAID awarded us a *Staged Vaccine Development* contract to produce our preventive HIV vaccine for use in future clinical trials. The award included a base contract of \$199,442 for the initial period from August 1, 2016 to December 31, 2017 (the “base period”) to support process development, as well as \$7.6 million in additional development options that can be exercised by NIAID. Prior to the end of the base period NIAID notified us that it did not plan to exercise the additional development option under the contract due to funds availability and NIAID’s programmatic needs. We do not expect this to have an impact on the human clinical trials of our preventive HIV vaccine currently being conducted by the HVTN, or future trials being planned.

HIV SBIR Grant. In April 2016, NIAID awarded us a SBIR grant entitled “*Enhancing Protective Antibody Responses for a DNA/MVA HIV Vaccine.*” The initial grant award was \$740,456 for the first year of a two-year project period beginning April 15, 2016, with a total project budget of \$1,398,615. In March 2017, NIAID awarded us \$658,159 for the second year of the project period to test the effects of adding two proteins to our vaccine regimen, and we subsequently received a one-year no-cost extension of the project period, which was completed during 2019.

Clinical Trial Support.

All our human clinical trials to date for our preventive HIV vaccines, including the recently completed HVTN 114 trial and the HVTN 132 trial currently planned, have been or will be conducted by the HVTN and funded by NIAID. This financial

support has been provided by NIAID directly to the HVTN, so has not been recognized in our financial statements, and we do not know the cost of these trials. See “Our Preventive HIV Vaccine Program” above for the current status of our human clinical trials.

Other Federal Support.

We have been the recipient of additional in-kind federal support through collaborative and intramural arrangements with CDC for our Zika vaccine program, the Rocky Mountain Laboratory facility of NIAID for our hemorrhagic fever virus vaccine program, and the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) for our hemorrhagic fever virus vaccine program. This support generally has been for the conduct or support of preclinical animal studies on our behalf.

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 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.

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, Lassa Fever, 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

We do not have the facilities or expertise to manufacture any of the clinical or commercial supplies of any of our products. 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.

We currently rely and intend to continue to rely on third-party contract manufacturers to produce vaccines needed for research and clinical trials. We have arrangements with third party manufacturers for the supply of our DNA and MVA vaccines 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 vaccine supplies to complete our currently planned clinical trials. Various contractors are generally available in the United States and Europe for manufacture of vaccines 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. Furthermore, there is currently a shortage of vaccine manufacturing capability due to demand for potential COVID-19 vaccines, which could affect our ability to have our vaccine candidates manufactured.

The MVA component of our vaccine is currently manufactured in cells that are cultured from embryonated eggs. We are exploring a number of approaches to growing MVA in continuous cell lines that can be grown in bioreactors more suitable for commercial-scale manufacturing.

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.

Competition

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be competitive with our products. As we develop and seek to ultimately commercialize our product candidates, we face and will continue to encounter competition with an array of existing or development-stage drug and immunotherapy approaches targeting diseases we are pursuing. We are aware of various established enterprises, including major pharmaceutical companies, broadly engaged in vaccine/immunotherapy research and development. These include Janssen Pharmaceuticals, Sanofi-Aventis, GlaxoSmithKline, Merck, Pfizer, and MedImmune. There are also various development-stage biotechnology companies involved in different vaccine and immunotherapy technologies including Aduro Biotech, Advaxis, BioNTech, Curevac, Dynavax, Juno, Moderna, and Novavax. If these companies are successful in developing their technologies, it could materially and adversely affect our business and our future growth prospects. The number of companies seeking to develop products and therapies for the treatment of unmet needs in these indications is likely to increase. Some of these competitive products and therapies are based on scientific approaches that are similar to our approaches, and others are based on entirely different approaches.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Our competitors' products may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any products that we develop and commercialize to compete based on, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payers.

There are currently three COVID-19 vaccines approved for use in the United States under emergency use authorizations (EUA) from the FDA -- from Pfizer-BioNTech, Moderna and Janssen (Johnson & Johnson). Vaccines from AstraZeneca and Novavax are in late-stage development, and many others are in earlier stages of development. There are currently no FDA licensed and commercialized HIV vaccines, Zika vaccines, or hemorrhagic fever virus vaccines (other than for Ebola) 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 HIV, these include Sanofi, GlaxoSmithKline, and Johnson & Johnson. Other HIV vaccines are in varying stages of research, testing and clinical trials including those supported by the NIH Vaccine Research Center, the U.S. Military, IAVI, the European Vaccine Initiative, and the South African AIDS Vaccine Initiative. 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, developed by Merck.

There are numerous FDA-approved treatments for HIV, primarily antiretroviral therapies, marketed by large pharmaceutical companies. Currently, there are no approved therapies for the eradication of HIV. We expect that major pharmaceutical companies that currently market antiretroviral therapy products or other companies that are developing HIV product candidates may seek to develop products for the eradication of HIV.

There are currently no commercialized vaccines to prevent malaria infection. A first-generation infection-blocking malaria vaccine, RTS, S, is under regulatory review. It requires 4 doses and has been recommended by the WHO for pilot implementation studies. Since this vaccine is based on a single antigen and has modest efficacy (30-40%, depending on the age of subjects), the WHO has defined a Road Map for developing and licensing of next generation malaria vaccines. These vaccines are expected to contain multiple antigens designed to block both infection and transmission of malaria with at least a 75% efficacy rate.

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.

Our Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our vaccines, including our Modified Vaccinia Ankara-Virus-Like Particle (MVA-VLP) based vaccines, and methods of treatment using our vaccines.

We 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 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 vaccine 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.

As of December 31, 2020, our owned and in-licensed patent estate, on a worldwide basis, includes 14 granted U.S. patents, 16 pending U.S. patent applications; 43 granted foreign patents, 13 pending foreign patent applications, and 1 Patent Cooperation Treaty (PCT) application spread over 19 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 IND and the submission date of a Biologics License Application (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 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.

Our current patent portfolio includes 5 patent families directed to various aspects of our DNA and MVA-based HIV vaccines, their genetic inserts expressing multiple HIV protein components, composition, structure, claim of immunization against multiple subtypes of HIV, routes of administration, safety and other related factors and methods of therapeutic and prophylactic use thereof including administration regimens. We have in-licensed patents from Emory University and the U.S. National Institutes of Health (NIH) relevant to our HIV-vaccine program. These patents will expire between 2022 and 2028, exclusive of any patent term adjustments or extensions. We wholly own one patent family directed to specific vaccine administration methods which, if issued, valid, and enforceable, will expire in 2037, exclusive of any patent term adjustments or extensions.

We wholly own one U.S. patent application directed to preventive vaccines against hemorrhagic fever viruses (Ebola, Sudan, Marburg and Lassa), and uses thereof. This application, if issued, valid, and enforceable, will expire in 2036, exclusive of any patent term adjustments or extensions.

We wholly own one U.S. patent application directed to preventive vaccines against Zika virus, and uses thereof. This application, if issued, valid, and enforceable, will expire in 2037, exclusive of any patent term adjustments or extensions.

We co-own one patent family with Georgia State University directed to preventive vaccines against human papilloma virus (HPV), and uses thereof. These applications, if issued, valid, and enforceable, will expire in 2037, exclusive of any patent term adjustments or extensions.

We wholly own one U.S. patent application directed to preventive vaccines against malaria, and use thereof. This application, if issued, valid, and enforceable, will expire in 2038, exclusive of any patent term adjustments or extensions.

We wholly own 3 patent families directed to our immuno-oncology vaccine compositions and methods of use thereof. The patent applications of these families, if issued, valid, and enforceable, will expire between 2037-2040, exclusive of any patent term adjustments or extensions.

We have a pending U.S. application directed to our virus-like particle (VLP) platform technology. This patent application, if issued, valid, and enforceable, will expire in 2037, 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. The patent applications in this family, 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 U.S. National Institutes of Health (NIH) 3 patent families directed to certain aspects of our MVA-viral backbone used in our SARS-CoV2 vaccine, which will expire between 2023 and 2032, exclusive of any patent term adjustments or extensions. 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, if issued, valid, and enforceable, will expire between 2037 and 2041, exclusive of any patent term adjustments or extensions.

We are the exclusive, worldwide licensee of several patents and patent applications, which we refer to as the Emory Technology, owned, licensed or otherwise controlled by Emory University for HIV or smallpox vaccines pursuant to a license agreement originally entered into on August 23, 2002 and restated on June 23, 2004 (the “Emory License”). The in-licensed Emory University patents will expire between 2022 and 2028, exclusive of any patent term extensions. Through the Emory License we are also a non-exclusive licensee of four issued United States patents owned by the NIH related to the ability of our MVA vector vaccine to operate as a vehicle to deliver HIV virus antigens, and to induce an immune response in humans. These in-licensed NIH patents will expire in 2023, exclusive of any patent term extensions.

The MVA backbone that we have been using in 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 National Institutes of Health 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. 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 2023 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 vaccine products. For example, in 2010, the United States enacted the Biologics Price Competition and Innovation Act (BPCIA). Under the BPCIA, innovator manufacturers of vaccine 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 vaccine product until 12 years after the date our vaccine 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 vaccine 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 vaccine products, or a product similar thereto, by submitting its own, original Biologics License Application (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.

Research and Development

Our expenditures for research and development activities were \$2,444,459 and \$1,910,715 during the years ended December 31, 2020 and 2019, 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 a number of leading scientists, on scientific and medical matters. The current members of our Scientific Advisory Board are:

<u>Name</u>	<u>Position/Institutional Affiliation</u>
Harriet L. Robinson, PhD.....	Chief Scientific Officer Emeritus, GeoVax
Stanley A. Plotkin, MD.....	Professor Emeritus, University of Pennsylvania, Adjunct Professor, Johns Hopkins University
Barney S. Graham, MD, PhD..	Senior Investigator, Vaccine Research Center, NIAID
Scott C. Weaver, PhD.....	Director, University of Texas Medical Branch Institute for Human Infections and Immunity Scientific Director, Galveston National Laboratory
Olivera J. Finn, PhD.....	Distinguished Professor of Immunology and Surgery, University of Pittsburgh

Properties

We lease approximately 8,400 square feet of office and laboratory space located at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia under a lease agreement which expires on December 31, 2022. We believe this space is adequate for our current needs.

Human Capital Resources

We currently have seven full-time and two part-time employees. None of our employees are covered by collective bargaining agreements and we believe that our employee relations are good.

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 available on this website under “Investors – SEC Reports,” free of charge, our SEC filings, 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 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

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 \$2,958,068 for the year ended December 31, 2020. 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.

Our business will require continued funding. If we do not receive adequate funding, we will 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.

The costs of conducting all of our human clinical trials to date for our preventive HIV vaccine have been borne by the HVTN, with funding by NIAID, and we expect NIAID support for additional clinical trials. GeoVax incurs costs associated with manufacturing the clinical vaccine supplies and other study support. We cannot predict the level of support we will receive from the HVTN or NIAID for any additional clinical trials of our HIV vaccines.

Our current operations are also partially supported by U.S. government grants awarded to us to support our COVID-19 and Lassa Fever vaccine programs. We are pursuing additional support from the federal government for our vaccine programs; however, as we progress to the later stages of our vaccine development activities, government financial support may be more difficult to obtain, or may not be available at all. Furthermore, there is some risk that actual funding for grants could be delayed, cut back, or eliminated due to government budget constraints. Therefore, it will be necessary for us to look to other sources of funding to finance our development activities.

We expect that our current working capital, combined with proceeds from current government grants, will be sufficient to support our planned level of operations into 2023. 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. 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.

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.

Our business could be adversely affected by widespread public health epidemics or other catastrophic events beyond our control.

In addition to our reliance on our own employees and facilities, we depend on our collaborators, laboratories and other facilities for the continued operation of our business. Despite any precautions we take, public health epidemics, such as COVID-19, or other catastrophic events, such as natural disasters, terrorist attacks, hurricanes, fire, floods and ice and snowstorms, may result in interruptions in our business.

In response to the COVID-19 pandemic, we have suspended all non-essential travel for our employees, are canceling or postponing in-person attendance at industry events, and limiting in-person work-related meetings. Currently, as a result of the work and travel restrictions related to the ongoing pandemic, several of our business activities are being conducted remotely which might be less effective than in-person meetings or in-office work. Despite these precautions, the necessary work within our laboratory and of our collaborators has continued without significant interruption. Although we continue to monitor the situation and may adjust our current policies as more information and guidance become available, temporarily suspending travel and limitations on doing business in-person has and could continue to negatively impact our business development efforts and create operational or other challenges, any of which could harm our business, financial condition and results of operations.

In addition, the COVID-19 pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees because of our limited staffing. COVID-19 related illness could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

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 U.S. Food and Drug Administration (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.

We face intense competition and rapid technological change that could result in products that are superior to 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 the HVTN, 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. There is also a risk of changes in clinical trial strategy and timelines due to the HVTN and NIAID altering their trial strategy.

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. 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 with whom we may contract.

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 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

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 new products have been subject to substantial patent rights litigation in the pharmaceutical industry. These lawsuits generally relate to the validity and infringement of patents or proprietary rights of third parties. Infringement litigation is prevalent with respect to generic versions of products for which the patent covering the brand name product is expiring, particularly since many companies that market generic products focus their development efforts on products with expiring patents. 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 conflict with those of our products. We expect to be subject to infringement claims from time to time in the ordinary course of business, and third parties could assert infringement claims against us in the future with respect to our current products or with respect to products that we may develop or license. 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, would likely delay the regulatory approval process, be costly and require significant time and attention of our key management and technical personnel.

Any inability to protect intellectual property rights in the United States and foreign countries could limit our ability to manufacture or sell 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.

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.

Neither the U.S. Patent and Trademark Office nor the courts have established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

Risks Related To Our Common Stock

Upon exercise of our outstanding warrants we will be obligated to issue a substantial number of additional shares of common stock which will dilute our present shareholders.

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. Currently outstanding warrants are exercisable for 2,994,969 shares. 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.

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.

We will need additional capital, and the sale of additional shares 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.

Certain provisions of our certificate of incorporation which authorize the issuance of additional 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. We have issued, and there are outstanding, 100 shares of Series B Convertible Preferred Stock. The remaining 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.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

We are subject to reporting obligations under the United States securities laws. The SEC, as required by the Sarbanes-Oxley Act of 2002, adopted rules requiring every public company to include a management report on such company's

internal controls over financial reporting in its annual report. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to achieve and maintain effective internal controls over financial reporting could result in the loss of investor confidence in the reliability of our financial statements, which in turn could negatively impact the trading price of our 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We lease approximately 8,400 square feet of office and laboratory space located at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia under a lease agreement which expires on December 31, 2022. We believe this space is adequate for our current needs.

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".

Holders

On March 17, 2021, there were 14 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

Effective as of May 1, 2020, we entered into a Customer Agreement and Subscription Agreement with Content Carnivores, LLC, pursuant to which the Company received services related to the management of our social media accounts in exchange for the monthly issuance of shares of our common stock valued at \$3,000. During the six-month period ended December 31, 2020, we issued 3,936 shares of our common stock to Content Carnivores, LLC at an aggregate value of \$18,000. In February 2021, we issued 1,472 shares of our common stock to Content Carnivores, LLC at an aggregate value of \$6,000. The Company relied on an exemption from the registration requirements of the Securities Act afforded by Section 4(a) (2) thereof and Rule 506 of Regulation D.

Effective as of November 1, 2020, we entered into a Marketing and Consulting Agreement and Subscription Agreement with CorProminence, LLC, pursuant to which the Company is receiving services related to shareholder information and relations. In November 2020, we issued 20,000 shares of our common stock to CorProminence, LLC as a restricted stock award under our 2020 Stock Incentive Plan with a value at that date of \$58,400. The Company relied on an exemption from the registration requirements of the Securities Act afforded by Section 4(a) (2) thereof and Rule 506 of Regulation D.

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

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of 2020.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information as of December 31, 2020 with respect to compensation plans under which our equity securities are authorized for issuance.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders	-0-	-0-	-0-
Equity compensation plans not approved by stockholders (1)	902,001	\$ 3.53	378,000

(1) 536,000 options are contingent upon receipt of stockholder approval.

A description of our equity compensation plans can be found in footnote 8 to our 2020 consolidated financial statements.

ITEM 6. SELECTED FINANCIAL DATA.

Part II, Item 6 is no longer required as the Company has adopted certain provisions within the amendments to Regulation S-K that eliminate Item 301.

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 "Selected Financial Data" and 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

GeoVax is a clinical-stage biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases using a novel vector vaccine platform (Modified Vaccinia Ankara-Virus Like Particle or "GV-MVA-VLP™"). During January 2020, we began a program to develop a vaccine for prevention of novel coronavirus (COVID-19) infection. That effort has resulted in four COVID-19 vaccine candidates. These COVID-19 vaccine candidates have been designed and constructed and are being tested using relevant experimental animal challenge models. Additional development programs are focused on preventive and therapeutic vaccines against Human Immunodeficiency Virus (HIV); preventive vaccines against hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa fever), Zika virus and malaria; as well as immunotherapies for solid tumor cancers.

For our infectious disease vaccines, our recombinant MVA vector expresses target proteins on highly immunogenic VLPs in the person being vaccinated, with the intended result of producing durable immune responses with the safety characteristics of the replication deficient MVA vector and cost-effective manufacturing.

In cancer immunotherapy, we believe that stimulating the immune system to treat or prevent cancers is a compelling concept and that the opportunity for immune-activating technologies is promising, especially in light of advancements such as checkpoint inhibitors leading the way in oncology. Despite drug approvals in limited indications and promising results in clinical trials, there remains a significant need and opportunity for further advancements. We believe our GV-MVA-VLP™ platform is well-suited for delivery of tumor-associated antigens and we plan to pursue development of our platform in this space.

Our most advanced vaccine program is focused on prevention of the clade B subtype of HIV prevalent in the regions of the Americas, Western Europe, Japan and Australia; our HIV vaccine candidate, GOVX-B11, will be included in an upcoming clinical trial (HVTN 132) managed by the HIV Vaccine Clinical Trials Network (HVTN) with support from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), which is targeted to begin in late 2021. Additionally, during August 2020 a consortium led by researchers at the University of California, San Francisco (UCSF) began a clinical trial using our vaccine as part of a combinational therapy to induce remission in HIV-positive individuals. Through the efforts of our collaborator, American Gene Technologies International, Inc. (AGT), we expect that our HIV vaccine will also enter clinical trials during 2021 in combination with AGT's gene therapy technology to seek a functional cure for HIV. Our other vaccine and immunotherapy programs are at various other stages of development.

Our corporate strategy is to advance, protect and exploit our differentiated vaccine/immunotherapy platform leading to the successful development of preventive and therapeutic vaccines against infectious diseases and various cancers. With our design and development capabilities, we are progressing and validating an array of cancer and infectious disease immunotherapy and vaccine product candidates. Our goal is to advance products through to 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.

We have not generated any revenues from the sale of the products we are developing, and we do not expect to generate any such revenues for at least the next several years. 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. We may not be successful in our research and development efforts, and we may never generate sufficient product revenue to be profitable.

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, 2020, which are included in this Form 10-K. 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.

Grant revenue – 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.

Research collaborations – 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 8 to our financial statements for additional stock-based compensation information.

Liquidity and Capital Resources

Our principal uses of cash are to finance our research and development activities. Since inception, we have funded these activities primarily from government grants and clinical trial assistance, and from sales of our equity and debt securities. At December 31, 2020, we had cash and cash equivalents of \$9,883,796 and total assets of \$10,393,899, as compared to \$283,341 and \$468,880, respectively, at December 31, 2019. At December 31, 2020, we had working capital of \$9,424,839, compared to a working capital deficit of \$1,568,929 at December 31, 2019.

Net cash used in operating activities was \$2,750,570 and \$1,398,497 for the years ended December 31, 2020 and 2019, respectively. Generally, the variances between periods are due to fluctuations in our net losses, offset by non-cash charges such as depreciation and stock-based compensation expense, and by net changes in our assets and liabilities. Our net losses generally fluctuate based on expenditures for our research activities, partially offset by government grant revenues. See "Results of Operations – Grant and Collaboration Revenues" below for additional details concerning our government grants.

NIAID has funded the costs of conducting all of our human clinical trials (Phase 1 and Phase 2a) to date for our preventive HIV vaccines, with GeoVax incurring certain costs associated with manufacturing the clinical vaccine supplies and other study support. We expect that NIAID will also fund the cost of the planned Phase 1 trial (HVTN 132) to further evaluate the safety and immunogenicity of adding "protein boost" components to our vaccine, GOVX-B11. We expect HVTN 132 to commence patient enrollment during 2021. Additionally, we are party to a collaboration with American Gene Technologies International, Inc. (AGT) whereby AGT intends to conduct a Phase 1 human clinical trial with our combined technologies, with the ultimate goal of developing a functional cure for HIV infection. AGT began the Phase 1 trial in late 2020, and we expect the addition of our vaccine into the trial during 2021. A similar effort is underway with a consortium led by researchers at the University of California, San Francisco (UCSF), using our vaccine as part of a combinational therapy to induce remission in HIV-positive individuals; this program entered clinical trials during August 2020. Each of these programs could experience delays as a result of the ongoing COVID-19 pandemic.

Net cash used in investing activities was \$156,791 and \$7,606 for the years ended December 31, 2020 and 2019, respectively. Our investing activities have consisted predominantly of capital expenditures for laboratory equipment.

Net cash provided by financing activities was \$12,507,816 and \$1,429,743 for the years ended December 31, 2020 and 2019, respectively. Net cash provided by financing activities during 2020 relates to (i) the sale in January 2020 of shares of our Series J Preferred Stock for net proceeds of \$300,000, (ii) \$170,200 of PPP loan proceeds received in April 2020 (see discussion below), (iii) \$888,500 of net proceeds received in June 2020 from our issuance of Convertible Debentures (see discussion below) (iv) net proceeds of approximately \$11.2 million received in September 2020 from the public offering of our equity securities (see discussion below), (v) \$2,500 of net proceeds from the exercise of warrants, and (vi) \$11,880 in principal repayments toward the GRA Note. Net cash provided by financing activities during 2019 relates to the sale of shares of our Series G and Series I convertible preferred stock for aggregate net proceeds of \$1,440,000 and \$10,257 in principal repayments toward the GRA Note.

PPP Loan. On April 17, 2020, we received a \$170,200 bank loan backed by the United States Small Business Administration pursuant to the Paycheck Protection Program (PPP) provisions of the CARES Act. The loan bears an annual interest rate of one percent and is due April 17, 2022. In October 2020, we applied to the lender to have the loan forgiven, based upon our submission of qualifying information regarding eligible expenses; as of the date of this report our forgiveness application has not been processed.

Issuance of Convertible Debenture and Subsequent Conversion to Equity. On June 26 2020, we entered into a securities purchase agreement with two institutional investors, pursuant to which we received gross proceeds of \$1,050,000 in exchange for the issuance of: (i) 5% Original Issue Discount Senior Secured Convertible Debentures (the “Convertible Debentures”) in the aggregate principal amount of \$1,200,000; and (ii) five-year warrants (the “June 2020 Warrants”) to purchase an aggregate of 120,000 shares of our common stock at an initial exercise price of \$10.00 per share. Net proceeds after deducting the original issue discount, finder’s fee and other debt issuance costs were \$888,500.

The Convertible Debentures were mandatorily convertible upon our consummation of a public offering of common stock with gross proceeds of \$6,000,000 or more, and which resulted in the listing of our common stock on a national securities exchange (a “Qualified Offering”). The conversion price upon the occurrence of a Qualified Offering was equal to the lower of (i) \$10.00 per share or (ii) 80% of the offering price. The conversion provisions of the Convertible Debentures were subject to a “conversion blocker” such that each of the purchasers could not convert the Convertible Debentures to the extent that the conversion would result in the purchaser and its affiliates holding more than 4.99% of our outstanding common stock.

Upon our consummation of the public offering discussed below, the \$1,200,000 maturity value of the Convertible Debentures and \$14,667 of accrued interest were automatically converted at \$4.00, the Qualified Offering discounted price, resulting in the issuance of 303,668 conversion units. Of the 303,668 conversion units: (a) 177,626 consisted of one share of common stock and a warrant to purchase one share of common stock (a “Conversion Warrant”), and (b) 126,042 consisted of one pre-funded warrant to purchase one share of common stock (a “Pre-Funded Warrant”) and a Conversion Warrant. The Pre-Funded Warrants provided the holder the right to purchase one share of Common Stock at an exercise price of \$0.01 per share and were exercised in full in January 2021. The Conversion Warrants provide the holder the right to purchase one share of common stock, are immediately exercisable at an exercise price of \$5.00 per share and expire five years after the issuance date. As a result of the public offering the exercise price of the June 2020 Warrants was reduced to \$5.00.

Public Offerings – On September 29, 2020, we closed an underwritten public offering (the “Offering”) of an aggregate of 2,560,000 units of our equity securities (the “Units”), with gross proceeds to us of approximately \$12.8 million. Net proceeds after deducting underwriting discounts and commissions and other offering expenses were approximately \$11.2 million.

Of the 2,560,000 Units sold in the Offering: (a) 2,310,000 Units consisting of one share of our common stock, and a Warrant to purchase one share of common stock (each, a “Unit Warrant”); and (b) 250,000 Units consisting of a Pre-Funded Warrant to purchase one share of common stock and a Unit Warrant. The Pre-Funded Warrants provided the holder the right to purchase one share of common stock at an exercise price of \$0.01 per share and were exercised in full during October 2020. The Unit Warrants provide the holder the right to purchase one share of common stock, are immediately exercisable at an exercise price of \$5.00 per share and expire five years after the issuance date. The public offering price was \$5.00 per Unit (\$4.99 for each Unit including a Pre-Funded Warrant).

Pursuant to the Underwriting Agreement, we issued to the representative of the underwriters, as a portion of the underwriting compensation, warrants to purchase up to a total of 128,000 shares of common stock (the “Representative Warrants”). The Representative Warrants have an exercise price of \$5.50 per share, are initially exercisable 180 days after the effective date of the Offering and have a term of three years from their initial exercise date.

On February 11, 2021, we closed an underwritten bought deal public offering of 1,644,000 shares of our common stock, including 204,000 shares sold pursuant to the full exercise of the underwriter’s option to purchase additional shares, at a price to the public of \$6.25 per share. Net proceeds after deducting underwriting discounts and commissions and other offering expenses were approximately \$9.4 million

2021 Warrant Exercises – During January and February 2021, holders of our warrants exercised 62,626 Series I Warrants, 126,042 Pre-Funded Warrants and 690,034 Unit Warrants, resulting in the issuance of 835,900 shares of our common stock for aggregate net proceeds to us of \$3,174,156.

Conversion of Deferred Compensation to Equity – From 2016 through August 2020, to help conserve the Company’s cash resources, our executive officers and non-employee directors agreed to defer receipt of all or a portion (at varying levels) of their respective cash compensation. On September 29, 2020, upon our consummation of the Offering, \$1,500,000 of the accumulated deferrals were converted at the \$5.00 offering price, resulting in the issuance of 300,001 units substantially similar to the units sold in the public offering, with each unit consisting of one share of our common stock and one warrant substantially similar to a Unit Warrant (a “Management Warrant”). The Company also paid the executive officers and non-employee directors \$525,198 of the deferred compensation in cash.

As of December 31, 2020, we had an accumulated deficit of \$45.8 million. We expect for the foreseeable future we will continue to operate at a loss. The amount of the accumulated deficit will continue to increase, as it will be expensive to continue our research and development efforts. We will continue to require substantial funds to continue our activities and cannot predict the outcome of our efforts. We believe that our existing cash resources, combined with funding from existing government grants and clinical trial support, will be sufficient to fund our planned operations into 2023. We may require additional funds to continue our planned operations beyond that date. We are currently seeking sources of capital through additional government grant programs and clinical trial support, and we plan to conduct additional offerings of our equity securities. Additional funding may not be available on favorable terms or at all and if we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs as well as reduce our general and administrative expenses.

Net Operating Loss Carryforwards

At December 31, 2020, we had consolidated net operating loss carryforwards for income tax purposes of \$61.8 million, of which approximately \$53.6 million will expire in 2021 through 2037 if not utilized. We also have research and development tax credits of approximately \$1.2 million available to reduce income taxes, if any, which will expire in 2022 through 2040 if not utilized. Section 382 of the Internal Revenue Code contains provisions that may limit our utilization of net operating loss and research 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.

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, other than the operating lease for our office and laboratory space.

Results of Operations

We recorded net losses of \$2,958,068 and \$2,370,629 for the years ended December 31, 2020 and 2019, respectively. Our operating results typically fluctuate due to the timing of activities and related costs associated with our research and development activities and our general and administrative costs, as described below.

Grant and Collaboration Revenues

We recorded grant and collaboration revenues of \$1,823,658 and \$1,175,896 for the years ended December 31, 2020 and 2019, respectively.

Grant Revenues – Our grant revenues relate to grants and contracts from agencies of the U.S. government in support of our vaccine development activities, and such revenues were 79% and 84% of our total revenues for 2020 and 2019, respectively. We record revenue associated with these grants as the related costs and expenses are incurred. The variance in our grant revenues from period to period relates to the timing and amount of our expenditures for activities supported by the grants. Additional detail concerning our grant revenues and the remaining funds available for use as of December 31, 2020 is presented in the table below.

Grant/Contract No.	Grant Revenue Recorded During		Unused Funds Available at December 31, 2020
	Year Ended December 31, 2020	Year Ended December 31, 2019	
Lassa Fever – U.S. Army Grant	\$ 1,438,465	\$ 674,179	\$ 165,500
Lassa Fever – SBIR Grant.....	-	147,042	-
Zika – NIH SBIR Grant.....	-	162,461	-
Total	<u>\$ 1,438,465</u>	<u>\$ 983,682</u>	<u>\$ 165,500</u>

Collaboration Revenues – In addition to the grant revenues above, during the years ended December 31, 2020 and 2019, we recorded revenues of \$385,193 and \$192,214 associated with several research collaborations with third parties. These were 21% and 16% of our revenues for 2020 and 2019, respectively.

Research and Development Expenses

Our research and development expenses were \$2,444,459 and \$1,910,715 for the years ended December 31, 2020 and 2019, respectively. Research and development expense for these periods includes stock-based compensation expense of \$7,156 and \$43,801 for 2020 and 2019, respectively (see discussion under “Stock-Based Compensation Expense” below).

Our research and development expenses can fluctuate considerably on a period-to-period basis, depending on the timing of expenditures related to our government grants and other research projects, and other factors. Research and development expenses increased by \$533,744, or 28% from 2019 to 2020. The fluctuation is primarily due to the timing of expenditures related to our government grants. Our research and development costs do not include costs incurred by the HVTN in conducting clinical trials of our preventive HIV vaccines; those costs are funded directly to the HVTN by NIAID.

We do not disclose our research and development expenses by project, since our employees’ time is spread across multiple programs and our laboratory facility is used for multiple vaccine candidates. We track the direct cost of research and development expenses related to government grant revenue by the percentage of assigned employees’ time spent on each grant and other direct costs associated with each grant. Indirect costs associated with grants are not tracked separately but are applied based on a contracted overhead rate negotiated with the NIH. Therefore, the recorded revenues associated with government grants approximate the costs incurred.

We expect our research and development costs to increase as we continue development of our various programs and as we move toward later stages of development, especially with regard to clinical trials. We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with vaccine 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 pre-clinical studies and clinical trials, we may elect to discontinue or delay vaccine development programs to focus our resources on more promising vaccine 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 number of patients that ultimately participate in the clinical trial; the duration of patient follow-up that seems appropriate in view of the results; the number of clinical sites included in the clinical trials; and the length of time required to enroll suitable patient subjects.

General and Administrative Expenses

Our general and administrative expenses were \$2,196,014 and \$1,637,674 for the years ended December 31, 2020 and 2019, respectively. General and administrative costs include officers’ salaries, legal and accounting costs, patent costs, and other general corporate expenses. General and administrative expense includes stock-based compensation expense of \$57,307 and \$283,699 for 2020 and 2019, respectively (see discussion under “Stock-Based Compensation Expense” below). Excluding stock-based compensation expense, general and administrative expenses were \$2,138,707 and \$1,353,975 for 2020 and 2019, respectively, representing an increase of \$784,732 or 58%. The increase from 2019 to 2020 is primarily related to higher legal fees, patent costs, investor relations consulting, and personnel costs. We expect that our general and administrative costs will increase in the future in support of expanded research and development activities and other general corporate activities.

Stock-Based Compensation Expense

For the two years ended December 31, 2020, the components of stock-based compensation expense were as follows:

	2020	2019
Stock option expense.....	\$ 18,730	\$ 104,420
Stock issued for non-employee services.....	45,733	223,080
Total stock-based compensation expense.....	<u>\$ 64,463</u>	<u>\$ 327,500</u>

As a result of the reverse stock splits enacted in April 2019 and in January 2020, we made adjustments and retroactive restatements to all of our outstanding stock options such that the balances in January 2020 were negligible. We therefore recorded no stock-based compensation expense related to our stock option plan for the majority of 2020. We re-initiated employee stock option grants in December 2020 and recorded a proportionate amount of expense for the year ended December 31, 2020.

In general, stock-based compensation expense is allocated to research and development expense or general and administrative expense according to the classification of cash compensation paid to the employee, consultant or director to whom the stock compensation was granted. For the two years ended December 31, 2020, stock-based compensation expense was allocated as follows:

	2020	2019
General and administrative expense.....	\$ 57,307	\$ 283,699
Research and development expense	7,156	43,801
Total stock-based compensation expense.....	<u>\$ 64,463</u>	<u>\$ 327,500</u>

Other Income (Expense)

Interest income was \$2,271 and \$6,359 for the years ended December 31, 2020 and 2019, respectively. The variances between years are primarily attributable to the cash available for investment and to interest rate fluctuations.

Interest expense was \$143,524 and \$4,495 for the years ended December 31, 2020 and 2019, respectively. Interest expense relates to the Convertible Debentures, GRA Note, PPP Loan, and financing costs associated with insurance premiums. For 2020, interest expense included \$14,667 of accrued interest payable and \$124,185 of amortized debt discount related to the Convertible Debentures. Subsequent to the full conversion of the Convertible Debentures into our equity securities on September 29, 2020, there will be no more interest expense associated with the Convertible Debentures, and we expect other interest expense will be minimal.

Impact of Inflation

For the two-year period ended December 31, 2020, we do not believe that inflation and changing prices had a material impact on our operations or on our financial results.

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, 2020 and 2019 and for the two-year period ended December 31, 2020 together with the independent registered public accounting firm’s report thereon, are set forth on pages F-1 to F-18 of this Annual Report on Form 10-K.

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.

An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2020. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2020 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, 2020 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, 2020, 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

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is included in our definitive proxy statement for our 2021 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.

Code of Business Conduct and Ethics

Our Board of Directors has adopted a written Code of Business Conduct and Ethics, a copy of which is available on our website at www.geovax.com. The Company will provide a copy of the Code of Ethics upon request to any person without charge. Such requests may be transmitted by regular mail in the care of the Corporate Secretary. We require all officers, directors and employees to adhere to this code in addressing the legal and ethical issues encountered in conducting their work. The code requires that employees avoid conflicts of interest, comply with all laws and other legal requirements, conduct business in an honest and ethical manner, and otherwise act with integrity and in our best interest. Employees are required to report any conduct that they believe in good faith to be an actual or apparent violation of the code. The Sarbanes-Oxley Act of 2002 requires certain companies to have procedures to receive, retain and treat complaints received regarding accounting, internal accounting controls or auditing matters and to allow for the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters. We have such procedures in place.

The Company will post on its website, www.geovax.com, or will disclose on a Form 8-K filed with the SEC, any amendments to, or waivers from, a provision of the Code of Ethics that applies to the Chief Executive Officer or the Chief Financial Officer, or persons performing similar functions, and that relate to (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair,

accurate, timely, and understandable disclosure in reports and documents that the Company files with, or submits to, the SEC and in other public communications made by the Company; (iii) compliance with applicable governmental laws, rules and regulations; (iv) the prompt internal reporting of violations of the Code of Ethics to an appropriate person or persons identified in the code; or (v) accountability for adherence to the Code of Ethics. Any waiver granted to an executive officer or a director may only be granted by the Board and will be disclosed, along with the reasons therefor, on a Form 8-K filed with the SEC. No such waivers were granted in 2020.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is included in our definitive proxy statement for our 2021 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 2021 annual meeting of stockholders to be filed with the SEC under the captions “Security Ownership of Principal Stockholders, Directors and Executive Officers” and “Securities Authorized for Issuance under Equity Compensation Plans” 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 2021 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 2021 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:

(1) Financial Statements	<u>Page</u>
Report of Independent Registered Public Accounting Firm.....	F-2
Consolidated Balance Sheets as of December 31, 2020 and 2019	F-4
Consolidated Statements of Operations for the years ended December 31, 2020 and 2019.....	F-5
Consolidated Statements of Stockholders’ Equity (Deficiency) for the years ended December 31, 2020 and 2019 ..	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019	F-7
Notes to Consolidated Financial Statements	F-8

(2) Financial Statement Schedules

The following financial statement schedule is set forth on page F-18 of this Annual Report on Form 10-K:
 Schedule II—Valuation and Qualifying Accounts for the years ended December 31, 2020 and 2019

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	Certificate of Incorporation (2)
3.1.1	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 13, 2010 (4)
3.1.2	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 27, 2010 (5)
3.1.3	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed August 2, 2013 (6)
3.1.4	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed May 13, 2015 (9)
3.1.5	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed June 14, 2016 (10)
3.1.6	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed August 4, 2017 (11)
3.1.7	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed April 30, 2019 (14)
3.1.8	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed January 21, 2020 (16)
3.1.9	Certificate of Amendment to the Certificate of Incorporation of GeoVax Labs, Inc. filed September 24, 2020 (23)
3.2	Bylaws (2)
4.1	Form of Stock Certificate representing the Company's Common Stock, par value \$0.001 per share (20)
4.1.1	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (8)
4.1.2	Form of Stock Certificate for the Series B Convertible Preferred Stock (8)
4.1.3	Form of Common Stock Purchase Warrant (22)
4.1.4	Form of Representative's Warrant Agreement (21)
4.1.5	Form of Warrant Agent Agreement (21)
4.1.6	Form of Warrant issued to certain Management Creditors (21)
4.1.7	Form of Common Stock Purchase Warrant, dated June 26, 2020 (19)
4.1.8	Form of Underwriters Warrant Agreement dated February 11, 2021 (26)
10.1 **	Employment Agreement between GeoVax Labs, Inc. and David A. Dodd (12)
10.2 **	Employment Agreement between GeoVax, Inc. and Mark W. Reynolds (3)
10.2.1 **	Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Mark W. Reynolds (7)
10.5 **	GeoVax Labs, Inc. 2020 Stock Incentive Plan (18)
10.5.1 *, **	Form of Non-Qualified Stock Option Agreement
10.6	License Agreement (as amended and restated) between GeoVax, Inc. and Emory University (1)
10.7	Patent and Biological Materials License Agreement with the National Institute of Allergy and Infectious Diseases, dated October 22, 2020 (24)
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 (25)
10.9	Office and Laboratory Lease between UCB, Inc. and GeoVax, Inc. (17)
10.10 *	Summary of the GeoVax Labs, Inc. Director Compensation Plan
10.11	Underwriting Agreement dated September 24, 2020 (26)
10.12	Senior Note Purchase Agreement between Georgia Research Alliance, Inc. and GeoVax Labs, Inc. (12)
14.1	Code of Ethics (13)
21.1	Subsidiaries of the Registrant (15)
23.1*	Consent of Wipfli LLP
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
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

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

*** XBRL (Extensible Business Reporting Language) information furnished hereto are deemed not 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, is

deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

- (1) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 4, 2006.
- (2) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 23, 2008.
- (3) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 8, 2010.
- (4) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 14, 2010.
- (5) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 28, 2010.
- (6) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 2, 2013.
- (7) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 23, 2013.
- (8) Incorporated by reference from the registrant's Current Report on Form 8-K filed December 17, 2013.
- (9) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 14, 2015.
- (10) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 16, 2016.
- (11) Incorporated by reference from the registrant's Current Report on Form 8-K filed August 4, 2017.
- (12) Incorporated by reference from the registrant's Current Report on Form 8-K filed September 7, 2018.
- (13) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 26, 2019.
- (14) Incorporated by reference from the registrant's Current Report on Form 8-K filed April 30, 2019.
- (15) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed November 7, 2019.
- (16) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 21, 2020.
- (17) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 24, 2020.
- (18) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 25, 2020.
- (19) Incorporated by reference from the registrant's Current Report on Form 8-K filed June 26, 2020.
- (20) Incorporated by reference from the Amendment No. 2 to registrant's Registration Statement on Form S-1 (File No. 333-239958) filed August 26, 2020.
- (21) Incorporated by reference from the Amendment No. 3 to registrant's Registration Statement on Form S-1 (File No. 333-239958) filed September 8, 2020.
- (22) Incorporated by reference from the Amendment No. 4 to registrant's Registration Statement on Form S-1 (File No. 333-239958) filed September 23, 2020.
- (23) Incorporated by reference from the registrant's Current Report on Form 8-K filed September 25, 2020.
- (24) Incorporated by reference from the registrant's Current Report on Form 8-K filed October 26, 2020. 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.
- (25) Incorporated by reference from the registrant's Current Report on Form 8-K filed November 30, 2020. 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.
- (26) Incorporated by reference from the registrant's Current Report on Form 8-K filed February 11, 2021.

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
David A. Dodd
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 23, 2021

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.

Signature / Name	Title	Date
<u>/s/ David A. Dodd</u> David A. Dodd	Director President and Chief Executive Officer (Principal Executive Officer)	March 23, 2021
<u>/s/ Mark W. Reynolds</u> Mark W. Reynolds	Chief Financial Officer (Principal Financial and Accounting Officer)	March 23, 2021
<u>/s/ Randal D. Chase</u> Randal D. Chase	Director	March 23, 2021
<u>/s/ David A. Dodd</u> David A. Dodd	Director	March 23, 2021
<u>/s/ Dean G. Kollintzas</u> Dean G. Kollintzas	Director	March 23, 2021
<u>/s/ Robert T. McNally</u> Robert T. McNally	Director	March 23, 2021
<u>/s/ John N. Spencer, Jr.</u> John N. Spencer, Jr.	Director	March 23, 2021

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, 2020 and 2019, and the related consolidated statements of operations, stockholders’ equity (deficiency) and cash flows for the years then ended and the related notes to the consolidated financial statements and schedule (collectively, the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Equity Transactions

As described in Notes 6 and 8 to the consolidated financial statements, the Company has multiple equity instruments with various levels of complexity and volumes including convertible debentures, convertible preferred stock, preferred stock, warrants and stock options.

The principal considerations for our determination that the complexity of the Company's equity structure should be a critical audit matter were based on the accounting for certain equity instruments including convertible debentures, convertible preferred stock and stock options requiring significant judgment and estimates as well as the volume of equity transactions, including conversions to common stock, common stock issuance activity and warrant activity making it challenging to ensure adequate disclosure of all equity transactions. Auditing such estimates and activity required extensive audit effort due to the volume and complexity of these transactions and a high degree of auditor judgment when performing the requisite audit procedures and evaluating the results of those procedures.

The primary audit procedures we performed to address this critical audit matter included:

- We evaluated the design effectiveness of controls over the Company's process for accounting for and recording equity transactions
- We evaluated management's judgments related to the application of U.S. GAAP by reviewing management's accounting analysis for convertible debentures and convertible preferred stock
- We tested the assumptions used within the Black-Scholes model calculation to estimate the value of stock options granted, which included key assumptions such as the estimated life of the stock options and volatility of the Company's stock price

Wipfli LLP

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

Atlanta, Georgia
March 23, 2021

GEOVAX LABS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 9,883,796	\$ 283,341
Grant funds and other receivables	182,663	68,603
Prepaid expenses and other current assets.....	168,689	95,320
Total current assets.....	10,235,148	447,264
Property and equipment, net (Note 3)	147,741	10,606
Deposits.....	11,010	11,010
Total assets.....	\$ 10,393,899	\$ 468,880
 LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	\$ 267,702	\$ 152,653
Accrued expenses (Note 4)	359,281	1,851,040
Current portion of notes payable.....	183,326	12,500
Total current liabilities	810,309	2,016,193
Note payable, net of current portion.....	14,738	27,243
Total liabilities.....	825,047	2,043,436
Commitments (Note 7)		
Stockholders' equity (deficiency):		
Preferred stock, \$.01 par value (Note 8):		
Authorized shares – 10,000,000		
Issued and outstanding shares – 100 and 2,486 at December 31, 2020 and 2019, respectively	76,095	1,932,433
Common stock, \$.001 par value:		
Authorized shares – 600,000,000		
Issued and outstanding shares – 3,834,095 and 14,992 at December 31, 2020 and 2019, respectively.....	3,834	15
Additional paid-in capital.....	55,294,504	39,340,509
Accumulated deficit	(45,805,581)	(42,847,513)
Total stockholders' equity (deficiency).....	9,568,852	(1,574,556)
Total liabilities and stockholders' equity (deficiency)	\$ 10,393,899	\$ 468,880

See accompanying notes to consolidated financial statements.

GEOVAX LABS. INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2020	2019
Grant and collaboration revenue	\$ 1,823,658	\$ 1,175,896
Operating expenses:		
Research and development.....	2,444,459	1,910,715
General and administrative.....	2,196,014	1,637,674
Total operating expenses.....	4,640,473	3,548,389
Loss from operations	(2,816,815)	(2,372,493)
Other income (expense):		
Interest income	2,271	6,359
Interest expense.....	(143,524)	(4,495)
Total other income (expense).....	(141,253)	1,864
Net loss.....	\$ (2,958,068)	\$ (2,370,629)
Basic and diluted:		
Loss per common share.....	\$ (2.14)	\$ (781.87)
Weighted average shares outstanding	1,383,829	3,032

See accompanying notes to consolidated financial statements.

GEOVAX LABS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)

	Preferred Stock (Note 8)		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	3,450	\$ 1,971,333	11	\$ -	\$ 37,483,204	\$ (40,476,884)	\$ (1,022,347)
Sale of convertible preferred stock for cash and cancellation of note payable	1,700	1,542,950	-	-	147,050	-	1,690,000
Conversion of preferred stock to common stock	(2,664)	(1,581,850)	14,819	15	1,581,835	-	-
Issuance of common stock for services	-	-	162	-	24,000	-	24,000
Stock option expense	-	-	-	-	104,420	-	104,420
Net loss for the year ended December 31, 2019	-	-	-	-	-	(2,370,629)	(2,370,629)
Balance at December 31, 2019	2,486	1,932,433	14,992	15	39,340,509	(42,847,513)	(1,574,556)
Sale of convertible preferred stock for cash	300	300,000	-	-	-	-	300,000
Conversion of preferred stock to common stock	(2,686)	(2,156,338)	716,790	717	2,155,621	-	-
Warrants issued in bridge financing	-	-	-	-	457,833	-	457,833
Issuance of common stock upon warrant exercise	-	-	286,902	287	2,213	-	2,500
Issuance of common stock upon debenture conversion	-	-	177,626	177	569,340	-	569,517
Issuance of common stock upon cancellation of accrued compensation	-	-	300,001	300	1,499,700	-	1,500,000
Sale of common stock for cash	-	-	2,310,000	2,310	11,156,186	-	11,158,496
Issuance of common stock for services	-	-	26,581	27	94,373	-	94,400
Stock option expense	-	-	-	-	18,730	-	18,730
Roundup of shares following reverse stock split	-	-	1,203	1	(1)	-	-
Net loss for the year ended December 31, 2020	-	-	-	-	-	(2,958,068)	(2,958,068)
Balance at December 31, 2020	100	\$ 76,095	3,834,095	\$ 3,834	\$ 55,294,504	\$ (45,805,581)	\$ 9,568,852

See accompanying notes to consolidated financial statements.

GEOVAX LABS. INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss.....	\$ (2,958,068)	\$ (2,370,629)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	19,656	8,350
Amortization of debt discount.....	124,185	-
Stock-based compensation expense	64,463	327,500
Changes in assets and liabilities:		
Grant funds and other receivables.....	(114,060)	53,211
Prepaid expenses and other current assets	(24,702)	(56,211)
Accounts payable and accrued expenses.....	137,956	639,282
Total adjustments.....	207,498	972,132
Net cash used in operating activities	(2,750,570)	(1,398,497)
Cash flows from investing activities:		
Purchase of property and equipment	(156,791)	(7,606)
Net cash used in investing activities.....	(156,791)	(7,606)
Cash flows from financing activities:		
Net proceeds from sale of preferred stock.....	300,000	1,440,000
Net proceeds from issuance of note payable	170,200	-
Net proceeds from bridge financing.....	888,500	-
Net proceeds from sale of common stock and warrants.....	11,158,496	-
Net proceeds from warrant exercises	2,500	-
Principal repayment of notes payable	(11,880)	(10,257)
Net cash provided by financing activities	12,507,816	1,429,743
Net increase in cash and cash equivalents	9,600,455	23,640
Cash and cash equivalents at beginning of period.....	283,341	259,701
Cash and cash equivalents at end of period.....	\$ 9,883,796	\$ 283,341

Supplemental disclosure of non-cash financing activities:

During the year ended December 31, 2020, 2,686 shares of preferred stock were converted into 716,790 shares of common stock and 36,902 shares of common stock were issued upon the “cashless” exercise of stock purchase warrants.

During the year ended December 31, 2019, 2,664 shares of preferred stock were converted into 14,819 shares of common stock and \$250,000 of notes payable were cancelled in exchange for shares of our preferred stock.

See accompanying notes to consolidated financial statements.

GEOVAX LABS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2020 and 2019

1. Description of Business

GeoVax Labs, Inc. (“GeoVax” or the “Company”), is a clinical-stage biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers using a novel vector vaccine platform (Modified Vaccinia Ankara (MVA) Virus-Like Particle, or “GV-MVA-VLPTM”). In this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into highly effective VLP immunogens in the person being vaccinated. The MVA-VLP virus replicates to high titers in approved avian cells for manufacturing but cannot productively replicate in mammalian cells. Therefore, 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.

Our current development programs are focused on preventive vaccines against novel coronavirus (COVID-19), Human Immunodeficiency Virus (HIV), Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, Lassa), and malaria, as well as immunotherapies for HIV and solid tumor cancers.

Our corporate strategy is to advance, protect and exploit our differentiated vaccine immunotherapy platform leading to the successful development of preventive and therapeutic vaccines against infectious diseases and various cancers. With our design and development capabilities, we are progressing and validating an array of cancer and infectious disease immunotherapy and vaccine product candidates. Our goal is to advance products through to 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.

Certain of our vaccine development activities have been, and continue to be, financially supported by the U.S. Government. This support has been both in the form of research grants and contracts awarded directly to us, as well as indirect support for the conduct of preclinical animal studies and human clinical trials.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration (FDA) in the United States, by the European Medicines Agency (EMA) in the European Union, and by comparable agencies in other countries. Obtaining approval for a new pharmaceutical product is never certain, may take many years and often involves expenditure of substantial resources. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners.

GeoVax is incorporated under the laws of the State of Delaware and our principal offices are located in the metropolitan Atlanta, Georgia area.

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Basis of Presentation

Unless otherwise noted, the accompanying consolidated financial statements, and all share and per share information contained herein, have been retroactively restated to reflect the reverse stock splits described in Note 8.

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 consolidated financial statements.

We are devoting substantially all of our present efforts to research and development of our vaccine and immunotherapy candidates. We have funded our activities to date from government grants and clinical trial assistance, corporate and academic collaborations, and from sales of our equity securities. We believe that our existing cash resources together with current government funding commitments, will be sufficient to continue our planned operations into 2023.

We expect to incur future net losses and require substantial funds as we continue our research and development activities. Our transition to profitability will be dependent upon, among other things, the successful development and commercialization of our product candidates. We may never achieve profitability or positive cash flows, and unless and until we do, we will continue to need to raise additional funding. We intend to fund future operations through additional private and/or public offerings of debt or equity securities. In addition, we may seek additional capital through arrangements with strategic partners or from other sources. There can be no assurance that we will be able to raise additional funds or achieve or sustain profitability or positive cash flows from operations.

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 a high credit quality financial institution. 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 which range from three to five years. 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 Update (ASU) No. 2016-02, *Leases* (ASU 2016-02), 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. Common share equivalents consist of common shares issuable upon conversion of convertible preferred stock, and upon exercise of stock options and stock purchase warrants. All common share equivalents are excluded from the computation of diluted loss per share since the effect would be anti-dilutive. The weighted average number of common share equivalents which were excluded from the computation of diluted loss per share, totaled 1,001,948 and 558 shares at December 31, 2020 and 2019, respectively.

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.

Grant revenue – 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.

Research collaborations – 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.

Research and Development Expense

Research and development expense primarily consists 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, and (v) costs to procure and manufacture materials used in clinical trials. These costs are charged to expense as incurred.

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 8 for additional stock-based compensation information.

Other Recent Accounting Pronouncements

Except as discussed above, 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. Property and Equipment

Property and equipment as shown on the accompanying Consolidated Balance Sheets is composed of the following as of December 31, 2020 and 2019:

	2020	2019
Laboratory equipment	\$ 532,100	\$ 534,577
Leasehold improvements.....	115,605	115,605
Other furniture, fixtures & equipment.....	11,736	11,736
Total property and equipment	659,441	661,918
Accumulated depreciation and amortization	(511,700)	(651,312)
Property and equipment, net.....	<u>\$ 147,741</u>	<u>\$ 10,606</u>

Depreciation expense was \$19,656 and \$8,350 during the years ended December 31, 2020 and 2019, respectively.

4. Accrued Expenses

Accrued expenses as shown on the accompanying Consolidated Balance Sheets is composed of the following as of December 31, 2020 and 2019:

	2020	2019
Accrued salaries and directors' fees	\$ 279,696	\$ 1,732,702
Other accrued expenses	79,585	118,338
Total accrued expenses.....	<u>\$ 359,281</u>	<u>\$ 1,851,040</u>

5. Notes Payable

GRA Note – On February 28, 2018, we entered into a Senior Note Purchase Agreement with Georgia Research Alliance, Inc. (GRA) pursuant to which we issued a five-year Senior Promissory Note (the “GRA Note”) to GRA in exchange for \$50,000. The GRA Note bears an annual interest rate of 5%, payable monthly, with principal repayments beginning in the second year. Future principal repayments are expected to be \$12,487 in 2021, \$13,126 in 2022, and \$2,252 in 2023. Interest expense related to the GRA Note was \$1,727 and \$2,097 for the years ended December 31, 2020 and 2019, respectively.

CARES Act Paycheck Protection Program Loan – On April 17, 2020, we received a \$170,200 bank loan backed by the United States Small Business Administration pursuant to the Paycheck Protection Program (PPP) provisions of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The loan bears an annual interest rate of one percent and is due April 17, 2022. We have accrued interest expense associated with the PPP Loan of \$1,203. In October 2020, we applied to the lender to have the loan forgiven, based upon our submission of qualifying information regarding eligible expenses; as of the date of this report our forgiveness application has not been processed.

6. Convertible Debentures

On June 26 2020, we entered into a Securities Purchase Agreement with two institutional investors, pursuant to which we received gross proceeds of \$1,050,000 in exchange for the issuance of: (i) 5% Original Issue Discount Senior Secured Convertible Debentures (the “Convertible Debentures”) in the aggregate principal amount of \$1,200,000; and (ii) five-year warrants (the “June 2020 Warrants”) to purchase an aggregate of 120,000 shares of our common stock at an exercise price of \$10.00 per share. Net proceeds after deducting the original issue discount, finder’s fee and other debt issuance costs were \$888,500. As a result of the public offering of our securities described in Note 8, on September 29, 2020 the exercise price of the June 2020 Warrants was reduced to \$5.00. The Convertible Debentures had an original maturity of twelve months, bore interest at a rate of 5% per annum, and were secured by substantially all of the Company’s assets until such time as they were paid or converted in full.

The Convertible Debentures were mandatorily convertible upon our consummation of a public offering of common stock with gross proceeds of \$6,000,000 or more, and which resulted in the listing of our common stock on a national securities exchange (a “Qualified Offering”). The conversion price upon the occurrence of a Qualified Offering was equal to the lower of (i) \$10.00 per share or (ii) 80% of the offering price. The conversion provisions of the Convertible Debentures were subject to a “conversion blocker” such that each of the purchasers could not convert the Convertible Debentures to the extent that the conversion would result in the purchaser and its affiliates holding more than 4.99% of our outstanding common stock.

On September 29, 2020, upon our consummation of the public offering discussed in Note 8, the \$1,200,000 maturity value of the Convertible Debentures and \$14,667 of accrued interest were automatically converted at \$4.00, the Qualified Offering discounted price, resulting in the issuance of 303,668 conversion units. Of the 303,668 conversion units: (a) 177,626 consist of one share of common stock and a warrant to purchase one share of common stock (a “Conversion Warrant”), and (b) 126,042 consist of one pre-funded warrant to purchase one share of common stock (a “Pre-Funded Warrant”) and a Conversion Warrant. The Pre-Funded Warrants provide the holder the right to purchase one share of Common Stock at an exercise price of \$0.01 per share, are immediately exercisable and will not expire until exercised in full. The Conversion Warrants provide the holder the right to purchase one share of common stock, are immediately exercisable at an exercise price of \$5.00 per share and expire five years after the issuance date.

Upon the issuance of the Convertible Debentures, we recorded a debt discount of \$769,334, including the \$150,000 original issue discount, \$457,833 of fair value allocated to the warrants (recorded as Additional Paid-in Capital), and \$161,500 of direct transaction costs incurred. The debt discount was amortized to interest expense over the 12-month term of the Debentures using the effective interest rate method, up to the date of conversion. As a result of the mandatory conversion of the Convertible Debentures on September 29, 2020, the remaining unamortized debt discount (\$645,150) was recorded as Additional Paid-in Capital. Interest expense associated with the Convertible Debentures recorded during 2020 was \$138,851, including \$124,185 of debt discount amortization.

7. Commitments

Lease Agreement

We lease approximately 8,400 square feet of office and laboratory space pursuant to an operating lease which expires on December 31, 2022. Rent expense for the years ended December 31, 2020 and 2019 was \$166,577 and \$161,673, respectively. Future minimum lease payments total \$171,213 in 2021 and \$176,356 in 2022, although the lease may be terminated at any time by either party with ninety days written notice.

Other Commitments

In the normal course of business, we enter into various firm purchase commitments related to production and testing of our vaccine, conduct of research studies, and other activities. As of December 31, 2020, we had approximately \$190,000 of unrecorded outstanding purchase commitments to our vendors and subcontractors, all of which we expect will be due in 2021. We expect \$165,500 of this amount to be reimbursable to us pursuant to currently outstanding government grants.

8. Stockholders' Equity

Convertible Preferred Stock

We are authorized to issue up to 10,000,000 shares of our Preferred Stock, \$.01 par value, which may be issued in one or more series. The table below presents our issued and outstanding series of preferred stock as of December 31, 2020 and 2019. Each series of our outstanding preferred stock has a stated value of \$1,000 per share. Further details concerning each series of preferred stock, and the changes in each series during the years ended December 31, 2020 and 2019 are discussed in the sections that follow the table.

	December 31, 2020		December 31, 2019	
	Shares	Carrying Value	Shares	Carrying Value
Series B Convertible Preferred Stock.....	100	\$ 76,095	100	\$ 76,095
Series H Convertible Preferred Stock.....	-	-	1,686	1,156,338
Series I Convertible Preferred Stock.....	-	-	700	700,000
Total.....	100	\$ 76,095	2,486	\$ 1,932,433

Series B Convertible Preferred Stock – Our Series B Convertible Preferred Stock, \$1,000 stated value (“Series B Preferred Stock”), has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series B Preferred Stock has no voting rights and is not entitled to a dividend. As of December 31, 2020, there were 100 shares of Series B Preferred Stock outstanding, convertible at any time at the option of the holder into shares of common stock at a fixed conversion price of \$7,000,000 per common share.

Series C Convertible Preferred Stock – Our Series C Convertible Preferred Stock, \$1,000 stated value (“Series C Preferred Stock”), has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series C Preferred Stock has no voting rights and is not entitled to a dividend. During 2019, 587 shares of our Series C Preferred Stock were converted into 2 shares of our common stock and the remaining 1,563 shares of Series C Preferred Stock were exchanged for Series F Preferred Stock. As of December 31, 2020, there were no shares of Series C Preferred Stock outstanding.

Series E Convertible Preferred Stock – Our Series E Convertible Preferred Stock, \$1,000 stated value, (“Series E Preferred Stock”) has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series E Preferred Stock has no voting rights and is not entitled to a dividend. During 2019, all outstanding shares of Series E Preferred Stock (1,200 shares) were exchanged for Series F Preferred Stock. As of December 31, 2020, there were no shares of Series E Preferred Stock outstanding.

Series F Preferred Stock – In February 2019, we entered into Exchange Agreements with holders of our Series C and Series E Preferred Stock, pursuant to which the holders exchanged all shares of Series C and Series E Preferred Stock held by them for an aggregate of 2,763 shares of Series F Convertible Preferred Stock (“Series F Preferred Stock”). Our Series F Preferred Stock has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series F Preferred Stock has no voting rights and is not entitled to a dividend. During 2019, 507 shares of Series F Preferred Stock were converted into 9 shares of our common stock and all remaining outstanding shares of Series F Preferred Stock (2,256 shares) were exchanged for Series H Preferred Stock. As of December 31, 2020, there were no shares of Series F Preferred Stock outstanding.

Series G Preferred Stock – In February 2019, we entered into a Securities Purchase Agreement with the purchasers identified therein (the “Purchasers”) providing for sale to the Purchasers of an aggregate of up to 1,000 shares of our Series G Convertible Preferred Stock (“Series G Preferred Stock”) and related warrants for gross proceeds of up to \$1.0 million, which was funded at three different closings. Our Series G Preferred Stock has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series G Preferred Stock has no voting rights and is not entitled to a dividend. At the first closing, which occurred in February 2019, we issued 500 shares of Series G Preferred Stock in exchange for the payment by the Purchasers of \$250,000 in the aggregate, plus the cancellation of Term Notes held by the Purchasers in the amount of \$250,000. At the second and third closings, which occurred in April and June 2019, we issued an aggregate of 500 additional shares of Series G Preferred Stock in exchange for the payment by the Purchasers of a total of \$500,000. During

July 2019, all outstanding shares of Series G Preferred Stock (1,000 shares) were exchanged for Series H Preferred Stock. As of December 31, 2020, there were no shares of Series G Preferred Stock outstanding.

Series H Preferred Stock – In July 2019, we entered into Exchange Agreements with holders of our Series F and Series G Preferred Stock, pursuant to which the holders exchanged all shares of Series F and Series G Preferred Stock held by them for an aggregate of 3,256 shares of Series H Convertible Preferred Stock (“Series H Preferred Stock”). Our Series H Preferred Stock has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series H Preferred Stock has no voting rights and is not entitled to a dividend. During 2019, 1,570 shares of Series H Preferred Stock were converted into 14,808 shares of our common stock. During 2020, 1,686 shares of our Series H Convertible Preferred Stock were converted into 469,697 shares of our common stock. As of December 31, 2020, there were no shares of Series H Preferred Stock outstanding.

Series I Preferred Stock – In July 2019, we entered into a Securities Purchase Agreement with the purchasers identified therein (the “Purchasers”) providing for sale to the Purchasers of an aggregate of 700 shares of our Series I Convertible Preferred Stock (“Series I Preferred Stock”) for gross proceeds of \$700,000. Our Series I Preferred Stock has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series I Preferred Stock has no voting rights and is not entitled to a dividend. During 2020, 700 shares of our Series I Convertible Preferred Stock were converted into 204,371 shares of our common stock. As of December 31, 2020, there were no shares of Series I Preferred Stock outstanding.

Series J Preferred Stock – In January 2020, we entered into a Securities Purchase Agreement with the purchasers identified therein (the “Purchasers”) providing for sale to the Purchasers of an aggregate of 300 shares of our Series J Convertible Preferred Stock (“Series J Preferred Stock”) for gross proceeds of \$300,000. Our Series J Preferred Stock has rights and privileges as set forth in the pertinent Certificate of Designation of Preferences, Rights and Limitations, including a liquidation preference equal to the stated value per share. The Series J Preferred Stock has no voting rights and is not entitled to a dividend. During 2020, 300 shares of Series J Preferred Stock were converted into 42,723 shares of our common stock. As of December 31, 2020, there were no shares of Series J Preferred Stock outstanding.

Common Stock

Reverse Stock Splits – On April 30, 2019, we effected a 1-for-500 reverse stock split of our common stock, on January 21, 2020, we effected a 1-for-2000 reverse split of our common stock and on September 25, 2020, we effected a 1-for-20 reverse split of our common stock.

Conversions of Preferred Stock – During 2020 and 2019 we issued an aggregate of 716,790 and 14,819 shares of our common stock, respectively, pursuant to the conversion of several series of our convertible preferred stock as discussed above.

Public Offering – On September 24, 2020, we entered into an Underwriting Agreement (the “Underwriting Agreement”) with Maxim Group LLC, as representative of the underwriters (the “Representative”), for an underwritten public offering (the “Offering”) of an aggregate of 2,560,000 units of our equity securities (the “Units”). The Offering closed on September 29, 2020, with gross proceeds to us of approximately \$12.8 million; net proceeds after deducting underwriting discounts and commissions and other offering expenses were approximately \$11.2 million.

Of the 2,560,000 Units sold in the Offering: (a) 2,310,000 Units consist of one share of our common stock, and a Warrant to purchase one share of common stock (each, a “Unit Warrant”); and (b) 250,000 Units consisting of a Pre-Funded Warrant to purchase one share of common stock and a Unit Warrant. The Pre-Funded Warrants provided the holder the right to purchase one share of common stock at an exercise price of \$0.01 per share and were exercised in full during October 2020. The Unit Warrants provide the holder the right to purchase one share of common stock, are immediately exercisable at an exercise price of \$5.00 per share and expire five years after the issuance date. The public offering price was \$5.00 per Unit (\$4.99 for each Unit including a Pre-Funded Warrant).

Pursuant to the Underwriting Agreement, we issued to the Representative, as a portion of the underwriting compensation, warrants to purchase up to a total of 128,000 shares of common stock (the “Representative Warrants”). The Representative Warrants have an exercise price of \$5.50 per share, are initially exercisable 180 days after the effective date of the Offering and have a term of three years from their initial exercise date.

Conversion of Deferred Compensation to Equity – From 2016 through August 2020, to help conserve the Company’s cash resources, our executive officers and non-employee directors agreed to defer receipt of all or a portion (at varying levels) of their respective cash compensation. On September 29, 2020, upon our consummation of the Offering, \$1,500,000 of the accumulated deferrals were converted at the \$5.00 offering price, resulting in the issuance of 300,001 units substantially similar to the units sold in the public offering, with each unit consisting of one share of our common stock and one warrant substantially similar to a Unit Warrant (a “Management Warrant”).

Conversion of Convertible Debentures to Equity – As discussed in Note 6, upon our consummation of the Offering, we issued an aggregate of 177,626 shares of our common stock, 126,042 Pre-Funded Warrants and 303,668 Conversion Warrants upon the mandatory conversion of \$1,214,667 of Convertible Debentures and accrued interest.

Other Common Stock Transactions – During 2020 and 2019 we issued 26,581 and 162 shares, respectively, of our common stock pursuant to consulting agreements. During 2020, certain warrants were exercised using the “cashless” exercise feature of the warrants, resulting in the issuance of an aggregate of 36,902 shares of our common stock.

Stock Options

We have a stock-based incentive plan (the “2020 Plan”) pursuant to which our Board of Directors may grant stock options to our employees. A total of 1,000,000 shares of our common stock are reserved for issuance pursuant to the 2020 Plan. 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 and generally vest over three years.

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. The significant assumptions we used in our fair value calculations were as follows:

	2020	2019
Weighted average risk-free interest rates	0.69%	N/A
Expected dividend yield	0.0%	N/A
Expected life of option (years)	7.0	N/A
Expected volatility	38.16%	N/A

A summary of stock option activity under the 2020 Plan as of December 31, 2020, and changes during the year then ended is presented below.

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (yrs)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	-	\$ -		
Granted	602,000	2.79		
Exercised	-	-		
Forfeited or expired	-	-		
Outstanding at December 31, 2020	602,000	\$ 2.79	9.9	\$ 355,180
Exercisable at December 31, 2020	-0-	\$ -	-	\$ -

The weighted-average grant date fair value of options granted during 2020 was \$1.12. No stock options were granted during 2019. Total employee and director stock-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2020 and 2019 was \$18,730 and \$104,420, respectively. As of December 31, 2020, there is \$655,510 of unrecognized compensation expense related to employee and director stock-based compensation arrangements that will be recognized over a weighted-average period of 2.9 years.

Stock Purchase Warrants

Summary of Warrants Outstanding – The table below presents summary information about our warrants outstanding as of December 31, 2020. Additional information concerning the warrants follows the table.

Warrant Description	Number of Shares	Exercise Price	Expiration
Series I Warrants	62,626	\$ 5.00	Oct-Dec 2024
June 2020 Warrants	120,000	5.00	Jun 2025
Pre-Funded Warrants.....	126,042	0.01	Perpetual
Unit, Conversion and Management Warrants	3,163,669	5.00	Sep 2025
Representative Warrants.....	128,000	5.50	Mar 2024
Total Warrants Outstanding at December 31, 2020	<u>3,600,337</u>		
Weighted-Average Exercise Price.....	\$ 4.84		
Weighted-Average Remaining Life (excluding Pre-Funded Warrants) (years)	4.7		

Series I Warrants – During July 2020, Series I Warrants were exercised using the “cashless” exercise feature of the warrants, resulting in the issuance of 29,755 shares of our common stock. As of December 31, 2020, there were 62,626 Series I Warrants outstanding, with an exercise price of \$5.00 per share, reflective of anti-dilution adjustments resulting from the Offering.

June 2020 Warrants – As discussed in Note 6, on June 26, 2020, in connection with the issuance of the Convertible Debentures, we issued warrants to purchase 120,000 shares of common stock, with a five-year term and an exercise price of \$10.00. As a result of the Offering, on September 29, 2020 the exercise price was reduced to \$5.00.

Warrants Issued Upon Conversion of Convertible Debentures – As discussed in Note 6, on September 29, 2020, upon the conversion of the Convertible Debentures into our equity securities, we issued 126,042 Pre-Funded Warrants and 303,668 Conversion Warrants to purchase our common stock.

Warrants Issued Upon Conversion of Deferred Compensation – As discussed above under “*Common Stock – Conversion of Deferred Compensation to Equity*”, on September 29, 2020, upon the conversion of amounts owed to current and former executive officers and directors, we issued Management Warrants to purchase 300,001 shares of common stock.

Warrants Issued in Connection with Public Offering – As discussed above under “*Common Stock – Public Offering*”, on September 29, 2020, in connection with the Offering, we issued Unit Warrants to purchase 2,560,000 shares of common stock, Pre-Funded Warrants to purchase 250,000 shares of common stock (fully exercised in October 2020), and Representative Warrants to purchase 128,000 shares of common stock.

Additional Stock-Based Compensation Expense

In addition to stock-based compensation expense related to the 2020 Plan (see *Stock Options* above), during the years ended December 31, 2020 and 2019, we recognized \$45,733 and \$223,080, respectively, of expense related to the issuance of our common stock pursuant to consulting and investment banking agreements. As of December 31, 2020, there is \$48,667 recorded as a prepaid expense for one of these arrangements, which will be recognized as expense during 2021 over the term of the related agreement.

9. 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, 2020 and 2019 our contributions to the 401k Plan were \$27,511 and \$25,876, respectively.

10. Income Taxes

At December 31, 2020, we have a consolidated federal net operating loss (“NOL”) carryforward of approximately \$61.8 million available to offset against future taxable income of which approximately \$53.6 million expires in varying amounts in 2021 through 2037. Additionally, we have approximately \$1.2 million in research and development (“R&D”) tax credits

that expire in 2022 through 2040 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. Significant components of our deferred tax assets and liabilities included the following at December 31, 2020 and 2019:

	2020	2019
Deferred tax assets:		
Net operating loss carryforward	\$ 14,737,240	\$ 15,328,336
Research and development tax credit carryforward.....	1,189,110	1,122,536
Stock-based compensation expense.....	4,870	1,877,284
Accrued salaries and directors' fees	72,721	450,503
Depreciation	-	8,571
Total deferred tax assets	16,003,941	18,787,230
Deferred tax liabilities		
Depreciation	28,274	-
Net deferred tax assets.....	15,975,667	18,787,230
Valuation allowance.....	(15,975,667)	(18,787,230)
Net deferred tax asset after reduction for valuation allowance	<u>\$ -0-</u>	<u>\$ -0-</u>

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. A reconciliation of the income tax benefit on losses at the U.S. federal statutory rate to the reported income tax expense is as follows:

	2020	2019
U.S. federal statutory rate applied to pretax loss.....	\$ (621,194)	\$ (497,833)
Permanent differences	65	278
Research and development credits	(66,574)	(47,053)
Change in valuation allowance, net of expired items and other adjustments	687,703	544,308
Reported income tax expense.....	<u>\$ -0-</u>	<u>\$ -0-</u>

11. Grants and Collaboration Revenue

We receive payments from government entities under our grants from the National Institute of Allergy and Infectious Diseases (NIAID) and from the U.S. Department of Defense in support of our vaccine research and development efforts. We record revenue associated with government grants as the reimbursable costs are incurred. During 2020 and 2019, we recorded \$1,438,465 and \$983,682, respectively, of revenue associated with these grants. As of December 31, 2020, there is an aggregate of \$165,500 in remaining grant funds available for use during 2021. During 2020 and 2019, we recorded \$385,193 and \$192,214, respectively, of revenues associated with research collaboration agreements with several third parties.

12. Subsequent Events

SBIR Grant – In January 2021, NIAID awarded us a Small Business Innovative Research (SBIR) grant in support of our development of a vaccine against SARS-CoV-2, the virus that causes COVID-19. The \$299,927 Phase 1 grant, titled, “*Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19*,” will support the ongoing design, construction and preclinical testing of our vaccine candidates in preparation for human clinical trials.

Warrant Exercises – During January and February 2021, holders of our warrants exercised 62,626 Series I Warrants, 126,042 Pre-Funded Warrants and 690,034 Unit Warrants, resulting in the issuance of 835,900 shares of our common stock for aggregate net proceeds to us of \$3,174,156.

Bought Deal Public Offering -- On February 11, 2021, we closed an underwritten bought deal public offering of 1,644,000 shares of our common stock, including 204,000 shares sold pursuant to the full exercise of the underwriter’s option to purchase additional shares, at a price to the public of \$6.25 per share. Net proceeds after deducting underwriting discounts and commissions and other offering expenses were approximately \$9.4 million.

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

For the Years Ended December 31, 2020 and 2019

<u>Description</u>	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, 2020.....	\$18,787,230	\$(2,811,563)	\$ -0-	\$ -0-	\$15,975,667
Year ended December 31, 2019.....	19,879,954	(1,092,724)	-0-	-0-	18,787,230

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