Company Description

GeoVax Labs, Inc. ("GeoVax" or "the Company") is a clinical-stage biotechnology company developing preventive and therapeutic human vaccines and immunotherapies against infectious diseases and cancer. The Company's proprietary GV-MVA-VLP™ vector vaccine technology utilizes a Modified Vaccinia Ankara (MVA) vector, a large virus capable of carrying several vaccine antigens, that are expressed as non-infectious virus-like particles (VLPs) in the individual receiving the vaccine (*in vivo*). VLPs mimic a natural infection, stimulating both the humoral (antibody) and cellular (T-cells) arms of the immune system to recognize, prevent, and control the target infection through durable immune responses. GeoVax is capitalizing on the safety and efficacy of its technology platform to address the need for a broadly-effective COVID-19 vaccine and is also developing vaccines against human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa Fever), and malaria. Furthermore, the Company is applying its MVA-VLP technology to cancer immunotherapy (immuno-oncology).

Key Points

- On September 28, 2021, GeoVax announced that it had entered into an Assignment and License Agreement with PNP Therapeutics, Inc. ("PNP"), granting GeoVax exclusive rights to develop and commercialize Gedeptin®, a novel patented product to treat solid tumors. While specific financial terms of the Agreement were not disclosed, they do include a combination of upfront payments, milestone fees, and royalties on net sales.
- The License Agreement provides exclusive worldwide rights to key intellectual property, including Gedeptin patents, know-how, regulatory filings, clinical materials, and trademarks. The patent portfolio covering Gedeptin was originally licensed from the University of Alabama at Birmingham (UAB) and Southern Research Institute (SRI) by PNP. Under this License, GeoVax becomes the successor to PNP under its license agreement with UAB/SRI. The Gedeptin technology was developed with funding support from the National Cancer Institute of the National Institutes of Health (NIH).
- A Phase 1/2 trial is enrolling to evaluate the safety and efficacy of repeat cycles of Gedeptin therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options. The initial stage of the study is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedeptin Orphan Drug status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities.
- The signing of this Agreement adds a clinical program in immuno-oncology to GeoVax's pipeline—a primary focus area for the Company. This license further opens additional opportunities to potentially develop novel therapies for other indications. GeoVax believes that potential synergies exist between the Gedeptin technology and its GV-MVA-VLP platform related to immuno-oncology, providing further expanded opportunities for developing novel cancer immunotherapies that may benefit cancer patients across multiple cancers. Accordingly, as GeoVax continues to advance its programs, such as MVA-VLP-MUC1, it expects to evaluate synergistic opportunities between the two technology platforms.
- GeoVax has had a pivotal year, in which the Company was successfully recapitalized, strengthening its balance sheet, and was listed on NASDAQ. It has also increased its cash reserves and advanced its product development priorities, with a specific focus on accelerating clinical development in the areas of immuno-oncology and its coronavirus vaccine program.

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GOVX (NASDAQ) One-Year Chart

Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (10/04/2021)	$4.18
52-week Range	$2.56 - 8.71
Shares Outstanding	6.3 million
Market Capitalization	$26.3 million
Avg. Volume	2,808,132
EPS (Qtr ended 06/30/21)	($0.21)
Employees	11

See page 5 for applicable disclosures.

GeoVax Acquires Clinical-Stage Cancer Program, Expanding its Immuno-Oncology Pipeline

GeoVax Labs, Inc. announced on September 28, 2021 that it has entered into an Assignment and License Agreement with PNP Therapeutics, Inc. ("PNP"), granting GeoVax exclusive rights to develop and commercialize Gedeptin®, a novel patented product to treat solid tumors and being evaluated to treat head and neck cancers. PNP Therapeutics, Inc. is a clinical-stage, biopharmaceutical company engaged in developing a platform technology and proprietary products to treat cancer. While details of the financial terms were not disclosed, they do include a combination of upfront payments, milestone fees, and royalties on net sales. Gedeptin® has been granted orphan drug status by the FDA for the treatment of head and neck cancers.

The License Agreement provides exclusive worldwide rights to key intellectual property, including Gedeptin patents, know-how, regulatory filings, clinical materials, and trademarks. The patent portfolio covering Gedeptin was originally licensed from the University of Alabama at Birmingham (UAB) and Southern Research Institute (SRI) by PNP. Under this License, GeoVax becomes the successor to PNP under its license agreement with UAB/SRI. The Gedeptin technology was developed with funding support from the National Cancer Institute of the National Institutes of Health (NIH).

A cycle of Gedeptin therapy consists of three intra-tumoral injections over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days. A Phase 1 dose ranging study, evaluating the safety of a single cycle of Gedeptin therapy found the therapy to be well tolerated, with evidence of a reduction in tumor size in patients with solid tumors.

A Phase 1/2 trial is currently enrolling to evaluate the safety and efficacy of repeat cycles of Gedeptin therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options. The initial stage of the study is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedeptin Orphan Drug status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities. The License further grants GeoVax the rights to expand the use of Gedeptin to all human diseases and/or conditions including, but not limited to, other cancers.

The signing of this Agreement adds a clinical program in immuno-oncology to GeoVax's pipeline—a primary focus area for the Company.

The initial stage (10 patients) of the ongoing clinical trial for Gedeptin is being funded by the FDA pursuant to its Orphan Products Grants Program, with five patients having been enrolled to date. The current objective is to accelerate patient enrollment to complete this stage and expand the trial to additional study sites to at least 25 patients. Based on PNP's End-of-Phase-1 meeting with the FDA, a successful outcome from the expanded trial may lead to labelling discussions with the FDA.

This license further opens additional opportunities to potentially develop novel therapies for other indications. GeoVax believes that synergies may exist between the Gedeptin technology and its GV-MVA-VLPTM platform related to immuno-oncology, providing further expanded opportunities for developing novel cancer immunotherapies that may benefit cancer patients across multiple cancers. Accordingly, as GeoVax continues to advance its programs, such as MVA-VLP-MUC1, and expects to evaluate synergistic opportunities between the two technology platforms.

The Company achieved a critical strategic watershed with the successful recapitalization, financing, and listing of GeoVax on the Nasdaq stock market approximately one year ago. Since then, GeoVax has further strengthened its resources and status, including its ability to finance the Gedeptin transaction. Importantly, the financing of the Gedeptin transaction includes expansion and acceleration of the clinical trial using GeoVax's current cash reserves.

GeoVax has further progressed its two core product development areas related to SARS-CoV-2 vaccines and immuno-oncology. This announcement accelerates the Company's progress within immuno-oncology, providing a pivotal clinical-stage status via the Gedeptin program, with the Company remaining focused on accelerating progress of its SARS-CoV-2 vaccine.

About the Gedeptin® Technology Platform

Many types of cancers (including prostate, breast, colon, lung, brain, melanoma, pancreas, ovarian, or kidney) become untreatable even with the best medical intervention and the highest standard of care, and ultimately become fatal. Chemotherapeutic agents may be able to destroy these tumors, but many are far too toxic to dispense systemically to patients who are already debilitated from cancer.

The majority of conventional anti-cancer drugs employed today derive their anti-tumor specificity from the ability to kill rapidly dividing cells. These drugs are appropriate for systemic administration since they are most toxic to cells that are dividing. Yet, many tumors, such as head and neck squamous cell carcinoma (HNSCC), are resistant to treatment as they have a very low growth fraction (i.e., a relatively small percentage of tumor cells dividing at any particular point in time). Compounds that are toxic to non-proliferating cells generally are not used in treating cancer because most of the cells in a patient are not proliferating and such compounds have no selectivity when administered systemically.

Gene therapy strategies for cancer treatment that have shown promise include GDEPT (Gene-Directed Enzyme Prodrug Therapy). In GDEPT, a vector is used to selectively transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a very toxic antitumor compound. A prodrug is a pharmaceutical compound that remains inactive in its biochemical form until it reaches its target site, such as an organ or tissue, and undergoes an immediate metabolic breakdown upon reaching the site; it then, at the point of delivery, releases the molecular compounds of the parent drug. Since the nonhuman gene is only expressed in tumor tissue, the nontoxic prodrug is only activated in tumor tissue. Thus, GDEPT is expected to result in selective killing of tumor cells with little or no systemic toxicity (unlike conventional chemotherapy).

GDEPT approaches that produce potent cytotoxic agents (active against nonproliferating and proliferating tumor cells) and that have high bystander activity could have dramatic effects on treating solid tumors. A bystander effect typically refers to the death, altered growth, or damage of cells that have not directly received chemotherapy or irradiation. Previous GDEPT approaches have demonstrated limited efficacy specifically due to poor bystander activity and inability to destroy non-proliferating tumor cells.

Gedeptin may be able to overcomes previous GDEPT limitations and accordingly could serve as a robust platform for development in multiple indications. Gedeptin consists of a non-replicating adenoviral vector expressing an optimized E. coli purine nucleoside phosphorylase (E. coli PNP) that is injected intra-tumorally, followed by intravenous or intra-tumoral administration of a prodrug.

Among the prodrugs that have been evaluated for use with Gedeptin, fludarabine phosphate (Fludara®) is of particular interest because (1) it is currently approved by the FDA for use in humans and (2) it has demonstrated excellent *in vivo* antitumor activity in murine models when only 2% to 3% of tumor cells express E. coli PNP. Fludarabine is currently approved by the FDA to treat chronic lymphocytic leukemia, but has not been shown to be effective against other solid tumors. However, when fludarabine is administered following Gedeptin, the combination exploits the selective expression of the E. coli PNP gene in tumor cells to utilize fludarabine phosphate as a prodrug, resulting in the localized production of fluoroadenine (F-Ade)—a potent cytotoxic compound with pronounced antitumor activity.

<u>Ongoing Phase 1/2 Clinical Trial</u>

Gedeptin is in a Phase 1/2 clinical trial, being conducted at Stanford University in collaboration with Emory University. The trial design involves repeat administration using Gedeptin followed by systemic fludarabine as a way to gain additional information prior to expansion towards a larger patient trial. The initial stage of the study (10 patients) is being funded by the FDA pursuant to its Orphan Products Grants Program. Five patients have been enrolled to date.

Orphan Drug Status

The FDA has granted orphan drug status to Gedeptin for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities. The orphan drug designation is awarded to drugs designed to treat a rare disease or condition that affect fewer than 200,000 people in the U.S., and it is applied specifically to novel therapeutics that could represent a major improvement in treatment. Orphan drug status provides regulatory incentives, reduced fees, and a more rapid review by the FDA, and stipulates that competing therapies can be blocked from the market for up to seven years. Additionally, this status qualifies the drug sponsor for various development incentives, including tax credits for qualified clinical testing.

Potential Synergy and Flexibility of Gedeptin Technology with GeoVax's Cancer Immunotherapy Program

Given the difficultly and complexity to successfully treat cancer, it is likely that combinations of both existing and new technologies and products are likely to be the solution in order to achieve the maximum benefit. GeoVax's approach is based on three components:

(1) active vaccination using the Company's proprietary MVA-VLP vaccine approach in combination with peptides and adjuvants to both induce and focus immune responses, both cellular and antibody responses, to the selected tumor-associated antigen;

(2) the induction of immune responses, where checkpoint inhibitors can be used to both augment and maintain effective levels of tumor specific responses, with checkpoint inhibitors already approved for human use and a standard of care for certain cancers, and their effectiveness perhaps increased when used in combination with other therapies, such as vaccines or the Gedeptin; and

(3) technology that effectively targets and directly kills tumor cells, which is the effect of using Gedeptin, where it can function independently but also additively, reducing the burden to the immune system by reducing the size of the tumor that the immune system must attack and control.

While each of GeoVax's modalities currently being developed could contribute to an effective treatment of cancer independently, the Company believes that synergy is likely to happen. For instance, in GeoVax's MUC1 program, the Gedeptin treatment of accessible tumors could lead to cell death, which would serve to initially induce immune responses. This basically means that as the tumor is dying, the cells themselves serve as the vaccine. The immune responses that are induced could be boosted or then further focused by vaccination with the MVA-VLP and peptides. These would then be augmented and maintained through the use of the approved checkpoint inhibitors. Thus, GeoVax could begin with the MUC1 vaccine, followed by Gedeptin treatment, and then followed by a checkpoint inhibitor.

The next steps involve determining which process will work best in animal models and clinical experimentation, which will determine optimal treatment regimens. This may be adapted for different tumor types and individuals and based on tumor locations in a manner that rapidly approaches individualized medicine.

Risks and Disclosures

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

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

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

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

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