**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**

**Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported):  November 5, 2020**

**GEOVAX LABS, INC.**

**(Exact name of registrant as specified in its charter)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Delaware** |  | **001-39563** |  | **87-0455038** |
| **(State or other jurisdiction of**  **incorporation or organization)** |  | **(Commission File No.)** |  | **(IRS Employee Identification No.)** |

**1900 Lake Park Drive, Suite 380**

**Smyrna, Georgia 30080**

**(Address of principal executive offices) (Zip code)**

**(678) 384-7220**

**(Registrant’s telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions.

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(e)-4(c))

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

|  |  |  |
| --- | --- | --- |
| Title of each class | Trading  Symbol(s) | Name of each exchange on which registered |
| Common Stock, par value $0.001 per share | GOVX | The Nasdaq Capital Market |
| Warrants to Purchase Common Stock | GOVXW | The Nasdaq Capital Market |

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 240.12b-2 of this chapter).

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 reporting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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This Form 8-K and other reports filed by GeoVax Labs, Inc. (the “Registrant” or the “Company”) from time to time with the Securities and Exchange Commission (collectively the “Filings”) contain forward looking statements and information that are based upon beliefs of, and information currently available to, the Registrant’s management as well as estimates and assumptions made by the Registrant’s management. When used in the Filings the words “anticipate”, “believe”, “estimate”, “expect”, “future”, “intend”, “plan” or the negative of these terms and similar expressions as they relate to the Registrant or the Registrant’s management identify forward looking statements.  Such statements reflect the current view of the Registrant with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Registrant’s industry, operations and results of operations and any businesses that may be acquired by the Registrant. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned. Except as required by law, the Registrant does not undertake to update its forward-looking statements.

|  |  |
| --- | --- |
| **Item 2.02** | **Results of Operations and Financial Condition.** |

On November 5, 2020 we issued a press release reporting our results of operations for the quarter ended September 30, 2020. A copy of the press release is attached to this Current Report.

|  |  |
| --- | --- |
| **Item 9.01** | **Financial Statements and Exhibits.** |

(d)     Exhibits

|  |  |
| --- | --- |
| Exhibit No. | Description |
| 99.1 | Press release dated November 5, 2020 |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 5, 2020

|  |  |  |  |
| --- | --- | --- | --- |
|  | GEOVAX LABS, INC. | |  |
|  |  | |  |
|  |  | |  |
|  | By: | /s/ Mark W. Reynolds |  |
|  |  | Mark W. Reynolds |  |
|  |  | Chief Financial Officer |  |
|  |  |  |  |

**GeoVax Reports 2020 Third Quarter Financial Results**

**Exhibit 99.1**

**and Provides Corporate Update**

***Public Offering Completed in September 2020 Provides Resources to Accelerate***

***COVID-19 Vaccine and Immuno-Oncology Programs***

**ATLANTA, GA, November 5, 2020** – GeoVax Labs, Inc. (NasdaqCM: GOVX, GOVXW), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers, today announced financial results for the quarter ended September 30, 2020 and provided an update on its corporate developments.

David Dodd, GeoVax’s Chairman & CEO, commented, “Our corporate development activities during the third quarter centered on securing the capital needed to advance our product development, with a focus on our **COVID-19 vaccine and cancer immunotherapy programs**. This culminated on September 29 with the closing of our $12.8 million public offering and listing of our common stock (GOVX) and warrants (GOVXW) on Nasdaq.

“The GeoVax COVID-19 vaccine program is based on our MVA-VLP technology which enables insertion of multiple antigen fragments, potentially allowing for broad-spectrum virus prevention. This differs from other technologies which only allow for specific genetic fragments and therefore may result in a tight, narrow focus of a single protein as the target. We believe that the GeoVax approach has the potential to provide a stronger and broader immune response without presenting an increased infectious risk to the vaccinated individual, perhaps in a single dose versus the multiple dosing anticipated from alternative vaccine approaches.”

“We use the same technology for our immuno-oncology program. Our cancer immunotherapy concept is to combine 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, which is why we’re focused in this area as one of our priorities.”

Though the primary use of proceeds from the offering will be to accelerate development of the Company’s COVID-19 vaccine and immuno-oncology programs, several other programs continue to advance through partnering and collaborative efforts, requiring minimal capital investment and additional resources from the Company:

* The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), is funding a clinical trial which includes our **HIV preventive vaccine** (GOVX-B11) through the HIV Vaccine Trials Network (HVTN). We expect the next trial (HVTN-132) to begin in early 2021, which will further evaluate the safety and immunogenicity of adding “protein boost” components to our vaccine.
* Through our mutual collaboration, American Gene Technologies International, Inc. (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**. We expect our vaccine to be added to an arm of the AGT trial in 2021.
* A consortium led by researchers at the University of California, San Francisco (UCSF) is using our vaccine as part of a **combinational therapy intended to induce remission in HIV-positive individuals**. This program entered clinical trials in August 2020.
* Our **Lassa Fever vaccine** continues to progress with funding under a cooperative agreement with the U.S. Department of Defense. 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.
* In August, we announced a multi-party collaboration for the development of our **Sudan ebolavirus (SUDV) and Marburg virus (MARV**) vaccine candidates. The collaboration between us, researchers at the University of Texas Medical Branch (UTMB), and Battelle Memorial Institute will utilize the suite of preclinical services from NIAID. Under the collaboration, GeoVax’s SUDV and MARV vaccine candidates will be tested for immunogenicity and efficacy in the benchmark nonhuman primate model. The studies will include two vaccine regimens -- single dose and prime/boost immunization -- for each vaccine tested. 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 and which were conducted with support from NIAID and USAMRIID.
* We continue to collaborate separately with Leidos, Inc. and the Burnet Institute for development of **malaria vaccine** candidates using our GV-MVA-VLPTM vaccine platform. Our 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). The vaccine candidates have recently entered initial animal testing with results expected as early as year-end 2020.
* All of our development programs are focused on areas of significant medical need and commercial opportunities. Six of the GeoVax vaccine programs (e.g., Ebola, Lassa, Marburg, Sudan, Malaria and Zika) address medical areas within the **FDA Priority Review Voucher** program, providing significant potential value if any of them are successful.

Mr. Dodd concluded, “With the funding from our September offering, we are progressing our COVID-19 vaccine program while we continue to have discussions with various funding agencies for more advanced and accelerated development toward human testing. We also now have the flexibility to pursue a clinical pathway for our immuno-oncology therapeutic effort and seek new strategic options for expanding this program. These opportunities allow us to potentially address significant unmet medical needs and create value for our shareholders.”

**Financial Results for the Period Ending September 30, 2020**

GeoVax reported a net loss of $570,648 for the three months ended September 30, 2020, compared to a net loss of $424,434 for the same period in 2019. For the nine months ended September 30, 2020, the Company’s net loss was $1,621,546 as compared to a net loss of $1,780,036 in 2019.

The Company reported grant and collaboration revenues of $415,458 and $1,572,037 for the three-month and nine-month periods of 2020, respectively, as compared to $333,209 and $907,382 reported for the comparable periods of 2019. These amounts primarily relate to GeoVax’s grant from the U.S. Department of Defense (DoD) for its Lassa Fever vaccine and its collaboration with Leidos, Inc. for its malaria vaccine program. As of September 30, 2020, there were $417,121 of approved funds remaining and available for use related to GeoVax’s grant from the DoD.

Research and development expenses were $416,756 and $1,687,113 for the three-month and nine-month periods of 2020, respectively, as compared to $467,674 and $1,474,619 for the comparable periods of 2019. Fluctuations in R&D expenses from period to period are primarily attributable to the timing of expenditures related to the DoD grant. General and administrative expenses were $435,013 and $1,364,650 for the three-month and nine-month periods of 2020, respectively, as compared to $291,475 and $1,214,189 for the comparable periods of 2019.

GeoVax reported cash balances of $11,580,594 at September 30, 2020, as compared to $283,341 at December 31, 2019. Contributing to the increase in cash balances were the sale of convertible preferred stock in January 2020 for proceeds of $300,000, the issuance of a note payable in April 2020 for proceeds of $170,200, the sale of convertible debentures in June 2020 for net proceeds of $888,500, and net proceeds of approximately $11.2 million from the September 2020 offering. In connection with the September offering, approximately $1.2 million of convertible debentures and accrued interest were converted into the Company’s equity securities. Additionally, $1.5 million of accumulated amounts owed to the Company’s current and former executive officers and directors were converted to equity.

Summarized financial information is included below. Further information concerning the Company’s financial position and results of operations are included in its Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission.

Conference Call

Management will host a conference call at 8:15 a.m. ET on Friday, November 6, 2020 to review financial results and provide an update on corporate developments. Following management’s formal remarks, there will be a question and answer session.

Participants are asked to pre-register for the call via the following link:

<https://dpregister.com/sreg/10149661/dc8783c368>

Please note that registered participants will receive their dial-in number upon registration and will dial directly into the call without delay. Those without Internet access or who are unable to pre-register may dial in by calling 1-866-777-2509 (domestic) or 1-412-317-5413 (international). All callers should dial in approximately 10 minutes prior to the scheduled start time and ask to be joined into the GeoVax Labs call.

The conference call will be available through a live webcast found here:

<https://services.choruscall.com/links/govx201106.html>

A webcast replay of the call will be available approximately one hour after the end of the call through February 6, 2021. The webcast replay can be accessed through the above links or by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10149661. The telephonic replay will be available until November 20, 2020.

**About GeoVax**

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines against infectious diseases and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) based vaccine platform. On this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens within (*in vivo*) the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax’s current development programs are focused on preventive vaccines against COVID-19, HIV, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines against multiple cancers. The Company has designed a preventive HIV vaccine candidate to fight against the subtype of HIV prevalent in the commercial markets of the Americas, Western Europe, Japan, and Australia; human clinical trials for this program are managed by the HIV Vaccine Trials Network (HVTN) with the support of the National Institutes of Health (NIH). GeoVax’s HIV vaccine is also part of two separate collaborative efforts to apply its innovative gene therapy approach toward a functional cure for HIV.

***Forward-Looking Statements***

*This release contains forward-looking statements regarding GeoVax’s business plans and financial result. This release and the related conference call discuss forward-looking statements regarding GeoVax’s ability to implement its business plan, expected revenues and future success. The words “believe,” “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 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 most recent Quarterly Report on Form 10-Q that we have filed 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.*

**Contact:**

GeoVax Labs, Inc.

investor@geovax.com

678-384-7220

**FINANCIAL TABLES FOLLOW**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **GEOVAX LABS, INC.** | | | | | | | |
| **Condensed Consolidated Statements of Operations Information** | | | | | | | |
| *(amounts in thousands, except share and per share information)* | | | | | | | |
|  |  |  |  | Three Months Ended | | Nine Months Ended | |
|  |  |  |  | September 30, | | September 30, | |
|  |  |  |  | 2020 | 2019 | 2020 | 2019 |
| Grant and collaboration revenue | | |  | $ 415 | $ 333 | $ 1,572 | $ 907 |
|  |  |  |  |  |  |  |  |
| Operating expenses: | | |  |  |  |  |  |
|  | Research and development | |  | 417 | 468 | 1,687 | 1,475 |
|  | General and administrative | |  | 435 | 291 | 1,365 | 1,214 |
|  |  |  |  | 852 | 759 | 3,052 | 2,689 |
| Loss from operations | | |  | (437) | (426) | (1,480) | (1,781) |
| Other income (expense), net | | |  | (134) | 2 | (142) | 1 |
|  |  |  |  |  |  |  |  |
| Net loss | | |  | $ (571) | $ (424) | $ (1,622) | $ (1,780) |
|  |  |  |  |  |  |  |  |
| Loss per common share | | |  | $ (0.73) | $ (1,282.28) | $ (2.85) | $ (14,016.03) |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condensed Consolidated Balance Sheet Information** | | | | | | | |
| *(amounts in thousands, except share information)* | | | | | | | |
|  | |  |  |  |  | Sep. 30,  2020 | Dec. 31,  2019 |
| Assets: | |  |  |  |  |  |  |
|  | Cash and cash equivalents | |  |  |  | $ 11,581 | $ 283 |
|  | Other current assets | |  |  |  | 154 | 164 |
|  | Total current assets | |  |  |  | 11,735 | 447 |
|  |  |  |  |  |  |  |  |
|  | Property and other assets, net | |  |  |  | 21 | 22 |
|  | Total assets | |  |  |  | $ 11,756 | $ 469 |
|  |  |  |  |  |  |  |  |
| Liabilities and stockholders’ equity (deficiency) | | |  |  |  |  |  |
|  | Total liabilities | |  |  |  | $ 942 | $ 2,043 |
|  | Stockholders’ equity (deficiency) | |  |  |  | 10,814 | (1,574) |
|  | Total liabilities and stockholders’ equity (deficiency) | | | |  | $ 11,756 | $ 469 |
|  |  | |  |  |  |  |  |
|  | Common Shares Outstanding | |  |  |  | 3,559,473 | 14,992 |