**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):  May 6, 2021**

**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. ☐

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 May 6, 2021 we issued a press release reporting our results of operations for the quarter ended March 31, 2021. 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 May 6, 2021 |

**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: May 7, 2021

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



**Exhibit 99.1**

**GeoVax Reports 2021 First Quarter Financial Results**

**and Provides Corporate Update**

***Additional Capital Raised to Support Acceleration of***

***Coronavirus and Immuno-Oncology Programs***

**ATLANTA, GA, May 6, 2021** – GeoVax Labs, Inc. (NasdaqCM: GOVX), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers, today announced its financial results for the three months ended March 31, 2021.

GeoVax’s management will host a live conference call and webcast at 4:30 p.m. Eastern Standard Time on Thursday, May 6 to discuss financial results and provide a general business update. Details are provided further below.

**First Quarter 2021 Highlights**

Capital Resources – On February 11, 2021, GeoVax supplemented its cash resources through a $10.3 million follow-on offering of common stock ($9.4 million net proceeds). During the first quarter, the Company also received $3.2 million from the exercise of outstanding warrants. Cash balances at March 31, 2021 were $20.8 million.

COVID-19 Vaccine– 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. GeoVax is focused on a single-dose vaccine against multiple COVID-19 variants that can be distributed with minimal/no refrigeration, as reflected in recent announcements by the NIH and other funding entities. Currently, GeoVax is conducting animal testing of its “universal coronavirus vaccine” candidates, from which the selection of a clinical development vaccine is expected.

Intellectual Property – During the first quarter of 2021, GeoVax filed international and U.S. patent applications in its key focus areas of SARS-CoV-2 (COVID-19) and cancer immunotherapy. The cancer immunotherapy filings cover updates to the Company’s MVA viral vector technology to amplify an immune response to a cancer antigen via vaccination, which could strengthen its intellectual property position in this space.

During April, GeoVax received a Notice of Allowance from the U.S. Patent and Trademark Office for a composition and method of use patent related to its HIV vaccine program. The Company also received a Notice of Allowance for a composition and method of use patent for its Hepatitis B vaccine supported by a collaboration with Georgia State University.

Following these filings, GeoVax’s 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.

**Management Commentary**

David Dodd, GeoVax’s Chairman and CEO, commented, “With the funding from our September 2020 offering and subsequent financings in the first quarter of 2021, we are well-positioned to advance several of our development programs, with a continued focus on our COVID-19 vaccine and our cancer immunotherapy programs. The additional capital has allowed us to make infrastructure and personnel investments, as well as funding commitments in support of other programs. We are also focusing on manufacturing process development for our MVA-produced vaccines with a view toward cost-effective, large-scale production for clinical and commercial distribution.

“We applaud the extraordinary COVID-19 vaccination efforts underway, and the rapid development of those vaccines, but the worldwide scientific community recognizes the reality that the fight is far from over. While we have seen great advances in vaccines developed against SARS-CoV-2, the coronavirus that causes COVID-19, variants of concern now pose a threat to this progress. They spread rapidly, can reinfect people who have been infected before, and they are rendering countermeasures less effective.

“Additionally, coronaviruses in general have now demonstrated their pandemic potential. SARS-CoV-2 is a type of coronavirus (a Betacoronavirus) that also causes Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). The SARS and MERS coronaviruses are associated with case fatality rates of 10%-35% (5-16 times worse than COVID-19) and we know that coronaviruses circulate widely in animal reservoirs. The emergence of a coronavirus combining the transmissibility of COVID-19 with the lethality of SARS or MERS would be devastating to civilization.

“GeoVax’s SARS-CoV-2 vaccine is based on our GV-MVA-VLPTM technology, which enables insertion of multiple COVID viral genes, potentially allowing for broad-spectrum virus prevention. Unlike 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 SARS-CoV-2 variants, and potentially provide cross-reactive protection against other coronaviruses. It is this broad-spectrum approach that we believe warrants additional funding support once we complete the ongoing small animal studies.

“Finally, we expect several data announcements in the forthcoming weeks and months, most notably in our program areas of COVID-19, Lassa Fever virus, Sudan/Marburg virus and malaria. I look forward to sharing news of our progress as those and other events occur,” concluded Mr. Dodd.

**Financial Review**

GeoVax reported a net loss for the three months ended March 31, 2021 of $1,562,778, as compared to $595,694 for the three months ended March 31, 2020.

Grant and collaboration revenues were $110,417 for the three months ended March 31, 2021, as compared to $715,977 for the same period in 2020. The 2021 period reflects amounts related to our grant from NIH in support of our COVID-19 vaccine program, while the 2020 period reflects amounts related to our grant from the U.S. Department of Defense (DoD) for our Lassa Fever vaccine and our collaboration with Leidos, Inc. for its malaria vaccine program. As of March 31, 2021, there is approximately $355,000 of approved funds remaining and available for use related to the COVID-19 and Lassa Fever grants.

Research and development (R&D) expenses were $602,783 for the three months ended March 31, 2021 compared with $808,936 for the comparable period in 2020, with the difference primarily relating to the timing of expenses associated with government grants. General and administrative (G&A) expenses were $1,071,710 and $502,345 for the three months ended March 31, 2021 and 2020, respectively, with the increase primarily attributable to higher Delaware franchise taxes, legal and patent costs, consulting fees and personnel costs.

GeoVax reported cash balances of $20.8 million at March 31, 2021, as compared to $9.9 million at December 31, 2020. Contributing to the increase in cash balances during the first quarter were net proceeds of $9.4 million from the sale of 1,644,000 shares of common stock, and $3.2 million from the exercise of warrants to purchase 690,034 shares of common stock.

Summarized financial information is attached. Further information is included in the Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission.

**Conference Call**

Management will host a conference call at 4:30 p.m. ET on Thursday, May 6, 2021 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 register for the call via the following link: <https://dpregister.com/sreg/10155713/e7b7b09fcc>

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/mediaframe/webcast.html?webcastid=8qJmr12T>

A webcast replay of the call will be available approximately one hour after the end of the call through August 6, 2021 and can be accessed through the above link. A telephonic replay of the call will be available until May 20, 2021 and can be accessed by calling 1-877-344-7529 using access code 10155713.

**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 in 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 and the related conference call contain forward-looking statements regarding GeoVax’s business plans and financial results. 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 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 registration statement on Form S-3 and the periodic reports on Form 10-Q and Form 10-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.*

**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 common share information)* | | | | | | | |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  | | Three Months Ended | |
|  |  |  |  |  | | March 31, | |
|  |  |  |  |  |  | 2021 | 2020 |
| Grant and collaboration revenues | | |  |  |  | $ 110 | $ 716 |
|  |  |  |  |  |  |  |  |
| Operating expenses: | | |  |  |  |  |  |
|  | Research and development | |  |  |  | 603 | 809 |
|  | General and administrative | |  |  |  | 1,071 | 502 |
|  |  |  |  |  |  | 1,674 | 1,311 |
|  | Loss from operations | |  |  |  | (1,564) | (595) |
|  | Other income (expense), net | |  |  |  | 1 | (1) |
|  |  |  |  |  |  |  |  |
| Net loss | | |  |  |  | $ (1,563) | $ (596) |
|  |  |  |  |  |  |  |  |
| Net loss per common share | | |  |  |  | $ (0.29) | $ (2.54) |
|  | | |  |  |  |  |  |
| Weighted average common shares outstanding | | |  |  |  | 5,332,058 | 234,395 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condensed Consolidated Balance Sheet Information** | | | | | | | |
| *(amounts in thousands, except common share information)* | | | | | | | |
|  | |  |  |  |  | March 31,  2021 | Dec. 31,  2020 |
| Assets: | |  |  |  |  |  |  |
|  | Cash and cash equivalents | |  |  |  | $ 20,843 | $ 9,884 |
|  | Other current assets | |  |  |  | 118 | 351 |
|  | Total current assets | |  |  |  | 20,961 | 10,235 |
|  | Property and other assets, net | |  |  |  | 154 | 159 |
|  | Total assets | |  |  |  | $ 21,115 | $ 10,394 |
|  |  |  |  |  |  |  |  |
| Liabilities and stockholders’ equity | | |  |  |  |  |  |
|  | Total liabilities | |  |  |  | $ 464 | $ 825 |
|  | Stockholders’ equity | |  |  |  | 20,651 | 9,569 |
|  | Total liabilities and stockholders’ equity | | | |  | $ 21,115 | $ 10,394 |
|  |  | |  |  |  |  |  |
|  | Common shares outstanding | |  |  |  | 6,315,467 | 3,834,095 |