

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): August 10, 2020

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-52091
(Commission File No.)

87-0455038
(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)

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

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 CFR 240.14a-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))

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 “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 Company’s management as well as estimates and assumptions made by the Company’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 Company or the Company’s management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Company’s industry, operations and results of operations and any businesses that may be acquired by the Company. 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 Company does not undertake to update its forward looking statements.

Item 2.02 Results of Operations and Financial Condition

On August 10, 2020 we issued a press release reporting our results of operations for the quarter ended June 30, 2020. A copy of the press release is attached to this Current Report.

Item 9.01 Financial Statements and Exhibits

The following exhibits are filed with this Current Report:

Exhibit 99.1 Press Release, dated August 10, 2020

SIGNATURE

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

Dated: August 10, 2020

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports 2020 Second Quarter Financial Results and Provides Corporate Update

Company Demonstrated Progress on COVID-19 Vaccine Development; Continued Progress in Other Infectious Disease and Immuno-Oncology Programs

ATLANTA, GA, August 10, 2020 – GeoVax Labs, Inc. (OTC: GOVX), a biotechnology company developing human vaccines, today announced financial results for the quarter ended June 30, 2020 and provided an update on its corporate developments.

David Dodd, GeoVax’s President & CEO, commented, “During the first half of 2020, GeoVax continued to make progress in various areas of product development and corporate business strategy by carefully managing our resources and prioritizing our activities toward our most advanced programs. Most notable was our decision to apply our expertise to help solve the global pandemic of COVID-19. In addition, we are diligently working to strengthen our capital position. In sum, we are confident in our progress and believe that our strategy to build the company and enhance shareholder value is on the right path to success.”

Update on Coronavirus (COVID-19) Vaccine

In January 2020, GeoVax announced initiation of efforts to develop a vaccine against novel coronavirus disease (COVID-19) caused by the SARS-CoV-2 coronavirus. The Company’s vaccine program was subsequently added to the “[Draft Landscape of COVID-19 Candidate Vaccines](#)” by the World Health Organization. We are pleased with the progress of our four vaccine candidates for COVID-19, which have now entered animal challenge testing. Our vaccine platform has a track record of safety in humans through our HIV vaccine program and the preclinical testing results we have seen with multiple vaccine programs (HIV, Ebola, Sudan, Marburg and Zika), which provide the scientific rationale to move forward confidently with this program.

Once the Company narrows to a single COVID-19 vaccine candidate, we plan to proceed directly to manufacturing and initial human clinical testing for safety and immunogenicity, subject to additional fundraising and/or support from U.S. funding agencies. Although other competitive vaccine candidates have been discussed in the public record, management believes that the GV-MVA-VLP™ platform could provide vaccine candidates with excellent efficacy, safety and durability, all critical attributes of any COVID-19 vaccine that will serve us – and the public – should we gain FDA approval and distribution worldwide.

Other Vaccine and Immunotherapy Programs

HIV Vaccines (Therapeutic) – GeoVax will participate in a planned clinical trial led by researchers at American Gene Technologies (AGT) to develop a therapy aimed at eliminating HIV from infected people (a “functional cure”). In late 2019, AGT submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for its lead HIV program, AGT103-T, a lentiviral vector-based gene therapy. Upon clearance by the FDA, this IND will allow AGT to initiate a Phase 1 clinical trial that will investigate the safety of AGT103-T in humans, measure key biomarkers, and explore surrogate markers of efficacy. GeoVax will provide its novel MVA-VLP-HIV vaccine (MVA62B) for evaluation in an arm of the clinical trial in combination with AGT103-T. AGT has stated its intention to begin recruiting patients for the Phase 1 study in 2020.

The Company is also participating in a collaborative effort led by researchers at the University of California, San Francisco (UCSF), to develop a combination therapy aimed at inducing remission in HIV-positive individuals (a separate approach towards a “functional cure”). Funded by amfAR, The Foundation for AIDS Research, the proposed clinical trial will enroll 20 HIV-infected adults who are on stable and effective anti-retroviral therapy (ART) and will involve a combination of vaccines, drugs and biologics. As with the AGT trial, GeoVax will provide MVA62B for use in the studies. Patient enrollment for the clinical trial is expected to commence in late 2020.

HIV Vaccines (Preventive) – The development of GeoVax’s preventive HIV vaccine (GOVX-B11) from

MORE

preclinical studies to human clinical trials has been supported by funding from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Following human studies by the HIV Vaccine Trials Network (HVTN) with support from NIAID, the Company is now planning for a new Phase 1 human clinical trial (designated HVTN 132) to further assess the safety, tolerability, and immunogenicity (elicited antibody responses) of a prime-boost regimen of GOVX-B11 in combination with protein boost vaccines. Management has expected that HVTN 132 would commence patient enrollment in late 2020, but now anticipates the trial to start during the first half of 2021 due to the trial sites being utilized for COVID-19 vaccine testing.

Malaria Vaccine (collaboration with Leidos, Inc.) – In February 2020, GeoVax expanded its ongoing 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 has selected the GeoVax MVA-VLP platform to be a part of this development effort. Our collaboration with Leidos complements our ongoing malaria vaccine development project with Burnet Institute in Australia.

Lassa Fever Vaccine (supported by U.S. Dept. of Defense) – GeoVax’s Lassa fever vaccine continues to progress toward nonhuman primate testing and manufacturing process development in preparation for human clinical trials through grant support from the U.S. Department of Defense.

Other Emerging Infectious Disease Vaccines – GeoVax has developed vaccines for several other pathogens, including Ebola, Sudan, Marburg and Zika virus, each of which, like COVID-19, represents a threat to world populations. In preclinical animal models, 100% protection with GeoVax’s vaccine candidates against each of these viruses was demonstrated.

Cancer Immunotherapy – In September 2019, GeoVax incorporated Immutak Oncology, Inc. as a wholly-owned subsidiary to focus on the advancement of its immuno-oncology programs and to seek additional complementary technologies and clinical-stage products in the oncology space. Management intends to leverage the completed and ongoing work with the Company’s collaborators at the University of Pittsburgh, ViaMune, Leidos, and others, and is exploring a separate financing effort in support of these programs. Management believes developing its programs in this area to be a key component for increasing the value of GeoVax and providing a future growth opportunity.

Capital Resources

Although GeoVax’s internal capital resources have been limited, the Company has continued to make progress in various areas through the support of collaborators and sponsors. GeoVax’s capital resources are also supplemented by the continued deferral of portions of management’s salaries and full deferral of fees to the Company’s Board of Directors. In April 2020, GeoVax augmented its cash resources through a \$170,200 loan under the Paycheck Protection Program provisions of the CARES Act. In June 2020, the Company secured an additional \$1 million of funding through the issuance of convertible debentures and warrants to an institutional investor, for continued work on various projects.

Financial Results for the Period Ending June 30, 2020

GeoVax reported a net loss of \$455,204 (\$0.03 per share) for the three months ended June 30, 2020, compared to a net loss of \$654,148 (\$1,994.35 per share) for the same period in 2019. For the six months ended June 30, 2020, the Company’s net loss was \$1,050,898 (\$0.11 per share) as compared to a net loss of \$1,355,602 (\$4,706.95 per share) in 2019.

The Company reported grant and collaboration revenues of \$440,602 and \$1,156,579 for the three-month and six-month periods of 2020, respectively, as compared to \$209,941 and \$574,173 reported for the comparable periods of 2019. As of June 30, 2020, there were \$650,051 of approved funds remaining and available for use related to GeoVax’s grant from the U.S. Department of Defense in support of its Lassa fever vaccine development program.

Research and development expenses were \$461,421 and \$1,270,357 for the three-month and six-month periods of 2020, respectively, as compared to \$451,227 and \$1,006,945 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 government grants. General and administrative expenses were \$427,292 and \$929,637 for the three-month and six-month periods of 2020, respectively, as compared to \$412,650 and \$922,714 for the comparable periods of 2019.

GeoVax reported cash balances of \$710,682 at June 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 gross proceeds of \$300,000, the issuance of a note payable in April 2020 for gross proceeds of \$170,200, and the sale of convertible debentures in June 2020 for gross proceeds of \$1,050,000.

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.

About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines against infectious diseases and cancer using a novel proprietary vaccine platform (GV-MVA-VLP™). On this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens within the person receiving the vaccine (*in vivo*). The production of VLPs in the person being vaccinated mimics 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 GV-MVA-VLP™ derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while typically providing the safety characteristics of a replication-defective vector.

GeoVax's current development programs are focused on preventive vaccines against COVID-19, HIV, Zika, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines against chronic Hepatitis B infections and multiple cancers. The Company has developed a preventive HIV vaccine candidate (GOVX-B11) for the clade B subtype of HIV prevalent in the Americas, Western Europe, Japan, and Australia, as well as a vaccine candidate for the clade C subtype prevalent in Africa and India. GOVX-B11 is scheduled for inclusion in an upcoming human clinical trial managed by the HVTN with the support of the National Institutes of Health (NIH). GeoVax's clade B HIV vaccine is also part of collaborative efforts to develop an immunotherapy as a functional cure for HIV.

Forward-Looking Statements

Certain statements in this document are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. 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, and other factors, over which GeoVax has no control. GeoVax assumes no obligation to update these forward-looking statements and does not intend to do so. More information about these factors is contained in GeoVax's filings with the Securities and Exchange Commission including those set forth at "Risk Factors" in GeoVax's Form 10-K.

Contact:

GeoVax Labs, Inc.
investor@geovax.com
678-384-7220

FINANCIAL TABLES FOLLOW

MORE

GEOVAX LABS, INC.
Condensed Consolidated Statements of Operations Information
(amounts in thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Grant and collaboration revenue	\$ 441	\$ 210	\$ 1,157	\$ 574
Operating expenses:				
Research and development	462	451	1,270	1,007
General and administrative	427	413	930	923
	<u>889</u>	<u>864</u>	<u>2,200</u>	<u>1,930</u>
Loss from operations	(448)	(654)	(1,043)	(1,356)
Other income (expense), net	(7)	-	(8)	-
Net loss	<u>\$ (455)</u>	<u>\$ (654)</u>	<u>\$ (1,051)</u>	<u>\$ (1,356)</u>
Loss per common share	<u>\$ (0.03)</u>	<u>\$ (1,994.35)</u>	<u>\$ (0.11)</u>	<u>\$ (4,706.95)</u>

Condensed Consolidated Balance Sheet Information
(amounts in thousands)

	June 30, 2020	Dec. 31, 2019
Assets:		
Cash and cash equivalents	\$ 711	\$ 283
Other current assets	227	164
Total current assets	<u>938</u>	<u>447</u>
Property and other assets, net	20	22
Total assets	<u>\$ 958</u>	<u>\$ 469</u>
Liabilities and stockholders' equity (deficiency)		
Total liabilities	\$ 2,808	\$ 2,043
Stockholders' equity (deficiency)	(1,850)	(1,574)
Total liabilities and stockholders' equity (deficiency)	<u>\$ 958</u>	<u>\$ 469</u>
Common Shares Outstanding	13,834,075	299,835

###