

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): **March 25, 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 March 25, 2020 we issued a press release reporting our results of operations for the year ended December 31, 2019. 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 March 25, 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: March 25, 2020

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports 2019 Year-End Financial Results And Provides Corporate Update

Recent Pivot to COVID-19 Vaccine Development; Continued Advancements in Other Infectious Disease and Immuno-Oncology Programs

ATLANTA, GA, March 25, 2020 – GeoVax Labs, Inc. (OTC: GOVX), a biotechnology company developing human immunotherapies and vaccines against infectious diseases and cancer, today announced its financial results for the year ended December 31, 2019 and provided an update on its corporate development progress.

David Dodd, President & CEO, commented, “During the past year and the early months of 2020, GeoVax made substantial progress in various areas of product development. This was combined with tough capital restructuring decisions that, while painful at the time, have now resulted in GeoVax being better positioned for future financing efforts in support of our programs and increasing shareholder value. I am pleased to share a few highlights here.”

Coronavirus Vaccine – In January 2020, we announced our initiation of efforts to develop a vaccine against novel coronavirus disease (COVID-19) caused by the SARS-Cov-2 coronavirus including a letter of intent for a collaboration with BravoVax, a vaccine developer in Wuhan, China. On March 18, 2020, we provided an update on the progress of our program, including the completion of three vaccine candidates and plans for advancing to human clinical trials. Our vaccine has been added to the “Draft Landscape of COVID-19 Candidate Vaccines” by the World Health Organization ([link](#)). We will continue to provide updates on our progress with this very important program.

Cancer Immunotherapy – In September 2019, we incorporated Immutak Oncology, Inc as a wholly-owned subsidiary of GeoVax. We established Immutak to focus on the advancement of our immuno-oncology programs and to seek additional, complementary technologies and clinical-stage products in the oncology space. We intend to leverage the work completed and ongoing with our collaborators at the University of Pittsburgh, ViaMune, Leidos, and others, and have initiated a separate financing effort in support of these programs. We believe developing our programs in this area to be a key component for strengthening the valuation of GeoVax and providing future value growth opportunity.

HIV Vaccines (Therapeutic) – We are participating 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 our novel MVA-VLP-HIV vaccine (MVA62B) for evaluation in an arm of the clinical trial in combination with AGT103-T. AGT has recently stated their intention to begin recruiting patients for the Phase 1 study in mid-2020.

In November 2019, we entered into an agreement with the University of California, San Francisco (UCSF), whereby we will participate in a collaborative effort to develop a combinational therapy aimed at inducing remission in HIV-positive individuals (another approach toward 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 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 during 2020.

HIV Vaccines (Preventive) – The development of our preventive HIV vaccine (GOVX-B11) from preclinical studies to human clinical trials has been financially supported by the National Institute of Allergy

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and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The HIV Vaccine Trials Network (HVTN) with support from NIAID, has conducted multiple human clinical trials of our preventive HIV vaccine candidates, and continues advancing our vaccine in clinical studies. We now are planning for a new Phase 1 human clinical trial (designated HVTN 132) with operational support from the HVTN and funding from the NIAID. 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 protein boost vaccines. The start of HVTN 132 has been delayed due to clarification of components other than our vaccine, but we currently expect HVTN to commence patient enrollment in late 2020.

Malaria Vaccine – In early 2019, we began a collaboration with Leidos, Inc. to develop malaria vaccine candidates. The work continued through 2019 and was expanded in early 2020 with support 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 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.

Emerging Infectious Disease Vaccines – The ongoing COVID-19 pandemic exemplifies the threat to global health posed by emerging infectious diseases, those known and unknown (so called “Disease X”). In addition to our COVID-19 vaccine, GeoVax has developed vaccines for several other pathogens, including Ebola, Marburg, Lassa fever, and Zika virus, each of which represents a threat to world populations. In preclinical animal models, we have demonstrated 100% protection with our vaccines against each of these viruses. Our 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.

Capital Restructuring – On January 3, 2020, our stockholders approved a 1-for-2000 reverse split of our common stock, which was executed on January 21. While this action was drastic, it was necessary in order to provide for sufficient authorized shares of our common stock both to fulfill our obligations to holders of our convertible preferred stock, as well as provide for additional authorized shares of common stock for use in future capital raises. As of December 31, 2019, we had approximately \$2.5 million (stated value) of convertible preferred stock on our balance sheet which has now been reduced to \$400,000, and our outstanding common shares stands at 13,791,601. This restructuring now places us in a better position for negotiating future financing transactions under more beneficial terms.

Financial Review

GeoVax reported a net loss for the year ended December 31, 2019 of \$2.4 million, as compared to \$2.6 million for the year ended December 31, 2018.

Grant and collaboration revenues were \$1.2 million for 2019, as compared to \$1.0 million in 2018. As of December 31, 2019, there is \$1.6 million of approved grant funds remaining and available for use during 2020, 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 relatively unchanged year over year (approximately \$1.9 million for each of 2019 and 2018), as were general and administrative expenses (approximately \$1.6 million for each of 2019 and 2018).

Summarized financial information is attached. Further information concerning the Company’s financial position and results of operations are included in its Annual Report on Form 10-K 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 (*in vivo*) the person receiving the vaccine. The production of VLPs in the person being vaccinated mimics virus production in a natural infection, stimulating both the humoral and cellular arms

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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 preventive HIV vaccine candidate (GOVX-B11) for the clade B subtype of HIV prevalent in the Americas, Western Europe, Japan, and Australia and 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 and BravoVax will enter into a binding agreement, 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:

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678-384-7220

FINANCIAL TABLES FOLLOW

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

	Year Ended December 31,	
	2019	2018
Grant and collaboration revenue	\$ 1,176	\$ 963
Operating expenses:		
Research and development	1,911	1,879
General and administrative	1,637	1,647
	3,548	3,526
Loss from operations	(2,372)	(2,563)
Other income (expense), net	2	3
	\$ (2,371)	\$ (2,560)
Net loss		
	\$ (39.25)	\$ (15.310)
Net loss per common share		
Weighted average shares outstanding	60,402	164

Condensed Consolidated Balance Sheet Information
(amounts in thousands, except common share information)

	December 31,	
	2019	2018
Assets:		
Cash and cash equivalents	\$ 283	\$ 260
Other current assets	164	360
Total current assets	447	620
Property and other assets	22	22
Total assets	\$ 469	\$ 642
Liabilities and stockholders' equity		
Total liabilities	\$ 2,043	\$ 1,664
Stockholders' equity (deficiency)	(1,574)	(1,022)
Total liabilities and stockholders' equity	\$ 469	\$ 642
Common Shares Outstanding	299,835	219

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