

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, 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 May 6, 2020 we issued a press release reporting our results of operations for the quarter ended March 31, 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 May 6, 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: May 6, 2020

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports 2020 First Quarter Financial Results and Provides Corporate Update

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

ATLANTA, GA, May 6, 2020 – GeoVax Labs, Inc. (OTC: GOVX), a biotechnology company developing human vaccines, today announced its financial results for the three months ended March 31, 2020 and provided an update on its corporate development progress.

David Dodd, President & CEO, commented, “During the early months of 2020, GeoVax continued to make progress in various areas of product development and corporate business strategy, despite the limited capital resources which have constrained our activities. Most notable was our decision to use our technology and expertise to develop a vaccine against novel coronavirus (COVID-19) as discussed in greater detail below. I am pleased to share a few highlights of our other development programs as well.”

Coronavirus (COVID-19) Vaccine

We are pleased with the progress of our three vaccine candidates for COVID-19. Safety, efficacy, and durability of protection (long-lasting) are the expected characteristics of our GV-MVA-VLP™ vaccine platform being used for constructing our vaccines. Our platform has a track record of safety in humans through our HIV vaccine program, and the preclinical testing results we have seen with our HIV vaccine, as well as our emerging infectious disease vaccines (Ebola, Sudan, Marburg and Zika), lead us to believe that our COVID-19 vaccine can demonstrate a similarly strong efficacy and durability profile.

From here, we will narrow to one vaccine candidate based on the safety, immunogenicity and protective efficacy of our PreMaster Seed Viruses observed when we conduct our animal studies. We plan to then proceed directly to manufacturing and initial human clinical testing for safety and immunogenicity, assuming adequate resources are available. We also continue to be in frequent communication with BravoVax, our collaborator in Wuhan, China. Upon completion of a definitive agreement, we expect BravoVax to provide testing and manufacturing support, as well as direct interactions with Chinese authorities, for a parallel regulatory pathway to what we will pursue in the United States. We have initiated discussions and submitted applications with U.S. funding agencies as well.

Our efforts have been recognized through the inclusion of our vaccine in the “Draft Landscape of COVID-19 Candidate Vaccines” by the World Health Organization ([link](#)). Though other vaccines may be advancing more rapidly toward clinical trials, we believe our vaccine could provide exceptional safety and, due to its multi-antigen components, broader efficacy than other vaccines produced using rapid platform technologies.

Other Vaccine and Immunotherapy Programs

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

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

We also are participating in a collaborative effort led by researchers at the University of California, San Francisco (UCSF) 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 late 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 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 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 or early 2021.

Malaria Vaccine (collaboration with Leidos, Inc.) – In February 2020, we expanded our 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 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) – 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.

Other 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 and Lassa Fever vaccines, GeoVax has developed vaccines for several other pathogens, including Ebola, Sudan, Marburg 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.

Capital Restructuring and Financing

Although our capital resources are limited, we have continued to make progress in various areas through the support of the collaborators and sponsors mentioned above, including NIAID, U.S. Dept. of Defense, Leidos, AGT, UCSF and others. Our capital resources are supplemented by the continued deferral of portions of management’s salaries and full deferral of fees by our Board of Directors. Due to the effect of the COVID-19 pandemic on our financing efforts and other impacts on our operations, in April 2020 we further supplemented our cash resources through a \$170,200 loan under the Paycheck Protection Program provisions of the CARES Act.

In January, we executed a reverse split of our common stock which provided 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. Our outstanding convertible preferred stock has been reduced to just \$400,000 of stated value (from nearly \$2.5 million at the end of 2019). This restructuring now places us in a better position for negotiating future financing transactions under more

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beneficial terms in support of our programs and increasing shareholder value. There can be no assurance that we will be successful in this effort.

Financial Review

GeoVax reported a net loss for the three months ended March 31, 2020 of \$595,694, as compared to \$701,454 for the three months ended March 31, 2019.

Grant and collaboration revenues were \$715,977 for the three months ended March 31, 2020, as compared to \$364,232 for the same period in 2019. As of March 31, 2020, there is approximately \$607,000 of approved 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 (R&D) expenses were \$808,936 for the three months ended March 31, 2020 compared with \$555,718 for the comparable period in 2019, with the difference primarily relating to the timing of expenses associated with government grants. General and administrative (G&A) expenses were relatively unchanged at \$502,345 and \$510,064 for the three months ended March 31, 2020 and 2019, respectively.

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.

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 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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FINANCIAL TABLES FOLLOW

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

	Three Months Ended March 31,	
	2020	2019
Grant and collaboration revenues	\$ 716	\$ 364
Operating expenses:		
Research and development	809	556
General and administrative	502	510
	1,311	1,066
Loss from operations	(595)	(702)
Other income (expense), net	(1)	1
Net loss	\$ (596)	\$ (701)
Net loss per common share	\$ (0.13)	\$(2,851.44)
Weighted average common shares outstanding	4,687,893	246

Condensed Consolidated Balance Sheet Information
(amounts in thousands)

	March 31, 2020	Dec. 31, 2019
Assets:		
Cash and cash equivalents	\$ 222	\$ 283
Other current assets	588	164
Total current assets	810	447
Property and other assets, net	21	22
Total assets	\$ 831	\$ 469
Liabilities and stockholders' equity (deficiency)		
Total liabilities	\$ 2,695	\$ 2,043
Stockholders' equity (deficiency)	(1,864)	(1,574)
Total liabilities and stockholders' equity (deficiency)	\$ 831	\$ 469
Common Shares Outstanding	13,791,601	299,835