

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 23, 2021

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-39563
(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)

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))

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 March 23, 2021 we issued a press release reporting our results of operations for the year ended December 31, 2020. A copy of the press release is attached to this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 23, 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: March 23, 2021

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports 2020 Year-End Financial Results And Provides Corporate Update

COVID-19 Vaccine Designed as Single-Dose Against Multiple Strains Immuno-Oncology Programs Advancing

ATLANTA, GA, March 23, 2021 – GeoVax Labs, Inc. (NasdaqCM: GOVX), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancer, today announced its financial results for the year ended December 31, 2020.

GeoVax’s management will host a live conference call and webcast at 8:00 a.m. Eastern Standard Time on Wednesday, March 24 to discuss financial results and provide a general business update. Details are provided further below.

GeoVax Program Updates and Other Highlights

COVID-19 Vaccine – Our SARS-CoV-2 (COVID-19) vaccine is based on our GV-MVA-VLP™ technology, which enables insertion of multiple antigen fragments, potentially allowing for broad-spectrum virus prevention. Unlike certain competitor 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.

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*,” will support the ongoing design, construction and preclinical testing of our vaccine candidates in preparation for human clinical trials.

Immuno-Oncology Program – Our cancer immunotherapy program is based on the concept of combining 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. In February 2021, we filed a U.S. patent application, covering updates to our MVA viral vector technology to amplify an immune response to a cancer antigen via vaccination, which could strengthen our intellectual property position in this space. Following our recent fund-raising activities, immuno-oncology is an important focus area for the Company and we are engaging with multiple collaborators. We expect to provide further details on our progress and plans to advance to human clinical testing in the near future.

Hemorrhagic Fever Vaccine Programs

- **Lassa Fever** – We continue to progress with grant funding from the U.S. Department of Defense for our Lassa Fever (LASV) vaccine program. 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. We expect to announce results from this work during the first half of 2021.
- **Sudan ebolavirus and Marburg virus** – In August 2020, we announced a multi-party collaboration for the development of our Sudan ebolavirus (SUDV) and Marburg virus (MARV) vaccine candidates. The collaboration between GeoVax, researchers at the University of Texas Medical Branch (UTMB), and Battelle Memorial Institute is utilizing the suite of preclinical services from NIAID. Under the

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collaboration, GeoVax's SUDV and MARV vaccine candidates are being tested for immunogenicity and efficacy in the benchmark nonhuman primate model. 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. We expect to announce results from this work during the first half of 2021.

Malaria Vaccine – We continue to collaborate separately with Leidos, Inc. and the Burnet Institute in development of malaria vaccine candidates using our GV-MVA-VLP™ vaccine platform. The 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). Several vaccine candidates have recently entered initial animal testing with results expected during the first half of 2021.

HIV Vaccine Programs

- **HIV Preventive Vaccine** – NIAID is funding a clinical trial that includes our HIV preventive vaccine (GOVX-B11) through the HIV Vaccine Trials Network (HVTN). The next trial (HVTN 132) has been delayed due to COVID-19, but we expect it to begin in late 2021. HVTN 132 will further evaluate the safety and immunogenicity of adding “protein boost” components to the GOVX-B11 vaccination regimen.
- **HIV Immunotherapy** – We are part of two separate efforts to develop a combination therapy to induce remission in HIV-positive individuals (a “functional cure”). In August 2020, a consortium led by researchers at the University of California, San Francisco (UCSF), began enrolling patients in a Phase 1 human clinical trial using our vaccine as part of a combination therapy intended to induce remission in HIV-positive individuals. In September 2020, American Gene Technologies International, Inc. (AGT) began enrolling patients in a Phase 1 clinical trial evaluating its gene therapy technology in this area; we expect our vaccine to be added to an arm of the AGT trial during 2021.

Licenses and Intellectual Property

In October 2020, we signed a license agreement with NIAID allowing us to use the materials and patent rights owned by agencies of the United States Department of Health and Human Services (HHS) in combination with our proprietary technology for the creation of a preventive vaccine that primes and/or boosts the immune system against COVID-19. The agreement provides GeoVax with nonexclusive rights to develop, manufacture and commercialize our COVID-19 vaccine.

In November 2020, we signed another license agreement with NIAID in support of our non-clinical development of preventive and/or therapeutic vaccines against numerous pathogens including Ebola-Zaire, Ebola-Sudan, Lassa virus, Marburg virus, Zika virus and malaria. The agreement also extends to our research and development efforts in certain oncology areas.

In February 2021, we filed international and U.S. patent applications in our key focus areas of SARS-CoV-2 (COVID-19) and cancer immunotherapy. Following these filings, our 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.

Capital Resources

In September 2020, we completed a public offering of our common stock (GOVX) and publicly traded warrants (GOVXW) with net proceeds of \$11.2 million. Our cash balance at December 31, 2020 was \$9.9 million at December 31, 2020, as compared to \$283,341 at the end of 2019.

During the first quarter of 2021, we further supplemented our cash resources with net proceeds of \$9.4 million from a follow-on offering of our common stock, and \$3.2 million from the exercise of outstanding warrants. We therefore expect to report total cash balances in excess of \$20 million at the end of the first quarter of 2021.

Management Commentary

David Dodd, GeoVax's Chairman & CEO, commented, “With the funding from our September offering and subsequent financing in early 2021, we are well-positioned to advance several of our development programs,

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with a continued focus on our COVID-19 vaccine and our cancer immunotherapy programs. As mentioned in this release, we expect several data announcements during the first half of this year, and I look forward to sharing news of our progress as those events occur.”

Financial Review

GeoVax reported a net loss for the year ended December 31, 2020 of \$3.0 million, as compared to \$2.4 million for the year ended December 31, 2019.

Grant and collaboration revenues were \$1.8 million for 2020, as compared to \$1.2 million in 2019. These amounts primarily relate to GeoVax’s 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 December 31, 2020, there were \$165,500 of approved funds remaining and available for use related to GeoVax’s grant from the DoD. In January 2021, NIAID awarded a \$299,927 SBIR grant to the Company in support of its COVID-19 vaccine program which will support the ongoing design, construction and preclinical testing of vaccine candidates in preparation for human clinical trials.

Research and development expenses were \$2.4 million for 2020, as compared to \$1.9 million in 2019. General and administrative expenses were \$2.2 million for 2020, as compared to \$1.6 million in 2019. Fluctuations in R&D expenses from period to period are primarily attributable to the timing of expenditures related to the DoD grant. Other income (expense) was (\$141,253) for 2020, as compared to \$1,864 in 2019, with 2020 including \$138,851 of interest expense and amortized debt discount related to convertible debentures that were retired during the year.

GeoVax reported cash balances of \$9.9 million at December 31, 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 under terms substantially the same as those offered to the public. During the first quarter of 2021, the Company further supplemented its cash resources with net proceeds of \$9.4 million from a follow-on offering of its common stock, and \$3.2 million from the exercise of outstanding warrants.

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.

Conference Call

Management will host a conference call at 8:00 a.m. ET on Wednesday, March 24, 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 pre-register for the call via the following link:

<https://dpregrister.com/sreg/10152894/e3a3a9bd2c>

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/govx210324.html>

A webcast replay of the call will be available approximately one hour after the end of the call through June 24, 2021. The webcast replay can be accessed through the above links or by calling 1-877-344-7529 (domestic)

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or 1-412-317-0088 (international) and using access code 10149661. A telephonic replay of the call can be accessed by calling 1-877-344-7529 and will be available until April 7, 2021.

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:

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FINANCIAL TABLES FOLLOW

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

	Year Ended December 31,	
	2020	2019
Grant and collaboration revenue	\$ 1,823	\$ 1,176
Operating expenses:		
Research and development	2,444	1,911
General and administrative	2,196	1,637
	4,640	3,548
Loss from operations	(2,817)	(2,372)
Other income (expense), net	(141)	2
Net loss	\$ (2,958)	\$ (2,371)
Net loss per common share	\$ (2.14)	\$ (781.87)
Weighted average shares outstanding	1,383,523	3,032

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

	December 31,	
	2020	2019
Assets:		
Cash and cash equivalents	\$ 9,884	\$ 283
Other current assets	351	164
Total current assets	10,235	447
Property and other assets	159	22
Total assets	\$ 10,394	\$ 469
Liabilities and stockholders' equity		
Total liabilities	\$ 825	\$ 2,043
Stockholders' equity (deficiency)	9,569	(1,574)
Total liabilities and stockholders' equity	\$ 10,394	\$ 469
Common Shares Outstanding	3,832,892	14,992

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