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 4, 2023

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. ☐

Forward-Looking Statements

This Current Report on Form 8-K and other reports filed by 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 4, 2023, GeoVax Labs, Inc. (the "Company") issued a press release reporting its results of operations for the quarter ended March 31, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 4, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 5, 2023

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds
Mark W. Reynolds
Chief Financial Officer

Exhibit 99.1

GeoVax Reports 2023 First Quarter Financial Results and Provides Corporate Update

Cancer Gene Therapy Program and Next-Generation COVID-19 Vaccine Advancing in Phase 2 Clinical Trials

Company to host conference call and webcast today at 4:30 p.m. ET

Atlanta, GA, May 4, 2023 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing vaccines and immunotherapies against cancers and infectious diseases, today announced its financial results for the three months ended March 31, 2023, and recent corporate highlights. GeoVax's leadership will host a live conference call and webcast today to discuss financial results and provide a general business update.

David Dodd, GeoVax's Chairman and CEO, commented, "During the first quarter of 2023, our corporate focus continued to be on the advancement of our ongoing clinical trials for our Gedeptin® cancer therapy targeting advanced head and neck cancers and CM04S1, our next-generation SARS-CoV-2 (COVID-19) vaccine. Positive initial data was recently presented for CM04S1 during the World Vaccine Congress, and our Gedeptin trial has expanded to additional NCI-designated Cancer Centers, allowing us to accelerate our patient enrollment efforts; we look forward to completing enrollment for this trial in the very near future. I look forward to reporting further progress on each of our ongoing clinical trials during the remainder of the year."

Mr. Dodd further commented, "In addition to clinical progress, the first quarter was filled with many notable achievements for GeoVax. Significant progress has been made in developing a high-yield, high-capacity, continuous avian cell line system for manufacturing our MVA-based vaccines and immunotherapies, such as CM04S1. We believe this will provide GeoVax the ability to respond to large-scale world needs in a timely manner. Additionally, the recent expansion of our CM04S1 rights to include development for Mpox (monkeypox) and smallpox adds to other rights we previously secured from the NIH covering preclinical, clinical and commercial uses of the NIH-MVA, potentially adding significant value to our MVA-based vaccines under development."

First Quarter 2023 and Recent Business Highlights:

- Unpublished data from the open-label portion of the Phase 2 trial of CM04S1 (ClinicalTrials.gov Identifier: NCT04977024) was presented during the 23rd Annual World Vaccine Congress. The trial is investigating CM04S1 in patients undergoing hematological cancer treatment (i.e., patients who have reduced immune system function as a result of treatment). The preliminary analysis indicates CM04S1 is highly immunogenic in these patients, inducing both antibody responses, including neutralizing antibodies, and T cell responses, which the Company believes are important to confer protection in the immunocompromised population. These data support the planned progression of the Phase 2 clinical study, which will include a direct comparison to currently approved mRNA vaccines.

- Data from recent nonhuman primate studies of GEO-MM01 against Marburg virus were presented during the 23rd Annual World Vaccine Congress. Of particular interest, immunization with GEO-MM01 conferred 80% survival in cynomolgus macaques following a lethal dose of Marburg virus. Vaccination protected nonhuman primates from viremia, weight loss and death following challenge with a lethal Marburg virus dose. Evaluation of immune responses following vaccination demonstrated the presence of both neutralizing antibodies and functional T cells, indicating a breadth of responses that combine for optimal protection.

- GeoVax expanded its rights under its license agreement with City of Hope (COH). The original license agreement with COH provides GeoVax exclusive worldwide rights to key patents, including the use of COH's proprietary synthetic MVA (sMVA) process, for developing COVID-19 vaccines, including CM04S1. The amended license now grants GeoVax development and commercialization rights against orthopoxviruses in addition to SARS-CoV-2. Orthopoxviruses include Mpox (monkeypox), smallpox, and other viruses that cause disease in humans.

- GeoVax announced significant progress in developing a high-yield, high-capacity, continuous avian cell line system for manufacturing its MVA-based vaccines and immunotherapies. The Company is accelerating activities towards

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fully implementing a proprietary, continuous cell line manufacturing system that will provide lower-cost, scalable versatility for broad MVA vaccine and immunotherapy applications. GeoVax is on course to expand MVA applications from stockpile-based solutions for niche medical markets to have the capability to respond to large-scale world needs on a timely basis.

- Impressive data were presented from a clinical study, led by researchers at the University of California, San Francisco (UCSF), of a combinational HIV therapy that included GeoVax's HIV vaccine candidate, MVA62B, at the Conference on Retroviruses and Opportunistic Infections (CROI). The data indicated very high levels of immunogenicity of the treatment, particularly the induction of T cell immunity, even though HIV infection compromises the immune system. Viral rebound kinetics also appeared to be impacted positively, measured as reduced viral load and delayed return of peak levels.

- Expanded the Gedeptin® Phase 1/2 trial with patients actively enrolling at National Cancer Institute (NCI) designated Cancer Centers – Stanford University Cancer Institute, Emory University Winship Cancer Institute, and the Thomas Jefferson University Sidney Kimmel Cancer Center. Funded in part by the US Food & Drug Administration (FDA) under its Orphan Products Clinical Trials Grants Program, the trial will guide the design of a larger study that also may involve patients with other anatomically accessible oral and pharyngeal cancers. Additionally, it may lead to labeling discussions with the FDA and initiation of further Gedeptin® investigations, including in combination with immune checkpoint inhibitors for other cancerous and non-cancerous tumor indications. The Company expects patient enrollment in the current phase of this trial to be completed during the second quarter of 2023.

- US Patent and Trademark Office issued a Notice of Allowance for Patent Application No. 17/000,768 titled, "*Method for Generating a ZIKV Immune Response Utilizing a Recombinant Modified Vaccinia Ankara Vector Encoding the NS1 Protein*." Preclinical studies demonstrated that a single dose of GEO-ZM02 provided 100% protection against a lethal dose of the Zika virus.

Financial Results

- **Net Loss**: Net loss for the three months ended March 31, 2023, was $4,037,916, or $0.15 per share, as compared to $2,427,515, or $0.34 per share, for the three months ended March 31, 2022.

- **R&D Expenses**: Research and development expenses were $2,819,189 for the three months ended March 31, 2023, compared with $1,330,544 for the comparable period in 2022, and an increase of $1,488,645.

- **G&A Expenses**: General and administrative expenses were $1,451,425 for the three months ended March 31, 2023, compared to $1,179,024 for the three months ended March 31, 2022, an increase of $272,401.

- **Cash Position**: GeoVax reported cash balances of $23,849,860 at March 31, 2023, as compared to $27,612,732 at December 31, 2022, a decrease of $3,762,872.

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 Details

Management will host a conference call, scheduled to begin at 4:30 p.m. ET today, May 4, 2023, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Domestic: 800-715-9871
International: 646-307-1963
Conference ID: 3978501
Webcast: GeoVax Earnings Webcast

A webcast replay of the call will be available for six months via the same link as the live webcast approximately two hours after the end of the call.

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About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing novel therapies and vaccines for cancers and many of the world's most threatening infectious diseases. The company's lead program in oncology is a novel oncolytic solid tumor gene-directed therapy, Gedeptin®, presently in a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. GeoVax's lead infectious disease candidate is GEO-CM04S1, a next-generation COVID-19 vaccine targeting high-risk immunocompromised patient populations. Currently in two Phase 2 clinical trials, GEO-CM04S1 is being evaluated as a COVID-19 vaccine for immunocompromised patients such as those suffering from hematologic cancers and other patient populations for whom the current authorized COVID-19 vaccines are insufficient. In addition, GEO-CM04S1 is in a Phase 2 clinical trial evaluating the vaccine as a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines. GeoVax has a leadership team who have driven significant value creation across multiple life science companies over the past several decades.

For additional information about GeoVax, visit our website: www.geovax.com.

Forward-Looking Statements

This release contains forward-looking statements regarding GeoVax's business plans. The words "believe," "look forward to," "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 is able to obtain acceptable results from ongoing or future clinical trials of its investigational products, GeoVax's immuno-oncology products and preventative vaccines can provoke the desired responses, and those products or vaccines can be used effectively, GeoVax's viral vector technology adequately amplifies immune responses to cancer antigens, GeoVax can develop and manufacture its immuno-oncology products and preventative vaccines with the desired characteristics in a timely manner, GeoVax's immuno-oncology products and preventative vaccines will be safe for human use, GeoVax's vaccines will effectively prevent targeted infections in humans, GeoVax's immuno-oncology products and preventative vaccines will receive regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete 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.

Further information on our risk factors is contained in our 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.

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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)

	Three Months Ended March 31,	
	2023	2022
Grant revenues	$ -	$ 82
Operating expenses:		
Research and development	2,819	1,331
General and administrative	1,451	1,179
	4,270	2,510
Loss from operations	(4,270)	(2,428)
Other income (expense), net	232	1
Net loss	$ (4,038)	$ (2,427)
Net loss per common share	$ (0.15)	$ (0.34)
Weighted average common shares outstanding	26,338,576	7,109,473

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

	March 31, 2023	Dec. 31, 2022
Assets:		
Cash and cash equivalents	$ 23,850	$ 27,613
Other current assets	2,139	1,326
Total current assets	25,989	28,939
Property and other assets, net	1,415	2,409
Total assets	$ 27,404	$ 31,348
Liabilities and stockholders' equity		
Total liabilities	$ 4,539	$ 4,748
Stockholders' equity	22,865	26,600
Total liabilities and stockholders' equity	$ 27,404	$ 31,348
Common shares outstanding	26,443,649	26,334,953

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