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 9, 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 August 9, 2023, GeoVax Labs, Inc. (the "Company") issued a press release reporting its results of operations for the quarter ended June 30, 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 August 9, 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: August 10, 2023

GEOVAX LABS, INC.

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

Exhibit 99.1

GeoVax Reports 2023 Second Quarter Financial Results and Provides Corporate Update

Progress and Promising Outlook for Gedeptin® and GEO-CM04S1
Phase 2 GEO-CM04S1 Clinical Trial Initiated for Patients with Chronic Lymphocytic Leukemia

Company to Host Conference Call and Webcast Today at 4:30 p.m. ET

Atlanta, GA, August 9, 2023 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing vaccines and immunotherapies against infectious diseases and cancers, today announced its financial results for the quarter ended June 30, 2023, and recent corporate highlights.

David Dodd, GeoVax's Chairman and CEO, commented, "The first half of 2023 has been highly productive for GeoVax, with continued enrollment in, and positive interim clinical data presented for, both of our lead programs, Gedeptin® and GEO-CM04S1. We are also excited to have recently announced the start of an important third Phase 2 clinical study for GEO-CM04S1, in patients with chronic lymphocytic leukemia. Our next-generation COVID-19 vaccine, which utilizes an MVA-vector containing the two antigens, S and N, induces broad and durable antibody and cellular immune responses that we believe has the potential to offer a more robust, durable degree of protection than the current authorized COVID-19 vaccines, particularly in highly vulnerable immunocompromised patients."

Mr. Dodd continued, "In addition to clinical progress, there are other notable achievements that set the stage for our future success. We have made significant progress in developing a high-yield, high-capacity, continuous avian cell line system for manufacturing our MVA-based vaccines and immunotherapies, and we recently partnered with Advanced Bioscience Laboratories, Inc. to support current Good Manufacturing Practices production of our MVA-based products through late-stage development and eventual commercialization. Additionally, the recent expansion of our GEO-CM04S1 rights to include development for Mpox and smallpox adds to other rights we previously secured from the NIH covering preclinical, clinical, and commercial uses of the NIH-MVA. This provides a compelling opportunity to leverage our MVA-based vaccine expertise and help expand the global public health supply options available for the worldwide public health threats posed by SARS-CoV-2, Mpox and smallpox. We expect significant clinical developments and other important events during the remainder of 2023, and we look forward to continuing to share news of our progress."

Recent Business Highlights:

- **New Clinical Trial Initiated for GEO-CM04S1**. In July, GeoVax announced the start of a Phase 2 COVID-19 vaccine booster investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355) in patients with chronic lymphocytic leukemia (CLL), a recognized high-risk group for whom current mRNA vaccines and monoclonal antibody (MAb) therapies appear inadequate relative to providing protective immunity. As a result of their medical status, CLL patients are largely unable to mount a sufficient antibody response to the mRNA vaccines. The trial is expected to enroll approximately 80 patients, comparing GEO-CM04S1 vs the Pfizer/BioNTech Bivalent vaccine. Completion of patient enrollment is expected within approximately six months. This investigator-initiated trial is being primarily funded by a private family foundation with GeoVax supporting the analysis of samples, so it is expected to have minimal impact on the Company's balance sheet.

- **Gedeptin® Clinical Trial Data.** Interim data from the Phase 1/2 clinical trial of Gedeptin® was presented at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference in July. The ongoing Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT03754933) is evaluating the safety and efficacy of repeat cycles of Gedeptin therapy in patients with recurrent head and neck cancers whose tumor(s) are accessible for injection, and who have no curable treatment options. The poster presentation, which can be viewed here, highlighted data from 8 patients enrolled in the study to date, noting no dose-limiting toxicities or serious adverse events definitively attributable to treatment, with impairment of tumor growth in targeted lesions observed in 5 of 7 patients (one patient remaining under study).

  The study is being funded in part by the U.S. Food and Drug Administration (FDA) pursuant to its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedeptin orphan drug status for the intra-tumoral treatment

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of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of the mouth, salivary gland, and other oral cavities. GeoVax expects to complete the current trial by year-end 2023, after which expanded development of Gedeptin is anticipated, both as monotherapy and combination therapy in conjunction with other therapies to potentially include immune checkpoint inhibitors, angiogenesis inhibitors, radiation, chemotherapy, etc.

- **GEO-CM04S1 Clinical Trial Data**. In April, unpublished data from the open-label portion of the Phase 2 trial of GEO-CM04S1 in patients with hematologic cancers receiving cell transplants or CAR-T therapy (ClinicalTrials.gov Identifier: NCT04977024) was presented during the 23rd Annual World Vaccine Congress. This trial is investigating GEO-CM04S1 in a profoundly immunosuppressed patient population due to their pre-transplant induction regimens. The preliminary analysis indicates GEO-CM04S1 is highly immunogenic in these patients, inducing both neutralizing antibodies and T cell responses, which the Company believes are important to confer protection against severe COVID-19. These data support the planned progression of the Phase 2 clinical study, which will include a direct comparison to currently approved mRNA vaccines and is anticipated to include multiple sites both within and outside the U.S.

  Further underscoring the need for next-generation COVID-19 vaccines such as GEO-CM04S1, GeoVax scientists co-authored an article titled, "*MVA-Vectored Universal Beta-Coronavirus Vaccine Design & Development*", published in the June 2023 issue of the online journal *Vaccine Insights*. The article, accessible here, provides expert insight into the emergence of SARS-CoV-2 (COVID-19), the risk of new "spillover events" from animal hosts, and how this risk can be addressed proactively. Regarding COVID-19 and its continually evolving variants, the authors describe the limitations of first-generation vaccines and the potential for MVA-vectored vaccines such as GEO-CM04S1 to overcome these limitations.

- **Mpox Vaccine Rights Added to GEO-CM04S1**. In April, GeoVax expanded its rights under its license agreement with City of Hope (COH) for GEO-CM04S1, which now grants GeoVax development and commercialization rights against orthopoxviruses in addition to SARS-CoV-2. Orthopoxviruses include Mpox, smallpox, and other viruses that cause disease in humans. GEO-CM04S1, which can induce strong antibody and T cell responses against the SARS-CoV-2 virus variants, also offers the possibility of protection against Mpox and smallpox diseases, further differentiating GEO-CM04S1 as compared to current mRNA-based COVID-19 vaccines. Such attributes may be especially important in vulnerable patient populations, such as the immune-compromised, and in geographic areas where both diseases are endemic. Such a vaccine may offer a simplified vaccine regimen for protection against diseases associated with SARS-CoV-2 and orthopoxviruses.

- **GEO-MVA (Mpox and smallpox vaccine).** Following the recent announcement of GeoVax acquiring the rights from NIH to develop, manufacture and commercialize MVA as a vaccine against Mpox and smallpox, the Company has advanced to active regulatory discussions related to an expedited regulatory path for registration. GeoVax is focused on being the first U.S. supplier of the vaccine, providing expanded supply options for public health worldwide.

- **Manufacturing Development Progress**. In May, GeoVax announced it had entered into an agreement with Advanced Bioscience Laboratories, Inc. (ABL) to support current Good Manufacturing Practices (cGMP) production of the company's vaccine candidates, including GEO-CM04S1. ABL, a subsidiary of Institut Mérieux, is a pure-play contract development and manufacturing organization (CDMO) specialized in the development and manufacturing of gene therapies, oncolytic viruses, and vaccine candidates. With cGMP facilities in the U.S. and Europe, ABL is well-positioned to support GeoVax's global development programs through late-stage development and eventual commercialization.

  Earlier in 2023, 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 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 worldwide requirements on a timely basis.

- **Preclinical Programs**. 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

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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 response capable of offering significant protection.

- **Patent Portfolio Development**. In July, GeoVax announced that the U.S. Patent and Trademark Office issued Patent No. 11,701,418 B2 to GeoVax, pursuant to the Company's patent application No. 15/543,139 titled "*Replication-Deficient Modified Vaccinia Ankara (MVA) and Matrix Protein (VP40).*" The claims granted by the patent generally cover GeoVax's vector platform for expressing ebolavirus antigens in virus-like particles (VLPs) utilizing an MVA viral vector. The claims encompass multiple ebolavirus strains, including Sudan ebolavirus, Zaire ebolavirus, Taï Forest ebolavirus, and Reston ebolavirus. GeoVax previously demonstrated that a single intramuscular (IM) dose of its vaccine candidate, GEO-EM01, provided 100% protection in rhesus macaques challenged with a lethal dose of Zaire ebolavirus (EBOV). Additionally, the Company's preclinical efficacy studies of its Sudan ebolavirus (SUDV) vaccine candidate demonstrated that a single dose of the vaccine protected 100% of small animals challenged with a lethal dose of SUDV.

  Earlier in 2023, GeoVax announced that the U.S. 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.

  These patents add to the Company's growing portfolio of wholly owned, co-owned, and in-licensed intellectual property, now standing at over 115 granted or pending patent applications spread over 24 patent families.

Financial Results

- **Net Loss**: Net loss for the three months ended June 30, 2023, was $5,927,620, or $0.22 per share, as compared to $2,241,699, or $0.18 per share, for the comparable period in 2022. For the six months ended June 30, 2023, the Company's net loss was $9,965,536 ($0.38 per share) as compared to a net loss of $4,669,214 ($0.47 per share) in 2022.

- **R&D Expenses**: Research and development expenses were $4,719,728 and $7,538,917 for the three-month and six-month periods ended June 30, 2023, compared to $1,307,177 and $2,637,721 for the comparable periods in 2022, with the increases primarily due to the cost of conducting clinical trials for GEO-CM04S1 and Gedeptin, costs of manufacturing materials for use in our clinical trials, additional personnel costs, technology license fees, costs of preclinical research activities and a generally higher level of activity.

- **G&A Expenses**: General and administrative expenses were $1,459,093 and $2,910,518 for the three-month and six-month periods ended June 30, 2023, compared to $935,311 and $2,114,335 for the comparable periods in 2022, with the increases primarily due to higher personnel costs, investor relations consulting costs, patent costs and other expenses supportive of a higher level of activity.

- **Cash Position**: GeoVax reported cash balances of $17,788,911 at June 30, 2023, as compared to $27,612,732 at December 31, 2022.

Summarized financial information is included. 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, August 9, 2023, to review financial results and provide an update on corporate developments. A question-and-answer session will follow management's formal remarks.

Domestic: 800-715-9871
International: 646-307-1963
Conference ID: 5604173

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Webcast: GeoVax Earnings Webcast

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

About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing novel therapies and vaccines for solid tumor 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 three Phase 2 clinical trials, GEO-CM04S1 is being evaluated as a primary 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, and as a booster vaccine in patients with chronic lymphocytic leukemia (CLL). 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 more information, 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.

Investor Relations Contact:
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FINANCIAL TABLES FOLLOW

GEOVAX LABS, INC.

Condensed Consolidated Statements of Operations Information

(amounts in thousands, except common share information)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Grant and collaboration revenue	$ -	$ -	$ -	$ 82
Operating expenses:				
Research and development	4,720	1,307	7,539	2,638
General and administrative	1,459	935	2,910	2,114
	6,179	2,242	10,449	4,752
Loss from operations	(6,179)	(2,242)	(10,449)	(4,670)
Interest income	251	-	484	1
Net loss	$ (5,928)	$ (2,242)	$ (9,965)	$ (4,669)
Loss per common share	$ (0.22)	$ (0.18)	$ (0.38)	$ (0.47)

Condensed Consolidated Balance Sheet Information

(amounts in thousands, except common share information)

	June 30, 2023	Dec. 31, 2022
Assets:		
Cash and cash equivalents	$ 17,789	$ 27,613
Other current assets	2,038	1,326
Total current assets	19,827	28,939
Property and other assets, net	1,422	2,409
Total assets	$ 21,249	$ 31,348
Liabilities and stockholders' equity		
Total liabilities	$ 4,085	$ 4,748
Stockholders' equity	17,164	26,600
Total liabilities and stockholders' equity	$ 21,249	$ 31,348
Common shares outstanding	26,443,649	26,334,953

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