

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 6, 2024**

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.

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 6, 2024, GeoVax Labs, Inc. (the “Company”) issued a press release reporting its results of operations for the quarter ended June 30, 2024. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 6, 2024
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 7, 2024

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds _____

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports Second Quarter 2024 Financial Results and Provides Business Update

Awarded BARDA Project NextGen (PNG) contract to advance GeoVax's multi-antigen vaccine candidate, GEO-CM04S1, into 10,000-participant randomized, comparative Phase 2b COVID-19 vaccine study

BARDA PNG award represents greater than \$350 million in support of PNG GEO-CM04S1 clinical trial, including direct funding of CRO partner Allucent

*Multiple planned data readouts for GEO-CM04S1 throughout second half of 2024
Gedepin® to advance into expanded Phase 2 clinical trial with activation in the first half of 2025*

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

ATLANTA, GA, August 6, 2024 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced financial results for the second quarter ended June 30, 2024, and provided a business update.

“The first half of 2024 has been marked by significant progress across our company, underscored by our recent announcement of the receipt of the BARDA Project NextGen award to evaluate GEO-CM04S1, our next-generation, dual-antigen COVID-19 vaccine. Additionally, we are pleased to partner with Allucent, a global CRO, to commence the trial and advance GEO-CM04S1 into the BARDA-funded 10,000-patient Phase 2b clinical study. With greater than \$350 million secured to conduct the trial, this recognition from the U.S. government not only validates our clinical strategy, but also provides the necessary resources to more rapidly advance our mission,” stated David Dodd, GeoVax’s Chairman and CEO.

“While first-generation COVID-19 vaccines were essential during the early days of the pandemic, they require frequent updates to combat waning efficacy and durability issues now that COVID-19 has proven to be endemic. GEO-CM04S1 has demonstrated potent, broadly reactive, and durable antibody and T cell immune responses in individuals with both healthy and compromised immune systems. Given the growing appreciation that strong T-cell responses are critically important for both antibody recall and protection against severe disease and hospitalization, GEO-CM04S1 is particularly well-positioned as a next-generation COVID-19 vaccine with the potential to greatly improve patient care,” Dodd continued.

“In addition, with support from an oncology clinical advisory committee, following a detailed review of Gedepin’s safety and efficacy data, we look forward to advancing an expanded Phase 2 clinical trial evaluating Gedepin in first-recurrence head and neck cancer patients. With multiple key catalysts in the remainder of 2024, we are in a strong position to create long term value as we execute on our clinical strategy and advance our robust portfolio of assets,” Dodd concluded.

Second Quarter Business Achievements

GEO-CM04S1

- **Received BARDA Project NextGen award** through the Rapid Response Partnership Vehicle (RRPV) to advance development of GEO-CM04S1, GeoVax’s dual-antigen next-generation COVID-19 vaccine, in a Phase 2b clinical trial. The direct award to GeoVax of approximately \$24.3 million, which may increase

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to as much as \$45 million, will fund the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities.

- Under the agreement, GeoVax will sponsor a 10,000-participant, randomized, Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of GEO-CM04S1 with a U.S. Food and Drug Administration (FDA) approved mRNA COVID-19 vaccine. Preparations for the study are underway, and execution of the study will be funded by BARDA under its Clinical Studies Network.
 - The RRPV is a Consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS).
 - Funding for this award is provided under Project NextGen, a \$5 billion initiative by HHS to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19 than the first generation COVID vaccines and medicines.
- **Announced Project NextGen CRO partnership with Allucent**, a global clinical research organization (CRO), to conduct the Phase 2b clinical trial of GEO-CM04S1. The combined value of the awards to GeoVax and Allucent for the clinical evaluation of GEO-CM04S1 is \$367-388 million.

GeoVax's role in this project is being funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction (OT) number: 75A50123D00005. Allucent's role in the project is being funded in whole or in part with federal funds from BARDA under contract 75A50120D00016/75A50123F33005.

- **Presented data on GEO-CM04S1**, at the 24th Annual World Vaccine Congress in April 2024. The presentation, titled “*Vaccine Induction of Broadly-Specific Antibody and T Cell Responses to Combat SARS-CoV-2 Variation*,” focused on GEO-CM04S1’s unique immune system driven mechanism and how it can contribute to the broad efficacy. The presentation highlighted that vaccine induced immunity protects against infections, serious disease symptoms and death against the original Wuhan variant as well as the Omicron XBB.1.5 variant, which is the basis of the currently approved mRNA booster vaccines.

Gedeptin®

- **Completed review of Gedeptin clinical results**, and recently announced decision to advance Gedeptin into an expanded Phase 2 clinical trial among patients with first-recurrence head and neck cancer. The primary goal of this trial will be to establish efficacy of neoadjuvant Gedeptin therapy combined with an immune checkpoint inhibitor in squamous cell head and neck cancer. The Company has initiated the necessary planning activities, including protocol development, manufacturing and CRO selection, with the trial activation anticipated during the first half of 2025.

Vaccine Manufacturing Process Development

- **Produced first lot of GEO-CM04S1 with a commercial manufacturing platform**, a critical step toward implementation of a validated chicken embryonic fibroblast (CEF) based production system for the company’s MVA-based vaccines. This milestone marks the successful completion of the transfer and scale-up of manufacturing from the research-focused Center for Biomedicine & Genetics at City of Hope to Oxford Biomedica, the Company’s cGMP (current Good Manufacturing Procedures) manufacturing partner.

Second Quarter 2024 Financial Results

- **Net Loss:** Net loss for the three-month period ended June 30, 2024, was \$5,064,042, or \$1.99 per share, as compared to \$5,927,620, or \$3.79 per share, for the comparable period in 2023. For the six-month

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period ended June 30, 2024, the Company's net loss was \$10,914,174, or \$4.68 per share, as compared to \$9,965,536, or \$5.66 per share, in 2023.

- **R&D Expenses:** Research and development expenses were \$4,276,868 and \$8,702,596 for the three-month and six-month periods ended June 30, 2024, compared with \$4,719,728 and \$7,538,917 for the comparable period in 2023, with the changes primarily due to timing of costs related to manufacturing of materials for use in the clinical trials of GEO-CM04S1 and Gedeptin as well as costs of various contracted research activities.
- **G&A Expenses:** General and administrative expenses were \$1,086,030 and \$2,543,383 for the three-month and six-month periods ended June 30, 2024, compared to \$1,459,093 and \$2,910,518 for the comparable periods in 2023, with the overall decrease primarily due to lower stock-based compensation expense, consulting costs, legal and patent costs, and travel costs.
- **Cash Position:** GeoVax reported cash balances of \$1,561,712 at June 30, 2024, as compared to \$6,452,589 at December 31, 2023.

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, August 6, 2024, 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: +1 (646) 307-1963

Conference ID: 3852178

Webcast: <https://edge.media-server.com/mmc/p/qj3e68n8>

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 vaccines for many of the world's most threatening infectious diseases and therapies for solid tumor cancers. The company's lead clinical program is GEO-CM04S1, a next-generation COVID-19 vaccine for which GeoVax was recently awarded a BARDA-funded contract to sponsor a 10,000-participant Phase 2b clinical trial to evaluate the efficacy of GEO-CM04S1 versus an approved COVID-19 vaccine. In addition, GEO-CM04S1 is currently in three Phase 2 clinical trials, being evaluated as (1) 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, (2) a booster vaccine in patients with chronic lymphocytic leukemia (CLL) and (3) a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines. In oncology the lead clinical program is evaluating a novel oncolytic solid tumor gene-directed therapy, Gedeptin®, in a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. GeoVax has a strong IP portfolio in support of its technologies and product candidates, holding worldwide rights for its technologies and products. The Company has a leadership team who have driven significant value creation across multiple life science companies over the past several decades. For more information about the current status of our clinical trials and other updates, visit our website: www.geovax.com.

Forward-Looking Statements

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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		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
Revenue from government contract	\$ 301	\$ -	\$ 301	\$ -
Operating expenses:				
Research and development	4,277	4,720	8,703	7,539
General and administrative	1,086	1,459	2,543	2,910
	<u>5,363</u>	<u>6,179</u>	<u>11,246</u>	<u>10,449</u>
Loss from operations	(5,062)	(6,179)	(10,945)	(10,449)
Other income (expense)	(2)	251	31	484
Net loss	<u>\$ (5,064)</u>	<u>\$ (5,928)</u>	<u>\$ (10,914)</u>	<u>\$ (9,965)</u>
Loss per common share	<u>\$ (1.99)</u>	<u>\$ (3.79)</u>	<u>\$ (4.68)</u>	<u>\$ (5.66)</u>

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

	June 30, 2024	Dec. 31, 2023
Assets:		
Cash and cash equivalents	\$ 1,562	\$ 6,453
Other current assets	2,282	1,433
Total current assets	<u>3,844</u>	<u>7,886</u>
Property and other assets, net	251	1,397
Total assets	<u>\$ 4,095</u>	<u>\$ 9,283</u>
Liabilities and stockholders' equity (deficit)		
Total liabilities	\$ 6,404	\$ 3,520
Stockholders' equity (deficit)	(2,309)	5,763
Total liabilities and stockholders' equity (deficit)	<u>\$ 4,095</u>	<u>\$ 9,283</u>
Common shares outstanding	4,178,700	1,977,152