

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 27, 2025**

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 March 27, 2025, GeoVax Labs, Inc. (the “Company”) issued a press release reporting its results of operations for the year ended December 31, 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 March 27, 2025
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: March 28, 2025

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds _____

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports 2024 Year-End Financial Results and Provides Business Update

GEO-CM04S1 BARDA/Project NextGen Phase 2b trial preparations ongoing with manufacturing of clinical trial materials underway and clinical sites confirmed

Additional data evaluating GEO-CM04S1 as booster to mRNA vaccines in healthy adults expected in first half of 2025

Clinical evaluation of GEO-MVA, vaccine candidate for protection against Mpox and Smallpox, expected to begin in second half of 2025

Planning underway for Phase 2 clinical trial of Gedeptin[®] as treatment for first recurrent head and neck cancer in combination with immune checkpoint inhibitor

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

ATLANTA, GA, March 27, 2025 – GeoVax Labs, Inc. (Nasdaq: GOVX), a clinical-stage biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced its financial results and key operational accomplishments for the year ended December 31, 2024.

“We are entering 2025 from a position of strength following a pivotal year for GeoVax,” stated David Dodd, GeoVax’s Chairman and CEO. “In June 2024, we received BARDA’s Project NextGen award of nearly \$400 million to advance GEO-CM04S1 in a Phase 2b clinical trial. Throughout the remainder of 2024, we were able to secure a high quality CRO partner and lay the foundation for our 10,000-patient study, progressing to producing the vaccine material for use in the clinical trial.”

“We continue to build on our growing body of clinical evidence in support of GEO-CM04S1. In April 2024, we presented data at the 24th Annual World Vaccine Congress, highlighting data demonstrating vaccine induced immunity protects against infections, serious disease symptoms and death. GeoVax also reported positive initial safety and immune response data from the Phase 2 clinical trial of GeoVax as a booster in healthy adults who had previously received the Pfizer or Moderna mRNA vaccine and observed statistically significant increases in neutralizing antibody responses against multiple SARS-CoV-2 variants. We continue to strive toward a solution for the critically underserved immunocompromised patient population, where the current mRNA vaccines do not provide adequate protection,” Dodd continued.

“In parallel, we are advancing our manufacturing capabilities to address emerging threats to public health and U.S. national security. The need for these measures is critical and urgent, as evidenced by the recent Mpox public health emergency declaration by the World Health Organization. GeoVax remains committed to bolstering global preparedness through GEO-MVA, our vaccine candidate in development for protection against Mpox and smallpox, and through our efforts to establish an advanced MVA manufacturing processes domestically to combat this ongoing public health crisis. We are enthusiastic about the potential of our therapies to address meaningful market opportunities and look forward to a catalyst-rich 2025,” Dodd concluded.

Clinical Trial Progress and Operational Developments

GEO-CM04S1

- **Completed interim data review** by the Data Safety Monitoring Board (DSMB) for the ongoing Phase 2 clinical trial of GEO-CM04S1, GeoVax's dual-antigen next-generation COVID-19 vaccine, as a booster vaccine for patients with chronic lymphocytic leukemia (CLL). Based on the interim analysis of immune responses from the patients enrolled to date, the DSMB determined that, while the mRNA control arm of the study failed to meet the predetermined primary endpoint, the study should continue enrollment of the experimental arm utilizing GeoVax's Next-Generation GEO-CM04S1 vaccine.
 - The Phase 2 trial is examining the use of two injections of GEO-CM04S1, three months apart, to assess immune responses in Chronic Lymphocytic Leukemia (CLL) patients, with an mRNA vaccine as the control arm. Thus far, participants have been randomized 1:1 to receive two boosters with either the GEO-CM04S1 or the mRNA control vaccine and the Company expects to complete the trial this year.
- **Confirmed target sites of BARDA Project NextGen trial**, and activities are underway in support of initiating the 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.
- **Announced planned site expansion** for the Phase 2 Immunocompromised/Stem Cell Transplant patient trial. GeoVax continues to advance its Phase 2 clinical trial of GEO-CM04S1 as a primary vaccine for immunocompromised patients undergoing stem cell transplantation. This study addresses a critical need for effective vaccination strategies in populations that may not respond adequately to existing vaccines.
- **Completed enrollment in booster vaccine study for healthy adult volunteers.** GeoVax has successfully completed enrollment in its Phase 2 clinical trial evaluating GEO-CM04S1 as a booster vaccine in healthy adults who previously received COVID-19 vaccines. This study aims to assess the vaccine's safety and immunogenicity at two different dose levels, with data readouts anticipated in the first half of 2025.
- **GEO-CM04S1 addresses a significant medical need worldwide** reflected in an estimated market potential at \$30B+

Gedepin®

- **Advancing Gedepin into Phase 2 clinical study** evaluating neoadjuvant Gedepin therapy in combination with an approved immune check point inhibitor (ICI) in 1st recurrent Head & Neck (H&N) cancer following an encouraging review of the data from the completed Phase 1 single-cycle and Phase 1/2 multi-cycle Gedepin trials among patients with advanced H&N tumors.
 - This trial is anticipated to be a single-cycle trial in approximately 36 patients with a pathologic response rate as the primary endpoint, and key endpoints will include pathologic response rates and overall treatment outcomes. Planning is underway with leading academic oncology centers, while clinical trial material is being produced.
 - As an FDA-designated Orphan Drug for anatomically accessible oral and pharyngeal cancers, Gedepin is strategically positioned to address not only head and neck cancers but also other solid tumor indications, such as triple-negative breast cancer, soft tissue sarcoma and melanoma, and represents a significant market opportunity.
- **Gedepin addresses a significant medical need worldwide** reflected in an estimated market potential at \$15B+

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Mpox and Smallpox Vaccine Platform

- **Initiation on track for clinical evaluations of GEO-MVA** while continuing discussions with various stakeholders regarding the opportunity to utilize GEO-MVA among underserved populations in regions including Africa. GEO-MVA is GeoVax's vaccine candidate in development for protection against Mpox and Smallpox which was developed on the proven Modified Vaccinia Ankara (MVA) platform. Clinical evaluation of the vaccine is expected to begin in late 2025.
- **Successfully manufactured clinical batch of GEO-MVA** in 2024 under current Good Manufacturing Practice (cGMP) production. The Company's innovative advanced MVA manufacturing process is anticipated to provide scalable, flexible and cost-effective vaccine production, reducing reliance on foreign vaccine manufacturers and reinforcing domestic biosecurity.
- **Actively pursuing strategic partnerships** with governments, NGOs, and private-sector stakeholders to maximize the impact and reach of its GEO-MVA platform.
- **GEO-MVA addresses a significant medical need worldwide** reflected in an estimated market potential at \$10B+

Corporate and Intellectual Property Developments

- **Announced plan to establish strategic presence in the United Kingdom** to advance manufacturing partnerships, European collaborations with service providers and academic partners, technology licensing opportunities and scientific expertise.
- **Intellectual property assets further strengthened** by multiple actions throughout 2024 by global patent offices. GeoVax currently has over 130 granted or pending patents across 23 different families.

2024 Full Year Financial Results

Net Loss: Net loss for the year ended December 31, 2024, was \$25.0 million, as compared to \$26.0 million for the year ended December 31, 2023.

Revenue. For the year ended December 31, 2024, the Company reported \$4.0 million of government contract revenues associated with the BARDA/RRPV Project NextGen award. There were no revenues reported during the comparable 2023 period.

R&D Expenses: Research and development expenses were \$23.7 million for 2024, compared to \$20.7 million in 2023, with the increase primarily due to the costs of manufacturing materials for use in our clinical trials of GEO-CM04S1 and other costs associated with the BARDA Project NextGen contract.

G&A Expenses: General and administrative expenses were \$5.4 million for 2024, compared to \$6.0 million in 2023, with the decrease primarily related to lower stock-based compensation expense, consulting costs, patent costs and franchise tax cost.

Cash Position: GeoVax reported cash balances of \$5.5 million at December 31, 2024, as compared to \$6.5 at December 31, 2023.

Summarized financial information is attached. Further information is included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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Conference Call Details

Management will host a conference call and live audio webcast today, March 27, 2025, at 4:30 p.m. ET to review financial results and provide an update on corporate developments. A question-and-answer session will follow management's formal remarks.

To access the live conference call, participants may register [here](#). The live audio webcast of the call will be available under "Events and Presentations" in the Investor Relations section of the GeoVax website at geovax.com/investors. To participate via telephone, please register in advance [here](#). Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. While not required, it is recommended that participants join the call ten minutes prior to the scheduled start.

An archive of the audio webcast will be available on GeoVax's website approximately two hours after the conference call and will remain available for at least 90 days following the event.

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®, having recently completed a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. A Phase 2 clinical trial in first recurrent head and neck cancer, evaluating Gedeptin® combined with an immune checkpoint inhibitor is planned. 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

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.

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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)

	Year Ended	
	December 31,	
	2024	2023
Revenue from government contract	\$ 3,955	\$ -
Operating expenses:		
Research and development	23,714	20,721
General and administrative	5,385	6,022
	29,099	26,743
Loss from operations	(25,144)	(26,743)
Other income (expense), net	152	776
Net loss	\$ (24,992)	\$ (25,967)
Net loss per common share	\$ (4.82)	\$ (14.29)
Weighted average shares outstanding	5,187,038	1,817,282

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

	December 31,	
	2024	2023
Assets:		
Cash and cash equivalents	\$ 5,507	\$ 6,453
Other current assets	2,428	1,433
Total current assets	7,935	7,886
Property and other assets	221	1,397
Total assets	\$ 8,156	\$ 9,283
Liabilities and stockholders' equity		
Total liabilities	\$ 3,107	\$ 3,520
Stockholders' equity	5,049	5,763
Total liabilities and stockholders' equity	\$ 8,156	\$ 9,283
Common Shares Outstanding	10,536,875	1,977,152

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