

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): November 12, 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 November 12, 2024, GeoVax Labs, Inc. (the “Company”) issued a press release reporting its results of operations for the quarter ended September 30, 2024. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01 Other Events.

The Company re-convened a Special Meeting of Stockholders (the “Special Meeting”) on November 12, 2024 (originally convened on September 17, 2024) and adjourned the Special Meeting without any business being conducted due to lack of the required quorum. The Company has determined to keep the polls open and reconvene the Special Meeting on December 18, 2024 at 8:30 a.m. Eastern Time to provide its stockholders additional time to vote on the proposals described in the proxy statement filed with the Securities and Exchange Commission on August 1, 2024. No changes have been made to the proposals to be voted on by stockholders at the Special Meeting.

At the time the Special Meeting was adjourned, proxies had been submitted by stockholders representing approximately 30.4% of the shares of the Company’s common stock outstanding and entitled to vote. Proxies previously submitted in respect of the Special Meeting will be voted at the reconvened Special Meeting unless properly revoked, and stockholders who have previously submitted a proxy or otherwise voted need not take any action.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 12, 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: November 13, 2024

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds _____

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports Third Quarter 2024 Financial Results and Provides Business Update

Progress in GEO-CM04S1 BARDA/Project NextGen Phase 2b trial; multiple data readouts of existing COVID-19 vaccine Phase 2 trials expected during fourth quarter 2024

Gedepin® on track to advance into Phase 2 clinical trial for first recurrent head and neck cancer in the first half of 2025

GEO-MVA Mpox vaccine advancing with cGMP clinical batch anticipated during fourth quarter 2024

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

ATLANTA, GA, November 12, 2024 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced financial results for the third quarter ended September 30, 2024, and provided a business update.

David Dodd, GeoVax’s Chairman and CEO, stated, “2024 has shaped up to be a year of steady progress and execution across our development programs. Following the BARDA/RRPV award of nearly \$400 million in support of evaluating GEO-CM04S1 in the Project NextGen program, we continue to collaborate closely with the BARDA Project NextGen team and our CRO, Allucent, preparing for the activation of the 10,000-patient Phase 2b clinical study. The necessary sites are confirmed, and we are working closely with Oxford Biomedica (“OXB”), our manufacturing partner, to produce the vaccine product required for study activation. We look forward to sharing further updates related to this exciting Phase 2b study.”

“In the third quarter, we also strengthened our balance sheet with additional funding, enabling us to confirm plans towards initiating a Phase 2 trial of Gedepin in conjunction with an immune checkpoint inhibitor, as therapy for first recurrent head and neck cancer patients,” Dodd continued. “We anticipate initiating this study during the first half of 2025. We have also made significant progress with GEO-MVA, our vaccine candidate for Mpox, and expect to achieve production of a cGMP clinical batch during the fourth quarter. With GEO-MVA, we intend to create the first U.S.-based source for a Mpox vaccine, an important biodefense goal.”

“Supported by our recent progress, we believe we are well-positioned to advance our priority programs in support of developing innovative solid tumor therapies and infectious disease vaccines. Our commitment to advancing life-changing treatments continues to drive us in our mission to improve patient care worldwide through innovative developments.”

Third Quarter Business Achievements and Updates

GEO-CM04S1

- BARDA Project NextGen Phase 2b trial: Target sites are confirmed, 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.
- Existing Phase 2 clinical studies: During the fourth quarter of 2024, GeoVax anticipates reporting interim results from (a) the comparative trial among Immunocompromised/Chronic Lymphocytic Leukemia (CLL) patients and (b) the booster trial among healthy adults. For the Immunocompromised/Stem Cell Transplant patient trial, additional sites have been added and patient enrollment continues.

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Gedepin®

- Activities underway in support of Phase 2 study of Gedepin combined with an immune checkpoint inhibitor as therapy among patients with first recurrent head and neck cancer.
- This trial is anticipated to be a single-cycle trial in approximately 36 patients with a pathologic response rate as the primary endpoint. The primary goal of this trial will be to establish efficacy of neoadjuvant Gedepin therapy combined with an immune checkpoint inhibitor in squamous cell head and neck cancer.

Mpox and Smallpox Vaccine Platform

- GEO-MVA is GeoVax's vaccine candidate in development for protection against Mpox and Smallpox.
- A cGMP Master Seed Virus has been successfully manufactured and released by OXB and a cGMP clinical batch is currently in production, anticipated to be completed during Q4.
- MVA is the vaccine recommended by both WHO and the CDC against both Mpox and Smallpox, recognized for its safety and efficacy among all patient populations, including pregnant women, children and immunocompromised individuals. MVA is the vaccine currently used and stockpiled in the United States Strategic National Stockpile for immunization against potential bioterrorism threats based on the smallpox virus.

Continuous Cell-line MVA Manufacturing Process Development

- Development activities are underway in support of the AGE.1 continuous MVA manufacturing process. Additional progress is expected to be reported during Q4.

Corporate Updates

- GeoVax Scientific Advisory Board: Appointed Teresa Lambe, PhD, OBE, FMedSci, professor of Vaccinology and Immunology at the Oxford Vaccine Group within the University of Oxford, to the Scientific Advisory Board.

Third Quarter 2024 Financial Results

- **Net Loss:** Net loss for the three-month period ended September 30, 2024, was \$5,815,468, or \$0.91 per share, as compared to \$8,408,818, or \$4.75 per share, for the comparable period in 2023. For the nine months ended September 30, 2024, the Company's net loss was \$16,729,642, or \$4.52 per share, as compared to \$18,374,354, or \$10.42 per share, in 2023.
- **Revenue.** During the three-month and nine-month periods ending September 30, 2024, the Company reported \$2,789,484 and \$3,090,161 of government contract revenues associated with the BARDA/RRPV Project NextGen award. There were no revenues reported during the comparable 2023 periods.
- **R&D Expenses:** Research and development expenses were \$7,402,884 and \$16,105,480 for the three-month and nine-month periods ended September 30, 2024, compared with \$6,947,979 and \$14,486,896 for the comparable period in 2023, with the changes primarily due to costs of manufacturing materials for use in our clinical trials of GEO-CM04S1 and other costs associated with the BARDA Contract.
- **G&A Expenses:** General and administrative expenses were \$1,241,176 and \$3,784,559 for the three-month and nine-month periods ended September 30, 2024, compared to \$1,651,775 and \$4,562,293 for the comparable periods in 2023, with the changes primarily due to lower stock-based compensation expense, consulting costs, legal and patent costs and franchise tax cost.
- **Cash Position:** GeoVax reported cash balances of \$8,592,523 at September 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.

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Conference Call Details

Management will host a conference call and live audio webcast to discuss third quarter 2024 financial results and provide a business update today, November 12, 2024, at 4:30 p.m. ET. 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 to initiate during the first half 2025. 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.

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.

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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		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Revenue from government contract	\$ 2,789	\$ -	\$ 3,090	\$ -
Operating expenses:				
Research and development	7,402	6,948	16,105	14,487
General and administrative	1,241	1,652	3,785	4,562
	<u>8,643</u>	<u>8,600</u>	<u>19,890</u>	<u>19,049</u>
Loss from operations	(5,854)	(8,600)	(16,800)	(19,049)
Other income (expense)	39	191	70	675
Net loss	<u>\$ (5,815)</u>	<u>\$ (8,409)</u>	<u>\$ (16,730)</u>	<u>\$ (18,374)</u>
Loss per common share	<u>\$ (0.91)</u>	<u>\$ (4.75)</u>	<u>\$ (4.52)</u>	<u>\$ (10.42)</u>

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

	Sep. 30, 2024	Dec. 31, 2023
Assets:		
Cash and cash equivalents	\$ 8,593	\$ 6,453
Other current assets	2,276	1,433
Total current assets	<u>10,869</u>	<u>7,886</u>
Property and other assets, net	243	1,397
Total assets	<u>\$ 11,112</u>	<u>\$ 9,283</u>
Liabilities and stockholders' equity		
Total liabilities	\$ 2,608	\$ 3,520
Stockholders' equity	8,504	5,763
Total liabilities and stockholders' equity	<u>\$ 11,112</u>	<u>\$ 9,283</u>
Common shares outstanding	8,609,308	1,977,152

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