

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): July 28, 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 July 28, 2025, GeoVax Labs, Inc. (the “Company”) issued a press release reporting its results of operations for the quarter ended June 30, 2025. 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 July 28, 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: July 28, 2025

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds

Mark W. Reynolds
Chief Financial Officer



Exhibit 99.1

GeoVax Reports Second Quarter 2025 Financial Results and Provides Business Update

GEO-MVA received favorable European regulatory guidance supporting streamlined development pathway

GEO-CM04S1 demonstrates superior robust immune responses in CLL patients; data presented at EHA 2025

Gedeptin® highlighted strong safety and efficacy for the treatment of solid tumors; data presented at AACR 2025

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

ATLANTA, GA, July 28, 2025 – GeoVax Labs, Inc. (Nasdaq: GOVX), a clinical-stage biotechnology company developing multi-antigenic vaccines and immunotherapies for infectious diseases and cancer, today announced financial results for the second quarter ended June 30, 2025, and provided a business update.

“The second quarter marked a pivotal period for GeoVax, with compelling clinical data and regulatory milestones reinforcing the strength of our pipeline and our focus on accelerating to commercial status,” said David Dodd, GeoVax’s Chairman and CEO. “The favorable European regulatory guidance for GEO-MVA, robust immune responses demonstrated by GEO-CM04S1 in immunocompromised patients, particularly those with Chronic Lymphocytic Leukemia (CLL), and the continued progress towards initiation of the Gedeptin® Phase 2 trial highlight our expanding footprint in oncology and global infectious disease preparedness. These achievements reflect our commitment to advancing innovative, vaccines and immunotherapies that address urgent and underserved medical needs.”

Clinical Trial Progress and Operational Developments

GEO-MVA

- Received favorable European Scientific Advice (SA) supporting streamlined development pathway for GEO-MVA based vaccine for the prevention of Mpox and smallpox. The SA supports the suitability of GeoVax’s clinical and nonclinical development strategy. This feedback from the European Medicines Agency (EMA) provides clear regulatory alignment and enables an efficient pathway toward potential approval, eliminating multiple development steps commonly required for vaccines. Key highlights below:
 - EMA confirmed that one Phase 3 immuno-bridging trial, if successful, meets criteria for market authorization in all 27 EU countries, and this guidance coincides with the WHO’s fourth Mpox PHEIC declaration and Clade I outbreaks across multiple continents.
 - GeoVax expects to initiate its Phase 3 trial in 2H 2026.
- GEO-MVA addresses a significant medical need worldwide reflected in an estimated market potential at \$10B+.

GEO-CM04S1

- Positive immune response data in CLL patients presented at European Hematology Association (EHA) 2025 Conference. Key findings from the study include:

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- GEO-CM04S1 demonstrated significantly enhanced T cell responses—specifically IFN- γ secretion and activation-induced markers (AIM+)—compared to a matched cohort receiving an authorized mRNA vaccine.
- While both vaccines stimulated humoral immune responses, only GEO-CM04S1 elicited statistically significant SARS-CoV-2 Nucleocapsid (N)-specific IgG and T cell responses.
- The mRNA vaccine failed to meet the pre-defined primary immunogenicity endpoint; as a result, further enrollment is now restricted to the GEO-CM04S1 arm only.
- Both vaccines were well-tolerated, with no grade ≥ 3 adverse events reported.
- Highlighted positive findings from studies at Keystone Symposia. This study evaluated the immunogenicity and protective efficacy of GEO-CM04S1, a clinical-stage multi-antigen MVA-vectored vaccine co-expressing spike (S) and nucleocapsid (N) proteins, in a K18-hACE2 mouse model. Mice were challenged intranasally with either the original B.1 strain or the Omicron XBB.1.5 subvariant. GEO-CM04S1 conferred full protection against clinical disease, lung injury, and inflammation in both viral challenge models.
- Presented dual protective potential of GEO-CM04S1 at the American Association of Immunology (AAI) 2025 Annual Meeting. The presentation, titled “*Immunogenicity of Synthetic MVA-based Vaccine COH04S1 Against SARS-CoV-2 in Post-HCT/CAR-T Patients and Its Cross-Protective Potential Against Mpox*” (Abstract Number: 9352), highlighted findings from an the initial segment of an ongoing Phase 2 clinical study in blood cancer patients receiving hematopoietic cell transplantation or CAR-T therapy that was conducted by investigators at City of Hope Medical Center with the next-generation multi-antigen COVID-19 vaccine COH04S1 (licensed by GeoVax as GEO-CM04S1), as well as studies with sera obtained from COH04S1-vaccinated healthy adults and non-human primates demonstrating induction of orthopox-specific and Mpox cross-reactive immune responses.
- Showcased strong clinical results following presentation of multi-antigen COVID-19 vaccine at the 25th Annual World Vaccine Congress. The presentation, titled “Phase 2b Study Results That Evaluated and Compared GeoVax’s Multi-Antigen Vaccine Candidate (GEO-CM04S1) to an Approved Vaccine Against COVID-19,” was given by Don J. Diamond, Ph.D. on April 24, 2025. It highlighted results across several Phase 1 and 2 clinical trials, including studies involving healthy volunteers as well as immunocompromised patients such as stem cell transplant recipients and those with chronic lymphocytic leukemia (CLL).
- GEO-CM04S1 addresses a significant medical need worldwide reflected in an estimated market potential at \$30B+.

Gedeptin®

- Presented clinical data at the American Association for Cancer Research (AACR) Annual Meeting. The presentation, titled “Viral-Vectored, Gene-Directed Prodrug Therapy (Gedeptin) in Needle-Accessible Solid Tumors,” was delivered by J. Marc Pipas, M.D., Executive Medical Director, Oncology at GeoVax, during the Phase II Clinical Trials 1 Poster Session on April 29, 2025. The session drew significant interest from researchers and clinicians, underscoring the growing recognition of Gedeptin’s therapeutic potential. The corresponding abstract was published in the AACR journal Cancer Research. Key Findings from the Clinical Study include:
 - Trial Design: Up to five treatment cycles were administered, each consisting of intratumoral (IT) injection of Gedeptin followed by intravenous (IV) administration of fludarabine.
 - Patient Population: Eight heavily pretreated patients (median four prior lines of systemic therapies) were enrolled, including those with squamous cell carcinoma, nasopharyngeal carcinoma, and lymphoepithelial carcinoma.
 - Efficacy & Safety:
 - Several patients achieved stable disease (SD) despite extensive prior therapy.
 - Median progression-free survival (PFS) and overall survival (OS) were both 7.0 months.
 - No dose-limiting toxicities (DLTs) were reported.
 - Treatment-related adverse events (AEs) were minimal, with injection site pain being the most common.

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- Serious adverse events (SAEs) observed in five patients were mostly attributed to the underlying disease.
- Gedeptin addresses a significant medical need worldwide reflected in an estimated market potential at \$15B+.

Other Corporate Updates

- Issued a patent covering novel vaccine construct for preventing Malaria infection. The U.S. Patent and Trademark Office has issued U.S. Patent No. 12,329,808, from patent application No.18,394,580, titled “Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria.”
- Issued additional patent claims covering the synergistic combination of Gedeptin therapy with radiation as a targeted approach for solid tumors. The U.S. Patent and Trademark Office has issued a Notice of Allowance related to U.S. patent application 17/502,101 entitled “Enhanced Therapeutic Usage of a Purine Nucleoside Phosphorylase or Nucleoside Hydrolase Prodrug”. The allowed claims further strengthen GeoVax’s intellectual property position in the oncology space.
- Strengthened its leadership team with appointment of Dr. Senthil Ranganathan as Vice President, Technical Development and CMC Operations. Dr. Ranganathan brings over 20 years of experience in biologics development to commercialization across vaccines, cell and gene therapies, monoclonal antibodies, and viral vector products.

Second Quarter 2025 Financial Results

Net Loss: Net loss for the three-month period ended June 30, 2025, was \$5,369,783, or \$0.35 per share, as compared to \$5,064,042, or \$1.99 per share, for the comparable period in 2024. For the six-month period ended June 30, 2025, the Company’s net loss was \$10,727,434, or \$0.79 per share, as compared to \$10,914,174, or \$4.68 per share, in 2024.

Revenue. During the three-month and six-month periods ending June 30, 2025, the Company reported \$852,282 and \$2,489,145 of government contract revenues associated with the BARDA/RRPV Project NextGen award, compared to \$300,677 and \$300,677 for the comparable periods in 2024. During the second quarter of 2025 GeoVax received notification that BARDA determined to terminate the contract for convenience to the government.

R&D Expenses: Research and development expenses were \$4,728,998 and \$10,083,586 for the three-month and six-month periods ended June 30, 2025, compared with \$4,276,868 and \$8,702,596 for the comparable period in 2024, with the overall increase primarily due to program-specific costs associated with the BARDA/RRPV contract and GEO-MVA, partially offset by lower costs for the GEO-CM04S1 clinical trials and manufacturing costs not covered by the BARDA/RRPV contract.

G&A Expenses: General and administrative expenses were \$1,542,190 and \$3,229,635 for the three-month and six-month periods ended June 30, 2025, compared to \$1,086,030 and \$2,543,383 for the comparable periods in 2024, with the overall increase primarily due to higher investor relations consulting costs and stock-based compensation expense.

Cash Position: GeoVax reported cash balances of \$3,093,862 at June 30, 2025, as compared to \$5,506,941 at December 31, 2024. During July 2025, the Company completed a public offering of common stock and warrants with net proceeds of approximately \$5.6 million.

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 today, July 28, 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 against infectious diseases and therapies for solid tumor cancers. The Company's lead clinical program is GEO-CM04S1, a next-generation COVID-19 vaccine 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. GeoVax is also developing a vaccine targeting Mpox and smallpox and, based on recent regulatory guidance, anticipates progressing directly to a Phase 3 clinical evaluation, omitting Phase 1 and Phase 2 trials. GeoVax has a strong IP portfolio in support of its technologies and product candidates, holding worldwide rights for its technologies and products. 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,

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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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue from government contract	\$ 852	\$ 301	\$ 2,489	\$ 301
Operating expenses:				
Research and development	4,729	4,277	10,083	8,703
General and administrative	1,542	1,086	3,230	2,543
	<u>6,271</u>	<u>5,363</u>	<u>13,313</u>	<u>11,246</u>
Loss from operations	(5,419)	(5,062)	(10,824)	(10,945)
Other income (expense)	49	(2)	97	31
	<u>\$ (5,370)</u>	<u>\$ (5,064)</u>	<u>\$ (10,727)</u>	<u>\$ (10,914)</u>
Net loss				
	<u>\$ (0.35)</u>	<u>\$ (1.99)</u>	<u>\$ (0.79)</u>	<u>\$ (4.68)</u>

Condensed Consolidated Balance Sheet Information

(amounts in thousands, except common share information)

	June 30, 2025	Dec. 31, 2024
Assets:		
Cash and cash equivalents	\$ 3,094	\$ 5,507
Other current assets	2,041	2,428
Total current assets	<u>5,135</u>	<u>7,935</u>
Property and other assets, net	215	221
Total assets	<u>\$ 5,350</u>	<u>\$ 8,156</u>
Liabilities and stockholders' equity		
Total liabilities	\$ 2,529	\$ 3,107
Stockholders' equity	2,821	5,049
Total liabilities and stockholders' equity	<u>\$ 5,350</u>	<u>\$ 8,156</u>
Common shares outstanding	15,924,593	10,536,875