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): May 14, 2024

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 May 14, 2024, GeoVax Labs, Inc. (the "Company") issued a press release reporting its results of operations for the quarter ended March 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

Exhibit No.	Description
99.1	Press Release dated May 14, 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: May 15, 2024

GEOVAX LABS, INC.

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

Exhibit 99.1

GeoVax Reports First Quarter 2024 Financial Results and Provides Business Update

Presented data on GEO-CM04S1 at World Vaccine Congress, delineating the unique immune system driven mechanisms that contribute to the broad efficacy of the vaccine candidate

Significant milestone achieved towards implementation of a commercially validated manufacturing system

Progress across pipeline with planned data readouts for GEO-CM04S1 in multiple trials and Gedeptin® in healthy patient boost trial on track for later this year

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

ATLANTA, GA, May 14, 2024 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced financial results for the first quarter ended March 31, 2024, and provided a business update.

David Dodd, Chairman and CEO of GeoVax, stated, "Throughout the first quarter of 2024, we made considerable progress across our pipeline of differentiated vaccines and immunotherapies. Our focus continued to be on the advancement of the ongoing clinical trials for our Gedeptin® cancer therapy targeting advanced head and neck cancers and GEO-CM04S1, our next-generation SARS-CoV-2 (COVID-19) vaccine. Positive initial safety and immune response findings from our Phase 2 clinical trial of GEO-CM04S1 were reported earlier in the year, and our Gedeptin Phase 1/2 clinical study in patients suffering from advanced head and neck cancer completed enrollment. Completion of this trial will be a significant milestone in the Gedeptin clinical development program. We look forward to reporting further progress on each of our ongoing clinical trials as well as our additional data readouts throughout the remainder of the year."

Dodd continued, "In addition to our pipeline progress, the first quarter had other notable achievements for GeoVax. With our transition to implementing a commercial validated manufacturing, we released the first lot of GEO-CM04S1 produced with a commercial manufacturing platform, marking the successful completion of the transfer and scale-up of manufacturing to our experienced CDMO at ABL Europe. Additionally, we recently received multiple actions by global patent offices, further strengthening our intellectual property assets. This is an exciting time for us as we continue to successfully execute on our long-term strategy across our portfolio of assets and look ahead to a catalyst-rich 2024."

First Quarter Business Achievements

GEO-CM04S1

- **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 results delineating the unique immune system driven mechanisms that contribute to the broad efficacy of GEO-CM04S1. The data presented were generated in collaboration with scientists at Georgia State University using the human ACE2 transgenic mice, one of the "gold standard" small animal models used for studying COVID vaccines. Overall, 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.

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- **Positive initial safety and immune response findings** from Phase 2 clinical trial at one month following administration of GEO-CM04S1. The trial, evaluating GEO-CM04S1 as a heterologous booster in 63 healthy adults who had previously received the Pfizer or Moderna mRNA vaccine (ClinicalTrials.gov Identifier: NCT04639466), was fully enrolled at the end of Sept 2023. The study is designed to evaluate the safety and immunogenicity of two GEO-CM04S1 dose levels. The trial remains blinded to dose of vaccine received, with study subjects being followed for a total of one year. To date, there have been no serious adverse events, and adverse events were in line with other routine vaccinations. The immunological responses measured throughout the study period include both neutralizing antibodies against SARS-CoV-2 variants and specific T-cell responses. Consolidated data from all subjects tested one-month post-vaccination, documented statistically significant increases in neutralizing antibody responses against multiple SARS-CoV-2 variants, ranging from the original Wuhan strain through Delta and Omicron XBB 1.5; additional testing against the JN.1 variant is underway.

Gedeptin®

- **Completion of patient enrollment** for the Phase 1/2 clinical study evaluating Gedeptin® in patients suffering from advanced head and neck cancer. Completion of this trial will be a significant milestone in the Gedeptin clinical development program. Allowing time for the maximum number of cycles of Gedeptin therapy and patient follow-up, GeoVax expects to complete the study by the third quarter of this year. In the interim, active discussions are taking place with advisors on protocol development in support of a follow-on Phase 2 or Phase 2/3 trial among patients with advanced head and neck cancer in whom current therapeutic options are suboptimal.

Vaccine Manufacturing Process Development

- **Achieved a significant milestone in manufacturing process development for Phase 3 and Commercial Production.** This is an important step toward implementation of a validated chicken embryonic fibroblast (CEF) based production system for the company's MVA-based vaccines, with the release of the first lot of GEO-CM04S1 (next-generation COVID-19 vaccine) produced with a commercial manufacturing platform. 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.

Intellectual Property Developments

- **Intellectual property assets further strengthened** by multiple actions by global patent offices strengthening the Company's intellectual property assets.

    - The Japanese Patent Office issued a Decision of Grant notifying GeoVax of the allowance of the Company's Patent Application No. 2022-153352 titled "Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen." The allowed claims are directed to recombinant MVA viral vectors comprising specific MUC-1 nucleic sequences used in GeoVax's MUC-1 tumor-associated antigen immunotherapy program. Pharmaceutical compositions for inducing immune responses, preventing or reducing neoplasm growth, or treating cancer are also covered by the granted claims.
    - The U.S. Patent and Trademark Office issued Patent No. 11,896,657 to GeoVax, pursuant to the Company's patent application No. 17/584,231 titled "Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Marburg Virus Glycoprotein (GP) and Matrix Protein (VP40)." The allowed claims generally cover GeoVax's vector platform for expressing Marburg virus antigens in virus-like particles (VLPs) utilizing an MVA viral vector.
    - The U.S. Patent and Trademark Office issued Patent No. 11,897,919 pursuant to the Company's patent application No. 17/409,574 titled "Multivalent HIV Vaccine Boost Compositions and Methods of

Use." The allowed claims generally cover a priming vaccination with a DNA vector encoding multiple HIV antigens in virus-like particles (VLPs), followed by a boost vaccination with GeoVax's vector platform for expressing HIV-1 antigens in VLPs utilizing an MVA viral vector.

- The U.S. Patent and Trademark Office issued Patent No. 11,857,611 to GeoVax, pursuant to the Company's patent application No. 17/726,254 titled "Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria." The claims granted by the patent generally cover compositions comprising GeoVax's modified vaccinia Ankara (MVA) vector expressing Plasmodium antigens and methods of inducing an immune response to malaria utilizing the compositions. The compositions and methods covered in the claims are useful both prophylactically and therapeutically and may be used to prevent and/or treat malaria.

First Quarter 2024 Financial Results

- **Net Loss**: Net loss for the three months ended March 31, 2024, was $5,580,132, or $2.47 per share, as compared to $4,037,916, or $2.30 per share, for the three months ended March 31, 2023.
- **R&D Expenses**: Research and development expenses were $4,425,728 for the three months ended March 31, 2024, compared with $2,819,189 for the comparable period in 2023, with the increase/decrease primarily due to primarily due to the costs of manufacturing materials for use in our clinical trials and other related costs, personnel costs, and costs of preclinical research activities.
- **G&A Expenses**: General and administrative expenses were $1,457,353 for the three months ended March 31, 2024, compared to $1,451,425 for the three months ended March 31, 2023.
- **Cash Position**: GeoVax reported cash balances of $768,859 at March 31, 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, May 14, 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: 4923340
Webcast: https://edge.media-server.com/mmc/p/m379oy9j

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®, which recently completed enrollment 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

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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.

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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 March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 4,426	$ 2,819
General and administrative	1,457	1,451
	5,883	4,270
Loss from operations	(5,883)	(4,270)
Other income (expense), net	33	232
Net loss	$ (5,850)	$ (4,038)
Net loss per common share	$ (2.47)	$ (2.30)
Weighted average common shares outstanding	2,367,050	1,755,905

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

	March 31, 2024	Dec. 31, 2023
Assets:		
Cash and cash equivalents	$ 769	$ 6,453
Other current assets	2,093	1,433
Total current assets	2,862	7,886
Property and other assets, net	496	1,397
Total assets	$ 3,358	$ 9,283
Liabilities and stockholders' equity		
Total liabilities	$ 3,304	$ 3,520
Stockholders' equity	54	5,763
Total liabilities and stockholders' equity	$ 3,358	$ 9,283
Common shares outstanding	2,308,309	1,977,152

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