

**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**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): June 12, 2024**

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**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 1.01 Entry into a Material Definitive Agreement

On June 12, 2024, GeoVax, Inc. (“GeoVax” or the “Company”) received an award (the “BARDA Contract”) 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 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).

Under the agreement, the Company 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 fully funded by BARDA under its Clinical Studies Network.

The direct award to GeoVax of approximately \$24.3 million, which may increase to as much as \$45 million, will fund the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. BARDA has made separate awards through its Clinical Studies Network to support execution of the study. That funding will represent approximately \$343M from the Project NextGen program for a CRO to execute the clinical trial using GeoVax’s vaccine.

The foregoing description of the BARDA Contract does not purport to be complete and is qualified in its entirety by reference to the full text of the BARDA Contract, which will be filed as an exhibit to the Company’s next periodic report on Form 10-Q.

On June 18, 2024, the Company issued a press release announcing its entry into the BARDA Contract, a copy of which is furnished 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 June 18, 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: June 18, 2024

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds \_\_\_\_\_

Mark W. Reynolds  
Chief Financial Officer



## **GeoVax Receives BARDA Project NextGen Award to Conduct Phase 2b Clinical Study Evaluating the Company’s Next-Generation COVID-19 Vaccine Candidate, GEO-CM04S1**

*10,000-participant randomized Phase 2b study will evaluate and compare GeoVax’s multi-antigen, vaccine candidate (GEO-CM04S1) to an approved vaccine against COVID-19 under BARDA’s Clinical Studies Network*

*Project NextGen is a \$5 billion initiative by the U.S. Department of Health and Human Services to develop innovative vaccines and therapeutics providing broader and more durable protection against current and future COVID-19 viral strains*

**Atlanta, GA, June 18, 2024** – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced that it received an 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 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).

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 fully funded by BARDA under its Clinical Studies Network.

The direct award to GeoVax of approximately \$24.3 million, which may increase to as much as \$45 million, will fund the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. BARDA has made separate awards through its Clinical Studies Network to support execution of the study. That funding will represent approximately \$343M from the Project NextGen program for a CRO to execute the clinical trial using GeoVax’s vaccine.

“We are honored and proud to receive this award from BARDA to advance our next-generation vaccine against COVID-19. This contract not only provides the vital resources for advancing the development of GEO-CM04S1, but it also advances our MVA platform in infectious diseases,” said David Dodd, Chairman & CEO of GeoVax.

Mr. Dodd continued, “First-generation COVID-19 vaccines were beneficial during the peak of the pandemic but are limited in breadth and durability of clinical protection, requiring frequent updates. Now that COVID-19 is in an endemic stage, many people continue to have their everyday lives impacted in meaningful ways. Furthermore, there are an estimated 23 million adults in the U.S. with immunocompromised conditions who are less likely to have an adequate response to current vaccines and are more likely to potentially experience severe COVID-19 symptoms, hospitalization and the risk of death, even after vaccination. GEO-CM04S1 was designed to address these limitations by inducing durable neutralizing antibody and T-cell-based immunity against current and future SARS-CoV-2 variants. Our vaccine has continued to demonstrate induction of potent immune responses with potential to drive broad and durable clinical protection, and we eagerly anticipate commencing the Phase 2b study to further demonstrate the value and advantages of our technology.”

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. BARDA is supporting the development of new vaccines and therapeutics to better address the waning immunity and resistance to current and future SARS-CoV2 viral strains. GeoVax’s vaccine candidate provides many of the features identified by BARDA including broader protection among

variants of concern (VOC) and a longer duration of protection.

This project is being funded 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.

### About GEO-CM04S1

GEO-CM04S1 is based on GeoVax's MVA viral vector platform, which supports the presentation of multiple vaccine antigens to the immune system in a single dose. GEO-CM04S1 encodes for both the spike (S) and nucleocapsid (N) antigens of SARS-CoV-2 and is specifically designed to induce both antibody and T-cell responses to those parts of the virus less likely to mutate over time. The more broadly functional engagement of the immune system is designed to protect against severe disease caused by continually emerging variants of COVID-19. Vaccines of this format should not require frequent and repeated modification or updating.

GEO-CM04S1 is currently being evaluated in three ongoing Phase 2 clinical trials:

- As a primary vaccine in immunocompromised patients (with hematologic cancers receiving cell transplants or CAR-T therapy). ClinicalTrials.gov Identifier: [NCT04977024](https://clinicaltrials.gov/ct2/show/study/NCT04977024). A recent presentation of unpublished data from the open-label portion of the trial indicates that GEO-CM04S1 is highly immunogenic in these patients, inducing both antibody responses, including neutralizing antibodies, and T-cell responses.
- As a booster vaccine in immunocompromised patients with chronic lymphocytic leukemia (CLL), a recognized high-risk group for whom current mRNA vaccines and monoclonal antibody (MAb) therapies appear inadequate relative to providing protective immunity. ClinicalTrials.gov Identifier: [NCT05672355](https://clinicaltrials.gov/ct2/show/study/NCT05672355).
- As a booster vaccine for healthy adults who have previously received the Pfizer or Moderna mRNA vaccine. ClinicalTrials.gov Identifier: [NCT04639466](https://clinicaltrials.gov/ct2/show/study/NCT04639466).

### 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, Gedepin<sup>®</sup>, 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 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](http://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*

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*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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