

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): December 15, 2021

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.

Item 7.01 Regulation FD Disclosure.

On December 15, 2021, GeoVax Labs, Inc. (“GeoVax” or the “Company”) issued a press release announcing the initiation of the Phase 2 trial of COH04S1, a multi-antigenic SARS-CoV-2 investigational vaccine, to evaluate its use as a universal booster to current FDA-approved vaccines. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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 “believe,” “look forward to,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “could,” “target,” “potential,” “is likely,” “will,” “expect” 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated December 15, 2021
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: December 15, 2021

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds _____

Mark W. Reynolds
Chief Financial Officer



GeoVax Announces Initiation of Phase 2 Clinical Trial for COVID-19 Vaccine Booster

Ongoing Phase 1/2 Trial Advancing to Phase 2 Evaluation of Multi-Antigen Vaccine, Targeting both Spike and Nucleocapsid Proteins, as a Universal Booster to Current FDA-Approved Vaccines

ATLANTA, GA, December 15, 2021 — GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, today announced the initiation of vaccine dosing in the Phase 2 portion of its Phase 1/2 clinical trial of COH04S1, a multi-antigenic SARS-CoV-2 investigational vaccine, designed to target both the spike (S) and nucleocapsid (N) proteins, to evaluate its use as a universal booster to current FDA-approved vaccines.

The clinical trial, titled “Phase 1/2 Dose Escalation Study to Evaluate the Safety and Biologically Effective Dose of COH04S1, a Synthetic MVA-based SARS-CoV-2 Vaccine, Administered as One or Two Injections or as a Booster to Healthy Adult Volunteers” is being conducted at City of Hope, a world-renowned cancer research and treatment organization near Los Angeles.

The Phase 1 portion of the trial was designed as a dose-escalation safety study in healthy individuals between the ages of 18 to 55, who had not been previously infected with SARS-CoV-2. The primary objectives were to evaluate the safety, tolerability and immunogenicity of the COH04S1 vaccine in healthy volunteers who were administered the vaccine at three different dose levels by intramuscular (IM) injection. Follow-up studies of the volunteers are continuing in order to better assess duration of immune responses and scientific presentations, and publications of results are planned for early 2022.

The Phase 2 booster study, for which vaccination is now underway, will include 60 healthy individuals, 18 years of age and older, who were previously vaccinated with one of the FDA-approved SARS-CoV-2 mRNA vaccines. The study is designed as a dose-escalation trial to specifically evaluate the safety profile and immunogenicity of COH04S1 as a booster shot. The immunological responses measured throughout the study will include both the level of SARS-CoV-2 neutralizing antibodies against SARS-CoV-2 variants of concern (VOC), including the newly identified Omicron VOC, and specific T-cell responses.

Mark Newman, PhD, GeoVax Chief Scientific Officer, commented, “Due to concerns with the duration of vaccine-induced neutralizing antibodies and the spread of SARS-CoV-2 variants – such as the newly identified Omicron – health officials are now advocating booster vaccinations for the current FDA-approved mRNA vaccines. We believe that the COH04S1 vaccine, when administered as a heterologous booster, targeting both the S and N proteins, will provide additional beneficial elements for immune system recognition versus a homologous boost using a vaccine based solely on the SARS-CoV-2 S protein. By inducing immune responses to both the S and N antigens, the COH04S1 vaccine may offer greater protection against the significant sequence variation observed with the S antigen, especially with the newly identified Omicron VOC that has more than 30 mutations in its S protein. The COH04S1 vaccine’s MVA backbone should also be more effective at inducing SARS-CoV-2 cellular immunity, since MVA strongly induces T cell responses, even in immunocompromised individuals.”

David Dodd, GeoVax President and CEO, added, “We are excited to begin this important study and look forward to sharing progress reports going forward on this trial, as well as the ongoing Phase 2 trial of COH04S1 in immunocompromised and other patients. We believe the COH04S1 vaccine, containing the two antigens, S and

N, along with the recognized antibody and cellular immune responses resulting from the MVA approach, has the potential to offer greater booster protection than that from the current vaccines in use, as well as provide a greater degree of protection within immunocompromised patients. In addition, our pan-coronavirus vaccine candidate, GEO-CM04, continues to progress, demonstrating promising preclinical data results.”

About COH04S1

COH04S1, a synthetic, attenuated modified vaccinia Ankara (sMVA) vector expressing spike (S) and nucleocapsid (N) antigens of the SARS-CoV-2 virus, was initially developed at City of Hope for immunocompromised and other patients. On November 9, 2021, GeoVax entered into an exclusive license agreement with City of Hope, granting GeoVax world-wide rights to the patents covering COH04S1 and to further develop and commercialize COH04S1.

In addition to the Phase 1/2 booster trial in healthy volunteers, COH04S1 is being studied in an ongoing Phase 2 clinical trial to evaluate its safety and immunogenicity, compared to the Pfizer mRNA-based vaccine, in patients who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant, or chimeric antigen receptor (CAR) T cell therapy. COH04S1 is the only COVID-19 vaccine that includes both SARS-CoV-2 S and N proteins to advance to a Phase 2 trial in cancer patients. Such vaccines also tend to produce an immune response quickly – in less than 14 days – with only mild side effects. The trial is also the first to compare an investigational multi-antigenic COVID-19 vaccine to the current Food and Drug Administration (FDA)-approved mRNA vaccine from Pfizer/BioNTech in people who are immunocompromised. Such patients have often shown a weak antibody response after receiving currently available COVID-19 vaccines.

About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines and immunotherapies against infectious diseases and cancer using novel proprietary platforms. The Company’s portfolio of wholly owned, co-owned, and in-licensed intellectual property stands at over 70 granted or pending patent applications spread over 20 patent families.

GeoVax’s product pipeline includes ongoing human clinical trials in COVID-19, head and neck cancer, and HIV. Additional research and development programs include preventive vaccines against Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as immunotherapies for multiple solid tumors.

For additional information about GeoVax, 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 the current Phase 2 clinical trial involving COH04S1 or additional 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

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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 registration statement on Form S-3 and the 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 U.S. federal securities law.

Contact:

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