

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): January 4, 2022

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 January 4, 2022, GeoVax Labs, Inc. (“GeoVax” or the “Company”) issued a press release announcing the release of a shareholder update letter. 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 January 4, 2022
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: January 4, 2022

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds _____

Mark W. Reynolds
Chief Financial Officer



GeoVax Issues Shareholder Update Letter

Letter from CEO Describes Achievements during 2021 and Sets Forth New Goals for 2022

ATLANTA, GA, January 4, 2022 — GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, today issued an update letter from Chairman and CEO, David Dodd, to the Company's shareholders and other interested parties. The letter is posted to the Company's website and is appended in its entirety to the end of this press release.

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. GeoVax's product pipeline includes two ongoing Phase 2 clinical trials of GEO-CM04S1 (formerly COH04S1) for COVID-19 as a universal booster vaccine to mRNA vaccines authorized by the U.S. Food and Drug Administration (FDA) and as a primary vaccine for use in immunocompromised patients. In addition to GEO-CM04S1 for COVID-19, GeoVax is developing GEO-CM02 as a pan-coronavirus vaccine. The Company is also conducting a Phase 1/2 clinical trial of Gedeptin[®] for treatment of head and neck cancer. Gedeptin[®] has been granted orphan drug status by the FDA. 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. 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.

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 ongoing or future clinical trials of its investigational products, GeoVax's immuno-oncology products and preventive 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 preventive vaccines with the desired characteristics in a timely manner, GeoVax's immuno-oncology products and preventive vaccines will be safe for human use, GeoVax's vaccines will effectively prevent targeted infections in humans, GeoVax's immuno-oncology products and preventive 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 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:

GeoVax Labs, Inc.

investor@geovax.com

678-384-7220

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January 4, 2022

Dear Fellow Shareholders:

2021 has represented an outstanding year of progress for GeoVax. Thank you for your continued support of GeoVax, and sharing in our efforts to advance the application of our expertise, science, and technology towards improving the lives of millions worldwide.

Heading into 2021, we established and communicated the following goals:

2021 GOALS

1. **Covid-19/SARS-CoV-2 Vaccine**
 - Achieve clinical development status within 12-18 months
2. **Immuno-oncology**
 - Achieve clinical development status within 12-18 months
3. **Hemorrhagic fever virus vaccines (Ebola, Lassa, Marburg, Sudan)**
 - Support National Institutes of Health (NIH) Preclinical Services and Department of Defense (DoD) activities related to animal testing evaluations of GeoVax vaccines
4. **Strengthen balance sheet** in support of achieving 2021 goals and beyond
5. **Strengthen resources and operations in support of our development goals**

In this message, I wish to highlight significant accomplishments achieved in support of our 2021 goals, while also outlining our goals and milestones set for 2022.

2021 ACHIEVEMENTS

Goal Achievement #1

Covid-19 vaccine: Advancing into Phase 2 Clinical Development and Potentially a Single-dose, Durable Coronavirus Vaccine

As a result of the exclusive license of **GEO-CM04S1** (formerly COH04S1) executed with City of Hope, we have **two Phase 2 clinical trials underway** related to Covid-19:

- Phase 2 trial among **immunocompromised patients**, directly comparing to the Pfizer/BioNTech mRNA vaccine;
 - This is the first trial to be conducted among a patient population with weakened immune systems as a result of cancer therapy. In this trial, we are conducting a direct comparison of GEO-CM04S1 to the Pfizer/BioNTech mRNA vaccine. We believe that our vaccine, eliciting both T-cell and antibody immunity, has the potential to provide better and more durable protection versus a vaccine that elicits primarily only antibody immunity. We also believe that the current vaccines, based on mRNA and adenovirus vaccine platforms, may be less effective and protective within immunocompromised populations. We believe that our approach of eliciting both T-cell and antibody immunity against multiple viral proteins may prove to be more potent and may provide better and more durable protection to such populations.
- Phase 2 trial among healthy volunteers as a **booster** to individuals fully vaccinated with a mRNA vaccine (i.e., two-shot regimen);
 - We also believe that GEO-CM04S1, which is designed to elicit both T-cell and antibody immunity, has the potential to provide broader protection and durability as a booster to mRNA vaccines versus simply providing a 3rd or 4th mRNA dose, which was designed primarily to induce neutralizing antibodies.

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In general, we believe that **GEO-CM04S1** provides a differentiated opportunity as a **vaccine against variants** (i.e., Omicron) versus the concept of “chasing the variants.”

- GEO-CM04S1 is designed to elicit both T-cell and antibody immunity by incorporating a multi-antigen design targeting both the spike (S) and nucleocapsid (N) proteins of the SARS-CoV-2 virus. We believe that this multi-antigen approach may provide broader and more durable protection than a single-antigen vaccine design. *In simple terms, we believe our vaccine has a better chance of addressing the issues and dangers of evolving variants of concern, which we expect will continue to emerge.*

Further strengthening our Covid-19 vaccine portfolio is **GEO-CM02**, a potential **universal coronavirus vaccine that could be effective against multiple variants**, which is showing promise in animal testing.

- We designed GEO-CM02 to incorporate three critical proteins to support the in vivo formation of highly immunogenic VLPs (Virus-Like-Particles) intended to elicit both an antibody immune response targeting the S protein and a T-cell immune response targeting the membrane (M) and envelope (E) proteins. Promising animal results were reviewed during the 2021 World Vaccine & Immunotherapy Conference, demonstrating protection with a single dose and protection against the Beta variant. Our focus with this program is towards a single-dose, durable universal coronavirus vaccine that could be effective against multiple variants and that can be distributed and administered without requiring extreme refrigeration or frozen state delivery.

Goal Achievement #2

Immuno-oncology: Phase 2 Clinical Development of Gedeptin[®] and Advancing MVA-VLP-MUC1 to IND-readiness

Our exclusive license of **Gedeptin[®]** provides a Phase 2 stage therapy for advanced head and neck cancers. The U.S. Food and Drug Administration (FDA) granted orphan drug status to Gedeptin[®] and we are currently expanding the number of trial sites in order to accelerate patient enrollment and validate the product for regulatory filing.

We will also evaluate additional opportunities to expand the use of Gedeptin in conjunction with other cancer therapies, such as Immune Checkpoint Inhibitors (ICIs).

Separately, our **MVA-VLP-MUC1** immunotherapy is advancing towards IND-filing through critical animal efficacy testing models. The focus is on combining our vaccine and ICIs with the goal of enhancing the therapeutic performance and utility of ICI therapy. During the fourth quarter, we received a Notice of Allowance regarding our cancer (MUC1) vaccine patent, documenting the novelty of our vaccine approach.

Goal Achievement #3

Hemorrhagic Fever Virus Vaccines: Ebola, Marburg, Lassa & Sudan Advancing with NIH & DoD Support

Thanks to the continued support of NIH Preclinical Services and the DoD, our hemorrhagic fever virus vaccines continue to demonstrate promising immune responses and efficacy measures in animal testing.

To date, we have demonstrated 100% protection with a single dose vaccine against Ebola in a lethal challenge non-human primate evaluation, and the data was recently presented at the 2021 World Vaccine & Immunotherapy Congress. During the fourth quarter, we received a Notice of Allowance for our Ebola vaccine patent, which represents the basis of our technology related to hemorrhagic fever virus vaccines.

Goal Achievements #4 and #5

Strong Balance Sheet – Enabling Transformative Business Developments into Phase 2 Status and Operational Strengthening

We began 2021 with a clean balance sheet, having successfully listed on the Nasdaq market, and in early 2021, we further strengthened our balance sheet. As a result, we have added strength and depth in various operational areas that are critical for us to successfully proceed through clinical development and potentially into regulatory registration and/or business partnering/collaborations. During 2021, we also successfully completed transformative exclusive license agreements relating to Gedeptin[®] and GEO-CM04S1 while also advancing our internal priority development programs.

As we enter 2022, our focus will be on **the continuing progress** of our **three Phase 2 clinical programs** and ensuring that we have appropriate internal/external resources to support both our clinical programs and our IND-enabling initiatives in support of our priority internal programs.

2022 GOALS

Goal #1

Covid-19/SARS-CoV-2

- Accelerate the two Phase 2 clinical trials to support the development of **GEO-CM04S1**
 - **Immunocompromised patients** – direct comparison against the Pfizer/BioNTech mRNA vaccine
 - **Booster** among healthy individuals who previously received the two-shot regimen of an mRNA vaccine
- Advance GEO-CM02, our potential single dose, universal coronavirus vaccine through IND-enabling activities
- *While our priority will be on accelerating our GEO-CM04S1 clinical program, we remain encouraged regarding the potential of GEO-CM02. Our developments are well aligned with organizations such as NIH and the Coalition for Epidemic Preparedness Innovations (CEPI), which have established priority goals in supporting the development of universal coronavirus vaccines. We anticipate providing updates as results become available. We also recognize potential opportunities exist for collaborations as well as out-licensing of our programs, especially those advancing through clinical trials, which we will evaluate and consider.*

Goal #2

Immuno-oncology

- Accelerate the expansion and enrollment of the **Gedeptin[®]** clinical program within advanced Head & Neck cancers
- Advance **MVA-VLP-MUC1** to through critical animal efficacy models to support IND-readiness
- *Our priority is to expand and accelerate the Gedeptin[®] clinical program. We anticipate providing updates throughout 2022 regarding the expansion and acceleration of the Gedeptin[®] program, as well as updates regarding the progress of MVA-VLP-MUC1. We also recognize potential opportunities exist for collaborations and out-licensing of these programs which we will evaluate and consider.*

Goal #3

Hemorrhagic Fever Virus Vaccines (Ebola, Lassa, Marburg, Sudan)

- We anticipate continued progress of these vaccines, working in conjunction with NIH and DoD, and we remain focused on the potential of clinical development support from such government entities.

Goal #4

Resources and Capabilities

- As we advance our portfolio, we will continue to strive to have appropriate organizational and operational resources to support advancing through clinical development into regulatory registration, including our abilities relative to collaboration and other corporate development activities. This will continue to be a critical area of focus and evaluation of internal and external opportunities.

In addition to these goals, we will continue to enhance the communications activities via our website, press releases, social media, broadcast media, relevant conference participation and other venues. Our intent is to provide timely updates regarding our programs and progress, while also increasing the awareness of GeoVax to various constituencies (i.e., potential investors; potential collaborators; etc.).

In summary, we appreciate your continued support. We are committed to accelerating the clinical development of GEO-CM04S1 and Gedepin[®], advancing our other programs, ensuring resources and capabilities are in place to support increasing our contributions towards improved health worldwide, providing significant value to our shareholders, and promoting a highly motivating environment for high performance-oriented individuals to develop their careers. On behalf of all of us associated with GeoVax, we wish you a healthy, prosperous and wonderful 2022. Thank you.

Sincerely,

David A. Dodd
Chairman, CEO
GeoVax Labs, Inc.

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