**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):  August 19, 2021**

**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 | TradingSymbol(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. ☐

This Form 8-K and other reports filed by GeoVax Labs, Inc. (the “Registrant” or 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 Registrant’s management as well as estimates and assumptions made by the Registrant’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 Registrant or the Registrant’s management identify forward looking statements.  Such statements reflect the current view of the Registrant with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Registrant’s industry, operations and results of operations and any businesses that may be acquired by the Registrant. 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 Registrant does not undertake to update its forward-looking statements.

|  |  |
| --- | --- |
| **Item 8.01**  | **Other Events.** |

On August 19, 2021, we issued a press release reporting the presentation of data from ongoing studies of our preventive vaccine against COVID-19. The presentation titled, “Design of a Universal SARS-CoV-2 Vaccine Against Evolving Variants,” was delivered virtually by Mark J. Newman, Ph.D., GeoVax’s Chief Scientific Officer, during the European Society of Medicine (ESMED) General Assembly, being held August 19-21 in Berlin, Germany.

A copy of the press release is attached to this Current Report. Dr. Newman’s full presentation is available on GeoVax’s website at [www.geovax.com/events](http://www.geovax.com/events).

|  |  |
| --- | --- |
| **Item 9.01**  | **Financial Statements and Exhibits.** |

(d)     Exhibits

|  |  |
| --- | --- |
|  Exhibit No. | Description |
| 99.1 | Press release dated August 19, 2021 |

**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: August 20, 2021

|  |  |  |
| --- | --- | --- |
|   | GEOVAX LABS, INC. |   |
|   |   |   |
|   |   |   |
|   | By: | /s/ Mark W. Reynolds |   |
|   |   | Mark W. Reynolds |   |
|   |   | Chief Financial Officer |   |
|   |   |   |   |

**Exhibit 99.1**

**GeoVax Presents COVID-19 Vaccine Data at the European Society of Medicine (ESMED) General Assembly**

***GeoVax Vaccine Being Developed as a Universal Vaccine to***

***Address Evolving SARS-CoV-2 Variants***

**ATLANTA, GA, August 19, 2021** – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, today presented data from ongoing studies of its preventive vaccine against COVID-19. The presentation titled, “Design of a Universal SARS-CoV-2 Vaccine Against Evolving Variants,” was delivered virtually by Mark J. Newman, Ph.D., GeoVax’s Chief Scientific Officer, during the European Society of Medicine (ESMED) General Assembly, being held August 19-21 in Berlin, Germany.

First-generation SARS-CoV-2 vaccines were rapidly developed and have proven highly efficacious in the human population and were designed to encode the prefusion stabilized Spike protein (S) with the goal of inducing high levels of neutralizing antibodies. However, potential limitations of narrowly focusing on S are becoming apparent with emerging variants that partially escape neutralization by vaccine induced antibodies. Thus, the effectiveness of these vaccines against new SARS-CoV-2 variants and future coronavirus spillover events remains in question.

Using its novel Modified Virus Ankara - Virus Like Particle (GV-MVA-VLPTM) platform, GeoVax has developed a design strategy for vaccines expected to induce broader immunity through inclusion of multiple structural and nonstructural proteins from the target pathogen. The GV-MVA-VLPTM platform is known to elicit a balanced humoral (antibody) and cellular response against a range of immunogens, possibly making immune escape against emerging variants less likely. Expression of the SARS-CoV-2 spike, membrane and envelope proteins by MVA supports the *in vivo* formation of virus like particles, or VLPs, which induce both antibody and T-cell responses. Incorporation of sequence-conserved nonstructural proteins can provide targets for T-cell responses to increase the breadth and function of vaccine-induced immune responses. This strategy provides the basis for generating a universal vaccine with augmented potential to alleviate the burden of disease caused by circulating coronaviruses.

In his talk, Dr. Newman discussed GeoVax’s vaccine design strategy for developing a universal SARS-CoV-2 vaccine and presented stability and protein expression data for the Company’s initial vaccine candidate, GEO-CM02, which encodes the Spike (S), Membrane (M) and Envelope (E) proteins. Dr. Newman also presented vaccine efficacy and immunogenicity data for GEO-CM02 from hamster and transgenic mice studies to date.

Dr. Newman’s presentation is available on GeoVax’s website at [www.geovax.com/investors/events](http://www.geovax.com/investors/events).

Dr. Newman commented, “Our studies to date support the use of MVA as a vector for the design and production of next-generation vaccines encoding multiple coronavirus proteins, using the S protein as the antibody target and the M and E proteins as T-cell targets. The combination of S, M and E protein expression supports VLP formation and optimal immunogenicity. In our studies, we observed the induction of functional antibodies and T-cell responses that mediate protection from infection and pathogenesis.”

David Dodd, GeoVax President and CEO, further commented, “The presentation of data from this study further validates our platform and approach to addressing COVID-19 and its variants. Our vaccines under development are intended to be used as either a primary vaccine or to boost other COVID-19 vaccines as part of vaccination strategies to provide immunity to a range of coronavirus variants. We believe a critical and significant opportunity exists for a pan-coronavirus vaccine with the attributes the GV-MVA-VLPTM technology can offer.”

**About GeoVax**

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines against infectious diseases and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) based vaccine platform. On this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens in the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax’s current development programs are focused on preventive vaccines against COVID-19, HIV, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines against multiple cancers. The Company has designed a preventive HIV vaccine candidate to fight against the subtype of HIV prevalent in the commercial markets of the Americas, Western Europe, Japan, and Australia; human clinical trials for this program are managed by the HIV Vaccine Trials Network (HVTN) with the support of the National Institutes of Health (NIH). GeoVax’s HIV vaccine is also part of a collaborative effort toward a functional cure for HIV.

***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 additional tests of its preventive vaccine against SARS-CoV-2, GeoVax’s vaccines can provoke the desired immune responses, and those vaccines can be used effectively as a primary or booster to other vaccines, GeoVax’s viral vector technology adequately amplifies immune responses to cancer antigens, GeoVax can develop and manufacture its vaccines with the desired characteristics in a timely manner, GeoVax’s vaccines will be safe for human use, GeoVax’s vaccines will effectively prevent targeted infections in humans, GeoVax’s vaccines will receive regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete vaccine 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-1 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