

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 2, 2019

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-52091
(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: None

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 “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 8.01 Other Events

On August 2, 2019, we issued a press release reporting the posting to our website of an update letter to our stockholders. A copy of the press release and the stockholder letter are filed as exhibits to this Current Report.

Item 9.01 Financial Statements and Exhibits

The following exhibits are filed with this Current Report:

- 99.1 Press Release, dated August 2, 2019
- 99.2 Letter to Stockholders, dated August 2, 2019

[SIGNATURES ON FOLLOWING PAGE]

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Current Report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 2, 2019

GEOVAX LABS, INC.

By: s/ Mark W. Reynolds

Mark W. Reynolds

Chief Financial Officer

GeoVax Issues Shareholder Update Letter

Updates Provided on Financial Status and Development Programs

ATLANTA, GA, August 2, 2019 – GeoVax Labs, Inc. (OTCQB: GOVX), a biotechnology company developing human vaccines and immunotherapies, today issued an update letter to its shareholders and other interested parties. In the letter, GeoVax President and CEO, David Dodd, addresses the recent erosion of GeoVax's common stock price and provides an update on each of the Company's development programs, including its shifting focus to immuno-oncology. The letter is posted to the Company's website and can be read in its entirety by visiting <https://www.geovax.com>.

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 within (*in vivo*) the person receiving the vaccine. The production of VLPs in the person being vaccinated mimics 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 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 HIV, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines against chronic Hepatitis B infections and multiple cancers. The Company has designed the leading preventative HIV vaccine candidate to fight against the subtype of HIV prevalent in the larger commercial markets of the Americas, Western Europe, Japan, and Australia; this program is currently undergoing human clinical trials 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 collaborative efforts to develop an immunotherapy as a functional cure for HIV. For more information, visit www.geovax.com.

Contact:

GeoVax Labs, Inc.
investor@geovax.com
678-384-7220



August 2, 2019

Fellow Shareholders,

In recent weeks, we have seen a severe and sharp erosion of GeoVax common stock price and resultant company valuation. In this update, I would like to address what we believe are the root causes of the decline, as well as offer some insight as to the promise of our core technology, our shift of focus to immuno-oncology, and the challenges that we still face. I hope that this candid assessment of our situation helps you, our shareholders, understand the motives behind our actions, as well as see the future potential that remains for GeoVax.

The share price decline can be directly attributed to both our current capital structure, as well as our decision to move forward with a reverse stock split on May 2. Our primary intent behind seeking shareholder approval for the reverse split was to position the Company for listing on Nasdaq in conjunction with a significant financing event, with the expectation that subsequent events would support a higher stock valuation. For various reasons, these plans did not materialize in the way we had hoped. Unfortunately, we were then compelled to execute the reverse split due both (i) to our need for increased authorized shares in support of continued capital development, including the need for available shares to support the sale of securities to our primary investors, to keep the Company operational, as well as (ii) to meet the minimum stock price required to maintain our listing on the OTC Market. Our primary investors often convert their preferred shares into common stock, or exercise their warrants to purchase our common stock, and sell those shares. Our dire need for additional authorized shares was such that we had no other alternative but to proceed with the reverse split. Most disappointingly, our share price immediately collapsed, eliminating our ability to proceed with the steps to achieve the “Nasdaq uplisting”.

While our financial status may be disheartening, we believe the promise of our technology and development programs continues to be impressive. But the reality is, GeoVax remains highly undercapitalized, and we have been unable to advance any of our promising non-HIV development programs into the critical realm of human clinical trials. We continue to seek strategic collaborations or partnerships with other companies that may result in funding arrangements which would reduce our need for additional equity capital or lead to such arrangements. While we have engaged in various such discussions, virtually all such funding agreements are predicated on our having advanced the respective product(s) into clinical development. In most discussions, we consistently receive highly positive and complimentary comments regarding the validation of our technology and expertise. Unfortunately, without having the requisite human clinical data, no potential collaborator or partner has been willing to proceed to a definitive agreement. This is the “Catch-22” in which we find ourselves... needing the human clinical data to support further corporate development and funding, but not having adequate financial resources to generate the data.

Our financing challenges are significant, but not insurmountable, and we remain confident in the promise of our technology. Consider the following achievements and progress:

Immuno-oncology– A Promising Opportunity. We believe immuno-oncology to be a key component to potentially strengthening the valuation of GeoVax and providing future growth opportunity. Immuno-oncology represents an area of significant medical need and our results thus far have been highly promising. To date, in humanized mice models, we have demonstrated significant tumor reduction, as well as tumor growth prevention. Our goal is to vigorously pursue development of immunotherapies relative to various cancers. Yet, only having preclinical data inhibits our ability to garner sufficient collaboration or strategic investment interest. Raising sufficient capital to advance into further product and clinical development in this area is critical to advancing these programs.

- Hemorrhagic Fever Virus Vaccines (Ebola, Lassa and Marburg) – Preventing Endemic and Bioterrorism Threats.** Hemorrhagic fever viruses are a continuing health threat from both the endemic and bioterrorism perspectives. Recently, the World Health Organization declared the current Ebola outbreak in the Democratic Republic of the Congo a global health emergency. In addition, nations worldwide recognize the potential of these viruses as possible bioterrorism threats, and seek simple, highly efficacious vaccines to protect against such viral risks. Our Ebola, Lassa Fever and Marburg vaccines have each demonstrated 100% preclinical protection, and have economical cold chain requirements, all critical attributes for such vaccines and their implementation. Our Lassa Fever vaccine continues to progress in advanced preclinical studies with support from the U.S. Department of Defense. We’re confident in the potential value of these vaccines to public health and are committed to seeing the contribution of these vaccines achieved and recognized. However, we lack the funding necessary to advance any of these programs into human clinical development. This is why we have recently taken the bold step to offer these vaccines (beginning with Ebola) to public health agencies worldwide, contingent on their funding the advancement into clinical development and human use. We recognize that should any public health entity advance these programs into human evaluation, our company valuation and validation will be significantly strengthened, thereby improving our ability to raise capital for other, more strategically important programs such as immuno-oncology.
- Zika Virus Vaccine – Preventing a Southern Hemisphere Threat.** Our Zika virus vaccine has also demonstrated 100% preclinical protection against a significant health risk in the Southern Hemisphere. In this area, we also face a lack of resources, so we are considering various options for progressing, similar to that of our hemorrhagic fever virus vaccines.
- HIV “Cure” Program – Advancing to Clinical Development.** Our collaboration with American Gene Technologies International, Inc. (AGT), for use of our vaccine in combination with AGT’s gene therapy for development of a functional cure for HIV, remains on track to enter a Phase 1 trial in the second half of 2019, sponsored by AGT. We have also signed a commitment, yet undisclosed, with another organization for the use of our vaccine in a similar effort, anticipated to begin later this year or early 2020, towards developing a cure for HIV infection.
- HIV “Prevention” Program – Continued Progress with NIH Support.** In October, positive results from HVTN 114, a phase 1 trial of our preventive HIV vaccine, were presented at the HIVR4P conference in Madrid. The clinical trial program for our preventive HIV vaccine continues to be supported by the NIH and the HIV Vaccine Trials Network (HVTN), with the next study (HVTN 132) expected to commence later this year. While we continue to view our preventive vaccine (GOVX-B11) as critical to the initiative to eradicate HIV/AIDS, advancing this program into a definitive clinical program can only occur through the support of NIH/HVTN. Despite the promising results that we’ve demonstrated over many years, we continue to be frustrated by the slow pace of funding progress relative to advancing GOVX-B11 into a pivotal, clinical program. Nonetheless, this program continues to move forward in human clinical trials.
- New Collaborations – New Opportunities, Challenging Needs for Funding.** In previous communications, we’ve highlighted various and promising new collaborations such as working with the Burnet Institute in Australia on our malaria vaccine program and with Georgia State University on our Hepatitis B immunotherapy program. We also added new collaborations with Scripps Research, Institute of Human Virology, and the Geneva Foundation for our Lassa Fever program; and with Enesi Pharma for developing a novel vaccine delivery platform utilizing several of our vaccines. Recently, we expanded our relationship with Leidos, Inc., adding a malaria program to our existing cancer collaboration. These collaborations provide multiple opportunities for success and demonstrate the high level of interest our MVA-VLP platform generates within the scientific and business development community. Still, without significant change to our capital structure, enabling us to secure the necessary capital, we won’t be able to advance any promising programs, especially those related to immuno-oncology, into human evaluation and use.

- **Scientific and Peer Recognition.** Despite our capital situation, the GeoVax team remains fully committed to developing novel, patented vaccines that have the potential to reduce infectious disease risks and provide critical immunotherapies worldwide. With a team of less than 10 individuals, some receiving reduced or no salary, their accomplishments and contributions are most impressive. All of us should be honored that our accomplishments were recognized through GeoVax’s selection for the 2018 “Best Biotech” Vaccine Industry Excellence (VIE) Award, and as a finalist for the “Best Prophylactic Vaccine” for our Zika vaccine candidate at the 18th World Vaccine Congress in Washington DC, as well as a finalist for 2018 Pipelines of Promise at the Buzz of BIO in Boston. In 2019, GeoVax was selected as a finalist in two categories for this year’s VIE Awards, at the 19th World Vaccine Congress -- for the “Best Therapeutic Vaccine Award” (MVA-VLP-MUC1 cancer) and “Best New Vaccine Technology Award” (MVA-VLP platform). This now marks two years in a row of recognition by industry peers of our continued progress in applying our expertise and technology to advance highly promising vaccines for the benefit of people worldwide. This recognition was achieved by probably the smallest, most underfunded vaccine development team in the industry, a team that knows no bounds relative to their commitment to excellence in vaccine development.

In summary, to achieve material improvement in GeoVax’s financial status, we will have to successfully pursue non-traditional paths, outside of traditional financing and capital development. We all are disappointed in the current financial status of the Company. Regardless, our primary commitment is to identify a path to achieving clinical development within our strategic area of focus, immuno-oncology. We believe that this can lead to a significantly improved company valuation, providing the basis for continued progress. We will continue to communicate regarding our progress, successes and disappointments, while we focus on improving the financial status and outlook of the Company. Thank you.

Sincerely,



David A. Dodd
President & CEO

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this document are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act. 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. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from those included in these statements due to a variety of factors, including whether: GeoVax raises required capital to enter into human clinical trials, complete vaccine development, or otherwise continue in business, GeoVax's ability to obtain and satisfy the requirements of existing and future government grants, GeoVax's promising results in the area of immuno-oncology will lead to additional developments permitting it to reach its goals, 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 collaborations, strategic partnerships, manufacturing or distribution agreements, GeoVax will be able to maintain its key employees, and other factors, over which GeoVax has no control. GeoVax assumes no obligation to update these forward-looking statements and does not intend to do so. More information about these factors is

contained in GeoVax's filings with the Securities and Exchange Commission including those set forth at "Risk Factors" in GeoVax's Form 10-K.