

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 14, 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 2.02 Results of Operations and Financial Condition

On August 14, 2019 we issued a press release reporting our results of operations for the quarter ended June 30, 2019. A copy of the press release is attached to this Current Report.

Item 9.01 Financial Statements and Exhibits

Exhibit 99.1 Press Release, dated August 14, 2019

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 14, 2019

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports 2019 Second Quarter Financial Results and Highlights Corporate Development Progress

ATLANTA, GA, August 14, 2019 – GeoVax Labs, Inc. (OTCQB: GOVX), a biotechnology company developing human immunotherapies and vaccines, today announced its financial results for the quarter ended June 30, 2019 and provided an update on its corporate development progress.

David A. Dodd, GeoVax President and CEO, commented, “Despite our limited financial resources, during the first half of 2019, we made progress in several product development areas. These accomplishments were made possible through the efforts of our dedicated staff as well as through the support of our various government and corporate collaborators. I am pleased to share some of our notable progress below.”

- **Cancer Immunotherapy** – We continued our work with Leidos, Inc. to evaluate delivery of Leidos’ novel PD-1 checkpoint inhibitors with the GeoVax MVA-VLP platform for multiple immunotherapeutic vaccine candidates. This collaboration adds to our overall immuno-oncology program, expanding our footprint in this space. To date, in humanized mice models evaluating our MUC-1 vaccine, we have demonstrated significant tumor reduction, as well as tumor growth prevention. Immuno-oncology represents an area of significant medical need and our results thus far have been highly promising. We believe immuno-oncology to be a key component to potentially strengthening the valuation of GeoVax and providing future value growth opportunity.
- **Malaria Vaccine** – We expanded our relationship with Leidos to include development of malaria vaccine candidates supported under a contract to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP).
- **Lassa Fever Vaccine** – We continued our progress in this program with support from a U.S. Department of Defense grant to advance our vaccine through nonhuman primate testing and manufacturing process development in preparation for human clinical trials.
- **Ebola and Marburg Vaccines** – Hemorrhagic fever viruses are a continuing health threat from both the endemic and bioterrorism perspectives, exemplified by the World Health Organization’s recent declaration of the current Ebola outbreak in the Democratic Republic of the Congo as a global health emergency. Our Ebola and Marburg vaccines have each demonstrated 100% preclinical protection, and have economical cold chain requirements, all critical attributes for such vaccines and their implementation. This is why we have recently offered these vaccines (beginning with Ebola) to public health agencies worldwide, contingent on their funding the advancement into clinical development and human use.
- **HIV Preventive Vaccine** – We are progressing to the next stage of human clinical testing with support from the HIV Vaccine Trials Network (HVTN) and funding from the National Institute of Allergy and Infectious Diseases (NIAID). The timing of the next study (HVTN 132) is uncertain, dependent upon clarification of components other than our vaccine, but we expect that HVTN will begin the study in 2020.
- **HIV “Cure” Program**; 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, is on track to enter human clinical trials sponsored by AGT before the end of 2019. We also are continuing discussions with another consortium for the use of our vaccine in similar efforts toward developing a cure for HIV infection.
- **Joint Development Collaborations** – In addition to the new collaboration with Leidos mentioned above, we also began a collaboration with Enesi Pharma related to their novel, needle-free ImplavaX® device. We expect this program to result in development of thermostable solid-dose needle-free vaccines for a variety of infectious diseases. We continue to engage in promising discussions related to additional joint development collaborations for new or existing programs.

MORE

Mr. Dodd continued, “GeoVax remains highly undercapitalized which constrains our ability to advance our non-HIV programs toward human clinical trials, which we believe is key to furthering our corporate development. During July, we bolstered our cash reserves through a \$700,000 infusion of additional equity capital. While this provides us with sufficient working capital into early 2020, it does not allow us to pursue our product development as vigorously as we would like. During the coming months, we intend to continue pursuing additional sources of capital, both through additional collaborations and through non-traditional paths, with a primary focus on our cancer immunotherapy program.”

Financial Review

GeoVax reported a net loss of \$654,148 (\$1.01 per share) for the three months ended June 30, 2019, compared to \$637,043 (\$2.05 per share) for the same period in 2018. For the six months ended June 30, 2019, the Company’s net loss was \$1,355,602 (\$2.37 per share) as compared to \$1,258,856 (\$4.50 per share) in 2018.

The Company reported grant and collaboration revenues of \$209,941 and \$574,173 for the three-month and six-month periods of 2019, respectively, as compared to \$93,265 and \$314,564 reported for the comparable periods of 2018. As of June 30, 2019, there is \$2,049,990 in approved grant funds remaining and available for use.

Research and development (R&D) expenses were \$451,227 and \$1,006,945 for the three-month and six-month periods of 2019, respectively, as compared to \$372,202 and \$859,196 for the comparable periods of 2018. Fluctuations in R&D expenses from period to period are primarily attributable to the timing of expenditures related to government grants. General and administrative (G&A) expenses were \$412,650 and \$922,714 for the three-month and six-month periods of 2019, respectively, as compared to \$359,197 and \$716,425 for the comparable periods of 2018.

GeoVax reported cash balances of \$216,411 at June 30, 2019, as compared to \$259,701 at December 31, 2018. The Company reported the sale of convertible preferred stock in July 2019 for gross proceeds of \$700,000, giving it sufficient cash resources to fund its current operations into the first quarter of 2020. Summarized financial information is attached. Further information concerning the Company’s financial position and results of operations are included in its Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission.

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

MORE

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.

Forward-Looking Statements

Certain statements in this document are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act. 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 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. 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.

Contact:

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

FINANCIAL TABLES FOLLOW

MORE

GEOVAX LABS, INC.
Condensed Consolidated Statements of Operations Information
(amounts in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Grant and collaboration revenue	\$ 210	\$ 93	\$ 574	\$ 315
Operating expenses:				
Research and development	451	372	1,007	859
General and administrative	413	359	923	717
	864	731	1,930	1,576
Loss from operations	(654)	(638)	(1,356)	(1,261)
Other income (expense), net	-	1	-	2
Net loss	\$ (654)	\$ (637)	\$ (1,356)	\$ (1,259)
Loss per common share	\$ (1.01)	\$ (2.05)	\$ (2.37)	\$ (4.50)

GEOVAX LABS, INC.
Condensed Consolidated Balance Sheet Information
(amounts in thousands)

	June 30, 2019	Dec. 31, 2018
Assets:		
Cash and cash equivalents	\$ 216	\$ 260
Other current assets	104	360
Total current assets	320	620
Property, net	12	11
Other assets	11	11
Total assets	\$ 343	\$ 642
Liabilities and stockholders' equity (deficiency)		
Current liabilities	\$ 1,639	\$ 1,624
Note payable, net of current portion	32	40
Stockholders' equity (deficiency)	(1,328)	(1,022)
Total liabilities and stockholders' equity (deficiency)	\$ 343	\$ 642
Common shares outstanding	814	438

###

MORE