



*Source: GeoVax, Inc.*

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## **GeoVax Reports 2021 Second Quarter Financial Results and Provides Corporate Update**

### ***Continued Progress on COVID-19 and Immuno-Oncology Programs***

ATLANTA, GA, Aug. 11, 2021 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers, today announced its financial results for the quarter ended June 30, 2021.

GeoVax's management will host a live conference call and webcast at 4:30 p.m. Eastern Standard Time on Wednesday, August 11 to discuss financial results and provide a general business update. Details are provided below.

### **2021 YTD Highlights and Development Program Status Update**

**COVID-19 Vaccine** – GeoVax's SARS-CoV-2 (COVID-19) vaccine is based on its GV-MVA-VLP™ technology, which enables insertion of multiple antigen fragments, potentially allowing for broad-spectrum virus prevention. Unlike other vaccines that target only the COVID-19 spike protein, the Company's vaccines are designed to provoke a response to multiple COVID-19 antigens, which means they could be less susceptible to viral mutations. The Company's vaccines 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. GeoVax believes a critical and significant opportunity exists for a pan-coronavirus vaccine with the attributes the GV-MVA-VLP technology can offer.

In January 2021, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), awarded GeoVax a Small Business Innovative Research (SBIR) grant for development of a COVID-19 vaccine. The Phase 1 grant, titled, "Preclinical Development of GV-MVA-VLP Vaccines Against COVID-19," supports the ongoing design, construction, and preclinical testing of GeoVax's vaccine candidates in preparation for human clinical trials.

Small animal studies are continuing and results to date support the Company's approach of using MVA as a vector for the design and production of "next-generation" vaccines encoding multiple proteins. Details of the studies will be presented on August 19 during the European Society of Medicine (ESMED) General Assembly. Based on the encouraging results, the Company recently submitted an application to NIAID for additional support for advanced testing.

**Cancer Immunotherapy** – GeoVax's cancer immunotherapy program is based on the concept of combining a tumor-associated antigen vaccine with a potent anti-tumor agent, such as an Immune Checkpoint Inhibitor ("ICI"), with the goal of achieving regression of tumor growth and development. In February 2021, the Company filed a U.S. patent application, covering updates to its MVA viral vector technology to amplify an immune response to a cancer antigen via vaccination, which could strengthen the Company's intellectual property position in this space. Immuno-oncology is an important focus area for the Company, and GeoVax is engaging with multiple collaborators. The initial animal studies, based upon a GeoVax-MUC1 vaccine/ICI combination, have been encouraging and additional studies are being planned with the goal of expanding the overall cancer immunotherapy program. The Company expects to provide further details on its progress and plans to advance to human clinical testing in the near future.

**Lassa Fever** – Progress continues using grant funding from the U.S. Department of Defense for the Company's Lassa Fever (LASV) vaccine program. The project award supports generation of immunogenicity and efficacy data for GeoVax's vaccine candidate in both rodent and nonhuman primate models, as well as manufacturing

process development and cGMP production of vaccine seed stock in preparation for human clinical trials. This work is in collaboration with U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation. Technical issues associated with the manufacturing process combined with the limited availability of nonhuman primates have resulted in delays to this program, but the work is advancing and results are now expected to be available in late 2021 or early 2022.

Sudan ebolavirus and Marburg virus – In July 2021, GeoVax announced results of preclinical efficacy studies of its Sudan ebolavirus (SUDV) vaccine candidate (MVA-VLP-SUDV). Immunogenicity and efficacy of MVA-VLP-SUDV were tested in a guinea pig lethal challenge model, in which a single intramuscular dose of the GeoVax vaccine protected 100% of animals challenged with a lethal dose of SUDV. A comparison between prime and prime-boost vaccinations of guinea pigs showed that both regimens elicited SUDV-specific binding and neutralizing antibody responses, and that the second immunization enhanced these responses. Challenge of vaccinated animals with guinea pig-adapted SUDV demonstrated complete protection against death and disease by the prime and the prime-boost regimens. This is the first report that a replication-deficient MVA vector may confer full protection against SUDV after a single dose. This work was conducted in collaboration with researchers at the University of Texas Medical Branch (UTMB).

Separately, GeoVax is leading a multi-party collaboration for the development of its (SUDV) and Marburg virus (MARV) vaccine candidates. The collaboration, between GeoVax, researchers at UTMB and Battelle Memorial Institute, utilizes the suite of preclinical services from NIAID. Under the collaboration, GeoVax's SUDV and MARV vaccine candidates are being tested for immunogenicity and efficacy in the benchmark nonhuman primate model. This work builds upon earlier studies in rodents and nonhuman primates for the Company's Ebola virus (EBOV) vaccine candidate that demonstrated 100% protection against a lethal dose of EBOV following a single immunization. The Company expects to announce additional results during the second half of 2021.

Malaria Vaccine – Exploratory studies in collaboration with the Burnet Institute in Australia and Leidos, Inc. have been encouraging. We continue to evaluate advancing this program into formal product development since a Malaria vaccine is not currently a product development initiative.

HIV Vaccine Programs – NIAID has funded multiple clinical trials of GeoVax's HIV preventive vaccine (GOVX-B11) through the HIV Vaccine Trials Network (HVTN). The next planned trial (HVTN 132) is designed to further evaluate the safety and immunogenicity of adding "protein boost" components to the GOVX-B11 vaccination regimen. The start of HVTN 132 has been delayed due to COVID-19, and the Company awaits further information from NIAID and HVTN on when the trial may commence. The Company is also part of efforts to develop a combination therapy to induce remission in HIV-positive individuals (a "functional cure"). In August 2020, a consortium led by researchers at the University of California, San Francisco (UCSF) began enrolling patients in a Phase 1 human clinical trial using our vaccine as part of a combination therapy intended to induce remission in HIV-positive individuals. Similar to HVTN 132, this trial has been affected by the pandemic, so we await further information regarding the status of patient enrollment and trial results. Our prior collaboration with American Gene Technologies International, Inc. (AGT) was recently discontinued due to AGT's remodeling of their clinical trial plans, but the Company remains open to additional collaborations.

Intellectual Property – In February 2021, GeoVax filed international and U.S. patent applications in our key focus areas of SARS-CoV-2 (COVID-19) and cancer immunotherapy, and in July 2021 the Company announced the issuance of a U.S. patent covering our Hepatitis B vaccine. Following these filings, GeoVax's wholly owned, co-owned, and in-licensed intellectual property portfolio now stands at over 70 granted or pending patent applications spread over 20 patent families.

## **Management Commentary**

David Dodd, GeoVax's Chairman and CEO, commented, "We remain enthusiastic about our development programs and expect several data announcements in the forthcoming weeks and months, most notably in our program areas of COVID-19, Lassa Fever virus, Sudan/Marburg virus and immuno-oncology. As with many other companies, the continuing COVID-19 pandemic has affected the timelines for some of our programs, most notably our HIV program. In addition, third-party technical disruptions have resulted in delays in completing various contracted animal studies. I look forward to sharing news of our progress as those studies are completed and other events occur. We remain encouraged and focused on completing these studies as soon as possible and announcing the various results.

"With our funding events from 2020 and early 2021, we are well-positioned to advance several of our development programs, with a continued focus on our COVID-19 vaccine and our cancer immunotherapy programs. The additional capital is allowing us to make infrastructure and personnel investments, as well as funding commitments in support of other programs, including manufacturing process development with a view toward cost-effective, large-scale production for clinical and commercial distribution. Our focus and goal is to advance into clinical development both within the areas of infectious diseases and immuno-oncology, providing significant potential growth in value for our shareholders while providing new vaccines and therapies for critical areas of health worldwide," concluded Mr. Dodd.

## Financial Review

GeoVax reported a net loss of \$1,314,033 (\$0.21 per share) for the three months ended June 30, 2021, compared to a net loss of \$455,204 (\$0.66 per share) for the same period in 2020. For the six months ended June 30, 2021, the Company's net loss was \$2,876,811 (\$0.49 per share) as compared to a net loss of \$1,050,898 (\$2.27 per share) in 2020.

Grant and collaboration revenues were \$79,708 and \$190,125 for the three-month and six-month periods of 2021, respectively, as compared to \$440,602 and \$1,156,579 reported for the comparable periods of 2020. The 2021 period reflects amounts related to our grant from NIH in support of our COVID-19 vaccine program, while the 2020 period reflects amounts related to our grant from the U.S. Department of Defense (DoD) for our Lassa Fever vaccine and our collaboration with Leidos, Inc. for its malaria vaccine program. As of June 30, 2021, there is \$275,302 of approved funds remaining and available for use related to the COVID-19 and Lassa Fever grants.

Research and development expenses were \$832,835 and \$1,435,618 for the three-month and six-month periods of 2021, respectively, as compared to \$461,421 and \$1,270,357 for the comparable periods of 2020, with the increases primarily related to our COVID-19 vaccine program, manufacturing process development, and a generally higher level of activity, offset in part by the timing and amount of external expenditures related to our government grants. General and administrative expenses were \$733,499 and \$1,805,209 for the three-month and six-month periods of 2021, respectively, as compared to \$427,292 and \$929,637 for the comparable periods of 2020, with the increase primarily attributable to higher Delaware franchise taxes; legal, accounting and patent costs; insurance costs; consulting fees; Nasdaq listing fees; investor relations costs; and personnel costs.

Other income (expense) was \$172,593 and \$173,891 for the three-month and six-month periods of 2021, respectively, as compared to \$(7,093) and \$(7,483) for the comparable periods of 2020. The 2021 periods include a \$172,056 gain on extinguishment of debt, reflecting forgiveness of the Company's loan pursuant to the Paycheck Protection Program.

GeoVax reported cash balances of \$19.5 million at June 30, 2021, as compared to \$9.9 million at December 31, 2020. Contributing to the increase in cash balances were net proceeds of \$9.4 million from the sale of 1,644,000 shares of common stock, and \$3.2 million from the exercise of warrants to purchase 690,034 shares of common stock.

Summarized financial information is included below. 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.

## Conference Call

Management will host a conference call at 4:30 p.m. ET on Wednesday, August 11, 2021 to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question and answer session.

Participants are asked to register for the call via the following link: <https://dpregrister.com/sreg/10159241/ebf4d52ffa>

Please note that registered participants will receive their dial-in number upon registration and will dial directly into the call without delay. Those without Internet access or who are unable to pre-register may dial in by calling 1-866-777-2509 (domestic) or 1-412-317-5413 (international). All callers should dial in approximately 10 minutes prior to the scheduled start time and ask to be joined into the GeoVax Labs call.

The conference call will be available through a live webcast found here: <https://services.choruscall.com/mediaframe/webcast.html?webcastid=xxw5fkQ6>

A webcast replay of the call will be available via the same link as the live webcast approximately one hour after the end of the call through November 11, 2021. A telephonic replay of the call can be accessed by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10159241. The telephonic replay will be available until August 25, 2021.

## 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, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), HIV, 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 a separate collaborative effort to apply its vaccine approach toward a functional cure for HIV.

### **Forward-Looking Statements**

*This release and the related conference call contain forward-looking statements regarding GeoVax's business plans and financial results. The words "believe," "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 and its collaborators are able to complete their work within the expected timeframes, GeoVax is able to obtain the patent protection sought, GeoVax's COVID-19 vaccines can provoke responses to multiple COVID-19 antigens, and those vaccines can be used effectively as a primary or booster to other COVID-19 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, the impact of the COVID-19 pandemic continues, 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 law.*

### **Contact:**

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

## **FINANCIAL TABLES FOLLOW**

### **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,         |          |
|                                 | 2021               | 2020   | 2021             | 2020     |
| Grant and collaboration revenue | \$ 80              | \$ 441 | \$ 190           | \$ 1,157 |
| Operating expenses:             |                    |        |                  |          |
| Research and development        | 833                | 462    | 1,436            | 1,270    |

|                             |                   |                  |                   |                   |
|-----------------------------|-------------------|------------------|-------------------|-------------------|
| General and administrative  | 733               | 427              | 1,805             | 930               |
|                             | <u>1,566</u>      | <u>889</u>       | <u>3,241</u>      | <u>2,200</u>      |
| Loss from operations        | (1,486)           | (448)            | (3,051)           | (1,043)           |
| Other income (expense), net | 172               | (7)              | 174               | (8)               |
|                             | <u>\$ (1,314)</u> | <u>\$ (455)</u>  | <u>\$ (2,877)</u> | <u>\$ (1,051)</u> |
| Net loss                    |                   |                  |                   |                   |
|                             | <u>\$ (0.21)</u>  | <u>\$ (0.66)</u> | <u>\$ (0.49)</u>  | <u>\$ (2.27)</u>  |
| Loss per common share       |                   |                  |                   |                   |

### Condensed Consolidated Balance Sheet Information

(amounts in thousands)

|  | June 30,<br>2021 | Dec. 31,<br>2020 |
|--|------------------|------------------|
| Assets:                                    |                  |                  |
| Cash and cash equivalents                  | \$ 19,539        | \$ 9,884         |
| Other current assets                       | 118              | 351              |
| Total current assets                       | <u>19,657</u>    | <u>10,235</u>    |
| Property and other assets, net             | 160              | 159              |
| Total assets                               | <u>\$ 19,817</u> | <u>\$ 10,394</u> |
| Liabilities and stockholders' equity       |                  |                  |
| Total liabilities                          | \$ 359           | \$ 825           |
| Stockholders' equity                       | 19,458           | 9,569            |
| Total liabilities and stockholders' equity | <u>\$ 19,817</u> | <u>\$ 10,394</u> |
| Common Shares Outstanding                  | 6,328            | 3,834            |