

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): March 23, 2023

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.

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 “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 March 23, 2023, GeoVax Labs, Inc. (the “Company”) issued a press release reporting its results of operations for the year ended December 31, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 23, 2023
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: March 24, 2023

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds _____

Mark W. Reynolds
Chief Financial Officer



GeoVax Reports 2022 Year-End Financial Results And Provides Corporate Update

Company Expands Ongoing Clinical Trials and the Breadth and Capacity of Its Novel Vaccine Platform Technology

Atlanta, GA, March 23, 2023 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced its financial results and key operational accomplishments for the year ended December 31, 2022.

GeoVax’s leadership will host a live conference call and webcast at 4:30 p.m. Eastern Time today, March 23, 2023, to discuss financial results and provide a general business update. Details are provided below.

2022 CLINICAL TRIAL PROGRESS AND OPERATIONAL DEVELOPMENTS

“Our corporate focus continues to be on the advancement of our ongoing clinical programs for our novel Gedeptin® cancer therapy targeting advanced head & neck cancers and, our SARS-CoV-2/Covid19 vaccine, stated David Dodd, GeoVax’s Chairman and CEO. “To that end, we have expanded to additional clinical sites and are accelerating patient enrollment for both programs, as noted in this update. We look forward to reporting milestone progress on these trials during the remainder of 2023.”

Dodd continued, “We are also delighted to have advanced our GeoVax MVA-VLP-MUC1 immuno-oncology candidate into IND-supportive studies. Thus far, the results from these studies are encouraging. We also secured rights to NIH-MVA technology for further development and commercial use against Monkeypox (MPox) and Smallpox viruses, which provides a compelling opportunity to leverage our MVA-based vaccine expertise and help expand the global public health supply options available for this ongoing worldwide public health threat. Our intent is to be the first U.S.-based, primary supplier of a MVA-vaccine against Mpox and Smallpox.”

Dodd concluded, “We recently announced important progress toward developing a high-yield, high-capacity, avian cell line system for manufacturing MVA-based vaccines. Developing such a process will be nothing short of transformational – for GeoVax, biomedicine, and public health worldwide. By advancing our MVA manufacturing to a modern, interchangeable process, we are on course to expand MVA applications from stockpile-based solutions for niche medical markets to have the capability to respond to world needs on a timely basis. This well positions us to potentially become the first US-based supplier of the MVA vaccine to prevent MPox, Smallpox, and other pox-related viruses. Finally, during a very difficult year for biotech capital development, with many companies furloughing programs and staff, GeoVax successfully strengthened our capital base in support of expanding and accelerating our growth and development programs. We have entered 2023 well positioned and capable of achieving our clinical and other business goals and milestones.”

GEDEPTIN® FOR ADVANCED HEAD AND NECK CANCER – PHASE 2 TRIAL EXPANSION

An ongoing Phase 1/2 trial (ClinicalTrials.gov Identifier: [NCT03754933](https://clinicaltrials.gov/ct2/show/study/NCT03754933)) is evaluating the safety and efficacy of repeat cycles of Gedeptin® therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options.

Gedeptin® is a novel patented product/technology for the treatment of solid tumors through a gene therapy strategy known as Gene-Directed Enzyme Prodrug Therapy (GDEPT). In GDEPT, a vector is used to selectively transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a very toxic antitumor compound *in situ*. A Phase 1 dose-ranging study, evaluating the safety of a single cycle of Gedeptin® therapy, found the therapy well-tolerated, with evidence of a reduction in tumor size in patients with solid tumors.

In February 2023, GeoVax announced the expansion of the Gedeptin® Phase 1/2 trial with patients actively enrolling at National Cancer Institute (NCI) designated Cancer Centers – Stanford University Cancer Institute, Emory University Winship Cancer Institute, and the Thomas Jefferson University Sidney Kimmel Cancer Center. Funded in part by the US

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Food & Drug Administration (FDA) under its Orphan Products Clinical Trials Grants Program, the trial will guide the design of a larger study that also may involve patients with other anatomically accessible oral and pharyngeal cancers. Additionally, it may lead to labeling discussions with the FDA and initiation of further Gedeptin® investigations, including in combination with immune checkpoint inhibitors for other cancerous and non-cancerous tumor indications.

SARS-CoV-2 VACCINES – TWO PHASE 2 CLINICAL TRIALS PROGRESSING

GEO-CM04S1 is a next-generation Covid-19 vaccine that expresses spike and nucleocapsid antigens of the SARS-CoV-2 (COVID-19) virus. GEO-CM04S1 continues to advance in two Phase 2 clinical studies, one as a primary vaccine for immunocompromised cancer patients, in direct comparison to either the Pfizer or Moderna mRNA vaccine (ClinicalTrials.gov Identifier: [NCT04977024](#)), and the second as a booster for healthy patients who have previously received either the Pfizer or Moderna vaccine as their initial inoculation (ClinicalTrials.gov Identifier: [NCT04639466](#)).

Two 2022 peer-reviewed publications in *The Lancet Microbe* (accessible [here](#)) and *iScience* (accessible [here](#)) report data from the Phase 1 study of GEO-CM04S1 showing robust neutralizing antibodies and T cells against SARS-CoV-2, including the Omicron and Delta variants. These data confirm the powerful dual action of the GeoVax vaccine, an important feature given the multiple mutations, leading to variants of concern and inconsistent protection from existing FDA-authorized vaccines. These findings suggest that T cell immunity stimulated by GEO-CM04S1 may constitute a critical second line of defense to provide long-term protection against SARS-CoV-2 variants among the population in general as well as among the 15 million patients in the US with compromised immune systems. Additionally, a recent article, published in the *New England Journal of Medicine* (accessible [here](#)) addressed the critical importance of addressing both antibodies and T cells in achieving protection against SARS-CoV-2.

MODIFIED VACCINIA ANKARA (MVA) & MONKEYPOX (MPOX)

MVA is the vaccine currently used and stockpiled in the US Strategic National Stockpile for immunization against the MPox and Smallpox viruses. GeoVax previously demonstrated that an experimental HIV vaccine, utilizing NIH-MVA as the vaccine vector, protected non-human primates challenged with a lethal dose of the MPox virus (publication accessible [here](#)). Further, in August 2022, City of Hope, which originally developed GEO-CM04S1, published results demonstrating that both their proprietary sMVA (synthetic MVA) and GEO-CM04S1 (referred to as “COH04S1” in the publication, accessible [here](#)) elicited robust orthopoxvirus-specific binding and neutralizing antibody responses. The authors conclude that GEO-CM04S1 and sMVA represent unique vaccine candidates to control the unforeseen global MPox outbreak.

In response to the global need to address the continued emerging threat from MPox and the unique opportunity offered by MVA-based vaccines, GeoVax secured rights from the NIH covering preclinical, clinical and commercial uses of the NIH-MVA against MPox or Smallpox viruses. The Company is now evaluating development and regulatory pathways towards expanding the public health options available to reduce and manage the risk of MPox worldwide with the intent to be the first U.S.-based supplier of a MVA-vaccine against MPox and Smallpox.

MVA MANUFACTURING PROCESS DEVELOPMENTS

In February 2023, GeoVax announced significant progress in developing a high-yield, high-capacity, continuous avian cell line system for manufacturing its MVA-based vaccines and immunotherapies. Currently, MVA vaccines are manufactured in cells cultured from chicken embryonic fibroblasts (CEF), a suboptimal and time-consuming process useful primarily for niche markets and stockpile reserves. Now, after exploring various approaches to growing MVA in continuous cell lines in bioreactors more suitable for high-yield, commercial-scale manufacturing, GeoVax will accelerate activities towards fully implementing a proprietary, continuous cell line manufacturing system that will provide lower-cost, scalable versatility for broad MVA vaccine and immunotherapy applications.

OTHER NOTABLE DEVELOPMENTS

In July 2022, GeoVax announced the publication of a peer-reviewed animal efficacy study of its MVA vectored vaccine against Sudan ebolavirus (SUDV) in *Nature Partner Journals (NPJ) Vaccines* (accessible [here](#)). The anticipated final stage of preclinical testing involving nonhuman primates has recently been completed and results are expected to be discussed during upcoming scientific conferences during the fourth quarter of this year.

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In January 2023, GeoVax announced that the US Patent and Trademark Office issued a Notice of Allowance for Patent Application No. 17/000,768 titled, “*Method for Generating a ZIKV Immune Response Utilizing a Recombinant Modified Vaccinia Ankara Vector Encoding the NS1 Protein.*” Preclinical studies demonstrated that a single dose of GEO-ZM02 provided 100% protection against a lethal dose of the Zika virus.

LEADERSHIP AND CAPITAL RESOURCES STRENGTHENED

During 2022, GeoVax strengthened its organizational and operational leadership team with appointments to several areas, including Kelly T. McKee, Jr., M.D., M.P.H. as Chief Medical Officer; Jeffrey Welch as Head, Process Development and Manufacturing Operations; John W. Sharkey, Ph.D. as Vice President, Business Development; Mark J. Newman, Ph.D. as full-time Chief Scientific Officer; the appointment of two new members to the GeoVax Board of Directors – Nicole Lemerond and Jayne Morgan, M.D.; and the appointment of Valerie Montgomery Rice, M.D., FACOG, President and CEO of Morehouse School of Medicine, to serve as a special advisor to the GeoVax Board of Directors.

During 2022, GeoVax added to its cash resources through offerings of common stock and exercises of warrants with combined net proceeds of approximately \$35.4 million. GeoVax’s cash balances at December 31, 2022 stood at \$27.6 million.

FINANCIAL REVIEW

Net loss for the year ended December 31, 2022, was \$14.0 million, as compared to \$18.6 million for the year ended December 31, 2021.

Research and development (R&D) expenses were \$9.1 million for 2022, as compared to \$15.6 million in 2021. Research and development expense for 2021 includes \$12.3 million of one-time license fees and other costs related to technology licensing agreements; excluding these costs, research and development expense increased by \$5.9 million from 2021 to 2022. The increase during 2022 relates primarily to higher personnel and consulting costs, costs of conducting clinical trials for GEO-CM04S1 and Gedeptin, costs of manufacturing materials for use in clinical trials, and a generally higher level of activity.

General and administrative expenses were \$5.0 million for 2022, as compared to \$3.6 million in 2021, with the increase primarily attributable to higher personnel and consulting costs, patent costs, investor relations costs, and travel expenses.

GeoVax reported cash balances of \$27.6 million at December 31, 2022, as compared to \$11.4 million at December 31, 2021. Contributing to the increase in cash balances were aggregate net proceeds of \$27.7 million from equity transactions during January and May 2022, and \$7.6 million from the exercise of warrants during August 2022.

Summarized financial information is attached. Further information concerning the Company’s financial position and results of operations are included in its Annual Report on Form 10-K filed with the Securities and Exchange Commission.

CONFERENCE CALL

Management will host a conference call, scheduled to begin at 4:30 p.m. Eastern Time today, March 23, 2023, to review financial results and provide an update on corporate developments. Following management’s formal remarks, there will be a question-and-answer session.

Domestic: 877-269-7756
International: 201-689-7817
Conference ID: 13736454
Webcast: [GeoVax 2022 Earnings Webcast](#)

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 June 23, 2023.

About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing novel therapies and vaccines for cancers and many of the world’s most threatening infectious diseases. The company’s lead program in oncology is a novel oncolytic

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solid tumor gene-directed therapy, Gedeptin[®], presently in a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. GeoVax's lead infectious disease candidate is GEO-CM04S1, a next-generation COVID-19 vaccine targeting high-risk immunocompromised patient populations. Currently in two Phase 2 clinical trials, GEO-CM04S1 is being evaluated as a COVID-19 vaccine for immunocompromised patients such as those suffering from hematologic cancers and other patient populations for whom the current authorized COVID-19 vaccines are insufficient. In addition, GEO-CM04S1 is in a Phase 2 clinical trial evaluating the vaccine as a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines. GeoVax has a leadership team who have driven significant value creation across multiple life science companies over the past several decades. For more information, 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 preventative 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 preventative vaccines with the desired characteristics in a timely manner, GeoVax's immuno-oncology products and preventative vaccines will be safe for human use, GeoVax's vaccines will effectively prevent targeted infections in humans, GeoVax's immuno-oncology products and preventative 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 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.

Investor Relations Contact:

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FINANCIAL TABLES FOLLOW

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

	Year Ended	
	December 31,	
	2022	2021
Grant revenue	\$ 81	\$ 385
Operating expenses:		
Research and development	9,123	15,554
General and administrative	4,987	3,577
	<u>14,110</u>	<u>19,131</u>
Loss from operations	(14,029)	(18,746)
Other income (expense), net	7	176
Net loss	<u>\$ (14,021)</u>	<u>\$ (18,570)</u>
Net loss per common share	<u>\$ (0.83)</u>	<u>\$ (3.04)</u>
Weighted average shares outstanding	16,973,194	6,099,933

Condensed Consolidated Balance Sheet Information
(amounts in thousands, except common share information)

	December 31,	
	2022	2021
Assets:		
Cash and cash equivalents	\$ 27,613	\$ 11,424
Other current assets	1,326	205
Total current assets	<u>28,939</u>	<u>11,629</u>
Property and other assets	2,409	168
Total assets	<u>\$ 31,348</u>	<u>\$ 11,797</u>
Liabilities and stockholders' equity		
Total liabilities	\$ 4,748	\$ 7,435
Stockholders' equity	26,600	4,362
Total liabilities and stockholders' equity	<u>\$ 31,348</u>	<u>\$ 11,797</u>
Common Shares Outstanding	26,334,953	6,381,541

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