

**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**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 9, 2022**

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**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 9, 2022, GeoVax Labs, Inc. (the “Company”) issued a press release reporting its results of operations for the year ended December 31, 2021. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

### Item 7.01 Regulation FD Disclosure.

On March 9, 2022, the Company hosted a conference call and webcast with accompanying slides regarding its results of operations for the year ended December 31, 2021. A transcript of the conference call and a copy of the slides are being furnished as Exhibit 99.2 and Exhibit 99.3, respectively, to this Current Report on Form 8-K. The foregoing summary of the conference call and of the slides is not complete and is qualified in its entirety by reference to the full text of Exhibit 99.2 and Exhibit 99.3. The Company undertakes no obligation to update, supplement or amend the materials attached hereto.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2 and 99.3, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 9, 2022
99.2	Conference Call Transcript dated March 9, 2022
99.3	Conference Call Slide Presentation dated March 9, 2022
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 10, 2022

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds \_\_\_\_\_

Mark W. Reynolds  
Chief Financial Officer



## **GeoVax Reports 2021 Year-End Financial Results And Provides Corporate Update**

### *Advancing Phase 2 Clinical Trials for COVID-19 and Immuno-Oncology*

**ATLANTA, GA, March 9, 2022** – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancer, today announced its financial results for the year ended December 31, 2021 and provided an update on product development programs. GeoVax’s management will host a live conference call and webcast at 4:30 p.m. Eastern Standard Time on Wednesday, March 9 to discuss financial results and provide a general business update. Details are provided further below.

### **Two Phase 2 Clinical Trials Underway for SARS-CoV-2**

**GEO-CM04S1 for Immunocompromised Patients** – GEO-CM04S1 is being studied in an ongoing Phase 2 clinical trial (NCT04977024) to evaluate its safety and immunogenicity, compared to the Pfizer/BioNTech mRNA-based vaccine, in patients who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant or chimeric antigen receptor (CAR) T cell therapy. GEO-CM04S1 is the only COVID-19 vaccine that includes both SARS-CoV-2 spike and nucleocapsid proteins to advance to a Phase 2 trial in cancer patients. Such vaccines tend to produce an immune response quickly – in less than 14 days – with only mild side effects. The trial is also the first to compare an investigational multi-antigenic COVID-19 vaccine to the current Food and Drug Administration (FDA)-approved mRNA vaccine from Pfizer/BioNTech in people who are immunocompromised. Such patients have often shown a weak antibody response after receiving currently available COVID-19 vaccines.

**GEO-CM04S1 as a Booster Vaccine** – In December 2021, patient enrollment began for the Phase 2 portion of a Phase 1/2 trial (NCT04639466) of GEO-CM04S1, evaluating its use as a universal booster vaccine to current FDA-approved two-shot mRNA vaccines from Pfizer/BioNTech and Moderna. The completed Phase 1 portion of the trial was designed as a dose-escalation safety study in healthy individuals who had not been previously infected with SARS-CoV-2. The ongoing Phase 2 booster study includes healthy individuals who were previously fully vaccinated with either the Pfizer/BioNTech or Moderna vaccine. The dose-escalation study is designed to specifically evaluate the safety profile and immunogenicity of GEO-CM04S1 as a booster. The immunological responses measured throughout the study will include the level of SARS-CoV-2 neutralizing antibodies against SARS-CoV-2 variants of concern (VOC), including the newly identified Omicron VOC, as well as specific T-cell responses.

### **IND-Enabling Activities Progressing for Pan Coronavirus Vaccine**

**GEO-CM02 as a Pan-Coronavirus Vaccine** – First-generation SARS-CoV-2 vaccines were designed to encode the spike (S) protein of the SARS-CoV-2 virus with the goal of inducing high levels of neutralizing antibodies. However, potential limitations of narrowly focusing on the spike (S) protein are becoming apparent with emerging variants capable of partially escaping neutralization by vaccine induced antibodies. Thus, the effectiveness of these vaccines against new SARS-CoV-2 variants and future coronavirus spillover events remains of immense concern.

GeoVax’s vaccine candidate (GEO-CM02) encodes the spike (S) protein as the neutralizing antibody target as well as the membrane (M) and envelope (E) proteins as T-cell targets and to support in vivo virus-like particle formation to augment potency. This strategy may provide the basis for generating a single dose universal coronavirus vaccine. Unique compared to other vaccines approved or under development, the GeoVax vaccine candidate is therefore specifically designed to provide a broader and more durable level of protective immunity against SARS-CoV-2, which may protect against emerging variants while avoiding the potential side effects that can limit vaccine utility and acceptance. In small animal studies, the Company measured functional

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immune responses after a single dose that mediated protection from infection and pathogenesis, including protection against the more virulent Beta variant. Additional studies are planned for 2022 to prepare for IND filing and subsequent human clinical trials.

### **Phase 2 Clinical Trial Underway for Advanced Head and Neck Cancer**

**Gedepin®** – Gedepin 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 September 2021, GeoVax entered into an assignment and license agreement with PNP Therapeutics, Inc. (“PNP”), granting GeoVax exclusive rights to develop and commercialize Gedepin. The Gedepin technology was developed with funding support from the National Cancer Institute (NCI), part of the NIH. GeoVax’s license to Gedepin includes the rights to expand the use of Gedepin to all human diseases and/or conditions including, but not limited to, other cancers.

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 cycle of Gedepin therapy consists of three intra-tumoral injections of Gedepin over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days. A Phase 1 dose ranging study, evaluating the safety of a single cycle of Gedepin therapy, found the therapy to be well tolerated, with evidence of a reduction in tumor size in patients with solid tumors.

A Phase 1/2 trial (NCT03754933), evaluating the safety and efficacy of repeat cycles of Gedepin therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options, is currently enrolling at Stanford University in collaboration with Emory University. The trial design involves repeat administration using Gedepin followed by systemic fludarabine, to gain additional information prior to expansion towards a larger patient trial. The initial stage of the study is being funded by the FDA under its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedepin orphan drug status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities. In January 2022, we engaged CATO SMS, a global provider of clinical research solutions, to manage the ongoing Phase 1/2 trial and to assist with the expansion of clinical sites and acceleration of patient enrollment and evaluation.

### **IND-Enabling Activities Progressing for MUC1-based Cancer Immunotherapy**

**MVA-VLP-MUC1** – Using our GV-MVA-VLP™ vaccine platform, we are developing a cancer immunotherapy based on the abnormal, aberrantly glycosylated forms of the cell surface-associated MUC1 protein that is expressed on a wide range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung, with the goal of raising therapeutic anti-tumor antibodies and T cell responses in cancer patients. Our 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.

The initial animal studies of our MVA-VLP-MUC1 vaccine and ICI combination, have been encouraging, showing that a combination of our MVA-VLP-MUC1 vaccine candidate with a MUC1 synthetic peptide was capable of breaking tolerance to human MUC1 in transgenic mice and inducing immune responses with efficacy against challenge in a lymphoma tumor model. Our studies also demonstrated a significant reduction of the tumor burden in a mouse model for colorectal cancer.

In 2022 we plan to further these animal studies in collaboration to define the optimal course and schedule of vaccination to define a protocol that can be evaluated in a Phase 1 clinical trial.

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## Other Infectious Disease Vaccine Programs

**Hemorrhagic Fever Virus Vaccines (Ebola, Sudan, Marburg and Lassa)** – Our initial preclinical studies in rodents and nonhuman primates for our MVA-VLP-EBOV vaccine candidate have shown 100% protection against a lethal dose of EBOV upon a single immunization. Recent studies in lethal challenge guinea pig models demonstrated that GeoVax vaccines MVA-VLP-SUDV and MVA-VLP-MARV conferred 100% protection from death. These vaccines were subsequently evaluated in a rigorous cynomolgus macaque infectious challenge model. Vaccination protected nonhuman primates from viremia, weight loss and death following challenge with a dose of Sudan or Marburg virus that is lethal in nonvaccinated animals. Evaluation of immune responses following vaccination demonstrated presence of both neutralizing antibodies and functional T cells, indicating a breadth of responses that combine for optimal protection. Likewise, our initial preclinical studies in rodents for our LASV vaccine candidate have shown 100% single-dose protection against a lethal dose of LASV challenge composed of multiple strains delivered directly into the brain. The nonhuman primate studies are ongoing in collaboration with NIAID and the U.S. Army and clinical development programs will be defined based on efficacy data and global priorities as potentially dangerous outbreaks occur.

**Malaria** – We have collaborated with the Burnet Institute, a leading infectious diseases research institute in Australia, for the development of a vaccine to prevent malaria infection. The project included the design, construction, and characterization of multiple malaria vaccine candidates using GeoVax’s GV-MVA-VLP™ vaccine platform combined with malaria *Plasmodium falciparum* and *Plasmodium vivax* sequences identified by the Burnet Institute. We also collaborated separately with Leidos, Inc. with work funded by a grant to Leidos from the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP). This program has recently been inactive as we have prioritized our other development programs. However, pending additional funding support via federal grants or other sources, we may further pursue this area.

**Zika** – To address the unmet need for a vaccine against Zika virus, we are developing novel vaccine candidates constructed using our GV-MVA-VLP™ platform. MVA has an outstanding safety record, which is particularly important given the need to include women of child-bearing age and newborns among those being vaccinated. Our Zika vaccine is designed around the NS1 gene product to eliminate the risk of Antibody Dependent Enhancement (ADE), which is a serious side effect observed when a vaccinated individual does not have a fully protective immune response which causes a more virulent reaction if infected. Our initial preclinical studies in rodents using our GEO-ZM02 vaccine candidate demonstrated 100% single-dose protection against a lethal dose of ZIKV delivered directly into the brain. In rhesus macaques, vaccination with GEO-ZM02 induced immune responses that effectively controlled the virus replication despite the fact the vaccine is not designed to induce ZIKV neutralizing antibodies. Further development of our Zika vaccine will be dependent upon partnering support.

**HIV** – Due to our corporate refocusing of development efforts prioritizing our SARS-CoV-2 and cancer immunotherapy programs, and to a lack of continuing government support for our HIV vaccine development efforts, we recently decided to discontinue active development of these programs. Our technology and intellectual property in this will remain available for out-license or partnering, but we will no longer devote any corporate resources to the programs.

## Management Commentary

David Dodd, GeoVax’s Chairman and CEO, commented, “Our primary corporate focus continues to be on our COVID-19 vaccine and our cancer immunotherapy programs, and the three ongoing Phase 2 clinical trials in those areas represent the achievement of highly important goals we established at the beginning of 2021. As recently communicated in our shareholder update letter in January, our 2022 goals include the acceleration and expansion of these clinical programs focused on generating relevant data as soon as possible. To that end, we have added organizational and operational resources to support advancing through clinical development into

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regulatory registration. We look forward to providing additional updates as we make progress in these, and other, programs.”

### **Financial Review**

GeoVax reported a net loss for the year ended December 31, 2021 of \$18.6 million, as compared to \$3.0 million for the year ended December 31, 2020.

Grant and collaboration revenues were \$0.4 million for 2021, as compared to \$1.8 million in 2020. These amounts primarily relate to grants from NIAID for our Covid-19 vaccine program, and from the U.S. Department of Defense (DoD) for our Lassa Fever vaccine program. As of December 31, 2021, there were \$81,526 of approved funds remaining and available for use related to GeoVax’s grant from the DoD.

Research and development (R&D) expenses were \$15.6 million for 2021, as compared to \$2.4 million in 2020. Contributing to the year-over-year increase in R&D expense were upfront payments and clinical trial expense reimbursements made pursuant to our in-license agreements with City of Hope and PNP Therapeutics, expenditures associated with our pan coronavirus vaccine program, manufacturing process development costs, and a generally higher level of activity.

General and administrative expenses were \$3.6 million for 2021, as compared to \$2.2 million in 2020, with the increase primarily attributable to higher Delaware franchise taxes; stock-based compensation expense; legal, accounting and patent costs; insurance costs; consulting fees; and investor relations costs.

Other income (expense) was \$175,506 for 2021, as compared to \$(141,253) in 2020. The 2021 amount includes a gain of \$172,056 recorded upon the extinguishment of the Company’s PPP loan principal and accrued interest. The 2020 amount includes \$138,851 of interest expense and amortized debt discount related to convertible debentures that were retired during 2020.

GeoVax reported cash balances of \$11.4 million at December 31, 2021, as compared to \$9.9 million at December 31, 2020. During the first quarter of 2022, the Company further supplemented its cash resources with net proceeds of \$9.4 million from a private placement of its common stock and warrants.

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 at 4:30 p.m. ET on Wednesday, March 9, 2022 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 pre-register for the call via the following link:

<https://dpreister.com/sreg/10164185/flaa6acaf6>

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=liKBkNK2>

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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 9, 2022. 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 3389318. The telephonic replay will be available until March 23, 2022.

## **About GeoVax**

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines and immunotherapies against infectious diseases and cancer using novel proprietary platforms. GeoVax's product pipeline includes two ongoing Phase 2 clinical trials of GEO-CM04S1 (formerly COH04S1) for COVID-19 as a universal booster vaccine to mRNA vaccines authorized by the U.S. Food and Drug Administration (FDA) and as a primary vaccine for use in immunocompromised patients. In addition to GEO-CM04S1 for COVID-19, GeoVax is developing GEO-CM02 as a pan-coronavirus vaccine. The Company is also conducting a Phase 1/2 clinical trial of Gedeptin<sup>®</sup> for treatment of head and neck cancer. Gedeptin<sup>®</sup> has been granted orphan drug status by the FDA. Additional research and development programs include preventive vaccines against Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa) and malaria, as well as immunotherapies for multiple solid tumors. The Company's portfolio of wholly owned, co-owned, and in-licensed intellectual property stands at over 70 granted or pending patent applications spread over 20 patent families.

For additional information about GeoVax, visit our website: [www.geovax.com](http://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 preventive 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 preventive vaccines with the desired characteristics in a timely manner, GeoVax's immuno-oncology products and preventive vaccines will be safe for human use, GeoVax's vaccines will effectively prevent targeted infections in humans, GeoVax's immuno-oncology products and preventive 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 registration statement on Form S-1 and 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 U.S. federal securities law.*

## **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 common share information)*

	Year Ended December 31,	
	2021	2020
Grant and collaboration revenue	\$ 385	\$ 1,823
Operating expenses:		
Research and development	15,554	2,444
General and administrative	3,577	2,196
	19,131	4,640
Loss from operations	(18,746)	(2,817)
Other income (expense), net	176	(141)
Net loss	\$(18,570)	\$ (2,958)
Net loss per common share	\$ (3.04)	\$ (2.14)
Weighted average shares outstanding	6,099,933	1,383,523

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

	December 31,	
	2021	2020
Assets:		
Cash and cash equivalents	\$ 11,424	\$ 9,884
Other current assets	205	351
Total current assets	11,629	10,235
Property and other assets	168	159
Total assets	\$ 11,797	\$ 10,394
Liabilities and stockholders' equity		
Total liabilities	\$ 7,435	\$ 825
Stockholders' equity	4,362	9,569
Total liabilities and stockholders' equity	\$ 11,797	\$ 10,394
Common Shares Outstanding	6,381,541	3,832,892

GeoVax Labs, Inc

Fourth Quarter 2021 Earnings Conference  
Call

Wednesday, March 09, 2022, 4:30 PM  
Eastern

**CORPORATE PARTICIPANTS**

**David Dodd** - *Chairman, Chief Executive Officer*

**Mark Reynolds** - *Chief Financial Officer*

**Mark Newman** - *Chief Scientific Officer*

**John Sharkey** - *Head of Business Development*

**Jules Abraham** - *Core IR*

## **PRESENTATION**

### **Operator**

Good afternoon, and welcome everyone to the GeoVax Fourth Quarter Year End 2021 Corporate Update Call. I am Chuck with Chorus Call, and will facilitate today's call.

With me are David Dodd, Chairman and CEO, Mr. Mark Reynolds, Chief Financial Officer, Mark Newman, Ph.D., Chief Scientific Officer and John Sharkey, Ph.D., and Head of Business Development. All participants will be in a listen-only mode. Should you need assistance, please signal a conference specialist by pressing the "\*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press "\*" then "1" on your telephone keypad, and to withdraw your question, please press "\*" then "2." Please note, this event is being recorded.

I would now like to turn the conference over to Mr. Jules Abraham of Core IR who will provide a forward-looking statement regarding the call, and information herein. Please go ahead, sir.

### **Jules Abraham**

Thank you Chuck. Good afternoon everyone. Please note the following. Certain statements in this presentation may constitute 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, whether GeoVax's vaccines will be safe for human use, whether GeoVax's vaccines will effectively prevent targeted infections in humans, whether GeoVax's vaccines will receive regulatory approvals necessary to be licensed and marketed, whether GeoVax raises required capital to complete vaccine development, and there is development of competitive products that maybe more effective or easier to use than GeoVax's products, whether 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.

With that, it's now my pleasure to introduce the Chairman and CEO of GeoVax, David Dodd. David?

### **David Dodd**

Thank you, Jules. Good afternoon, and thank you for participating in the 2021 fourth quarter year end update call. We're pleased to have this opportunity to review our successful acceleration in the Phase 2 clinical development within COVID-19 and immuno-oncology, while we continue to secure critical resources in support of GeoVax growth and development, while advancing our IND enabling programs.

Over the past year, we utilized our balance sheet to catapult in the Phase 2 clinical development, through the strategic and licensing of both GEO-CM04S1 and Gedepatin. CM04S1 which we in licensed exclusive global rights from City of Hope National Medical Center is a next generation COVID-19 vaccine, targeting both antibody and cellular immunity with the goal of providing more robust and durable protection in the current authorized vaccines.

Gedepin is a cancer immunotherapy which we in license exclusive global rights from PNP Therapeutics in the University of Alabama, Birmingham. Currently being evaluated among patients suffering from advanced head and neck cancers, it has received orphan drug status from the FDA. In addition, we're advancing encouraging internal programs on the path to IND filing.

In January, we issued a 2021 milestone report addressing the goals we established and communicated early last year. Entering 2021, we built a strong balance sheet supporting both strategic transactions and an organization with the expertise to accelerate our growth and development. We successfully executed our plans propelling our status in the Phase 2 clinical development within both COVID-19 and immuno-oncology. In addition, we advanced our internal programs within COVID-19 and immuno-oncology, as well as reported encouraging results in support of our hemorrhagic fever virus vaccine program.

This included a scientific presentation at the 2021 World Vaccine and Immunotherapy Congress in early December, validating our COVID-19 vaccine approach of a multi antigenic vaccine eliciting strong antibody and cellular immune responses, potentially providing more robust and durable protection beyond the current authorized vaccines, which are primarily designed to induce neutralizing antibodies.

In fact, in a well validated lethal challenge transgenic mouse model, our CMO2 candidate which is the first step towards a universal Coronavirus vaccine provided complete protection following a single dose, even in the absence of measurable neutralizing antibodies. To our knowledge, these results are unprecedented. I'll note that both our Phase 2 COVID-19 vaccines CM04S1 and our CMO2, both are multi antigenic COVID-19 vaccines, designed to strongly elicit both antibody and cellular immune responses. At that same Scientific Congress, we also reported further encouraging results in support of our Marburg and Sudan vaccines. During this year, we anticipate reporting milestones and progress related to both our clinical and IND enabling programs.

So let's move into further discussion related to our exciting programs and activities underway at GeoVax. As we entered this year, we further strengthened our balance sheet, while focusing on the acceleration of our CM04S1 and Gedepin Phase 2 programs, and completing the IND enabling activities in support of our CMO2 vaccine for COVID 19, our MUC1 vaccine and immuno-oncology and our hemorrhagic fever virus vaccines, the latter of which are supported via non-dilutive funding and activities.

In addition, we have further enhanced our resources and expertise in support of successfully executing upon our 2022 and beyond plans for growth and development of the company.

Our priority focus this year is to accelerate the recruitment and enrollment of our three Phase 2 programs. This includes our multi-site clinical trial in support of Gedepin and our two clinical trials in support of CM04S1. Since our recent Gedepin announcement, we have confirmed two additional clinical sites on the assignment of CATO SMS, as our CRO partner, responsible for leading the expansion acceleration of the Gedepin clinical program.

Our goal is to complete patient enrollment towards the end of 2022 or early 2023, followed by a completion of patient evaluations by the end of 2023. Should the results be supportive, a BLA filing will likely shortly happen thereafter.

In parallel with the ongoing clinical program, we are also engaged with a CDMO to prepare for commercial manufacture. We are confident that the Gedeptin Phase 2 program will be successfully managed by CATO SMS and our clinical operations team, with this possible expansion of further additional clinical sites soon. We're highly excited about the outlook and promise of Gedeptin within advanced head and neck cancer. We're just received orphan drug designation from the FDA, and has previously provided encouraging potential for such patients.

In addition, there are promising opportunities relative to expanded use of Gedeptin in other indications, as well as the GDEPT technology in conjunction with other therapies and potential synergy with our MVA-VLP tumor associated antigen approach. We're looking forward to providing milestone updates throughout this year about the progress of our Gedeptin program.

In November of last year, we announced exclusive worldwide license of a Phase 2 COVID-19 vaccine from City of Hope National Medical Center. This exciting vaccine is now referred to as GEO-CM04S1, which I typically refer to as CM04S1.

CM04S1 utilizes synthetic, Modified Vaccinia Ankara MVA technology similar to our other vaccine programs under development at GeoVax. This transaction literally propelled us into a critical stage of clinical development. CM04S1 works by inducing immunity to SARS-CoV-2 by stimulating the immune system to produce antibodies against SARS-CoV-2 that can block the virus from entering healthy cells, while the immune system can also grow new disease fighting T-cells that can recognize and destroy infected cells. The vaccine includes both SARS-CoV-2 spike and nuclear capsid proteins. By inserting these proteins the MVA delivery vehicle is able to drive the expression of both proteins within the body of the vaccine recipient, inducing immune responses.

The role of the S protein is to elicit a neutralizing antibody response against the initial infection, while the M protein elicits a T-cell response to directly attack virus infected cells, reduce viral replication and reduce severity and clearance. Thus, the vaccine is designed to induce both neutralizing antibodies and T-cell responses specific for the S protein and the M protein.

This vaccine design was implemented specifically to induce an expanded immune response to better combat and clear infections regardless of the circulating SARS-CoV-2 variants. Our goal is to provide a vaccine that gets ahead of the variants versus having to chase the variants, which have successfully reduced reliance on the repeated administration of booster doses of existing vaccines.

Frankly, we believe that such a multi-pronged approach has the potential to providing more robust and durable immune response and protection than the current authorized vaccines. We also believe that various high risk populations such as immune compromised individuals would greatly benefit from such a two-pronged approach.

CM04S1 is currently being evaluated in two Phase 2 clinical trials. One trial is the first comparative trial of an investigative COVID-19 vaccine with the current FDA approved Pfizer vaccine and people that have received or are undergoing specific blood cancer therapies associated with transplantation or CAR- T therapy to suppress or severely reduced pre-existing immunity to COVID-19 vaccine.

Multiple clinical trials have demonstrated that such patients failed to respond optimally to the current generation vaccines. And we believe the CM04S1 will prove to be more potent because this is multiple antigenic and delivered using the MVA factor. We believe this will differentiate

CM04S1 from the other vaccines by providing both a strong antibody response and a sustained T-cell response to these patients who are still at high risk due to their immuno compromised status of severe COVID-19.

The other trial currently underway is evaluating CM04S1 is a booster for healthy patients who have previously received either the Pfizer or Moderna, mRNA vaccines. We believe that providing a heterologous booster, rather than a third or fourth shot of the same vaccine may provide more robust and durable immune response and protection. Heterologous prime boost immunizations are well studied in other fields such as HIV, and are being evaluated in multiple countries using different COVID vaccines.

We are working with CATO SMS and Pharm-Olam, following the recent merger to oversee the acceleration and management of these two exciting clinical programs, working in conjunction with our internal clinical operations team.

Finally, the ongoing GeoVax effort to develop a manufacturing process based on a continuously growing avian cell line to increase production consistency and capacity will mesh with the clinical development activities and full development schedule associated with the CM04S1 and the CMO2 vaccines. The potential benefits of this transaction to the GeoVax program are highly significant and timely.

Now, I'd like to turn the presentation over to Mark Reynolds, GeoVax's, Chief Financial Officer for a review of our recent results and financial status. Mark?

### **Mark Reynolds**

Thank you, Dave. So starting with our income statement, Grant and Collaboration revenues were down to \$385,000 in '21 versus \$1.8 million in 2020. And as the '21 period revenues relate entirely to our Grant from NIH for COVID-19 vaccine for the pan-Coronavirus program, while the 2020 amount includes revenues from our Grant from the US Army supporting a loss of fever vaccine program, which had begun to wind down during that period. That's the reason for the reduction.

Research and development expenses were \$15.6 million in '21 versus \$2.4 million in 2020, with the increase primarily associated with our license fees, both paid and accrued, and clinical trial expenses related to our license agreement with City of Hope for the COVID-19 vaccine program, as well as for our license GDEPT. Also contributing to the increase were expenses related to our universal Coronavirus vaccine program, manufacturing process development and generally a higher level of activity.

G&A expenses were \$3.6 million in '21 versus \$2.2 million in 2020. A large portion of the increase here is related to our annual Delaware franchise tax, which is based on our capitalization and was minimal during 2020. Other increases in insurance premiums, patent costs, legal fees, consulting fees and personal costs are generally associated with preparing our organization for a higher level of activity following capital raises.

Other income and expense for '21 included a \$172,000 gain on extinguishment of debt associated with a forgiveness of repeat PPP loan we received in early 2020, comparable figure for 2020 includes interest expense of \$144,000, related to convertible debentures that were retired during that year. The overall net loss for '21 was \$18.6 million or \$3.04 per share, versus \$3 million in 2020, or \$2.14 per share, again with the increase primarily associated with our licensing, and R&D activity.

Turning now to the balance sheet. Our cash balances at the end of this past year were \$11.4 million as compared to \$9.9 million at the end of 2020. The change in cash balances is reflective of approximately \$11 million used in operating activities, offset by proceeds from our stock offering in early '21 which generated net proceeds to us of \$9.4 million.

During the year of 2021, we also received \$3.4 million from the exercise of our publicly traded warrants. Subsequent to year end in January of this year, 2022, we raised an additional \$9.2 million through a private placement priced at \$3.26 per share. So as of today, GeoVax has cash balances of approximately \$17 million.

Now that we've got three ongoing Phase 2 clinical programs in COVID-19, and our cancer immunotherapy, our cash needs have obviously increased not only for license fees and direct costs associated with plentiful programs, but also for the facilities, personnel and other costs to support those programs.

And while we don't provide specific forward-looking estimates of cost to complete these programs, what we can say at this time, is that our existing cash resources are sufficient to fund our operations and our current business plan priority programs into the second quarter of 2023. We believe the advancement of these programs will create an attractive investment opportunity for new fundraising...new fundraising opportunities as they present themselves.

And I'll be happy to answer any questions during the Q&A. And I'll now turn call back over to Dave.

#### **David Dodd**

Thank you. Mark. My colleagues and I will now answer your questions. And joining us for the Q&A session are Drs. Mark Newman and John Sharkey, our Chief Scientific Officer and Head of Business Development, respectively. I'm therefore turning the call over to the operator for instructions on the Q&A period.

#### **QUESTION AND ANSWER**

##### **Operator**

We will now begin the question and answer session. To ask a question, you may press "\*" then "1" on your telephone keypad. If you are using a speakerphone, please pick up your handset before pressing the keys and to withdraw your question, please press "\*" then "2." And at this time, we will pause momentarily to assemble our roster.

And the first question will come from Jason McCarthy with Maxim Group. Please go ahead.

##### **Jason McCarthy**

Hi, guys. Thanks for taking the questions. Let's start with the 04S1 program. And maybe any of you could speak a little bit more broadly about the state of COVID vaccines and the pandemic now, because the data that we were seeing on the mRNA side with Omicron was less than fantastic or desirable, like we saw with Delta and some of the other variants. And then you and I both know that it's not the last letter in the Greek alphabet, there probably will be more variants or probably be looking at something again, surging next year. So the Omicron data, does that change the importance now of 04S1 and the need for doing something different than just mRNA?

**David Dodd**

Thank you, Jason. This is David Dodd. I'll start and then I'll ask Mark Newman to pick up and I'd say that we share your outlook for how there will continue to be emerging variants, we can't predict what letters of the alphabet they're based on, what their constructs will be. But clearly there is a need for other than mRNA vaccines that are out there. So the current authorized vaccine in a number of manners are insufficient and especially among high risk populations. Those who have compromised immune system, we know that they are being highly insufficiently served by the existing vaccines. But in general, we need additional ones so that we can as we refer to get ahead of the variants, and be able to strongly elicit both antibody, as well as the T-cells to be able to provide a better protection, more robust and durable protection.

But I'll ask Mark Newman to pick up from here. Mark?

**Mark Newman**

Sure, thanks. So, I think what you're seeing, we've seen the world start to recognize is that targeting the S protein alone and focusing on neutralizing antibodies have some limitations. So this is impacting primarily the vaccines that are based on just the receptor binding domain, that part that interacts and you know, mediates the infection to a cell.

Now, that is not the current generation mRNA vaccines, there it total S protein, but that's the mutations are mutating around the receptor binding domain primarily. We just had a World Health Organization conference a couple weeks ago, which I participated in and it's interesting, because the new variants, while we're not being protected as well with the current generation vaccines, the immune responses they're generating don't protect against previous infections as well. So it's almost like the virus can go first full circle, and that was actually the way it was described. They actually come back into where it started. And of course, you don't have long-lived immunity, one of the issues that's being pointed out with the mRNA vaccine.

So I've been saying for a year now that we need to have a broader response, we need to focus on T-cell responses to the conserved structural proteins. These are the things that make a Coronavirus, a Coronavirus. There's conserved regions in the S protein, but also the M and the nucleocapsid, which are in the CMO2 and the 04S1 respectively. And so the world is starting to come to realize that. The difficulty is while everyone accepts it, how would you measure and how do you design a vaccine. Heterologous prime boosts are back in vogue. Those of you who followed HIV vaccine work for decades will remember that there was multiple attempts to boost immune responses by using different product formats.

Now you're hearing about what they call mix and match. You know, if you got the J&J vaccine, go get a different one, go get one of the mRNA, if you got an mRNA you can boost it with the J&J or an AstraZeneca vaccine, if you're living in Europe. And so, those are the approaches that are being taken. Obviously, the evolution of variants drives the need for next generation products. But if you're holding one of the current generation products, you're going to try and find a way of using it. And you're seeing both of these aspects, float into the medical world. So prime boost using existing vaccines, and then next generation vaccines that are designed to induce a broader response.

There is some interest in the mRNA field in particular in making Omicron, but by the time maybe Omicron vaccine got it into Phase 1, the Omicron cousin was already out there, that was B1, now, B2. And so, chasing variants, as David said, is just not something that we feel is a logical approach. So does that answer your question?

**David Dodd**

Jason?

**Mark Newman**

Perhaps you're muted Mr. McCarthy.

**Operator**

Okay, to move on?

**David Dodd**

Yes, please.

**Operator**

Our next question will come from Shubhendu Senroy with Brookline Capital. Please go ahead.

**Shubhendu Senroy**

Hi. I'm Shubhendu for Kumar from Brookline. Appreciate the update. Thank you. So with regards to the Sudan and Marburg programs, first of all, congratulations on the encouraging preclinical data. My understanding is that the clinical trials would move with federal funding. So I was wondering if you have any inputs from the Department of Defense or USA or BARDA regarding the clinical studies. And how are you thinking in terms of taking these programs further?

**David Dodd**

And you're specifically addressing the hemorrhagic fever, right?

**Shubhendu Senroy**

Yeah, yes.

**David Dodd**

Okay. Thank you. Thanks. I just wanted to make sure. Well, we...currently those programs have been supported through NIH preclinical services, through non-human primate testing and during the course of our progress with these products, you may be aware that we initially demonstrated for Ebola, Zaire vaccine showed 100% protection in a single dose without the use of any adjuvant. And I think that's unprecedented in non-human primate models to achieve that result in a single dose.

And then we had moved forward with our current products also. In the course of all that we have been and continued to be in dialogue with BARDA about the Strategic National Stockpile program and the progress of our products in the potential. Time will tell. We believe that with the progress we've seen and support through the non-human primates from NIHs preclinical services, that depending on the outcome, we would anticipate that if there is the opportunity to move it forward in the clinical development, we would more than likely be supported through non-dilutive funding. And that's consistent with discussions that we've had on an ongoing basis. So Mark, do you want to add anything?

**Mark Newman**

Well, yeah, I can just add that, you know, the real world is that when COVID hit, you couldn't get...couldn't get non-human primates to do the testing. And so that slowed us down. But that has picked back up and everything is back on schedule. And we fully anticipate...we were analyzing data, yeah, yesterday. So we're seeing all sorts of different results come in through

these contracts. And we fully anticipate having a BARDA tech watch meeting this year. We'll just have to see what the data looks like. But everything is back on track, just dealing with the shortage of test animals.

**Shubhendu Senroy**

Great, thanks. This was helpful. Now with regards with pan-Coronavirus CMO2 program that elicits both VNT cell responses in preclinical models, can I get some more color to your future plans? And are you planning to develop this for other Coronavirus, like MERS?

**Mark Newman**

Yeah, so the...again, remember that, so in MERS, it's significantly different S protein, right. Some of it's the same as with COVID. But it's a different...uses a different receptor. But the matrix, the nucleocapsid, the envelope, a lot of the non-structural proteins, like the enzymes and things that the virus uses to process proteins and DNA, those are all very highly shared amongst beta Coronaviruses.

And what we're doing is when you are...you know, it's an ongoing program, looking at other targets, we can roll into the existing CMO2. So CMO2 is now basically the backbone, because the 04S1 is fairly similar. And that's in Phase 2 trial. So we don't want to necessarily play a lot of games with that one. But the CMO2 is where we can start rolling these open reading frame, proteins in that are highly conserved because have enzymatic activity, other structural and non-structural proteins. And we're making those, we have a next gen...our next product is being sequenced right now to see if it's holding up and looks like we won.

And that's why you know the program that we pitched and discussed with groups like CEPI and the NIH involve again shifting away from the S protein and reliance on neutralizing antibodies, not that we wouldn't have S protein, but expanding it. And all this is rolling along. It's all in, either in the construction phase or goes into small animal models, you know, at first.

So it's on track, it was always an extended, you know, two to four year program, depending on where we are successful and how the world has evolved. We can rely a little bit on what people are seeing in the human population as people recover you can measure their immune response to determine what genes should also be targeted. And so we are using that to continually guide our process. And what would the next CMO2 look like and what else would we add? So that's still going, but it's separate and it's more research focused from the 04S1, which is targeting the existing pandemic and the immune compromised patients. So the CMO2 is really the beta Coronavirus vaccine of the future. That's how we're looking at that.

**David Dodd**

I would just add that we are...I was going to say, our plan is to drive through the clinical development 04S1 because we believe that it can more immediately address populations that are highly at risk, that are not being adequately protected with the current vaccines and then that we can follow along with the...with even further development that will give greater protection going forward as we see Coronavirus has continued to evolve.

**Shubhendu Senroy**

Perfect. That makes sense. Just one final question with regards to the cancer vaccine program. Do you plan a non-human primate studies for the MVA-VLP MUC1 program? What kind of data do you think will be sufficient to you know, get it into the clinic now? Thanks.

**Mark Newman**

For the cancer programs, no, we don't envision going into non-human primates. Those are typically handled through transplantable tumor models. And so we just initiated another trial, another animal experiment using human transgenic mice that, you know, for the MUC1 program, a well established model. And so, there, what you do is you vaccinate and challenge with the tumor by transplant...transplanting the tumor in or you transplant the tumor in first and then you start vaccinating, and see if you can retard tumor growth. So that's the type of study that's done for those.

With a...there's no transplantable tumors you could use for the non-human primates. So you can't just sit around and wait and see if they get cancer. So if that's...those are under control, that way. The path forward that we're taking is we're piggybacking on other programs...what others have done involving the MUC1 gene. So there's a significant history about targeting immune responses against aberrantly glycosylated MUC1. And it's a situation where your body raises immune responses on its own, sometimes the adenocarcinomas. And so, these had been...there are products that have been tested in clinical trials through one of our collaborators, University of Pittsburgh. And so, this is how we'll be moving this. The goal is to take something that's already been in Phase 1 and Phase 2 trial, and then add the MVA to that. So, you're looking at two experimental products, but two experimental products that have a great deal of safety and initial evaluation behind them. That's what will allow us to put them together through an FDA-approved study. But no non-human primates. That's just not something we do for cancer.

**Shubhendu Senroy**

Okay, great. Thank you for taking my question.

**Operator**

The next question will come from Jason McCarthy with Maxim Group. Please go ahead.

**Jason McCarthy**

Hey, guys, sorry, I got cut off. So I think a lot of my COVID-related questions were subsequently answered. But I wanted to touch on the Gedepin program. We think it's really important. Can you give us David an update on where those first 10 patients are in terms of enrollment or their progress? And then, what are the expectations in terms of how many patients you think you might have to add for this program to make it registrational? And the third part to that question is, what would be considered a good objective response rate? And a second line head and neck cancer to be 10%, 20%, 30%, what do you think would be clinically meaningful for this program?

**David Dodd**

Thank you. Let me ask John Sharkey, would you like to answer that?

**John Sharkey**

Sure. At last I recall, there have been five patients enrolled, there's two patients who are being evaluated for the enrollment. And so, that would be 7 of the 10. The expansion of the trial to basically make a registration, currently our thinking is the range of 30 patients for that...for the additional trial on top of the 10. Looking at a higher dose of the drug to maximize the effect. And, as far as, the...what sort of increase would we see? This is going to be personal opinion at this point. We are putting the stuff together to initiate a discussion with the agency on this. But I would imagine it would probably be in the range of 20% to 30%, against current standard of care, because this would be for an end stage. But that's purely, I'd have to say, speculation at

this point when we have that discussion with the agency. Hopefully that answers your question, Jason.

**Jason McCarthy**

Yes, it does. Thank you. And if you're successful, with a 20% to 30%, whatever the response rate that you're going to need, it's your view. It's not what the FDA has said just yet, would it be optional to then move to first line for a trial. And we've seen that with a few other programs out there, and Merck is doing this with another group for a combination study. The data looks so good and you know one cohort of the second line head neck program that they immediately went to a first-line program. That was the interaction with regulators so was the outcomes. Is that's something that the Gedeptin program could follow at about a similar path to that?

**John Sharkey**

For head and neck it's...given its mechanism of action as a single agent, I will...I personally don't think it would likely move into first line. However, as we've also said, we're looking at it early on with combination with checkpoint inhibitors. And the data suggests that you would improve the response of metastatic disease to checkpoint inhibitors with an animal model, when you use Gedeptin. That potentially could move up into an earlier stage treatment paradigm for...in combination with checkpoint inhibitors, certain patient populations. That I could see happening. My...again personal opinion, given this mechanism of action, and end stage disease, I think people would try other treatment paradigms versus a standalone agents.

**Jason McCarthy**

And lastly, is the expectation...you haven't not met with regulators yet, that it would only be about 30 people? That you'd have to add in some of the one-sided trials that we've seen for approvals, they've ranged right from anywhere as low as 30, but to as high as 150 people to gain or to be sufficient for filing. Is it possible that they could want more than 30, even less than 30? We've seen some sarcomas studies where they'll take like 15-20 people. That's more than enough, given the unmet need?

**John Sharkey**

Dealing with the agency, anything is possible.

**Jason McCarthy**

Right.

**John Sharkey**

But that's the reality. But given that it's an end stage disease, and they have no other treatment options, the way the trial was designed that it's most likely I would expect to be on the lower end of the range of what you would see for these types of trials. That it is an...these are end-stage things.

**David Dodd**

Yes, I would add, Jason that based upon this discussion, that was held with the agency following the Phase 1 program, the indication was given that a number of patients in the current Phase 2 trials lower than what we have. We're exceeding it by more than...by 10 more. We've been looking for something more like 20 in total. And we're looking at adding potentially 30 on top of the 10. So that would be almost double the number and they were looking for, for that as a minimal number. So, what we have invested in and what we're investing in is to increase the number of basically significantly beyond the number that had previously been indicated, but to also engage in discussions as we add these additional sites, and expand beyond that and

accelerate the enrollment, which is what our...that's what we're focused on for this year. But we do believe we will end up completing more than the number of patients who had previously been indicated.

**Jason McCarthy**

Great. Thank you for taking the questions.

**David Dodd**

Thank you.

**Operator**

This concludes our question and answer-session. I would like to turn the conference back over to Mr. David Dodd for any closing remarks. Please go ahead.

**CONCLUSION**

**David Dodd**

Well, thank you. And thank you, everyone, for participating in this conference call, sharing in our milestone achievements, resulting in clinical stage development within both immunology...

**Operator**

Pardon me. It seems that Mr. David Dodd has disconnected. Would someone else like to give closing remarks?

**Mark Reynolds**

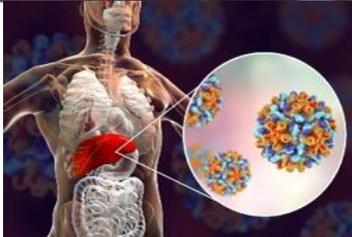
I'll finish it off by just saying thanks everybody participating and hope everybody has a pleasant evening.

**Operator**

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.



# Q4/Year-End 2021 Corporate Update Conference call



**March 9, 2022**

**NASDAQ: GOVX**

# Forward Looking Statements

Certain statements in this presentation may constitute "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.



## **GeoVax Reports 2021 Year-End Financial Results and Provides Corporate Update**

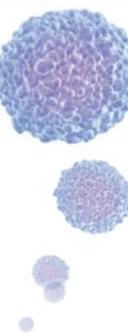
### *Advancing Phase 2 Clinical Trials for Covid-19 and Immuno-Oncology*

**ATLANTA, GA, March 9, 2022** – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancer, today announced its financial results for the year ended December 31, 2021 and provided an update on product development programs. GeoVax’s management will host a live conference call and webcast at 4:30 p.m. Eastern Standard Time on Wednesday, March 9 to discuss financial results and provide a general business update.

- **Two Phase 2 Clinical Trials Underway for SARS-CoV-2**
  - **IND-Enabling Activities Progressing for Pan Coronavirus Vaccine**
- **Phase 2 Clinical Trial Underway for Advanced Head and Neck Cancer**
  - **IND-Enabling Activities Progressing for MUC1-based Cancer Immunotherapy**

David Dodd, GeoVax’s Chairman and CEO, commented,

**“Our primary corporate focus continues to be on our COVID-19 vaccine and our cancer immunotherapy programs, and the three ongoing Phase 2 clinical trials in those areas represent the achievement of highly important goals we established at the beginning of 2021. As recently communicated in our shareholder update letter in January, our 2022 goals include the acceleration and expansion of these clinical programs focused on generating relevant data as soon as possible. To that end, we have added organizational and operational resources to support advancing through clinical development into regulatory registration. We look forward to providing additional updates as we make progress in these, and other, programs.”**

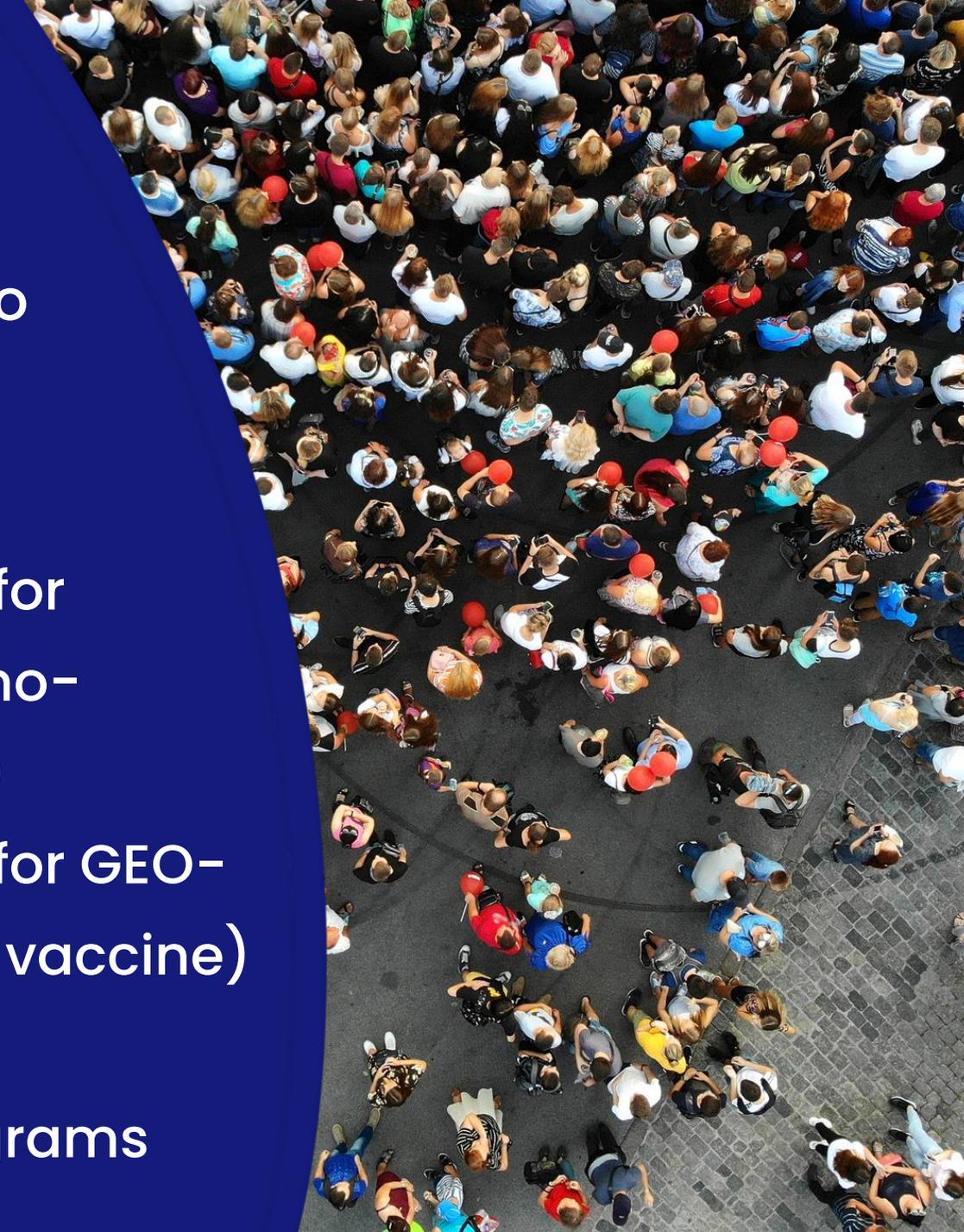


# GOAL

Strengthen balance sheet to support 2021 goals and operations

# ACHIEVED

- Exclusive licenses for Gedeptin® (immuno-oncology vaccine)
- Exclusive licenses for GEO-CM04S1 (Covid-19 vaccine)
- Advanced internal development programs





2021

What we set out to do.

What we did.

2022

What's next.



## **GeoVax Announces \$10 Million Private Placement**

**ATLANTA, GA, January 14, 2022** — GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, announced today that it has entered into a securities purchase agreement with a single institutional investor to raise approximately \$10.0 million through the private placement of 707,484 shares of common stock, 2,360,000 pre-funded warrants to purchase common stock and accompanying warrants to purchase an aggregate of up to 3,067,484 shares of common stock. Each share of common stock (or pre-funded warrant in lieu thereof) is being sold together with an accompanying warrant at a combined effective purchase price of \$3.26. The warrants will be exercisable immediately at an exercise price of \$3.26 per share and will expire five years from the date of issuance. The closing of the private placement is expected to occur on January 19, 2022, subject to the satisfaction of certain customary closing conditions set forth in the securities purchase agreement.

# Immuno-Oncology Vaccine: Gedeptin<sup>®</sup>



## Phase 2 : Advanced Head and Neck Cancers

- FDA orphan drug status granted
- Bring on additional clinical sites to accelerate patient enrollment
- Evaluating broader use of Gedeptin in conjunction with Immune Checkpoint Inhibitors (ICIs)



# COVID-19 and Variants

**GOAL**

Achieve clinical development status within 12-18 months

**ACHIEVED**

Licensed GEO-CM04S1, Covid-19 vaccine; currently in two Phase 2 trials



# COVID Vaccine: GEO-CM04S1



## Phase 2 : For the Immunocompromised

- 1st trial to specifically evaluate a Covid-19 vaccine in patients with weakened immune systems
- Direct comparison to the Pfizer/BioNTech mRNA vaccine



## Phase 2: Booster

- For healthy population fully vaccinated with an mRNA vaccine
- Potential for broader and more durable protection versus a 3rd or 4th mRNA dose



# Financial Update



# GeoVax Labs, Inc.

## Consolidated Statements of Operations Information

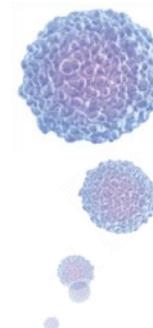
*(amounts in thousands, except share and per share information)*

	Year Ended December 31,	
	2021	2020
Grant and collaboration revenue	\$ 385	\$ 1,823
Operating expenses		
Research and development	15,554	2,444
General and administrative	3,577	2,196
	19,131	4,640
Loss from operations	(18,746)	(2,817)
Other income (expense), net	176	(141)
Net loss	\$ (18,570)	\$ (2,958)
Loss per common share	\$ (3.04)	\$ (2.14)

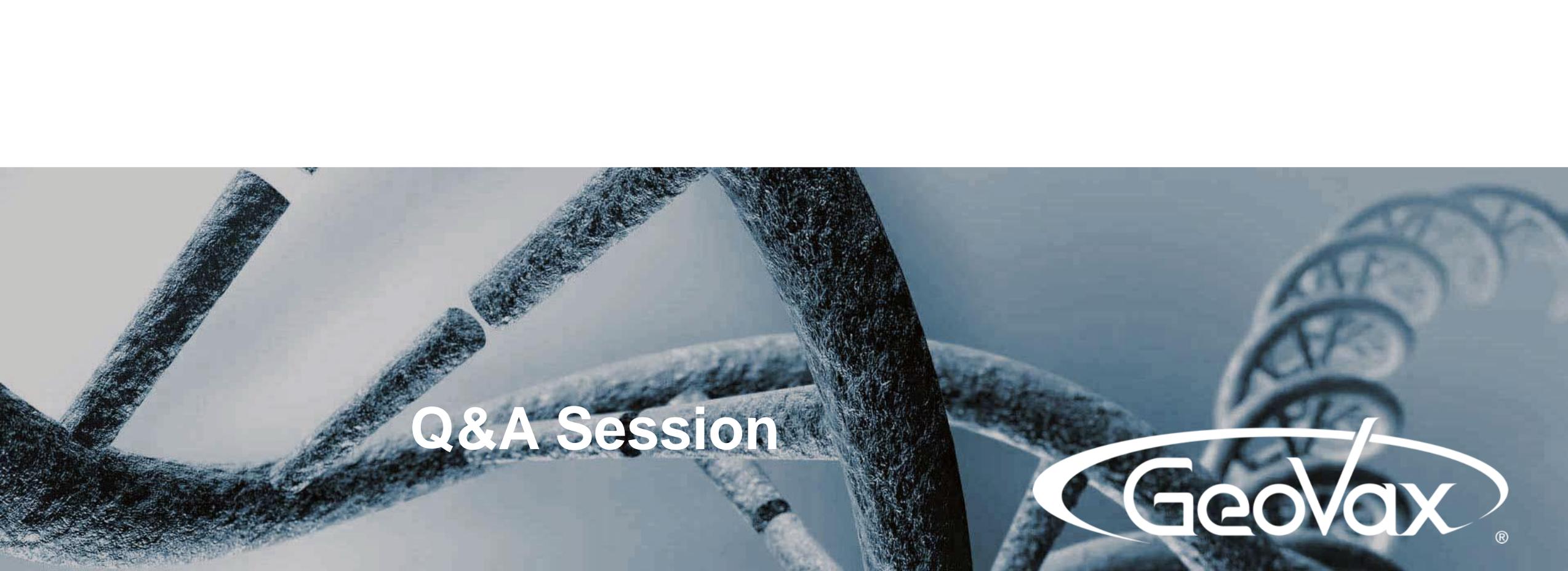
# GeoVax Labs, Inc.

## Consolidated Balance Sheet Information

*(amounts in thousands, except share information)*



	December 31,	
	2021	2020
<b>Assets</b>		
Cash and cash equivalents	\$ 11,424	\$ 9,884
Other current assets	205	351
Total current assets	11,629	10,235
Property and other assets, net	168	159
Total assets	\$ 11,797	\$ 10,394
 <b>Liabilities and stockholders' equity</b>		
Total liabilities	\$ 7,435	\$ 825
Stockholders' equity	4,362	9,569
Total liabilities and stockholders' equity	\$ 11,797	\$ 10,394
Common shares outstanding	6,381,541	3,832,892



# Q&A Session





# 2022

## Focus.

- Successfully advance the three Phase 2 clinical programs in support of Gedeptin® and GEO-CM04S1
- Ensure appropriate resources to support the IND-enabling initiatives of our priority internal programs and operational enhancements and developments





**GeoVax**<sup>®</sup>  
Vaccines Serving Humanity