

**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): November 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 November 9, 2022, GeoVax Labs, Inc. (the “Company”) issued a press release reporting its results of operations for the quarter ended September 30, 2022. 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 November 9, 2022, the Company hosted a conference call and webcast with accompanying slides regarding its results of operations for the quarter ended September 30, 2022. 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 November 9, 2022
99.2	Conference Call Transcript dated November 9, 2022
99.3	Conference Call Slide Presentation dated November 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: November 10, 2022

GEOVAX LABS, INC.

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

Mark W. Reynolds  
Chief Financial Officer



## GeoVax Reports 2022 Third Quarter Financial Results and Provides Corporate Update

### *Phase 2 Clinical Trials Advance for COVID-19 and Immuno-Oncology Company Secures Rights to NIH-MVA for Protection Against Monkeypox and Smallpox*

ATLANTA, GA, November 9, 2022 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced its financial results for the third quarter ended September 30, 2022.

GeoVax’s management will host a live conference call and webcast at 4:30 p.m. EST on Wednesday, November 9, 2022, to provide a general business update and discuss financial results. Further details are provided below.

### **THIRD QUARTER 2022 DEVELOPMENTS & PROGRESS**

“Our unwavering focus is on the advancement of our GEO-CM04S1 and Gedeptin® clinical programs. To that end, we are expanding to additional clinical sites and accelerating patient enrollment for both programs,” said David Dodd, GeoVax’s Chairman and CEO. “We are also delighted that we have secured rights to the NIH-MVA for further development and commercial use against Monkeypox (MPX) and Smallpox (SPX) 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 successful financing activities during the year provide us with adequate resources to advance these programs, including the production of additional drug product for use in these clinical trials. We are also now well-positioned to advance the preclinical studies for our GEO-CM02 pan-coronavirus vaccine candidate and our MVA-VLP-MUC1 cancer immunotherapy program to further solidify our promising pipeline of human vaccines and immunotherapies.”

#### **CORONAVIRUS VACCINES**

GeoVax has been focused on advancing its two Phase 2 clinical studies of GEO-CM04S1 against COVID-19, one as a primary vaccine for immunocompromised cancer patients, in direct comparison to the Pfizer mRNA vaccine (NCT04977024), and the second as a booster for healthy patients who have previously received either the Pfizer or Moderna vaccine as their initial inoculation (NCT04639466). During the November 9<sup>th</sup> Corporate Update call, GeoVax will provide a progress report on study expansion developments.

Earlier this year, data from a Phase 1 study of GEO-CM04S1 were published in the *The Lancet Microbe*. This peer-reviewed publication (accessible [here](#)) reports data showing that GEO-CM04S1 produced robust neutralizing antibodies and T cells against SARS-CoV-2 with no significant side effects. These data confirm the powerful dual action of the GeoVax vaccine, an important feature given the multiple spike antigen mutations, leading to variants of concern and inconsistent protection from existing FDA-approved vaccines. Should a new mutation arise in the spike antigen that interferes with antibody recognition, a person vaccinated with GEO-CM04S1 may still have substantial T-cell immunity against both the nucleocapsid and spike antigens.

In July, additional analyses of data from the Phase 1 study of GEO-CM04S1 published in the peer-reviewed journal, *iScience* (accessible [here](#)) show that GEO-CM04S1 demonstrated potent and equivalent T-cell cross-reactivity against Delta and Omicron variants. 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. Further details and potential implications of these findings will also be discussed on the November 9<sup>th</sup> update call.

Building on earlier findings, during the third quarter GeoVax also initiated new preclinical studies of its pan-coronavirus vaccine candidate (GEO-CM02) to prepare for an Investigational New Drug (IND) application and subsequent human clinical trials as a potential single-dose universal coronavirus vaccine.

#### **IMMUNO-ONCOLOGY DEVELOPMENTS**

A Phase 1/2 trial (NCT03754933) evaluating the safety and efficacy of repeat cycles of Gedeptin® therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC) has broadened from a single site at Stanford University

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to additional sites at Emory University and Thomas Jefferson University. Funded in part by the US Food & Drug Administration 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, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities.

To further evaluate the Company's additional immunotherapy candidate for solid tumors (MVA-VLP-MUC1), GeoVax recently began a preclinical study with Dr. Pinku Mukherjee at the University of North Carolina at Charlotte, to define the optimal course and schedule of vaccination for incorporation into a Phase 1 clinical protocol.

### **HEMORRHAGIC FEVER VIRUS VACCINES**

In July 2022, GeoVax announced the publication of a peer-reviewed animal efficacy study of its modified vaccinia Ankara (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.

### **MODIFIED VACCINIA ANKARA (MVA) & MONKEYPOX**

MVA is the vaccine vector utilized by GeoVax in a number of its vaccine candidates, including those for COVID-19, various hemorrhagic fever viruses, the GeoVax MVA-VLP-MUC1 cancer immunotherapy and others. Importantly, MVA is also the vaccine used and stockpiled for immunization against the MPX and SPX viruses.

In response to the global need to address the continued emerging threat from MPX and the unique opportunity offered by MVA-based vaccines, GeoVax recently secured rights from the NIH covering preclinical, clinical and commercial uses of the NIH-MVA against MPX or SPX viruses. The Company is now evaluating development and regulatory pathways towards expanding the public health options available to reduce and manage the risk of MPX worldwide.

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 MPX virus three years post vaccination (publication accessible [here](#)). In August 2022, the City of Hope team, which originally developed GEO-CM04S1, published results demonstrating that both their proprietary sMVA (synthetic MVA) and GEO-CM04S1, which utilizes sMVA as the vaccine vector, (referred to as "COH04S1" in the publication, accessible [here](#)) elicited robust orthopoxvirus-specific binding and neutralizing antibody responses. They also reported that healthy adults, vaccinated with COH04S1 at different dose levels, developed robust orthopoxvirus-specific humoral and cellular immune responses that are durable for over six months post-vaccination. The authors conclude that "COH04S1 and sMVA represent unique vaccine candidates to control the unforeseen global MPXV outbreak."

### **FINANCIAL REVIEW**

GeoVax reported a net loss of \$3,968,102 (\$0.17 per share) for the three months ended September 30, 2022, compared to a net loss of \$1,950,503 (\$0.31 per share) for the same period in 2021. For the nine months ended September 30, 2022, the Company's net loss was \$8,637,316 (\$0.63 per share) as compared to a net loss of \$4,827,314 (\$0.80 per share) in 2021.

Research and development expenses were \$2,721,196 and \$5,358,917 for the three-month and nine-month periods of 2022, respectively, as compared to \$1,224,362 and \$2,659,980 for the comparable periods of 2021, with the increases primarily due to higher personnel and consulting costs, costs of conducting clinical trials for GEO-CM04S1 and Gedeptin and costs of manufacturing materials for use in clinical trials.

General and administrative expenses were \$1,249,337 and \$3,363,672 for the three-month and nine-month periods of 2022, respectively, as compared to \$757,432 and \$2,562,541 for the comparable periods of 2021, with the increases primarily attributable to higher personnel costs and consulting costs, patent costs, investor relations costs and travel costs, all associated with a generally higher level of activity during 2022.

GeoVax reported cash balances of \$34.7 million on September 30, 2022, as compared to \$11.4 million on December 31, 2021. Contributing to the increase in cash balances during the nine-month period were aggregate net proceeds of \$27.7 million from sales of our common stock and warrants during January and May, and \$7.6 million from the exercise of warrants during August.

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Summarized financial information is attached. Further information is included in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission.

## CONFERENCE CALL

Management will host a conference call, scheduled to begin at 4:30 p.m. EST today, November 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.

Domestic: 877-269-7756

International: 201-689-7817

Conference ID: 13733113

Webcast: [GeoVax 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 February 9, 2023. A telephonic replay of the call can be accessed by calling 877-660-6853 (domestic) or 201-612-7415 (international), using access code 13733113. The telephonic replay will be available until November 23, 2022.

## 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 solid tumor gene-directed therapy, Gedeptin<sup>®</sup>, 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 single-dose 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 has driven significant value creation across multiple life science companies over the past several decades. For more information, 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 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*

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*result of new information, future developments or otherwise, except as may be required by law.*

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**FINANCIAL TABLES FOLLOW**

**MORE**

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Grant revenue	\$ -	\$ 30	\$ 82	\$ 221
Operating expenses:				
Research and development	2,721	1,224	5,359	2,660
General and administrative	1,249	758	3,364	2,563
	<u>3,970</u>	<u>1,982</u>	<u>8,723</u>	<u>5,223</u>
Loss from operations	(3,970)	(1,952)	(8,641)	(5,002)
Other income (expense), net	2	1	4	175
Net loss	<u>\$ (3,968)</u>	<u>\$ (1,951)</u>	<u>\$ (8,637)</u>	<u>\$ (4,827)</u>
Loss per common share	<u>\$ (0.17)</u>	<u>\$ (0.31)</u>	<u>\$ (0.63)</u>	<u>\$ (0.80)</u>

**Condensed Consolidated Balance Sheet Information**  
*(amounts in thousands)*

	Sep. 30, 2022	Dec. 31, 2021
Assets:		
Cash and cash equivalents	\$ 34,677	\$ 11,424
Other current assets	1,460	205
Total current assets	<u>36,137</u>	<u>11,629</u>
Property and other assets, net	2,433	168
Total assets	<u>\$ 38,570</u>	<u>\$ 11,797</u>
Liabilities and stockholders' equity		
Total liabilities	\$ 6,789	\$ 7,435
Stockholders' equity	31,781	4,362
Total liabilities and stockholders' equity	<u>\$ 38,570</u>	<u>\$ 11,797</u>
Common shares outstanding	26,334	6,382

**GeoVax**  
**Third Quarter 2022 Earnings**  
**November 9, 2022**

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**Presenters**

**Gabrielle DeGravina - CG Capital**

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

**Mark Reynolds - Chief Financial Officer**

**Mark Newman - Chief Scientific Officer**

**Kelly McKee - Chief Medical Officer**

**Q&A Participants**

**Jeffrey Kraws - Crystal Research Associates**

**Leah Lowe - H.C. Wainwright**

**Robert LeBoyer - Noble Capital**

**Operator**

Good afternoon and welcome everyone to the GeoVax Third Quarter 2022 Corporate Update Call. My name is Ralph, and I will facilitate today's call. With me are David Dodd, Chairman and CEO; Mark Reynolds, Chief Financial Officer; Mark Newman, Ph.D., Chief Scientific Officer; Kelly McKee, MD, MPH, Chief Medical Officer; and John Sharkey, Ph.D., Vice President, Business Development.

At this time all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. As a reminder this conference is being recorded. Please note, this event is being recorded. And at this time I am turning the call over to Gabbie DeGravina of CG Capital.

**Gabrielle DeGravina**

Thank you. 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; 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. It is now my pleasure to introduce the Chairman and CEO of GeoVax, David Dodd.

**David Dodd**

Good afternoon and thank you for participating in GeoVax corporate update call. The third quarter represented continued progress for GeoVax as we advanced the phase 2 clinical programs in support of Gedeptin, our cancer therapy for patients with advanced head and neck cancers, and GEO-CM04S1, our next generation COVID-19 vaccine. In addition, we continue to progress our preclinical development stage programs. We also further strengthened our balance sheet during a very difficult investment environment, especially for the biotech industry.

As a result of our successful financings this year, we are well capitalized to complete our current phase 2 clinical programs, including expansion of the Gedeptin, multi-site trial and expanding the CM04S1 COVID-19 vaccine trial among immunocompromised patients to additional sites. We are focused on accelerating our programs with anticipated, initial data readouts over the next six to nine months.

Our mission is to provide immunotherapies and vaccines that improve lives worldwide, preventing or treating some of the world's most challenging cancers and infectious diseases. Also, we recently initiated business development discussions towards partnering and collaborations to ensure worldwide access to our products and up (audio gap) value to our stakeholders.

Gedeptin and CM04S1 provide significant value expansion opportunity for the company, our shareholders, and our stakeholders. As a reminder, Gedeptin is a cancer therapy currently in an expanded, multi-site evaluation among patients suffering from advanced head and neck cancers. The product has received orphan drug designation from the FDA, as well as the initial funding and support of the current clinical trial coming from the FDA orphan drugs clinical trials program.

Our focus is on accelerated and expanded patient enrollment, now that additional Gedeptin sites are on board. Our goal is to complete patient enrollment in 2023, followed by completion of patient evaluations before the end of 2024. In the interim, we expect to engage with the FDA regarding the results with the focus on clarifying the opportunity for an expedited biologics license application filing. We're excited about the outlook and promise of Gedeptin within advanced head and neck cancers.

In addition, there are promising opportunities relative to expanded use of Gedeptin in other indications, as well as application of the underlying technology in conjunction with other therapies and potential synergy with our internally developed MUC1 tumor-associated antigen approach. We also anticipate expanded discussions related to partnering and collaborations related to Gedeptin.

CM04S1 is our leading, next-generation COVID-19 vaccine, currently in phase 2 clinical development, targeting both the antibody and cellular arms of the immune system, with the goal of providing more robust and durable protection than the currently authorized vaccines. This vaccine holds promise over the current authorized vaccines from several critical areas of differentiation and value to various patient populations. Our focus is on accelerating the clinical development of each of these products, including the potential for expedited regulatory review. Meanwhile, we continue to advance other internal development programs in the path to IND filing.

We remain focused on accelerating efforts towards our milestones over the next 12 to 18 months in support of both the Gedeptin and the CM04S1 COVID-19 vaccine programs. We expect to report not only on the expansion of the Gedeptin study to additional sites, but also initial clinical data which we anticipate reporting during the first half of 2023. We also anticipate reporting initial clinical results in support of CM04S1 during the first half of 2023.

In addition, we will continue to provide updates related to the progress of our programs that are advancing the clinical status. Since January, we have added \$37 million to our balance sheet, despite this year representing what many consider the most challenging year in over a decade for capital development within the biotech industry. Our successful financing supports efforts towards the completion of the current clinical programs.

We continue to receive strong interest related to investment capital, which we'll evaluate, but we're focused on execution towards our 2022 and 2023 goals of building shareholder value. We're committed to the clinical development of CM04S1 against COVID-19, specifically as an invaluable medical tool to address the continually emerging variance of concern while also providing critically important value to those with compromised immune systems.

CM04S1 induces immunity to SARS-CoV-2 by stimulating the immune system to produce antibodies that can block the virus from entering healthy cells, while also inducing the growth of new disease-fighting T cells that can recognize and destroy infected cells. This is an important distinction between CM04S1 and the first generation COVID-19 vaccines. Our vaccine includes both SARS-CoV-2 spike and nucleocapsid proteins as immunogens differing from the current authorized vaccines, which only include the spike protein.

By inserting both of these viral genes, the vaccine is able to drive the expression of both proteins within the body of the vaccine recipient. Again, this is an important distinction as CM04 is specifically designed to induce an expanded immune response, offering significant potential for improved levels of efficacy and differentiation within the field. 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. The vaccine is the first step in the worldwide goal to provide a vaccine that actually gets ahead of the variants versus having to chase the variants.

Our approach of using the spike and nucleocapsid viral proteins was recently validated by multiple independent academic research groups and animal models using MVA and other vaccine platforms. Assuming continued success, this vaccine will likely reduce the requirement to continually adjust the vaccine and the reliance on the repeated administration of booster doses. This is what we mean in stating getting ahead of the variants versus chasing the variants.

In July, analysis of data from the phase 1 study of CM04S1 published in the peer-reviewed journal Eye Science showed that the vaccine, which is based on the same Wuhan strain as the first generation approved vaccines, induced potent and equivalent T-cell cross reactivity against Delta and Omicron variants. These findings suggest that T-cell immunity, simulated by CM04S1, may constitute a critical line of defense to provide long-term protection against SARS-CoV-2 variants.

We also believe that the multi-punch approach has the potential of providing a more robust and durable immune response and protection in various high risk populations, specifically immunocompromised individuals, who will benefit from such a multi-pronged approach, resulting in broader and more durable protection. The vaccine is currently being evaluated in two, phase 2 clinical trials. One is a comparative study of our vaccine as the primary vaccine versus the current FDA approved Pfizer vaccine in individuals that have received or are undergoing specific blood cancer therapies associated with transplantation or CAR T therapy, which severely reduced preexisting immunity to COVID-19 vaccines.

Clinical evidence indicates that such patients fail to respond optimally to the current generation vaccines and we believe that CM04S1 will prove to be more potent because it is multi-antigenic and delivered using the highly potent MVA viral vector. We believe this will differentiate CM04S1 from the other vaccines by inducing strong and sustained antibody T-cell responses in patients who are at severe risk of COVID disease, due to their immunocompromised status.

The other phase 2 trial underway is evaluating CM04S1 as a booster for healthy patients who have previously received either the Pfizer or Moderna vaccines. We believe that providing a heterologous booster rather than continued multiple shots of the same vaccine will induce more robust and durable immune responses and protection. Heterologous prime booster immunizations are well-studied in other fields, such as HIV, and are being evaluated in multiple countries using different COVID-19 vaccines. Our goal is to provide a vaccine that ends the requirement of multiple boosters throughout a year.

Finally, I want to reinforce the concept that our internal effort to develop an advanced MVA manufacturing process based on continuously growing avian cell lines to increase production, consistency, capacity, and flexibility will mesh with the clinical development activities. In total, this represents the full development scope associated with the GeoVax coronavirus vaccines.

Monkeypox cases continue to increase worldwide with nations enacting procedures and policies in support minimizing the health risk their populations. There's also concern that more virulent

and infectious forms of monkeypox might evolve, resulting in an increased spread of disease and deaths. The vaccine vector, modified vaccinia Ankara, or MVA, which is utilized in numerous GeoVax vaccines, including our CM04S1 COVID-19 vaccine, is the primary vaccine used to prevent the global monkeypox threat.

As you may know, MVA is currently stockpiled and utilized to protect against both monkeypox and smallpox. In August, our colleagues at City of Hope published results demonstrating that both CM04S1 and the synthetic MVA used in the construct of CM04S1, induced robust antibody and cellular immune responses against monkeypox that were durable for over six months post-vaccination. The authors also concluded that CM04S1 and synthetic MVA represent unique vaccine candidates to control the expanding global monkeypox outbreak.

GeoVax is evaluating development regulatory pathways towards this opportunity as the need for expanding the MVA vaccine availability beyond the current limited, single-source provider is a global and increasing concern. And in fact, just today, we've announced our securing the rights of the NIH MVA for use against monkeypox and smallpox.

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

### **Mark Reynolds**

Thank you, David. So starting with our income statement, the first thing to note is the minimal amount of grant revenues reported during 2022 as compared to 2021, which is reflective of the expected wind down of our grant from the U.S. Army and the NIH for our Lassa fever programs and our COVID-19, preclinical program as we've now focused moving our attention to the clinical programs for both COVID-19 and Gedeptin. We do intend to seek additional non-dilutive funding for our development programs in the future, and I'll make that point.

R&D expenses, or research and development expenses, were \$2.7 million for the third quarter of 2022, and \$5.4 million for the nine-month period, reflecting a substantial increase versus 2021 amounts, of \$1.2 million and \$2.7 million, respectively. These increases were planned and expected as they are associated with new clinical trial activity for our CM04S1 and Gedeptin programs, including manufacturing costs for clinical trial materials. The increase is also reflective of higher personnel and consulting costs as we staffed up earlier in the year.

General administrative expenses were \$1.2 million for the third quarter of '22 and \$3.4 million for the nine-month period, as compared to \$758,000 and \$2.6 million in 2021, with the increases, again, associated with higher personnel, consulting, and higher patent costs.

So overall net loss for the third quarter of 2022 was \$4 million, or \$0.17 per share versus \$2 million in 2021 or \$0.31 per share. For the nine-month period, our net loss was \$8.6 million in 2022 or \$0.63 per share versus \$4.8 million in 2021 or \$0.80 per share. Again, the increases

during 2022 were primarily associated with the ramp up of our organizational infrastructure and other costs associated with the CM04S1 and Gedeptin clinical trials.

Turning now to the balance sheet, our cash balances at September 30 were approximately \$35 million, as compared to \$31 million at the end of the last quarter, and \$1.4 million at the end of 2021. The change in cash balances for 2022 is reflective of \$12 million used in operating activities, offset by proceeds from stock offerings in January and May, with combined net proceeds to us of nearly \$28 million, and an additional \$7.6 million proceeds from the exercise of warrants during the third quarter.

Our outstanding common shares now stand at 26.3 million. So in summary, we are well positioned to accelerate and advance our clinical programs with a cash runway sufficient to fund our operations and our priority programs through the end of next year. Funding our three, ongoing, phase 2 clinical programs and preparing for the next stages of development are the most significant use of our cash and our top financial priority.

So I'll be happy to answer any of the questions during the Q&A. I'll turn the call back to David now.

**David Dodd**

Thank you, Mark. My colleagues and I will now answer your questions. Joining us for the Q&A session are, as mentioned earlier, Dr. Mark Newman, Dr. Kelly McKee, Dr. John Sharkey, our Chief Scientific Officer, Chief Medical Officer, and Vice President of Business Development, respectively. Therefore, turning the call over to the operator for instructions on the Q&A period.

**Operator**

Thank you. We will not be conducting the question-and-answer session. If you would like to ask a question today, please press\*1 from your telephone keypad and a confirmation tone will indicate your line is in the question queue. You may press \*2 if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. One moment, please, while we poll for questions. Thank you.

Thank you. Our first question is from the line of Jeffrey Kraws with Crystal Research Associates. Please proceed with your questions.

**Jeffrey Kraws**

Thank you very much. Nice job on moving so many programs ahead and on schedule of what you had told us you were going to almost a year ago. I have a few questions. The first is on the COVID-19 immunocompromise trial. You had mentioned in your announcement that you were going to be expanding the number of centers. Can you please elaborate on how many centers you're planning to elaborate to and what we can expect out of that?

**David Dodd**

Sure. Jeff, thank you. I appreciate your question. I'll ask Kelly McKee to address that. Dr. McKee?

**Kelly McKee**

Yeah, hi. Thanks for the question. Yeah, our current plan is to expand up to somewhere between 20 and 30 centers. It's a work in progress. We're making slow but steady process -- progress with enlisting interested sites, but our ultimate goal is probably 20 to 30 sites.

**Jeffrey Kraws**

Okay. Thank you very much. With your expertise in MVA right now and certainly the positive responses you're getting, what is the status rate now with -- regarding -- with regard to monkeypox?

**David Dodd**

Okay, thank you. I'll ask Dr. John Sharkey to address that. He is our point person on that. John?

**John Sharkey**

Sure. Thanks for the question. There are two aspects of the monkeypox, and I'll touch first upon the addition of a monkeypox indication to our MVA platform vaccine, such as COVID-19 and Ebola and the others. And we've been in discussions with our regulatory experts, mostly outside. And we've come to the conclusion that there is a clear regulatory pathway to getting both the monkeypox and the smallpox indication and on to what we refer to as a primary MVA vaccine, such as our COVID-19 or an Ebola or something else.

As we work through this and, to put it simply is, the primary vaccine indication, for example, COVID-19, will dictate the development timeline. But we believe, in parallel, we can collect the additional information required so that, at the time of registration, or quickly thereafter, we could add that indication. In regards to what we announced today with the rights to the NIH MVA for monkeypox and smallpox, we're looking to develop an MVA vaccine. We know MVA is effective here.

We believe that with the amount of information known about MVA, the safety profile of MVA, remembering that it was developed, used in immunocompromised population, that there should be an abbreviated pathway, an expedited pathway to getting this through. With the MVA in hand, we started activities of scaling up our master C batches, which would allow us to move into CGMP production and working with select regulatory agencies, we're going to map out, as I said, an expedited pathway to getting this to market. That's our intention.

**Jeffrey Kraws**

Great. That's very impressive. Last question, your head and neck centers, obviously, are active. Can you provide some of your thoughts as to what we should expect to see, as far as progress from those centers and will we expect to see you at ASH? Thank you.

**David Dodd**

Dr. McKee would you like to answer that -- respond, please?

**Kelly McKee**

Sure. So our ongoing Gedeptin trial is now -- involves three, academic medical centers. The first one, Stanford, is the center that enrolled the initial five patients, and we've added two more. Both of them are now under contract, up and running, and actively seeking patients to screen and enroll. And we anticipate getting the -- that -- this study fully enrolled, hopefully, by the end of this year or at, the latest, early next year.

And as for ASH, I will be attending ASH, actually, so.

**Jeffrey Kraws**

Okay. Thank you very much. That's all my questions.

**David Dodd**

Thank you, Jeff.

**Operator**

The next question comes from the line of Vernon Bernardino with H.C. Wainwright. Please proceed with your question.

**Leah Lowe**

Hello everyone. Thank you for taking our call -- or our questions. This is Leah Lowe (ph) dialing in for Vernon. And I was just curious if you can provide us with some color on -- with what GeoVax thinks about recent results from competitors, specifically how it will relate to these immunocompromised individuals?

**David Dodd**

Sure. I would ask maybe Mark Newman -- Dr. Newman, you'd like to start off and maybe Kelly would like to then add on? And if I feel something else needs to be added, I'll add that (audio gap). Dr. -- Mark?

**Mark Newman**

Yes, sure I can try. So when you say news from competitors, what specifically are you talking about?

**Leah Lowe**

Well, I was just referring like, overall, say like the green scheme (ph). Right? There was just some news that came out from Novavax with the vivillin (ph) vaccine. Right? And just, overall, the question of, how should we be approaching a variant specific vaccine? And, I mean, all of this has been done in, not immunocompromised individuals. I'm just wondering, like, what does this

mean for immunocompromised individuals? At least how does GeoVax see the landscape for that specific patient population?

**Mark Newman**

Okay, yes, sure. So, remember, the MVA was developed as a smallpox vaccine specifically for use in patients with some level of immunocompromised immune systems. So the safety and everything is unique, but it's also the potency. This is a product that is very effective at driving antiviral responses, particularly T-cell responses. And so I think there's somewhat of a unique niche in the way that the vector is used. You don't get this with, like an mRNA product, per se. There's none of the additional kind of antiviral effects to it.

Beyond that, if -- you probably recall, and we've been focusing on the concept of breadth of response. And so, the virus, coronavirus does a lot of proteins and it's great to target just the S (ph), but the immune system gets a chance to see everything. And so, we're more closely trying to mimic a normal response, something that you would see if you recover on your own. So it's induction of an antibody response, not only to S, but also to N, the T-cell responses, as well.

And then, the -- just been a lot of independent research that's starting to get published kind of routinely now, both in animal models and in clinical trials, showing that immune responses that are more broadly targeted, S plus N, can actually protect animals from infectious challenge. This is, like I said, coming up from independent studies, which it -- but it's really nice. It's validating what we've got into a phase 2 trial.

But there's also a number of clinical trials, one just crossed my desk yesterday, or studies on humans, that have recovered from infection showing the types of responses that are correlated. And yesterday's papers, how important cellular immune response is to the nuclear capsid are for these patients. So the -- it's -- I think it's really lining up well. We've been talking about this for about 18 months to two years now, and finally getting a lot of traction and it's -- we kind of joke a little bit.

It's nice to see these animal studies validating what we already are -- knew and are seeing in clinical trials. So I think there's a lot of opportunities here. How to be used in the end, it's -- be some regulatory questions and things to address, as well. Because there's always going to be that standard of care product that's out there, and with each individual patient population, there might be a unique approach to the how you would administer the vaccine in combinations, as David said, heterologous prime-boost; or as individual products; yearly boosters; every five-year boosters, all those will probably have to be fine-tuned.

**Leah Lowe**

Thank you for that. That actually is very helpful. And then I did have some problems with my connection, so I'm sorry if you're going to repeat yourself with my next question, but I just wanted to know if I maybe missed if there were any changes to any of that current catalyst?

**David Dodd**

I don't believe so.

**Leah Lowe**

Okay.

**David Dodd**

I was going to add, Leah, on that first issue, about the immunocompromised. Based on the discussions we're having with various advisors, consultants, we believe that there may very well be expedited pathways for focusing on certain immunocompromised populations, relative to the continued development of our COVID-19 vaccine, so the CMO4S1. And we'll be further refining those through discussions, not just amongst ourselves and consultants, but also with the FDA, as we go forward into 2023, and as we start sharing the initial data results that we're getting from the existing trials. So we'll keep everyone update on that.

But we do believe that by focusing specifically on populations with immunocompromise -- who are immunocompromised, that there may be expedited pathways and in much stronger points of differentiation for us than, obviously, going toe-to-toe with the very large players who could - - dealing with relatively healthy people. They're going to continue to have their challenges of addressing variants of concern, but we do believe that there is a strong point of distinction, differentiation that will be -- bode very well for GeoVax.

**Leah Lowe**

Thank you.

**Operator**

Thank you. The next question is from the line of Robert LeBoyer with Noble Capital. Please proceed with your question.

**Robert LeBoyer**

Thank you. First, congratulations on all the progress. And my question was partially answered with the previous answer. And I was going to ask about the current environment for COVID vaccines and requirements for approval as the virus is evolving and variants are coming out, specifically in terms of what the regulatory path might be, and in terms of size of trials, next trials, or any light that you can shed on the next steps, after the phase 2 data comes out for either trial.

**David Dodd**

Thank you, Robert. I think our anticipation is that that will be clarify (audio gap) as we engage in discussions, having data from these trials as they're coming out, with the FDA. Now, what we will be also addressing is the advice we're receiving, and we believe in it also rather strongly, is that there are certain populations for which we may have a very compelling argument or proposal to make to the regulatory agencies about targeting specific populations who clearly are not being

well served, or served at all, by the current vaccines, even if they modify them to chase after a new, emerging variant.

And we plan to focus on that very strongly as we gather the data that we'll begin to see in the not too distant future and will engage in those discussions. And then, as we learn more, we'll keep you updated, but that's sort of the basis of the pathway that we're looking at.

**Robert LeBoyer**

Okay. That's helpful. Thank you very much.

**David Dodd**

Thank you.

**Operator**

Thank you. At this time, we have reached the end of our question-and-answer session and I'll hand the floor to management for further remarks.

**David Dodd**

Okay, thank you. This concludes our question-and-answer session. So what I'd like to now do is thank everybody for participating in this update call, sharing in our achievements, our progress, and our outlook. We're quite excited about what is being achieved and what we're advancing here at GeoVax, and in relatively short time. It was approximately just a little over two years ago that we did the recapitalization of list from NASDAQ. And your interest is greatly valued and appreciated. So thank you.

Going forward, our focus is on (audio gap) reporting updates and progress for Gedepin, for CMO4S1, and our other development programs, as well as expansion of our capabilities and resources. Our goal and focus is to build shareholder and stakeholder value.

I want to also acknowledge and thank our Board of Directors, our GeoVax staff, and the many other parties that continue to support, assist, and advise us towards achieving success. For all of us, it is indeed a great pleasure serving our shareholders and being a part of this team and on the pathway that we're pursuing. So have a safe, enjoyable day and again, thank you for your interest.

**Operator**

This will conclude today's conference. You may disconnect your lines at this time. Thank you for your participation.

Exhibit 99.3

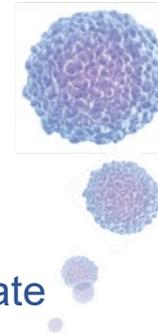


# Q3 Corporate Update Conference call

November 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.

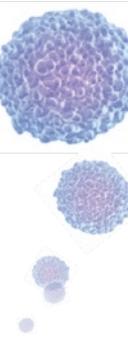


## **GeoVax Reports 2022 Third Quarter Financial Results and Provides Corporate Update**

***Phase 2 Clinical Trials Advance for COVID-19 and Immuno-Oncology  
Company Secures Rights to NIH-MVA for Protection Against Monkeypox and Smallpox***

ATLANTA, GA, November 9, 2022 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced its financial results for the third quarter ended September 30, 2022.

GeoVax’s management will host a live conference call and webcast at 4:30 p.m. EST on Wednesday, November 9, 2022, to provide a general business update and discuss financial results. Further details are provided below.



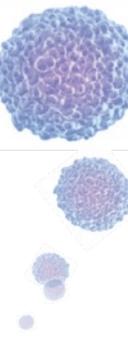
## Gedepin® Product Profile

### Initial Indication: Advanced Head and Neck Cancers

- Ph 1 Clinical results indicate tumor shrinkage and strong safety profile
  - Orphan Drug Status granted
- Develop for further tumor indications
- Develop in combination with ICIs



# COVID Vaccine

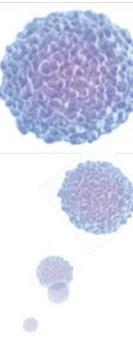


## GEO-CM04S1 Product Profile

- Targeting the Immunocompromised populations as a primary vaccine
- As a more robust, durable booster for 1<sup>st</sup> generation COVID-19 vaccines
- Uniquely inducing both Antibody & Cellular immune responses
- *Single-dose; durable; recognized safety; minimal refrigeration*



# 2022-2023 Clinical Trial Milestones



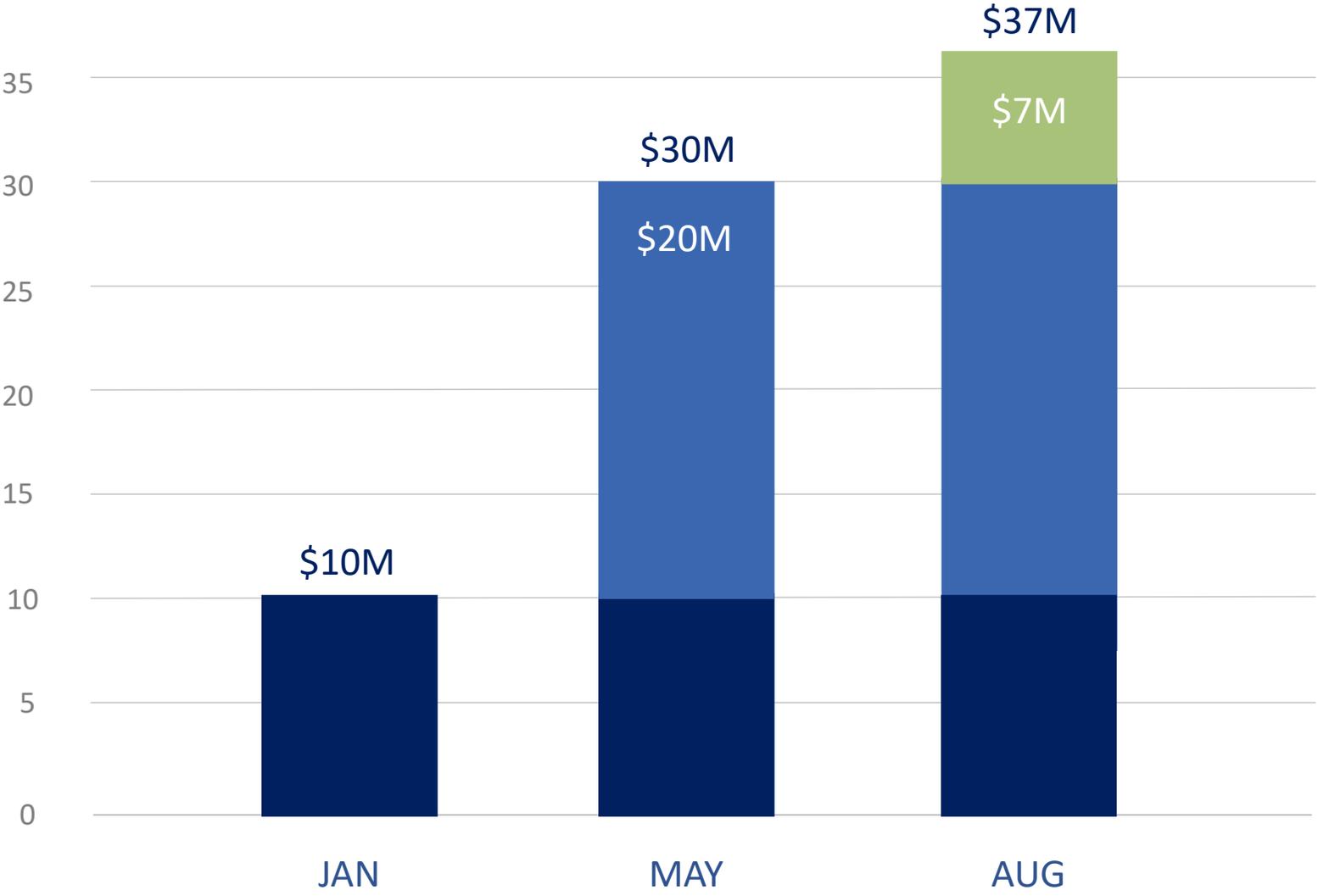
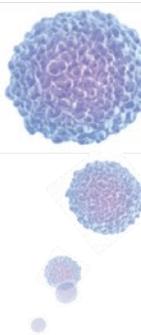
## **Gedepin<sup>®</sup> (Advanced Head and Neck Cancers)**

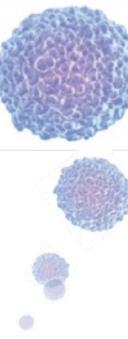
- 2022: IND transferred to GeoVax
- 2022: CRO (Allucent) engaged; Multi-site expansion of clinical trial
- 2023: Regulatory discussions re expedited registration pathway
- 2023: Completion of patient enrollment

## **GEO-CM04S1 (COVID-19)**

- 2022: IND transferred to GeoVax
- 2022: CRO (Allucent) engaged
- 2022: Completion of enrollment (booster trial)
- 2023: Expansion of trial to multi-sites (Immunocompromised trial)
- 2023: Initial data read-out, booster trial
- 2023: Regulatory discussion re expedited registration pathway (immunocompromised patients)

# Successful Capital Development Cumulative YTD 2022



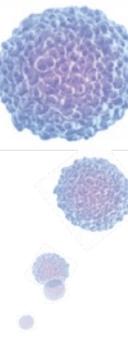


## **MVA as a vector supports the design and production of “next-generation” vaccines encoding multiple viral proteins**

- **Spike protein as both the antibody and T-cell immunogen**
  - Neutralizing antibodies induced after two doses
- **Nucleocapsid and Spike as the T-cell immunogen**
  - Responses induced with a single dose
  - Epitopes are conserved Wuhan to Omicron
  - Antibodies specific for N also induced

**Combination of Spike + Nucleocapsid provides coverage for Variants of Concern (VoCs)  
– Omicron, Delta, etc.**

***Other vaccine platforms (e.g., mRNA, etc.) are unable to encode multi-antigens into a single vaccine***



## GEO-CM04S1 – Phase 2 Clinical Trials

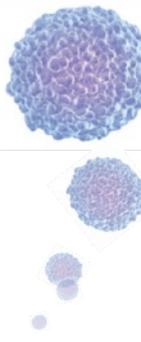
### Phase 2: For the Immunocompromised

- As a primary vaccine in direct comparison to the Pfizer mRNA vaccine
- Most advanced trial to specifically evaluate a multi-antigen COVID-19 vaccine in patients with hematologic malignancies vs mRNA vaccine

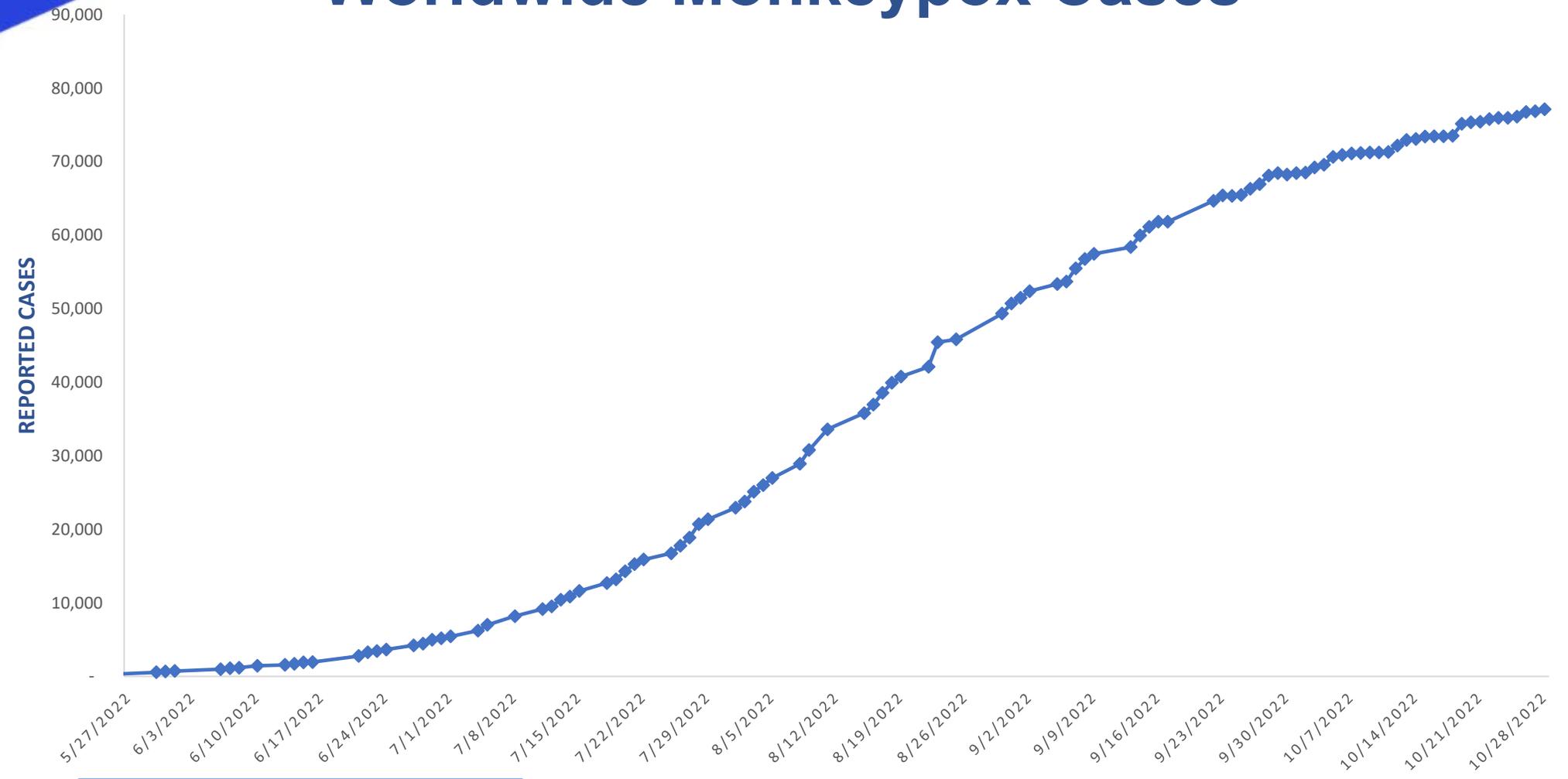
### Phase 2: Booster

- In the healthy population following vaccination with an mRNA vaccine
- Potential for broader and more durable protection versus a 3rd or 4th mRNA dose

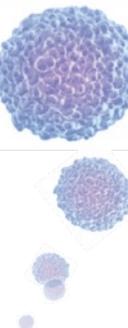
# Monkeypox



## Worldwide Monkeypox Cases



Data source – Airfinity Limited

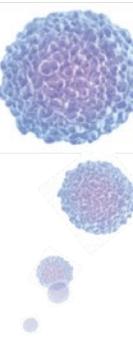


## CM04S1: COVID-19 + Monkeypox (validation in non-human primates; human-adults)

Flavia Chiuppesi, John A. Zaia, Sandra Ortega Francisco, Minh Ly, Felix Wussow, Don J. Diamond  
**Synthetic modified vaccinia Ankara vaccines confer potent monkeypox immunity in non-human primates and healthy adults.** *medRxiv* <https://doi.org/10.1101/2022.07.26.22277958> 2022

## GeoVax Secures Rights to NIH-MVA for Use Against MPXV & Related Viruses

**GeoVax Labs, Inc.**  
**Consolidated Statements of Operations Information**  
*(amounts in thousands, except share and per share information)*

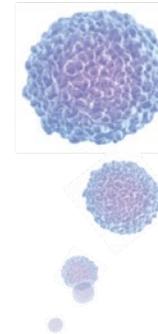


	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Grant revenue	\$ -	\$ 30	\$ 82	\$ 221
Operating expenses				
Research and development	2,721	1,224	5,359	2,660
General and administrative	1,249	758	3,364	2,563
	<u>3,970</u>	<u>1,982</u>	<u>8,723</u>	<u>5,223</u>
Loss from operations	(3,970)	(1,952)	(8,641)	(5,002)
Other income (expense), net	<u>2</u>	<u>1</u>	<u>4</u>	<u>175</u>
Net loss	<u>\$ (3,968)</u>	<u>\$ (1,951)</u>	<u>\$ (8,637)</u>	<u>\$ (4,827)</u>
Loss per common share	<u>\$ (0.17)</u>	<u>\$ (0.31)</u>	<u>\$ (0.63)</u>	<u>\$ (0.80)</u>

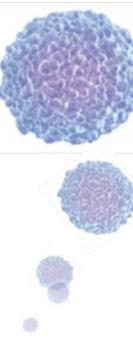
# GeoVax Labs, Inc.

## Consolidated Balance Sheet Information

*(amounts in thousands, except share information)*



	September 30, 2022	December 31 2021
<b>Assets</b>		
Cash and cash equivalents	\$ 34,677	\$ 11,424
Other current assets	1,460	205
Total current assets	36,137	11,629
Property and other assets, net	2,433	168
Total assets	\$ 38,570	\$ 11,797
 <b>Liabilities and stockholders' equity</b>		
Total liabilities	\$ 6,789	\$ 7,435
Stockholders' equity	31,781	4,362
Total liabilities and stockholders' equity	\$ 38,570	\$ 11,797
Common shares outstanding	26,334,953	6,381,541



Q&A Session



GeoVax®