SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 11, 2021

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

Emerging growth company □

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)

under any of the following provisions.	is intended to simultan	eously satisfy the filing obligation of the Registrant						
☐ 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 CFR240.14a-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	t:							
	Trading							
Title of each class	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						

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. \Box

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).

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 11, 2021, GeoVax Labs, Inc. (the "Company") issued a press release reporting its results of operations for the quarter ended September 30, 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 November 11, 2021, the Company hosted a conference call and webcast with accompanying slides regarding its results of operations for the quarter ended September 30, 2021, as well as the previously disclosed license agreement with City of Hope granting the Company exclusive worldwide rights to develop and commercialize COH04S1, a multi-antigenic SARS-CoV-2 investigational vaccine for immunocompromised patients, currently undergoing Phase 2 human clinical trials.

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	
Ex	<u>hibit No.</u>	<u>Description</u>
99.	1	Press Release dated November 11, 2021
99.2	2	Conference Call Transcript dated November 11, 2021
99.3	3	Conference Call Slide Presentation dated November 11, 2021
104	ļ.	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 12, 2021

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds

Mark W. Reynolds Chief Financial Officer



GeoVax Reports 2021 Third Quarter Financial Results and Provides Corporate Update

Progress in Clinical Development of COVID-19 and Immuno-Oncology Programs

ATLANTA, GA, November 11, 2021 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers, today announced its financial results for the quarter ended September 30, 2021 and provided a corporate update.

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

Recent Developments

 On November 9, GeoVax announced that it had entered into an exclusive license agreement with City of Hope ("COH") that grants GeoVax exclusive rights to further develop and commercialize COH04S1, a synthetic, attenuated modified vaccinia Ankara (sMVA) vector expressing spike (S) and nucleocapsid (N) antigens of the SARS-CoV-2 virus, which shows potential to be used in the general population as a primary and/or general booster vaccine against COVID-19 worldwide.

A Phase 2 clinical trial to evaluate the safety and immunogenicity of the COH04S1 investigational vaccine, 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 is currently underway. The trial is also the first to compare an investigational multi-antigenic COVID-19 vaccine to the current 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.

The ongoing Phase 2 trial is designed to evaluate COH04S1 in immunocompromised patients. An additional Phase 1/2 trial to evaluate COH04S1 as a universal booster to current FDA-approved vaccines is anticipated to open soon for enrollment in healthy volunteers.

- In September, GeoVax expanded its clinical-stage immuno-oncology pipeline and added a new technology platform through the acquisition of exclusive rights to develop and commercialize Gedeptin[®], a novel patented product for the treatment of solid tumors through a gene therapy strategy known as GDEPT (Gene-Directed Enzyme Prodrug Therapy). 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. A cycle of Gedeptin[®] therapy consists of three intra-tumoral injections over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days. A Phase 1/2 trial is currently enrolling to evaluate the safety and efficacy of repeat cycles of Gedeptin[®] therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options. The initial stage of the study is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grants Program. The FDA has granted Gedeptin[®] Orphan Drug status for the treatment HNSCC. GeoVax's license to Gedeptin[®] includes rights to expand its use to all human diseases and/or conditions including, but not limited to, other cancers.
- In August, the Company presented data from ongoing studies of its preventive vaccine against COVID-19 during the European Society of Medicine (ESMED) General Assembly. The Company's initial vaccine candidate, GEO-CM02, encodes the Spike (S), Membrane (M) and Envelope (E) proteins from the SARS-CoV-2 virus. In this initial format, the simultaneous expression of the SARS-CoV-2 proteins supports the *in vivo* formation of virus like particles, or VLPs, which induce both antibody and T-cell responses. The

Company also presented vaccine efficacy and immunogenicity data for GEO-CM02 from hamster and transgenic mice studies completed to date. Incorporation of sequence-conserved nonstructural proteins can provide targets for T-cell responses to further increase the breadth and function of vaccine-induced immune responses. This strategy provides the basis for generating a universal vaccine with augmented potential to alleviate the burden of disease caused by circulating coronaviruses. The Company's ESMED presentation is available on GeoVax's website at www.geovax.com/investors/events.

• The Company recently announced that the U.S. Patent and Trademark Office has issued a Notice of Allowance for Patent Application No. 15/543,139 entitled "Replication-Deficient Modified Vaccinia Ankara (MVA) Expressing Ebola Virus Glycoprotein (GP) and Matrix Protein (VP40)." GeoVax has demonstrated that a single intramuscular (IM) dose of its vaccine candidate, GEO-EM01, provided 100% protection in rhesus macaques challenged with a lethal dose of Ebola virus (EBOV). This is the first report that a replication-deficient MVA vector can confer full protection against a lethal EBOV challenge after a single-dose vaccination in macaques. GEO-EM01 is based on the Company's novel Modified Vaccinia Ankara (MVA) Virus-Like Particle (VLP) platform, which generates noninfectious VLPs in the individual being vaccinated. VLPs mimic a natural infection, triggering the body to produce a robust and durable immune response with both antibodies and T cells.

In addition to its vaccine for EBOV, GeoVax is also developing preventive vaccines for other hemorrhagic fever viruses highly lethal to humans. In July 2021, the Company announced results of preclinical efficacy studies of its Sudan ebolavirus (SUDV) vaccine candidate, in which a single dose of the vaccine protected 100% of animals challenged with a lethal dose of SUDV. This is the first report that a replication-deficient MVA vector may confer full protection against SUDV after a single dose. This work was conducted in collaboration with researchers at the University of Texas Medical Branch (UTMB). Separately, GeoVax is leading a multi-party collaboration for the development of its SUDV and Marburg virus (MARV) vaccine candidates. The collaboration, between GeoVax, researchers at UTMB and Battelle Memorial Institute, utilizes the suite of preclinical services from NIAID. Under the collaboration, GeoVax's SUDV and MARV vaccine candidates are being tested for immunogenicity and efficacy in the benchmark nonhuman primate model. GeoVax's vaccine against Lassa Fever virus (LASV) is progressing in preclinical studies with funding support from the U.S. Department of Defense.

Management Commentary

David Dodd, GeoVax's Chairman and CEO, commented, "The signing of the license agreements for Gedeptin® and COH04S1 were each highly significant events for GeoVax and our stockholders, as they added clinical programs in both immuno-oncology and COVID-19, the primary focus areas for our company, to our pipeline,. The initial stage (10 patients) of the ongoing Gedeptin® clinical trial is being funded by the FDA pursuant to its Orphan Products Grants Program, with five patients having been enrolled to date. Our immediate objective will be to accelerate patient enrollment to complete this stage, then expand the trial to additional study sites and at least 25-30 patients in total.

"The addition of COH04S1 to our product pipeline is synergistic with, and complementary to, our ongoing development of GEO-CM02. Both vaccine candidates are potential second-generation COVID-19 vaccines, with COH04S1 representing a near-term opportunity for a niche-market indication for use in immunocompromised patients and possible expansion to a broader market indication as a universal booster vaccine. GEO-CM02, in contrast, is being developed as single-dose pan coronavirus vaccine. Our funding events from 2020 and early 2021 have positioned us well to advance each of these development programs," Mr. Dodd concluded.

Financial Review

GeoVax reported a net loss of \$1,950,503 (\$0.31 per share) for the three months ended September 30, 2021, compared to a net loss of \$570,648 (\$0.73 per share) for the same period in 2020. For the nine months ended September 30, 2021, the Company's net loss was \$4,827,314 (\$0.80 per share) as compared to a net loss of \$1,621,546 (\$2.85 per share) in 2020.

Grant and collaboration revenues were \$30,414 and \$220,539 for the three-month and nine-month periods ended September 30, 2021, respectively, as compared to \$415,458 and \$1,572,037 reported for the comparable periods of 2020. As of September 30, 2021, there is \$244,888 of approved funds remaining and available for use related to the Company's COVID-19 grant from NIAID and Lassa Fever grant from the U.S. Army.

Research and development expenses were \$1,224,362 and \$2,659,980 for the three-month and nine-month periods ended September 30, 2021, respectively, as compared to \$416,756 and \$1,687,113 for the comparable periods of 2020, with the increases primarily related to the Company's COVID-19 vaccine program, manufacturing process development, and a generally higher level of activity, offset in part by the timing and amount of external expenditures related to government grants. General and administrative expenses were \$757,432 and \$2,562,641 for the three-month and nine-month periods of 2021, respectively, as compared to \$435,013 and \$1,364,650 for the comparable periods of 2020, with the increase attributable to higher Delaware franchise taxes; legal, accounting and patent costs; insurance costs; consulting fees; Nasdaq listing fees; investor relations costs; and personnel costs.

Other income (expense) was \$877 and \$174,768 for the three-month and nine-month periods ended September 30, 2021, respectively, as compared to \$(134,337) and \$(141,820) for the comparable periods of 2020. The 2021 periods include a \$172,056 gain on extinguishment of debt, reflecting forgiveness of the Company's loan pursuant to the Paycheck Protection Program.

GeoVax reported cash balances of \$18.1 million at September 30, 2021, as compared to \$9.9 million at December 31, 2020. Contributing to the increase in cash balances during 2021 were net proceeds of \$9.4 million from the sale of common stock in February, and an aggregate of \$3.4 million from the exercise of warrants during the nine-month period ended September 30, 2021.

Summarized financial information is included below. Further information concerning the Company's financial position and results of operations are included in its Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission.

Conference Call

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

Participants are asked to pre-register for the call via the following link: https://dpregister.com/sreg/10161852/ef8e798f78

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 call.

The conference call will be available through a live webcast found here: https://services.choruscall.com/mediaframe/webcast.html?webcastid=1oc5dy2h

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 11, 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 10161852. The telephonic replay will be available until November 25, 2021.

About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines against infectious diseases and cancer using novel patented platforms. GeoVax's Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) based vaccine platform utilizes MVA, a large virus capable of carrying several vaccine antigens, that expresses proteins that assemble into VLP immunogens in the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the

target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax's MVA-VLP development programs are focused on preventive vaccines against COVID-19, HIV, Zika Virus, and hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), as well as therapeutic vaccines against multiple cancers. The Company has designed a preventive HIV vaccine candidate to fight against the subtype of HIV prevalent in the commercial markets of the Americas, Western Europe, Japan, and Australia; human clinical trials for this program are managed by the HIV Vaccine Trials Network (HVTN) with the support of the National Institutes of Health (NIH). GeoVax's HIV vaccine is also part of a collaborative effort toward a functional cure for HIV.

On November 9, 2021, GeoVax entered into a license agreement with City of Hope ("COH"), granting GeoVax exclusive rights to further develop and commercialize COH04S1, a synthetic attenuated modified vaccinia Ankara (sMVA) vector expressing spike and nucleocapsid antigens of the SARS-CoV-2 virus. In a placebo-controlled Phase 1 clinical trial of healthy adults, COH04S1 was shown to be safe and immunogenic. A Phase 2 clinical trial to evaluate the safety and immunogenicity of the COH04S1 investigational vaccine, compared to the Pfizer 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 is currently underway. 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. The ongoing Phase 2 trial is designed to evaluate COH04S1 in immunocompromised patients. An additional Phase 1/2 trial to evaluate COH04S1 as a universal booster to current FDA-approved vaccines is anticipated to open soon for enrollment in healthy volunteers.

In September 2021, GeoVax expanded its immuno-oncology pipeline and added a new technology platform through the acquisition of exclusive rights to Gedeptin®, a novel patented product for the treatment of solid tumors through a gene therapy strategy known as GDEPT (Gene-Directed Enzyme Prodrug Therapy). 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. A Phase 1/2 trial is currently enrolling to evaluate the safety and efficacy of repeat cycles of Gedeptin® therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumors accessible for injection and no curable treatment options. The initial stage of the study is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grants Program. A cycle of Gedeptin® therapy consists of three intra-tumoral injections over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days. The FDA has granted Gedeptin Orphan Drug status for the treatment HNSCC. GeoVax's license to Gedeptin® include rights to expand its use to all human diseases and/or conditions including, but not limited to, other cancers.

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 registration statement on Form S-3 and the periodic reports on Form 10-Q and Form 10-K that we have filed and will file with the SEC. Any forward-looking statement made by us herein speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

Contact:

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

FINANCIAL TABLES FOLLOW

GEOVAX LABS, INC.

Condensed Consolidated Statements of Operations Information

(amounts in thousands, except per share data)

	Three Months Ended September 30,				N	Ended 30,		
	2021		2020		2021			2020
Grant and collaboration revenue	\$	30	\$	415	\$	221	\$	1,572
Operating expenses:								
Research and development		1,224		417		2,660		1,687
General and administrative		758		435		2,563		1,365
		1,982		852		5,223		3,052
Loss from operations	(1,952)		(437)	(5,002)		(1,480)
Other income (expense), net		1		(134)	_	175		(142)
Net loss	\$ (1,951)	\$	(571)	\$ (4,827)	\$	(1,622)
Loss per common share	\$	(0.31)	\$	(0.73)	\$	(0.80)	\$	(2.85)

Condensed Consolidated Balance Sheet Information

(amounts in thousands)

	Sep. 202		Ι	Dec. 31, 2020	
Assets:					
Cash and cash equivalents	\$	18,107	\$	9,884	
Other current assets		53		351	
Total current assets		18,160		10,235	
Property and other assets, net		180		159	
Total assets	\$	18,340	\$	10,394	
Liabilities and stockholders' equity					
Total liabilities	\$	336	\$	825	
Stockholders' equity		18,004		9,569	
Total liabilities and stockholders' equity	\$	18,340	\$	10,394	
Common Shares Outstanding		6,382		3,834	

GeoVax Labs, Inc.

Third Quarter 2021 Financial Results

Thursday, November 11, 2021, 4:30 PM Eastern

CORPORATE PARTICIPANTS

Jules Abraham - Investor Relations

David Dodd - Chairman and Chief Executive Officer

Mark Newman - Chief Scientific Officer

Mark Reynolds - Chief Financial Officer

John Sharkey - Head, Business Development

Don Diamond - Professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope

PRESENTATION

Operator

Good afternoon and welcome, everyone, to the GeoVax Third Quarter 2021 Corporate Update Call. I am Rocco (PH) with Chorus Call and 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; John Sharkey, Ph.D., Head, Business Development; and Don Diamond, Ph.D., Professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope.

All participants will be in 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. To withdraw your questions, please press "*" then "2." Please note this event is being recorded. I would now like to turn the conference over to Jules Abraham of CORE IR, who will provide a forward-looking statement regarding this call and information herein.

Jules Abraham

Thank you, Rocco, and 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 amounts of 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. It's now my pleasure to introduce the Chairman and CEO of GeoVax, David Dodd. David?

David Dodd

Thank you. Good afternoon. Thank you, everyone, for participating in the 2021 third quarter update call. We are pleased to have this opportunity to review and discuss our continued progress and accelerating our priority development programs towards clinical development and continuing to secure significant resources in support of GeoVax growth and development. We remain focused on delivering meaningful results and value milestones over the next 12 to 18 months focused on our priority programs related to COVID-19 and immunooncology, developing increased value for shareholders, stakeholders, and public health worldwide.

Over the past year, we have strengthened our cash position while advancing towards important data milestones related to several of our programs. We remain pleased with the progress and outlook for GeoVax. Over the past few weeks, we have announced the successful entry of clinical development within both immunooncology and COVID-19 vaccine developments. These successful milestones are consistent with our goal of accelerating clinical stage status within each

of these strategic areas, while providing a strong foundation for further developments of novel differentiated products within these critical medical areas.

Since our recent Gedeptin announcement, we have confirmed two additional clinical sites and initiated the IND transfer to our responsibility. Further expansion and acceleration of the Gedeptin trial is underway. We are most excited about the outlook and promise of Gedeptin within head and neck cancer where it has received orphan drug designation from the FDA. In addition, there is promising opportunities relative to expanded use of the GDEPT technology in conjunction with other therapies and in conjunction with our MVA VLP tumor associated antigen approach.

Regarding the licensing of the Phase 2 COH04S1 vaccine program relative to COVID-19 and the expanded opportunities we expect in conjunction with our CM02 program, we will discuss those opportunities later in the call. In addition to the significant milestones achieved relative to Gedeptin and 04S1, our programs related to hemorrhagic fever virus vaccines continue to successfully progress via non-dilutive funding and support from the federal government.

This is well addressed in our press release noting the continued progress of these programs, especially through the suite of preclinical services from NIAID, for which GeoVax's Sudan and Marburg vaccine candidates are being tested for immunogenicity and efficacy in the benchmark non-human primate model. Our vaccine against Lassa Fever virus is in preclinical studies with funding support from the U.S. Department of Defense. We believe that our portfolio of hemorrhagic fever virus vaccines potentially offer valuable addition to preventing these highly dangerous and threatening viral challenges. We look forward to continued reporting on the progress of these programs.

Tuesday afternoon of this week, we announced the completion of an exclusive license pertaining to the COH04S1 vaccine, a Phase 2 COVID-19 vaccine from City of Hope, a world recognized research institution NCI-designated comprehensive cancer center. The Phase 2 clinical trial currently enrolling patients is the only one of its kind to prospectively study the safety and effectiveness of an investigational COVID-19 vaccine and blood cancer patients who have received a bone marrow transplant or CAR-T therapy. 04S1 utilizes modified vaccinia Ankara MVA technology, similar to our programs underway at GeoVax. We anticipate significant synergy with and complement to our program, but this transaction propels us into a critical stage of clinical development.

Created from a synthetic MVA, 04S1 works by inducing immunity to SARS-CoV-2 by stimulating the immune system to produce antibodies against the virus that can block the virus from entering healthy cells. With 04S1, the immune system can also grow new disease fighting T-cells that can recognize and destroy infected cells. This product has already been tested for safety and potency in healthy volunteers and induces strong T-cell responses. 04S1 is also the only COVID-19 vaccine to advance the Phase 2 trials in cancer patients that includes both SARS-CoV-2 spike and nucleocapsid or the M protein.

By inserting these proteins into the MVA delivery vehicle, the MVA is able to drive the expression of both proteins within the body of the vaccine recipient, spurring immunity against the virus. Giving 04S1 after CAR-T therapy may work better in reducing the chances of contracting COVID-19 or developing a severe form of COVID-19 in patients with blood cancer compared to the current vaccine options.

This trial is also the first comparative study of an investigational COVID-19 vaccine, with the FDA approved Pfizer/BioNTech and people receiving immunosuppressive therapy. For patients who

are likely to have difficulty mounting an antibody response due to extended B-cell aplasia post-therapy, the T-cell response to vaccine will be critical. But now in order to delve deeper into 04S1 in this transaction, it's my pleasure to introduce Dr. John Sharkey, Head of Business Development at GeoVax. John?

John Sharkey

Thank you, David. The transaction that was announced relative to COH04S1 provides a strong basis for propelling GeoVax's presence in the SARS-CoV-2 preventions market, a Phase 2 trial designed to evaluate immunogenicity and safety of the multi-antigenic 04S1 vaccine to the currently approved Pfizer/BioNTech mRNA vaccine in patients having recently undergone a hematopoietic cell transplant, or CAR-T therapy.

It's currently enrolling and strongly positions us in a market segment with significant unmet medical need. In addition, a planned Phase 1/2 trial to evaluate the immunogenic--response, pardon me, as a booster to healthy volunteers previously vaccinated with mRNA-based vaccines has the potential to expand the use of 04S1 into a significantly larger market segment.

We believe the transaction we announced, which grants us exclusive worldwide rights to 04S1 vaccine as well as the other underlying sMVA technology for use in the field of COVID-19, significantly accelerates our development activities in the COVID-19 prevention market. Now, I'd like to pass the discussion to Dr. Don Diamond, Professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope, who lead the development of this exciting product. Don?

Don Diamond

Thank you. First of all, I am delighted to be involved in this exciting new collaboration. My laboratory has been developing vaccine since the late 90s, but we consider COH04S1 our finest achievement. Let's discuss some data I brought along that illustrates some of the favorable properties of the vaccine. The key scientific breakthrough was the development of the synthetic platform shown on the slide is a virtual copy of the wild type vaccine virus, MVA.

As we published, the whole MVA genome was split into three pieces. And through sophisticated virologic science, all three pieces recombined into a circular viral DNA as shown on the right that is triggered to form an actual virus by another clever virologic method, detailed in our published report and patent filing. To make COH04S1 despite nucleocapsid genes from the original Wuhan strain of SARS-CoV-2 were inserted into individual plasmid components as shown in the slide. And once again, the three components recombined and with the aid of a helper virus, called FPV to form COH04S1, our clinical vaccine.

To investigate the properties of the vaccine, various preclinical models were evaluated, as detailed on the slide. We illustrate pivotal protection studies in hamsters and investigations into non-human primates. All the work pointed in one very positive direction. We applied to the FDA for permission to conduct a Phase 1 trial in healthy volunteers and were granted that permission. In this slide, we summarized the main objectives and outcomes of the clinical trial. We achieved the goal of developing a vaccine that elicited at both humoral and cellular immunity as shown on the slide. The immunity that we found was potent and had the right characteristics to be protective against SARS-CoV-2 infection and symptoms arising from that infection.

Here, we show some exciting data illustrating that, at all dose levels, there is a strong response to the vaccine generating the main components of a successful immune response. Antibodies, neutralizing antibodies, and TH1 bias T-cells observed the durability out to 100 days, 180 days

for all of the illustrated parameters. These observations bode well for a solid protective response that will last beyond the 180 days we show here. The full observation period for each subject is 1 year.

Here, we show that all important neutralizing antibody responses against the variants of concern. This is synonymous with protective humoral immunity. Of note, the titers are more durable and have higher magnitude at dose level 2 and dose level 3 for the nasty beta variant. All of the data will be publicly available once we submit this study for peer review and the manuscript is accepted.

Here are the results of LS-5 (PH) that detects the good T-cells, left panels, and the ones that are associated with disease enhancement, right panels. Note that the good T-cells are durable out to 180 days and the levels are still comparable or better to what other vaccines are eliciting and the bad T-cells never rise, even after 180 days. What we are seeing at 180 days, are memory T-cells that fall from the apex, but stabilize at levels that are reasonable for any chronic immune response. They don't disappear.

Our recently FDA permitted trial in our stem cell and CAR T-cell recipients recently got underway. We think this will differentiate our vaccines from the other products by sustaining a T-cell response in these very hard to treat patients who are still at high risk of severe COVID-19. We are excited to begin our first booster trial. We believe that delivering a different platform after multiple mRNA vaccines may cause more durable immunity that is long-lasting. We hope to open the trial shortly and expect rapid accrual. Now, I'd like to turn the discussion over to Dr. Mark Newman, GeoVax Chief Scientific Officer. Mark?

Mark Newman

Thank you, Don. Obviously, my team and I are delighted to have the opportunity to work with Dr. Diamond and the City of Hope and to have the City of Hope 04S1 vaccine as what is now the lead candidate--lead clinical stage candidate for our SARS-CoV-2 vaccine portfolio. Not only will this vaccine move the GeoVax effort forward in the clinic, but there are also multiple other valuable synergistic aspects to this partnership, which I am going to point out here.

First, as noted by both Dr. Diamond and David Dodd, the City of Hope 04S1 vaccine is based on the use of MVA. As you know from previous presentations, this is the viral vector modality of which is a foundational base of the GeoVax programs. Very comfortable with this and excited to work with the new variant. Second, the vaccine design is multi-antigen with both the SARS-CoV-2S or spike protein and nucleocapsid proteins being expressed in the body as the vaccine immunogens. Again you recall multi-antigen is our firm bias.

The vaccine induces in both neutralizing antibodies and T-cell responses specific for the spike protein and induces antibodies and T-cell responses before the nucleocapsid protein. This design concept was implemented specifically to induce the potency and to expand the immune response specifically to better combat and clear infections, regardless of the circulating SARS-CoV-2 variants, as Dr. Diamond showed you.

As we previously presented, the GeoVax approach is also focused on the induction of immune responses, specifically immune responses specific to proteins beyond the S-protein. As such, the City of Hope 04S1 clinical stage vaccine represents an ideal initial step as the basis of next generation vaccines specifically designed to augment and boost T-cell responses.

Finally, the ongoing GeoVax efforts to develop a manufacturing process that is based on a continuously growing avian cell line, specifically to increase production consistency and capacity

will mesh very nicely with the clinical development plans and clinical development schedule associated with the City of Hope 04S1 vaccine. I think, clearly, the benefits of this transaction to GeoVax program are highly significant and timely. Now, I am going to turn the presentation over to Mark Reynolds, the Chief Financial Officer.

Mark Reynolds

Thank you, Mark. So I am going to go through much of this pretty rapidly. I know this was the original purpose of this conference call, but I think our focus clearly is on the development programs versus the financials.

But anyway, starting with our balance sheet review, cash balances at September 30th were \$18 million compared with just under \$10 million at December 31st of last year. Working capital was \$17.8 million compared to \$9.4 million. And the increase, we have talked about this before, but the increase in cash balance is due primarily to our February offering--stock offering with net proceeds to us of \$9.4 million. And year-to-date we have also received \$3.4 million from the exercise of publicly traded warrants. Those are traded under the symbol, GOVXW.

Turning to the income statement, I am going to focus on the comparative figures for the 9-month periods of '21 versus '20, the grant and collaboration's revenues were \$220,000 during the '21 period versus \$1.6 million in 2020. The '21 period revenues relate entirely to our Grant from the NIH supporting our COVID-19 vaccine, while the 2020 amount includes revenues from our Grant from the U.S. Army supporting the loss of fever vaccine program. That Grant is continuing. We just have this timing of external expenditures on that that Grant will continue in the next year.

Research and development expenses were \$2.7 million in 2021 versus \$1.7 million in 2020, with the increase associated with license fees and warrant expense related to the end license of Gedeptin, expenses related to our COVID-19 vaccine program, manufacturing process development, and a generally higher level of activity. G&A expenses were \$2.6 million versus \$1.4 million. A large portion of the increase there relates through our annual Delaware State franchise tax, which is based on capitalization. That amount was minimal in 2020. Other increases were in insurance premiums, patent costs, legal fees, consulting fees, and personnel costs generally associated with preparing our organization for a much higher level of activity following our capital raises.

Other income and expense for '21 includes \$172,000 gain on extinguishment of debt associated with the forgiveness of our PPP loan. And overall, the net loss for the 9-month period of 2021 of \$4.8 million or \$0.80 a share compared to \$1.6 million of prior year or \$2.85 per share with the variance in the per share amounts primarily due to the dilutive effect of the offerings in September of last year and in February of this year.

And a few notes on our capital structure, there are 6.4 million common shares outstanding, 1.8 million of the GOVXW publicly traded warrants outstanding. Those are exercisable at \$5 a share. And if they are exercised in full, they can bring in another \$9.1 million into company's conference.

Our net cash flow from operating activities during '21 was nearly the same as our net loss of \$4.5 million. With the addition of the Gedeptin clinical program in September and now the City of Hope COVID-19 clinical program, our cash needs are obviously going to increase substantially, not only for the license fees and the direct cost associated with the clinical programs, but also for facilities, personnel, and other costs to support those programs.

While we aren't providing any specific forward-looking estimates and costs complete to these research programs, what we can say at this time is that our existing cash reserves are sufficient to rapidly move these programs forward through mid-2022. And we believe strongly that the nature of these programs and our overall product pipeline do create a very attractive investment opportunity for new fundraising activities. And I will be happy to answer any further questions during the Q&A. And now I am going to turn the call back over to David.

David Dodd

Thank you, Mark. Before opening the Q&A session, I'd like to highlight some key changes and progress we have achieved over the past year. It was about a year ago, November 6th last year, that we hosted our first quarterly conference call as a recapitalized newly financed NASDAQ listed GeoVax. At that time, we discussed our focus on achieving clinical stage status within the priority areas of SARS-CoV-2 and immunooncology, while also enhancing our resources and capabilities to rapidly manufacture and distribute products.

As the following two slides illustrate, we've remained focused on these priorities and we now have clinical stage program within both of the areas of immunooncology and SARS-CoV-2. Furthermore, we have additional program in each of these areas progressing successfully. And we have underway the expansion of MVA manufacturing processes and capabilities intended to support much higher manufacturing capacity within time periods to address epidemics and even pandemics.

Now, my colleagues and I will now answer your questions. Unfortunately, Dr. Diamond has had to leave our call, but Dr. Newman is prepared to address any questions you may have related to the 04S1 vaccine program. I am therefore turning the call over to the operator for instructions on the question-and-answer period.

QUESTION AND ANSWER

Operator

Thank you. 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. To withdraw your question, please press "*" then "2." Today's first question comes from Jason McCarthy of Maxim Group. Please go ahead.

Jason McCarthy

Hi, guys. Hope you are well. Thanks for taking the questions. I'd like to start with the 04S1 vaccine, clearly. Is there data out there that shows that the mRNA vaccines are insufficient in bone marrow transplant patients or people of immunocompromised? We have seen some publications starting to pop up in solid organ transplant patients that have been boosted like two, three, four, five times and they get nothing. Is that what the basis of targeting this population is?

Mark Newman

Yes. So, this is Mark Newman. Let me answer that two ways. Yeah. Certainly there is data out there that the existing S-only vaccines, the mRNA vaccines function sub-optimally in immunocompromised patients. And I think that that would be anticipating, right? Now, this--one of the other reasons for--one of the main reasons for focusing on this with City of Hope is they are a world leading institution dealing with this population, right? It's a transplant and cancer therapy center. So this is the type of patients that they work with.

And Dr. Diamond has actually talked during the period of reviewing these data, how motivated he was to make something for that patient population. So yeah, this is definitely--that's the initial focus. And the reason that we think it's got some real promise here is just like we talked about previously with the GeoVax vaccine. So MVA is a good vector. Itself adjuvating (PH). It gives its own little booster response, plus the multi-antigen inducing both helper T lymphocytes, toxic T lymphocytes and antibodies, that are more complex and broad response, we think will have a better chance of functioning in these immunocompromised patients.

And I just will mention, of course, that the patient population we are focused on is one where City of Hope is clearly the world's leader, but immunocompromised patients represent a much larger population group than what this initial study we will be focusing on. So we anticipate opportunities to expand studies.

Jason McCarthy

Great. And when you look towards doing a booster study that Phase 1/2 that's planned in healthy subjects, what type of patient do you, or subject rather, do you think you would enroll in terms of age? There is different criteria for how long the like an mRNA vaccine right now as opposed to last? I don't even know if it's quite clear in the literature. So what would you be looking for, specifically in that study? Would you be doing an mRNA comp as a booster versus the 04S1, or how would that work?

Mark Newman

Yeah. So there's a--you have to look at the combination of what is doable in the real world, especially in a timely manner. And what that you would really like to do. What is doable. And the approach for this is actually to work with healthcare workers, for example, doctors and nurses at City of Hope, who have all received the Pfizer vaccine as part of the campaign to immunize healthcare workers. And then, these people will be literally healthy volunteers and participate in the study.

So we are not looking at--we are not anticipating looking at groups that would be in any way limited or immunocompromised. These will be people that are relatively healthy, healthy volunteers. But the focus on the recruiting is going to be the healthcare workers.

Jason McCarthy

And would a large component of that data or immunogenicity data be geared towards what the T-cell responses are?

Mark Newman

Oh, absolutely. I mean, that's our thing, right? But it's boosting pre-existing. So we understand that the world of COVID vaccines is neutralizing antibodies, which are specific to the S protein. And Dr. Diamond showed a snapshot of data that they have generated measuring responses to the receptor binding domain, including the RBD of multiple variants. So you are looking at boosting that response. What is it when the patient came in and gave their first sample prior to immunizing, what happens two weeks later, what happens four weeks later and so on.

But obviously, T-cell responses is where we think is--it's where we're taking the program. We think this is going to be the difference. It's not designed simply to differentiate us from everybody else. It's done because T-cell responses are critically important to control to the induction and to the maintenance of efficacious viral immune responses. So the goal is to broaden the response. And nucleoprotein, nucleocapsid protein is one of the more highly dominant targets for immunity-

-T-cell immunity in the natural infection. So it's a perfect fit, antibody target and a nucleoprotein at the T-cell target.

Jason McCarthy

Great. And if you could just briefly jump over to the Gedeptin program in head and neck, that Phase 1/2 trial is enrolling. Do you have any idea of time-wise of when we could see a data readout from that program?

Mark Newman

I am going to ask somebody else that they have got more--a better answer for that. John or David?

David Dodd

This is David, Jason. Right now, we've just recently assumed that we have just expanded the size. So we have the five patients thus far in the Stanford, but the others are just starting to go forward. So at this time, it would be difficult to discuss--to be able to project a data readout. I would say probably, we can address that much more meaningful at the next conference call. But for right now, we are in the process transferring IND, of getting the two new sites fully up and running, and basically are doing the final selection of a CRO to oversee the entire program.

Jason McCarthy

And initiating manufacturing, so--

David Dodd

--Exactly.

Jason McCarthy

Got it. And then, so since it's in the second line head and neck, we've seen some activity in the-it's got a relatively low bar in terms of response rates. And we've seen some other programs. You take that what you get in second line and kind of catapult right up to first line possibly with checkpoints of different varieties at this point. Is that a long-term goal that GeoVax is considering for the Gedeptin program?

David Dodd

Yeah. It's being evaluated and related studies are going on right now if you look at just that concept, so yes.

Jason McCarthy

Got it. Okay. Thank you, fellows.

David Dodd

Thank you.

Operator

And ladies and gentlemen, as a reminder, if you'd like to ask a question, please press "*" then "1." Our next question comes from Kumar Raja with Brookline Capital Markets. Please go ahead.

Shavindu

Hi. I'm Shavindu (PH) calling in for Kumar. Thanks for the update. With respect to the clinical development of the 04S1 vaccine on immunocompromised patients, do you plan to expand it to other immunocompromised patient groups as well, like HIV or immunodeficiency diseases or just limit it to cancer patients on immunotherapy?

Mark Newman

Yeah. So obviously, all of that is under discussion and evaluation. Kind of like going back and discussing the Gedeptin, we are now in the process of making the handoff from City of Hope to the GeoVax management, all of those things first. The act of Phase 2 is where the focus will be. We don't want to get diluted out, but it will be data driven, right? If we are seeing some good results, you can bet we will be interested in expanding.

David Dodd

And Kumar, this--excuse me. I mean, Kumar's a colleague, I will say. This is David Dodd. I will just say that what you outlined, I mean, the initial program will be focused on this initial group. But certainly, other immunocompromised cohorts are of high interest to us. But as Mark Newman has pointed out, we will be guided by what we learn in this first program what we are seeing in the data.

But our anticipation and hope is that we will be able to move this into additional trials, in various immunocompromised populations for the simple reason that that is a group, represents multiple groups who are not being appropriately served well by the current vaccines that are out there. And so what we are hoping is to fill that void, make it much broader, but targeted for immunocompromised populations. And we've always felt that that was a very strong opportunity and area that could be filled by MVA type of vaccines.

Shavindu

Great. Got it. That's useful. Now, with respect to the clinical results of the CMO2 program, the anti-spike immunoglobulin persisted for at least 56 days in hamsters. Have you looked beyond it and if you could comment on the persistence of the T-cell response as well? And also, what kind of longevity of the IgG and T-cell responses, do you expect in moving into the human trials?

Mark Newman

Well, so to your first question about the animal models, so yes, the animal model testing is ongoing. And we will be making presentations and scientific--well, one is next week. We have a scientific presentation where we'll be introducing our new data. So we are not only evaluating the pathogenesis in the hamster model, but also protection of single, multiple doses protection levels in the transgenic H2 mouse model. So those data will be released next week for the first time at our next conference. We have a series of scientific presentations coming through between now and the end of the year.

And then, as far as durability of the responses, I think the data that we have been associated with is from our HIV program, which indicates that the MVA and the VLP process, which is what the CMO2 is based on, induces a very durable response. We think that's the nature of the adjuvant effect that you are getting from the FDA or MVA.

So, I would expect to see something very similar with the City of Hope. But as Dr. Diamond mentioned, he's showing you data out six months. It looks very nice at six months, but he has got a year follow-up plan. And so we will be continually presenting it. But if you look at, as I said, data that we generated previously in our HIV program and now the data that Dr. Diamond has showed, I think there is every indication that the responses are going to be as durable if not more durable than what we are seeing with the mRNA.

Shavindu

Okay, got it. So finally, I was just wondering if you could provide some color to the ongoing preclinical studies with NIH for the Marburg and Sudan viruses? And for the IND application, do you think that the ongoing tests are going to be enough or do we expect more studies moving forward?

Mark Newman

So again, at the end of the year, we are making a summary presentation at the World Vaccine Conference in San Diego, and one of our presentations will be on the hemorrhagic fever vaccines and where we are. So we are testing in non-human primates. Whether these move into a clinical trial is actually more driven probably by market forces. We fully anticipate based on guinea pigs and rodent models that the primate data will suggest or indicate that these are good vaccines and that they will induce responses that you would predict would be--that are protective in a primate.

And then, in the clinical trial, of course, you don't--these are not efficacy trials, these are just safety and immunogenicity trials, but those are actually driven and the selection process will be made based on need. So we have a Marburg outbreak sort of boiling along a couple of places in the world. If that expands that will drive attention and then our Marburg vaccines are more likely to flow to the top and be pushed up in the queue as far as clinical testing.

But as we've always pointed along--always pointed out, these processes are moved along with federal funding either to the Department of Defense or USAID, BARDA. And so we rely on what they determine is the priority and they will actually be tested through their network relationships. So I can't tell you that we are going to actually have an IND ready to go at the end of the year if the monkey data looks good. We could, but we don't--that will be someone else's decision to push us down that pathway.

Shavindu

Okay, sounds good. Great. Thanks for taking my questions.

CONCLUSION

Operator

And Ladies and gentlemen, this concludes our question-and-answer session. I'd like to turn the conference back over to David Dodd for closing remarks.

David Dodd

Okay, thank you. And thank you, everyone, for participating in this conference call sharing in our milestone achievements resulting in clinical stage status within these two critical areas of immunooncology and SARS-CoV-2. Look, for us, this is just a start as we accelerate our pace of development and progress. We look forward to updating you over the next several weeks and months regarding upcoming milestones for Gedeptin, 04S1, CM02, and other development programs as well as expansion of our capabilities and resources.

Finally, I want to acknowledge and thank the GeoVax 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 a great pleasure serving our shareholders and being part of this team. Again, thank you. Have a safe and enjoyable evening.

Operator

Thank you. This concludes today's conference call. We thank you all for attending today's presentation. You may now disconnect your lines and have a wonderful evening.



November 11, 2021

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 forwardlooking 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 Third Quarter Financial Results and Provides Corporate Update

Progress in Clinical Development of COVID-19 and Immuno-Oncology Programs

ATLANTA, GA, November 11, 2021 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers, today announced its financial results for the quarter ended September 30, 2021 and provided a corporate update.

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

2021 YTD Highlights and Development Program Status Update...

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

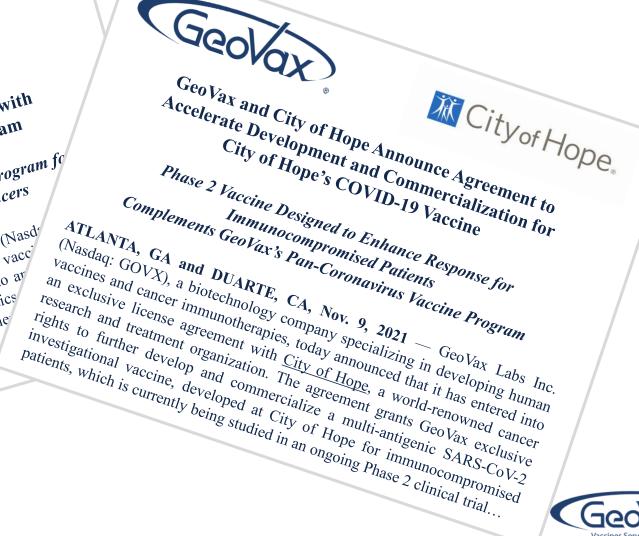
"The signing of the license agreements for Gedeptin and COH04S1 were each highly significant events for GeoVax and our stockholders, as they added clinical programs in both immuno-oncology and COVID-19 to our pipeline, the primary focus areas for our company. The initial stage (10 patients) of the ongoing Gedeptin clinical trial is being funded by the FDA pursuant to its Orphan Products Grants Program, with five patients having been enrolled to date. Our immediate objective will be to accelerate patient enrollment to complete this stage, then expand the trial to additional study sites and at least 25-30 patients in total."

"The addition of COH04S1 to our product pipeline is synergistic with, and complementary to, our ongoing development of GEO-CM02. Both vaccine candidates are potential second-generation COVID-19 vaccines, with COH04S1 representing a near-term opportunity for a niche-market indication for use in immunocompromised patients and possible expansion to a broader market indication as a universal booster vaccine. GEO-CM02, in contrast, is being developed as single-dose pan coronavirus vaccine. Our funding events from 2020 and early 2021, have positioned us well to advance each of these development programs," Mr. Dodd concluded.

Accelerating Clinical Development

GeoVax Expands Immuno-Oncology Pipeline with GeoVax Acquisition of Clinical-Stage Cancer Program License of Gedeptin® Adds Orphan Drug Clinical Program fo Treatment of Advanced Head and Neck Cancers ATLANTA, GA, September 28, 2021 - GeoVax Labs, Inc. (Nasd. biotechnology company specializing in developing human vaccing in developing human vaccing in the state of th immunotherapies, today announced that it has entered into ar minunomerapies, way announced mat it has emered into a Therapeutics

License Agreement (the "License") with PNP Therapeutics grants GeoVax exclusive rights to develop and comme grams Octivas exclusive rights to develop and continuous novel patented product for the treatment of solid tumors





Addressing Deadly Challenges Worldwide

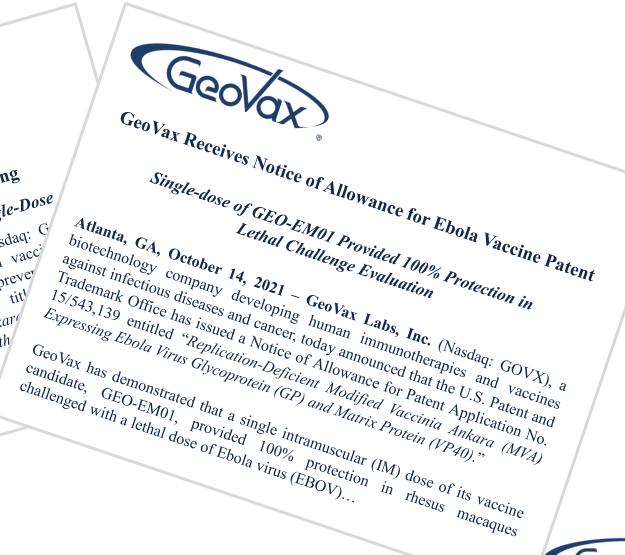
GeoVax Announces Presentation of Sudan Ebolavirus Vaccine Data at the American Society for Virology Annual Meeting GeoVax Vaccine Achieves 100% Protection in a Single-Dose ATLANTA, GA, July 22, 2021 - GeoVax Labs, Inc. (Nasdaq: Ghiotochalom, common, consisting in devolution human man. biotechnology company specializing in developing human vacci biotechnology company specializing in developing human vaccan announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of data from a study of its prever announced the presentation of the preventation of the pr announced the presentation of data from a study of its F

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Annual Meeting of the American Society





19-23...





GeoVax and City of Hope Announce Agreement to Accelerate Development and Commercialization for City of Hope's COVID-19 Vaccine

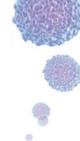
Phase 2 Vaccine Designed to Enhance Response for Immunocompromised Patients Complements GeoVax's Pan-Coronavirus Vaccine Program

ATLANTA, GA and DUARTE, CA, Nov. 9, 2021 — GeoVax Labs Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, today announced that it has entered into an exclusive license agreement with <u>City of Hope</u>, a world-renowned cancer research and treatment organization. The agreement grants GeoVax exclusive rights to further develop and commercialize a multi-antigenic SARS-CoV-2 investigational vaccine, developed at City of Hope for immunocompromised patients, which is currently being studied in an ongoing Phase 2 clinical trial and shows a strong potential to be used in the general population as a primary and/or general booster vaccine against COVID-19 worldwide...

David Dodd, GeoVax President and CEO, said, "This license agreement represents a significant and exciting milestone for GeoVax and our shareholders, as it adds an additional Phase 2 clinical program in a primary focus area for our company, complementing our expertise in MVA technology. We look forward to a strong working relationship with Dr. Diamond and his colleagues at City of Hope, as we accelerate the clinical advancement of this promising vaccine for patients and look for opportunities for further collaboration in other areas of vaccine and immunotherapy needs."

"It is important to note that the addition of COH04S1 to our product pipeline is synergistic with, and complementary to, our ongoing development of GEO-CM02," Dodd continued. "Both vaccine candidates are potential second-generation COVID-19 vaccines, with COH04S1 representing a near-term opportunity for a niche-market indication for use in immunocompromised patients and possible expansion to a broader market indication as a universal booster vaccine. GEO-CM02, in contrast, is being developed as a single-dose pan coronavirus vaccine. With today's announcement, in conjunction with our September announcement of our licensing of Gedeptin®, we have advanced our two core product development areas related to SARS-CoV-2 vaccines and immuno-oncology into clinical-stage testing. We look forward to providing further updates soon."

Transaction Provides Exclusive IP Rights to an Advanced Covid-19 Vaccine in Phase 2 Clinical Testing



- Licensing of COH04S1 immediately strengthens our presence in SARS-CoV-2 prevention market
- Currently evaluating the safety and immunogenicity of the multiantigen COH04S1 vaccine to a single antigen mRNA vaccine in patients following hematopoietic cell transplant or CAR-T therapy
- An expansion of the recently completed Phase 1 protocol in healthy volunteers to a Phase 1/2 study evaluating the safety and immunogenicity of COH04S1 as a booster in patients previously receiving an mRNA vaccine is near initiation.









CLINICAL DEVELOPMENT OF COH04S1

A synthetic multiantigen modified-vaccinia Ankara-based COVID-19 vaccine expressing SARS-CoV-2 Spike and Nucleocapsid antigens

NOVEMBER 11, 2021

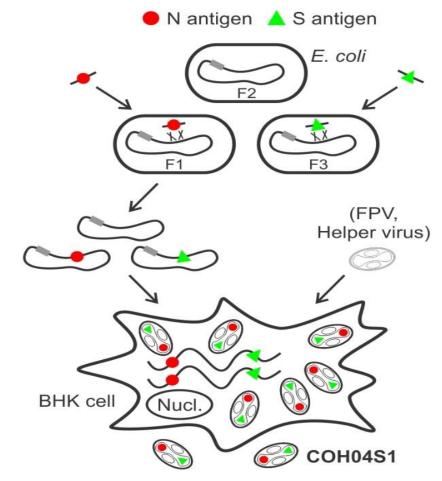
Flavia Chiuppesi, Ph.D., Felix Wussow, Ph.D. and Don J. Diamond, Ph.D. Department of Hematology & Hematopoietic Cell Transplantation City of Hope

Synthetic MVA (sMVA) as a vaccine platform for COH04S1



- Spike (S) full-length, Wuhan strain:
 - Main target of neutralizing antibodies
 - Co-dominant target of cellular immunity

- Nucleocapsid (N), Wuhan strain:
 - Co-dominant target of cellular immunity
 - Less prone to viral escape than S



Co-expression of full-length S and N antigen sequences by single vaccine vector



Summary of COH04S1 Preclinical Studies



- sMVA platform and COH04S1 immunogenicity in mice published in 2020
- COH04S1 showed protective efficacy in animal models: hamsters and non-human primates (NHP)
- COH04S1 conferred protection against SARS-CoV-2 via parenteral and mucosal vaccination
- Immunogenicity and protective efficacy observed with 1 and 2 doses in NHP
- COH04S1 induced robust neutralizing antibodies against Alpha, Beta, Gamma, and Delta variants of concern (VOC)
- COH04S1 showed complete protection against VOC infection within 2 days of challenge in hamsters
- COH04S1 induced robust humoral and cellular responses against both S and N antigens
- Demonstrated Th1-biased antibody or T-cell responses

COH04S1 Phase 1 Clinical Trial in Healthy Adults

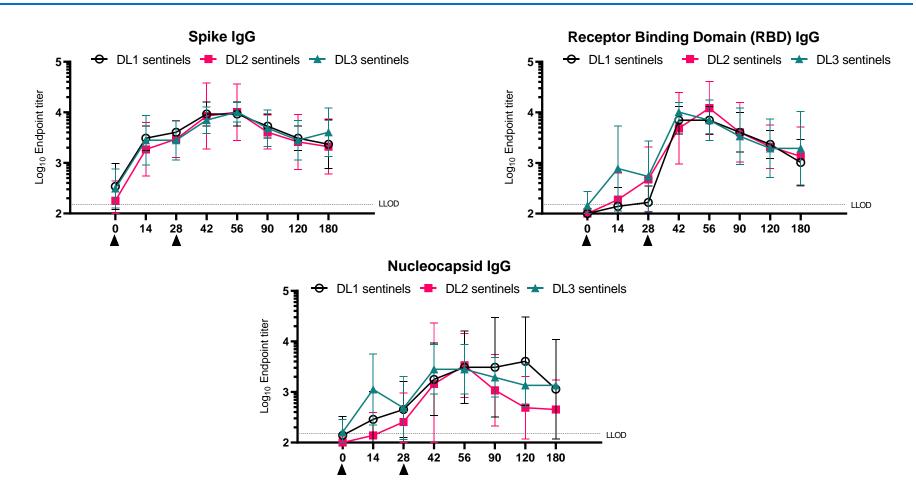


- ClinicalTrials.Gov NCT04639466 (12/10/2020 started, 06/02/21 closed for accrual)
- Trial design: 3 dose levels (DL1-3) with 4-6 open-label sentinels at each DL followed by 35 randomized against placebo
- DL1=1x10⁷pfu/dose, same low dose as used in mice
- DL2=1x108pfu/dose, DL3=2.5x108 pfu/dose. All doses are compatible with large-scale production
- Prime-boost immunizations with COH04S1 are safe and well tolerated in DL1, DL2 and DL3 sentinels
- 100% of sentinels tested seroconverted to S and N antigens and developed Th1 T cell responses
- 100% of sentinels tested (DL1, DL2 and DL3) developed neutralizing antibodies
- Cross-NAb against D614G, Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1) variants



Binding Antibodies to S, RBD, N in Healthy Adults Immunized with COH04S1 at different dose levels (DL)



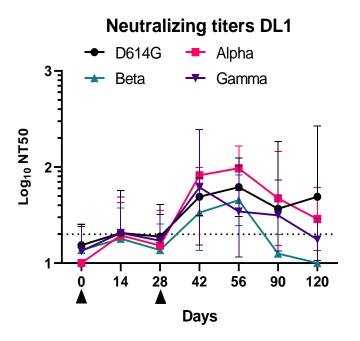


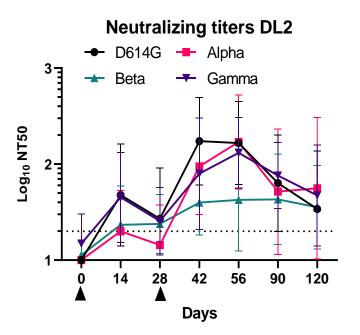
Binding antibody endpoint titers induced by COH04S1 in sentinel subjects vaccinated with DL1, DL2, and DL3

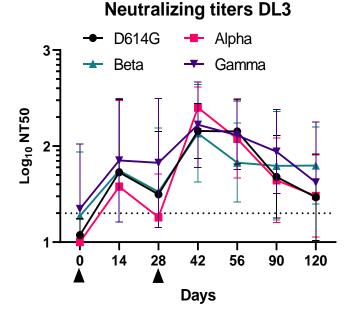


Neutralizing Antibodies Against Wuhan (D614G), Alpha (B.1.1.7), Beta (B.1.351), and Gamma (P.1) VOC by Pseudovirus Assay





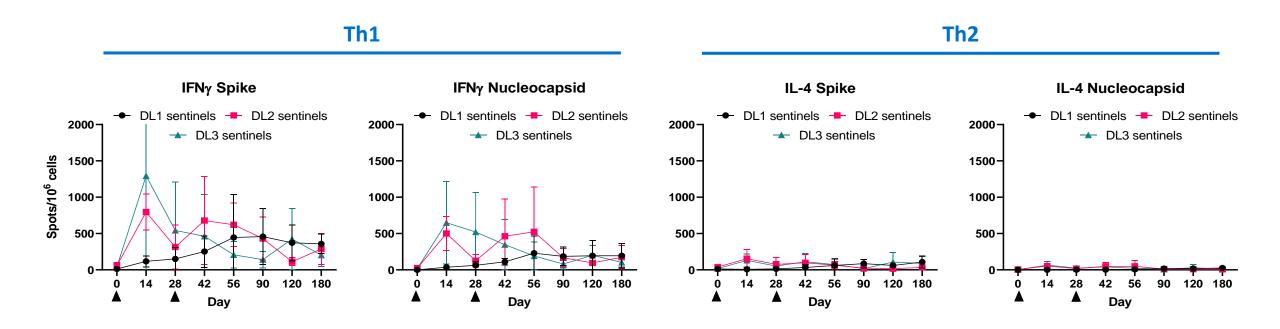




Neutralizing antibody titers (NT50) induced by COH04S1 against ancestral SARS-CoV-2 and variants of concern (VOC) in sentinel subjects vaccinated with DL1, DL2, and DL3

T-Cell Responses to S and N antigens (IFNγ and IL-4 secretion)





At all DL COH04S1 predominantly induced robust T cell responses of the Th1-type (IFNγ) rather than Th2-type (IL-4)



Phase 2 Trial – Immunocompromised Patients



- Diminished antibody responses compared to healthy vaccinated individuals have been shown in immunocompromised patients provided mRNA COVID-19 vaccines
- A COVID-19 vaccine which favors broader induction of cellular immune responses may confer improved protective immunity in the immunocompromised population that poorly responds to current vaccines
- NCT04977024: A Phase 2 Randomized, Multi-center, Observer-Blind Study of COH04S1 Versus Pfizer
 SARS-COV-2 Vaccine in Patients Post Cellular Therapy for Hematological Malignancies.
- City of Hope started enrolling trial volunteers on 09/02/2021

Phase 2 Trials – Booster vaccination



- Governments have started recommending 3rd doses of currently authorized COVID-19 vaccines
- In the US high risk subjects are eligible for a booster if they received Pfizer/Modena vaccines. All individuals
 who have received J&J vaccine are eligible for a booster with any authorized vaccine
- COH04S1 will be evaluated as a booster in Phase 2 trials in healthy adults
- Local IRB approval is pending
- FDA had no comments on the booster trial in healthy adults

GeoVax – COH04S1: Synergies

- The use of MVA as a vaccine vector is the core technology of GeoVax
 - Experimental products for use against a diverse set of infectious diseases in different stages of preclinical and clinical development
 - Funding partnerships with multiple US government agencies
- COH04S1 Multi-Antigen Design
 - Designed specifically to induce both antibody and T-cell responses to S and N proteins
 - Similar concept to the GeoVax MVA-VLP design approach
- MVA production using high-capacity, scalable technologies and continuous avian cells is under development





GeoVax Labs, Inc.Consolidated Balance Sheet Information

(amounts in thousands, except share information)

	Sep 30,			Dec 31,		
	2021			2020		
Assets						
Cash and cash equivalents	\$	18,107	\$	9,884		
Other current assets		53		351		
Total current assets		18,160		10,235		
Property and other assets, net		180		159		
Total assets	\$	18,340	\$	10,394		
Liabilities and stockholders' equity Total liabilities Stockholders' equity Total liabilities and stockholders' equity	\$	336 18,004 18,340	\$	825 9,569 10,394		

Common shares outstanding

6,381,541

3,834,095



GeoVax Labs, Inc.

Consolidated Statements of Operations Information (amounts in thousands, except share and per share information)

	Thre	ee Months Ende	ed Sep 30,	Nine Months Ended Sep 30,						
		2021	2020		2021	2020				
Grant and collaboration revenue	\$	30 \$	415	\$	221 \$	1,572				
Operating expenses										
Research and development		1,224	417		2,660	1,687				
General and administrative		758	435		2,563	1,365				
		1,982	852		5,223	3,052				
Loss from operations		(1,952)	(437)		(5,002)	(1,480)				
Other income (expense), net		1	(134)		175	(142)				
Net loss	\$	(1,951) \$	(571)	\$	(4,827) \$	(1,622)				
Loss per common share	\$	(0.31) \$	(0.73)	\$	(0.80) \$	(2.85)				



GeoVax Immuno-Oncology Portfolio 2020 vs. 2021

MUC1 Solid tumors

- MVA-VLP based, experimental
- 2. Preclinical
- 3. Internal funding

MUC1 Solid tumors

- Clinical candidate selected
- 2. GMP manufacturing initiated
- 3. Research and clinical testing relationships under final negotiation
- 4. Assembling oncology advisory board
- Established grant development relationship with FreeMind

Head & Neck Cancer

- 1. HPV focused
- 2. MVA-based
- 3. Preclinical
- 4. Internal funding

Head & Neck Cancer

- 1. Gedeptin®
- 2. Ad5 vector based, expanded viral vector technology base
- 3. GMP manufacturing established and ongoing
- 4. Active Phase 2 trial Stanford University with multi-site expansions underway
- 5. FDA financial support Orphan Drug program
- 6. Potential for registration upon completion of ongoing clinical trial
- 7. Opportunities for clinical testing in combination with marketed CPI





GeoVax Infectious Diseases Portfolio 2020 vs. 2021

SARS CoV-2 Universal "Pan" Coronavirus

- MVA-VLP based
- 2. Design and construction
- Internal funding

SARS CoV-2 COH04S1

 A City of Hope concept for unique product

SARS CoV-2 Universal "Pan" Coronavirus

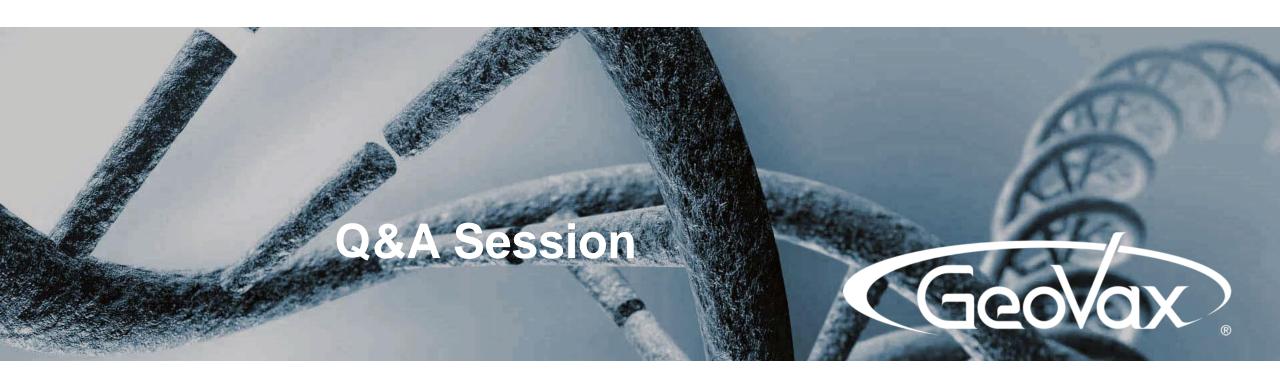
- Lead candidate identified GEO-CM02
- 2. Preclinical testing advanced, single dose protection from variants
- 3. Expanded research relationships under negotiation for expanded variant testing
- 4. Assembling infectious disease advisory board
- 5. CEPI proposal in review; FreeMind
- 6. Ongoing evaluation of modern and scalable manufacturing

SARS CoV-2 COH04S1

- Clinical candidate designed and produced with new "rapid cloning" technology
- 2. IND enabling animal testing completed
- . Pilot scale GMP manufacturing process established and product released
- 4. Phase 1 dose escalation, safety and immunogenicity completed
- 5. Phase 2 clinical trial immune- compromised patients initiated
- 6. Phase 1-2 clinical trial as booster vaccine initiated
- 7. GeoVax lead candidate next-generation vaccine







Thank You







Creating Vaccines to Serve Humanity



For More Information

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